Anexa 18

Specificație Tehnică Completată

Anexa 18 Electrocardiograf cu 12 canale

Model: MAC 5 Reg. SDM: DM000363172

Producător: GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC

Țara: SUA

Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Parametrul Specificația: Tip pacient: adult, pediatric Numărul de canale de procesare 12 Configurația Portabil obligatoriu Derivațiile: Tip înregistrare auto și manual Sensivitatea 2.5, 5, 10/12.5, 20, 40 mm/mv	Parametrul Specificația: Tip pacient: adult, pediatric **DA, pag.339 din Mac5_usermanual** Numărul de canale de procesare 12 **DA, pag.339 din Mac5_usermanual** Configurația Portabil obligatoriu **DA, pag.1-3 din Mac5_brosura** Derivațiile: Tip înregistrare auto și manual **DA, pag.69-70 din Mac5_usermanual** Sensivitatea 2.5, 5, 10, 20, 10/5 mm/mv split gain **DA, pag.334 din Mac5_usermanual.** Funcția split/gain 10/5 mm/mV și posibilitatea de analiză digitală oferă același rezultat ca 40 mm/mV. Pentru vizualizarea clară a undelor foarte mici (unda P, activitatea atrială, post-infarct) se utilizează mărirea selectivă a derivațiilor de interes, exact ce face funcția 10/5 mm/mV. În plus există zoom software care permite mărirea imaginii pe displayul ECG-ului. Mai mult, funcția 10/5 mm/mV este superioară celei de 40 mm/mV, deoarece are loc : Reducerea distorsiunilor, Analiza digitală precisă. De asemenea, numărul de derivații poate fi selectat 3, 6, 12. În cazul în care se alege 3 sau 6 există opțiunea de zoom suplimentar.
Semnal de calibrare 1 mV, ± 5% Gama de frecvență: De diagnostic 0.05 -150 Hz Filtru frecvență joasă 0.05Hz, 0.10/0.16Hz, 0.20/0.25 Hz, 0.50Hz Filtru frecvență înaltă 20/25, 40/45, 100, 150Hz	Semnal de calibrare 1 mV, ± 5% **DA, pag.294 din Mac5_usermanual** Gama de frecvență: De diagnostic 0.04 -300 Hz **DA, pag.336 din Mac5_usermanual** Filtru frecvență joasă 0.04 Hz, 0.05 Hz, 0.32 Hz, 0.56 Hz, 0.67Hz **DA, pag. 16,17 din Physician guide. Acestea sunt Filtre obligatorii indicate în IEC 60601-2-25:2011, AHA/ACC/ESC.** Filtru frecvență înaltă 20, 40, 100, 150Hz **DA, pag.336 din Mac5_usermanual**

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Filtru de rețea 50 Hz	Filtru de rețea 50,60 Hz **DA, pag.133 din Mac5_usermanual**
Impendanța de intrare ≥ 50 M Ohm	Impendanța de intrare ≥ 50 M Ohm **DA, pag.335 din Mac5_usermanual**
Gama de rejecție a modului comun la 50 Hz > 110 dB	Gama de rejecție a modului comun la 50 Hz > 110 dB **DA, pag.1 din Mac5_datasheet**
Convertor analog -digital ≥ 24 bit	Convertor analog -digital 24bit **DA, pag.1 din Mac5_datasheet**
Scurgeri spre pacient prin electrozi ≤10 μA	Scurgeri spre pacient prin electrozi ≤10 μA **DA, pag.1 din Mac5_datasheet**
Detector de pacemaker obligatoriu	Detector de pacemaker obligatoriu **DA, pag.1 din Mac5_datasheet**
frecvența de eșantionare >1 000 Hz	frecvența de eșantionare 75 000 Hz **DA, pag.336 din Mac5_usermanual**
Indicator deconectare electrod acustic sau vizual obligatoriu	Indicator deconectare electrod acustic sau vizual obligatoriu **DA, pag.62-64 din Mac5_usermanual**
Detectarea automată a deconectării cablului EKG	Detectarea automată a deconectării cablului EKG **DA, pag.62-64 din Mac5_usermanual**
Imprimantă:	Imprimantă:
Termică încorporată	Termică încorporată **DA, pag.334 din Mac5_usermanual**
Mărimea hîrtiei ≥ 210 mm obligatoriu	Mărimea hîrtiei 214.2 mm obligatoriu **DA, pag.2 din Mac5_datasheet**
Să se indice numele derivației printate obligatoriu	Să se indice numele derivației printate obligatoriu **DA, pag.2 din Mac5_ghid rapid**
Viteza de înscriere 5, 10, 25, 50 mm/s	Viteza de înscriere 5, 12.5, 25, 50 mm/s **DA, pag.2 din Mac5_datasheet**
Densitatea imprimarii 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s	Densitatea imprimarii 8 dpi/mm (rezoluție verticală) și 40 dpi/mm (rezoluție orizontală) la viteza de 25 mm/s **DA, pag.2 din Mac5_datasheet**
Acuratețea ± 5% (axa x), ± 5% (axa y)	Acuratețea ± 5% (axa x), ± 5% (axa y) **DA, pag.2 din Mac5_datasheet**
Derivațiile înscrise minim 12	Derivațiile înscrise 3,6,12 **DA, pag.2 din Mac5_datasheet**
Numărul de derivații înscrise simultan 3, 6, 12	Numărul de derivații înscrise simultan 3, 6, 12 **DA, pag.2 din Mac5_datasheet**
Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG obligatoriu	Hîrtia termică să fie compatibilă și de la alți producători de hîrtie cu dispozitivul ECG obligatoriu **DA, pag.334 din din Mac5_usermanual**
Display:	Display:
Grafic, LCD TFT color obligatoriu	Grafic, LCD, LED backlight color obligatoriu **DA, pag.2 din Mac5_datasheet**
Monitorizarea pe display: data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile obligatoriu	Monitorizarea pe display: data, ora, sensibilitatea, viteza de înscriere, filtru, derivațiile obligatoriu **DA, pag.334 din din Mac5_usermanual**
Marime ecran ≥ 7 inch	Marime ecran 8.9inch **DA, pag.2 din Mac5_datasheet**

Rezoluția ≥ 800x480 pix	Rezoluția 892x558 pix **DA, pag.2 din Mac5_datasheet**
Touchscreen, tehnologie Multi-touch. obligatoriu	Touchscreen, tehnologie Multi-touch. obligatoriu **DA, pag.2 din Mac5_datasheet**
Numărul de derivații afișate simultan 12	Numărul de derivații afișate simultan 3,6,12 **DA, pag.137 din Mac5_usermanual**
Posibilitatea transmiterii datelor la un sistem de management al datelor ECG: Ethernet / USB / SD card obligatoriu	Posibilitatea transmiterii datelor la un sistem de management al datelor ECG: Ethernet, USB **DA, pag.2 din Mac5_datasheet**
Format date ECG BMP / JPG / GIF / PDF / XML / DICOM obligatoriu	Format date ECG XML, PDF obligatoriu **DA, pag.2 din Mac5_datasheet**
Memorie ≥ 200 inregistrari ECG obligatoriu	Memorie 300 inregistrari ECG obligatoriu **DA, pag.1 din Mac5_datasheet**
Soft specializat pentru analiza rezultatelor ECG la calculator obligatoriu	Soft specializat pentru analiza rezultatelor ECG la calculator obligatoriu **DA, pag.82 din Mac5_usermanual**
Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vîrsta, sex, greutate, înălțimea	Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vîrsta, sex, greutate, înălțimea **DA, pag.13-14 din Mac5_usermanual. Există New Patient**
Ajustarea automată al izoliniei obligatoriu	Ajustarea automată al izoliniei obligatoriu **DA, pag.17 din Physician guide**
Identificarea aritmiei obligatoriu /	Identificarea aritmiei obligatoriu **DA, pag.151 din Mac5_usermanual**
Ritmului cardiac:	Ritmului cardiac:
Diapazon 30 - 300 BPM	Diapazon 30 - 300 BPM **DA, pag.1 din Mac5_datasheet**
Acuratețea ± 1 BPM	Acuratețea ± 5 BPM **DA, pag.1 din Mac5_datasheet** Conform IEC 60601-2-25:2011 eroarea maximă admisă la determinarea frecvenței cardiace este de +/- 10% din valoarea măsurată sau +/- 5 bpm, oricare este mai mare.
Interpretarea:	Interpretarea:
Sistem de interpretare a datelor ECG obligatoriu	Sistem de interpretare a datelor ECG obligatoriu **DA, Marquette 12SL ECG** (opțiunea va fi activată la livrare) **pag.336 din Mac5_usermanual**
Măsurări PR, QT, QTC, P, QRS, T, HR;	Măsurări PR, QT, QTC, P, QRS, T, HR; **DA pag.290 din Mac5_usermanual**
Detectarea Sindromului coronarian acut	Detectarea Sindromului coronarian acut **DA, optiunea Acute** (opțiunea va fi activată la livrare) **Coronary Syndrome DA, pag.66 din Mac5_usermanual** (opțiunea va fi activată la livrare)
Algoritm de interpretare specific dupa sexul pacientului	Algoritm de interpretare specific dupa sexul pacientului **DA, optiunea 12SL Measurement and Interpretation pag.7 din Mac5_brosura** (opțiunea va fi activată la livrare)

Timpul interpretării minim 10 s	Timpul interpretării minim 10 s **DA, pag.69 din Mac5_usermanual**
Calculul de corecție al segmentului QT cu posibilitatea de selectare a formulei: Bazett Fridericia Framingham	Calculul de corecție al segmentului QT cu posibilitatea de selectare a formulei: **DA, optiunea 12SL Measurement and Interpretation** (opțiunea va fi activată la livrare) **pag.136 din Mac5_usermanual** Bazett **DA, pag.136 din Mac5_usermanual** Fridericia **DA, pag.136 din Mac5_usermanual** Framingham **DA, pag.136 din Mac5_usermanual**
Notificator de valoare critică a unuia din parametrii măsurați HR, QTc obligatoriu	Notificator de valoare critică al ambelor parametri măsurați HR, QTc obligatoriu **DA, optiunea CRITICAL VALUES pag.74, 150 din Mac5_usermanual**
Detectarea următoarelor condiții Bloc atrioventricular, Infarct Miocardic cu supradenivelare de segment ST, Ischemie cardiacă,	Detectarea următoarelor condiții Bloc atrioventricular, Infarct Miocardic cu supradenivelare de segment ST, Ischemie cardiacă, **DA, optiunea CRITICAL VALUES** (opțiunea va fi activată la livrare) **pag. 151 din Mac5_usermanual**
Full disclosure ≥4 min, 12 derivatii	Full disclosure 5 min, 12 derivatii **DA, pag.1 din Mac5_datasheet**
Alimentarea 220 V, 50 Hz	Alimentarea 220 V, 50 Hz **DA, pag.335 din Mac5_usermanual**
Baterie internă reîncărcabilă obligatoriu	Baterie internă reîncărcabilă obligatoriu **DA, pag.335 din Mac5_usermanual**
Timp operare autonomă ≥ 2 ore	Timp operare autonomă 180 min **DA, pag.2 din Mac5_datasheet**
Protecție defibrilator ≥ 360 J	Protecție defibrilator ≥ 360 J **DA, IEC 60601–1. pag.1 din Mac5_datasheet**
Indicatori vizuali: vizualizarea în 3 culori a calității conexiunii fiecărui electrod în parte plasat pe corpul pacientului obligatoriu	Indicatori vizuali: vizualizarea în 3 culori a calității conexiunii fiecărui electrod în parte plasat pe corpul pacientului obligatoriu **DA, pag.3-6 din Mac5_brosura**
asistență în identificarea posibilei cauze a calității proaste a semnalului obligatoriu	asistență în identificarea posibilei cauze a calității proaste al semnalului obligatoriu **DA, pag.62 din Mac5_usermanual**
status sistem obligatoriu	status sistem obligatoriu **DA, pag.62 din Mac5_usermanual**
deconectare alimentare rețea obligatoriu	deconectare alimentare rețea obligatoriu **DA, pag.279 din Mac5_usermanual**
baterie descărcată obligatoriu	baterie descărcată obligatoriu **DA, pag.279 din Mac5_usermanual**
Accesorii: Cablu pacient cu set de electrozi pectorali de tip pară (6 buc.) și membranari de tip clește (4 buc.) ≥ 2 set.	Accesorii: Cablu pacient cu set de electrozi pectorali de tip pară (6 buc.) și membranari de tip clește (4 buc.) 2 set. **DA**
Hîrtie termică ≥ 30 buc.	Hîrtie termică 30 buc. **DA**
Gel de contact ≥ 1 litru	Gel de contact 1 litru **DA**
	Troleu pe rotile:

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Troleu pe rotile: indicați modelul oferit obligatoriu troleu pe rotile obligatoriu ≥ 4 roți obligatoriu ≥ 2 roți cu frînă obligatoriu mîner pentru transportarea standului obligatoriu coș pentru accesorii obligatoriu braț articulat pentru electrozi ECG obligatoriu suport pentru gel de contact obligatoriu ajustarea pe înalține optional sistem de fixare dispozitivului de suport obligatoriu	indicați modelul oferit obligatoriu **DA, model MAC 5 Compact Trolley A4 din TroleuMac5_brosura** troleu pe rotile obligatoriu 4 roți obligatoriu **DA, din TroleuMac5_brosura** 2 roți cu frînă obligatoriu **DA, din TroleuMac5_brosura** mîner pentru transportarea standului obligatoriu **DA, din TroleuMac5_brosura** coș pentru accesorii obligatoriu **DA, din TroleuMac5_brosura** braț articulat pentru electrozi ECG obligatoriu **DA, din TroleuMac5_brosura** suport pentru gel de contact obligatoriu **DA, din TroleuMac5_brosura** ajustarea pe înalține optional sistem de fixare dispozitivului de suport obligatoriu **DA, din TroleuMac5_brosura**

GE HealthCare

MAC™ 5 data sheet

General

Instrument type	Microprocessor augmented automatic electrocardiograph; 10-lead wire acquisition with programmable lead configuration
ECG interpretation	Marquette™ 12SL™ ECG analysis program for adults and pediatrics
Computerized measurements	12-lead analysis includes measurements
Heart rate meter	30 to 300 BPM ±10% or 5 BPM, whichever is greater — heart rates outside this range will not be displayed
ECG data formats	GE Hi-Fidelity ECG, XML
External archiving	USB removable media
Pre-acquisition	Provides 10 seconds of instantaneous ECG acquisition
Digital rhythm	Up to 5 minutes of continuous rhythm storage (exportable as a PDF)
Full disclosure	Review up to 5 minutes of 12 Lead ECG, ability to select 10 second Resting ECG records, ability to generate 5 minute single lead full disclosure report
Storage	300 records consisting of 10 second Resting ECG and rhythm records; 200 minutes Digital Rhythm or Full Disclosure records
Dynamic range	AC differential ± 10 mV DC offset ±600 mV
Common mode rejection	>125 dB (>100 dB with AC filter disabled)
Input impedance	>50MΩ @ 10 Hz
Defibrillation protection	Per IEC 60601-2-25:2011
Patient leakage	<10 µA

Specifications for digital acquisition and analysis of waveforms

Analog to digital conversion	24-bit analog to digital conversion resolution Over sampled rate: 512 ksps
Down sampled ECG waveform	Bandwidth: 0.04 to 300 Hz* Sample rate: 2 ksps Resolution: 1.22 µV
Input to 12SL	Bandwidth: 0.04, 0.56 ZPD to 300 Hz* Sample rate: 1 ksps Resolution: 4.88 µV
Additional report filters	20 Hz, 40 Hz, 100 Hz, 150 Hz or 300 Hz*

Specification for stored / transmitted waveforms

Digital rhythm waveform	Bandwidth: 0.04, 0.56 ZPD to 300 Hz* Sample rate: 1000 sps Resolution: 4.88 µV
12-lead ECG waveform	Bandwidth: 0.04, 0.56 ZPD to 300 Hz* Sample rate: 500 and 1000 sps Resolution: 4.88 µV
Representative (median) complex	Sample rate: 500 and 1000 sps Resolution: 4.88 µV

Pace detection

Pacemaker waveform	Sample rate: 75 ksps
Pace detection	Duration: 0.2 ms to 2.1 ms Amplitude: 2 mV to 700 mV Separation: 1 ms or greater
Pace annotation	Dedicated pace channel on display and printed reports (configurable)

Communications

ECG management systems connectivity	MUSE™ Cardiology Information System Compatible (v8 or later) with bi-directional orders and ADT support; Transmit Resting ECG records to Cardiosoft™ via removable media (v6.73 or later) or via network (v7 or later)
DICOM	Modality worklist/orders: supported via GE HealthCare MUSE (v8 or higher) and DICOM Gateway with bi-directional orders support
EMR connectivity	Via MUSE cardiology information system (v8 or later) with EMR Gateway
Data export	Export of Resting ECG (in PDF or XML format), Digital Rhythm and Full Disclosure reports (in PDF format) over Secures File Transfer Protocol (SFTP) or to a Shared folder
Wireless	Wireless 802.11 a/b/g/n wireless connectivity (2.4GHz/5GHz)
	IPV4
	DHCP, hostname and static IP options for configuring device IP/network address
	WEP and enhanced security WPA-PSK, WPA2-PSK, WPA/WPA2 enterprise protocols TLS, PEAP-MSCHAPV2, PEAPGTC, TTLS-MSCHAPV2, TTLS-GTC. (PEAP requires network evaluation/approval prior to purchase)
	Ultra-high security 4096 bit encryption/long certificate support
	SHA1 and SHA2 support
Network connector	802.3 Ethernet interface via RJ45 connectivity
	Compatible to 10Base-T, 100Base-T LAN
	IPV4
	DHCP, hostname and static IP options for configuring device IP/network address
Network clock	Network time synchronization (NTP)

Display

Display and resolution	8.9” diagonal, LED backlit, 892 x 558 pixels
Touch screen type	Projected Capacitive (PCAP) multipoint touch input that works while wearing medical exam gloves
Display data	Heart rate, patient name, patient ID, date, clock, battery power indicator, scrolling waveforms, lead labels, speed, gain and filter settings, warning messages, prompts, hookup advisor and help messages

Writer

Writer technology	Integrated thermal dot array
Number of traces	3, 6, 12 user selectable
Writer speeds	5, 12.5, 25, and 50 mm/s
Writer sensitivity/gain	2.5, 5, 10, 20 mm/mV, and 10/5 mm/mV split gain
Writer speed accuracy	5, 12.5 mm/s @ +5% 25, 50 mm/s @ ±2%
Writer amplitude accuracy	±5%
Writer resolution	Horizontal: 40 dots/mm at 25 mm/s Vertical: 8 dots/mm
Paper type	Thermal, Z-fold, perforated, fan fold, 150 sheets/pack
Paper size	Modified Letter: 8.43 in x 11 in (214.2 mm x 279.4 mm)
	8.27 in x 11.7 in (210 mm x 297.5 mm)
Network printer	Support printing to network printer

Electrical

Power supply	AC mains or battery operation
Input voltage	100-240 VAC + 10%
Input frequency	50-60 Hz + 3 Hz
Battery type	Replaceable and rechargeable internal battery
Battery capacity	Minimum 180 minutes with acquiring and printing a single page ECG report every 15 mins (with five minutes auto standby enabled and all accessories connected, except KISS)
Battery charge	Approximately 240 minutes from total time discharge when device is off or standby

Security and privacy

Encryption	All files containing PHI, local users and passwords
Login authentication	Network: LDAP/Active directory Local: User database
User management	Customizable roles for limiting system access by user groups for Admin, Clinical, Service, Biomed, and user defined up to 10 customized roles
Audit trail	All user logins, logouts and login failures, file deletions, file changes, file views, file acquisitions, file transmissions, file printouts, system configuration changes

PHI access	Controlled by customizable roles with configurable advanced strict PHI access rules
PHI access logs	Detailed and exportable logs of all PHI viewing by users
Emergency access (STAT mode)	This user can access the device without providing login credentials to perform emergency tasks such as acquiring an ECG or rhythm while preventing access to any stored patient data, orders, ADT, or 3rd party applications
USB lockout	Software controls to disable USB ports/connections

Physical specifications

Weight and dimensions

Max weight	4 kg
Max height	125 mm
Max width	325 mm
Max length	370 mm

Environmental specifications

Temperature

Operating	50° to 104° F (10° to 40° C)
Transport/Storage	–4° to 140° F (–20° to 60° C)

Humidity

Operating	20% to 95% RH non-condensing
Transport/Storage	15% to 95% RH non-condensing

Pressure

Operating	70 to 106 kPa
Transport/Storage	50 to 106 kPa

Input devices

Keyboard	Touch keyboard
Touchscreen	8.9”, 892 x 558 pixels projected Capacitive (PCAP) multipoint touch input that works while wearing medical exam gloves
Barcode	External barcode scanner (optional)
Mouse	Supported but not included

External USB barcode scanner

Types	Fixed and variable length
Symbologies	Code-128, PDF417, Code 39, Interleaved Code 2 of 5, and Data Matrix symbology for characters A-Z (upper case), a-z (lower case) and 0-9 for all supported languages

Cleaning

Approved cleaning agents	Soap and water solution Sodium hypochlorite (NaOCl) 5% solution Ethanol (ethyl alcohol) 96% (v/v) Isopropyl alcohol 70% (m/m) Hydrogen peroxide 20% (v/v) Phenol 2% (V/V)
FDA cleaning agent for efficacy	Super Sani-Cloths

Certification

Certification marks	cTUVus
Standards complied with	EN 60601-1:2006/A1:2013 EN 60601-1-2:2007 +AC 2010 EN 60601-1-2:2015 EN 60601-2-25:2015 IEC 62366-1:2015 EN 62304:2006+A1:2015
Pharma mode*	Support 21CFR Part 11 clauses for the control of electronic records in closed systems when Phrama mode option is activated. No support for electronic signature

Ordering information

Available user interface languages	Chinese, Danish, Dutch, English, French, Finnish, German, Italian, Norwegian, Swedish, Korean, Japanese, Russian, Spanish, Portuguese, Brazilian Portuguese, Polish

** The feature is not supported in China.*

MAC 5

DOC2563553 rev 1 A4/JB07676US

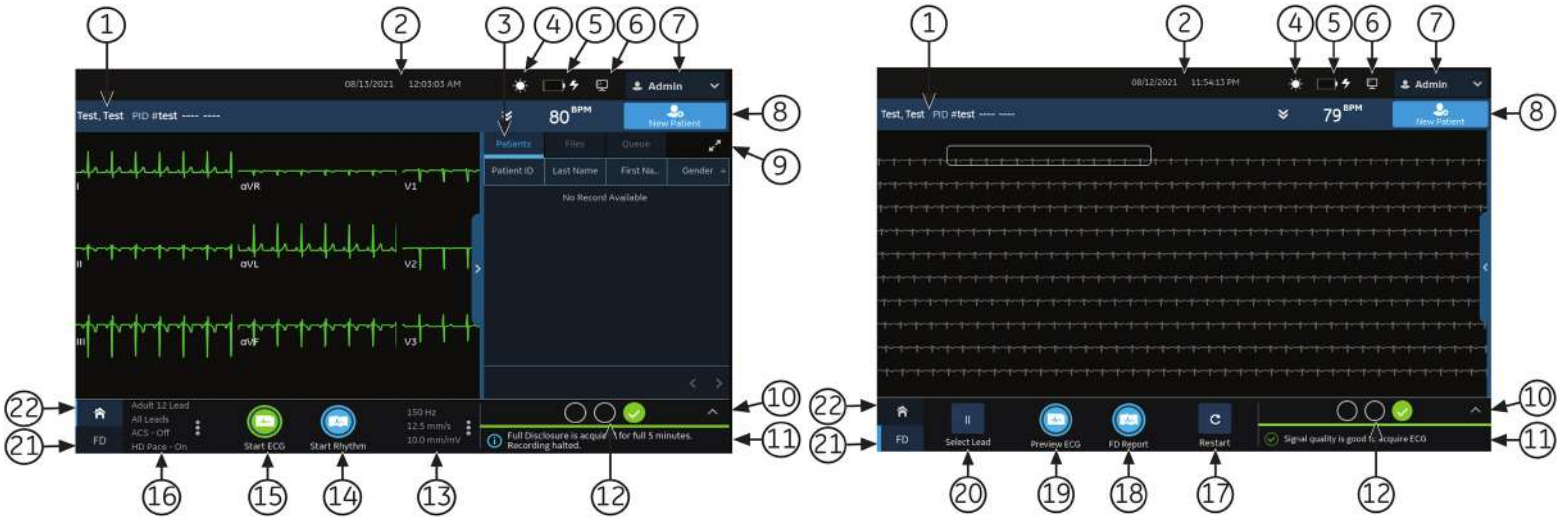
Our augmented reality experience allows you to explore key features and see how easily MAC ECG products can fit into your existing office or hospital environment

Point your camera at the QR code.
Tap the banner that appears on your screen.

MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System

5864335-005-2
QUICK REFERENCE GUIDE

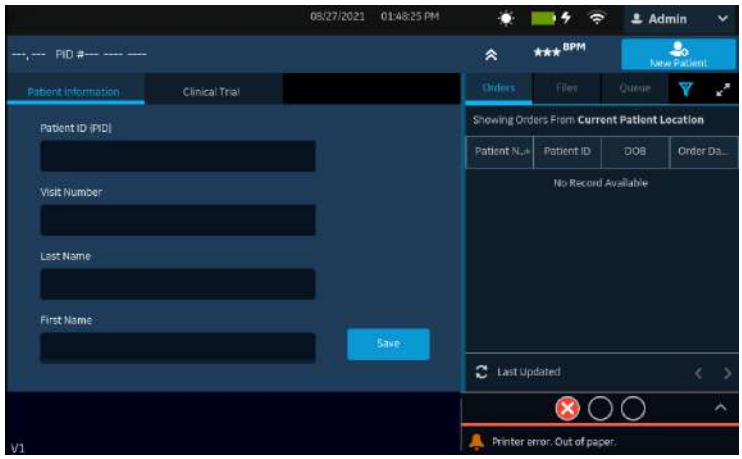
Acquisition Screen



Item	*Name*	*Description*
1	**Patient Information banner**	Displays Patient Information such as first name, last name, and gender.
2	Date and Time	Current local date and time in the configured date and time format.
3	**Orders/Patients, Files,** and **Queue** tabs	Select the appropriate tab to open the Orders list, files, or queue.
4	Brightness icon	Allows you to adjust the screen brightness.
5	Battery or AC Power icon	Shows the battery status.
6	Network Status icon	Shows the wireless or LAN connection status.
7	User Menu	Displays the name of the user logged into the device.
8	**New Patient** icon	Select to enter patient data for a new patient test.
9	**Expand** icon	Expands the list of the Orders/Patient, Files, or Queue tabs.
10	Electrode Placement Image	Select the arrow to expand and view the image.
11	Notification Area	Displays the printing status, report transmission status, and **Hook Advisor** lead quality status.
12	**Hookup Advisor** Lead Quality Status Indicator	Displays the overall lead quality status.
13	Filter, Speed and Gain	Displays the default waveform filter, speed, and gain.
14	**Start Rhythm** icon	Allows you to print or digitally record a rhythm report.
15	**Start ECG** icon	Allows you to start recording an ECG.
16	Lead Set and Display Format	Displays the default test type and display format.
17	**Restart** icon	Allows you to restart the Full Disclosure ECG.
18	**FD Report** icon	Allows you to generate the Full Disclosure report.
19	**Preview ECG** icon	Allows you to preview the recorded 10 seconds of ECG data.
20	**Select Lead** icon	Allows you to select the leads you want to display on the screen and the FD report.
21	**Full Disclosure** tab	Displays full disclosure ECG.
22	Home tab	Displays the live waveform for the current patient connected to the device.

Start a New Patient

1. Select **New Patient** on the acquisition screen.
2. Prepare and connect the leadwires to the patient.
3. Enter patient information on the **Patient Information** screen using any of these options:
   - Scan the patient's barcode
   - Perform order or ADT query
   - Attach a patient record from the **Patients** list
   - Attach an order from the **Orders** list
   - Use the device keyboard to manually enter the patient information.
4. Select **Save** to save the patient information.
5. Verify that the Hookup Advisor status is green and review the waveform.
6. Select **Start ECG** to record an ECG or **Start Rhythm** to record a rhythm.



Record a Rhythm

1. Select **Start Rhythm** on the acquisition screen. If the rhythm mode is:
   - **Paper Only**, the rhythm is printed. Select **Stop Rhythm** at any time to stop printing the rhythm strip.
   - **Digital Only**, the rhythm is digitally recorded for a configured duration and saved in the **Files** list. The rhythm does not print. Select **Stop Rhythm** at any time to stop recording. The saved rhythm report displays in the **Rhythm** tab.
   - **Both**, the rhythm digitally records and prints for a configured duration and saves in the **Files** list. Select **Stop Rhythm** at any time to stop recording and printing the rhythm strip. The saved rhythm report displays in the **Rhythm** tab.
2. Review the rhythm report.
   To continue with the same patient, go to the **Home** tab and continue to record the ECG.
   To start a new patient, select **Done** or **New Patient** on the screen.

Record an ECG

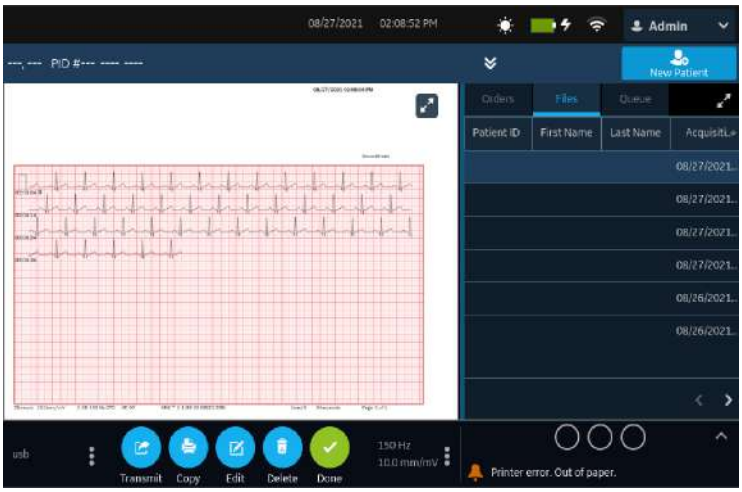
1. Select **Start ECG** on the acquisition screen.
   - The patient report preview displays in the **ECG** tab if you enable Print Preview. Select **Accept** to accept the ECG and save the patient report in the **Files** list. Select **Reject** to return to the live waveform display.
   - The patient report displays in the **ECG** tab and saves to the **Files** list if you disable print preview.

   The patient report automatically prints in the report format configured on your device.
2. Review the ECG patient report.
   To continue with the same patient, go to the **Home** tab and continue to record the ECG.
   To start a new patient, select **Done** or **New Patient** on the screen.

Record a Full Disclosure ECG

The Full Disclosure ECG option shows one lead of the patient waveform for a maximum of 5 minutes.

1. Enable the **Full Disclosure** option in the **Settings** screen.
2. The device automatically records the full disclosure ECG when you start a new patient test. It runs in the background.
3. Select the **FD** tab on the Acquisition screen to view the Full Disclosure ECG.
4. Select the **Preview ECG** tab on the Acquisition screen to preview the recorded 10 seconds of ECG data.
5. Select the **FD Report** tab to generate the full disclosure ECG report.
   To continue with the same patient, go to the **FD** tab and continue to record the full disclosure ECG.
   To start a new patient, select **Done** or **New Patient** on the screen.



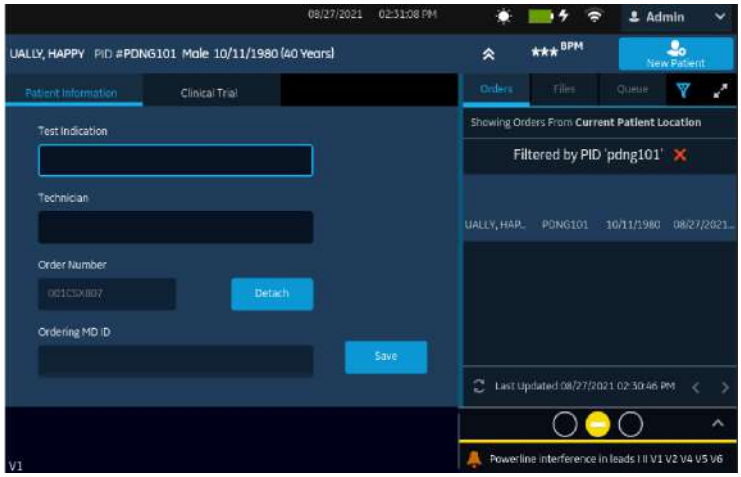
Review Patient Reports

1. From the Acquisition screen, select the **Files** tab.
2. In the **Files** list, select a patient report. The patient report displays in the **ECG** or **Rhythm** tab.
3. Review the patient report and perform any of these tasks:
   - To transmit the report, select a destination from the **Destination** menu and select **Transmit**.
   - To print a copy of the report in the displayed format, select **Copy**.
   - To edit patient information, select **Edit**, or select anywhere in the **Patient Information** banner.
   - To delete the report, select **Delete**.
   - To close the report, select **Close**.

Query Orders or ADT Data

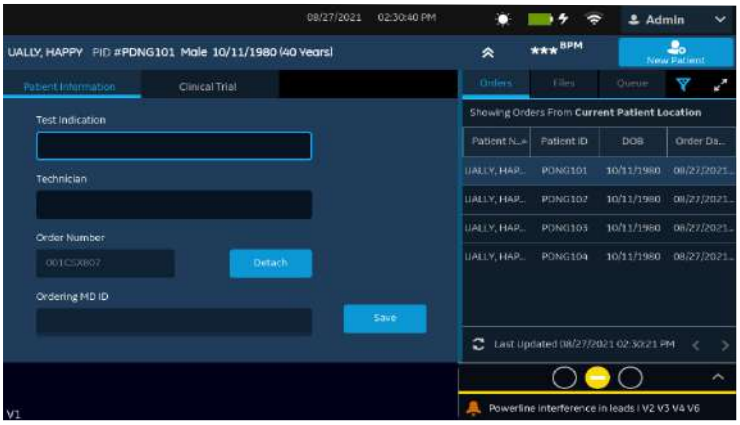
Make sure that you configure remote patient query and you have the required privileges to query patient demographics.

1. Start a new patient test.
2. Scan the patient's barcode, or enter the **Patient ID** or **Visit Number** on the **Patient Information** screen. Press the **Search Icon** to initiate the query.
   - If multiple orders for one patient are found, they are listed in the **Orders** list. Double-tap an order to attach.
   - If one matching order is found, it populates the **Patient Information** screen.
   - If no orders are found, the system will query for ADT.
   - If an ADT record is found, it populates the **Patient Information** screen.
   - If no matching order or ADT information is found, the data scanned or entered is used to populate the **Patient Information** screen.



Attach an Order to a New Patient Test

1. Double-tap the correct patient order found from the patient query to attach it to the patient test.
   Data from the order is populated in the **Patient Information** screen and the screen expands. Some populated fields are read-only.
2. Edit the remaining fields and save the patient information.
3. In the **Orders** list, verify that the order status is **Attached**.
4. Record the ECG.



Related Manuals

Part Number	*Document Title*	*Description*
5864335-001	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Operator's Manual	Reference manual for details of how to use features of the device and software.
5864335-002	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Service Manual	Information for servicing of the device, updating the software, overview of the device hardware, FRU parts, and part numbers.
5864335-003	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Privacy and Security Manual	Required privacy and security information.
5864335-004	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System XML Technical Reference Manual	Reference manual for usage of xml fields.
5864335-006	MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite Resting ECG Analysis System Quick Setup Guide	Guide for quick setup of the device.
5858128-01	KISS™+ EEAS/KISS™+ Multilead Electrode Application System Operator's Manual	Reference manual for the KISS™ multilead electrodes.
2102946-001	Supplies and Accessories Guide Diagnostic Cardiology	All required supplies and accessories information.
2056246-007	Marquette™ 12SL™ ECG Analysis Program	Reference manual for the Marquette™ 12SL™ Program
NA - Refer to OEM Manual	Compact Trolley Instruction	Reference manual for the compact trolley.

GE Medical Systems
Information Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226 USA

EC REP
GE Medical Systems S.C.S.
283 rue de la Minière
78530 BUC, France

CE 0197

gehealthcare.com

MAC 5

Streamline your ECG workflow.

Simple. Precise. Secure.

Building a world that works

Cardiac care is action packed. Let’s make it flow more easily. MAC 5, the latest addition to GE Healthcare’s touchscreen ECG family, is designed to help streamline workflow and facilitate effective care in today’s healthcare environments.

With input from thousands of users like you, we’ve built a system that makes your whole team more productive. Complete a high-quality exam in just a few clicks. Then send the results anywhere, quickly and securely. All with minimal training or support. Plus, you can move the compact MAC 5 wherever you need it. And clean it with ease, too.

We mean it when we say MAC 5 is

Simple. Precise. Secure.

Simple.

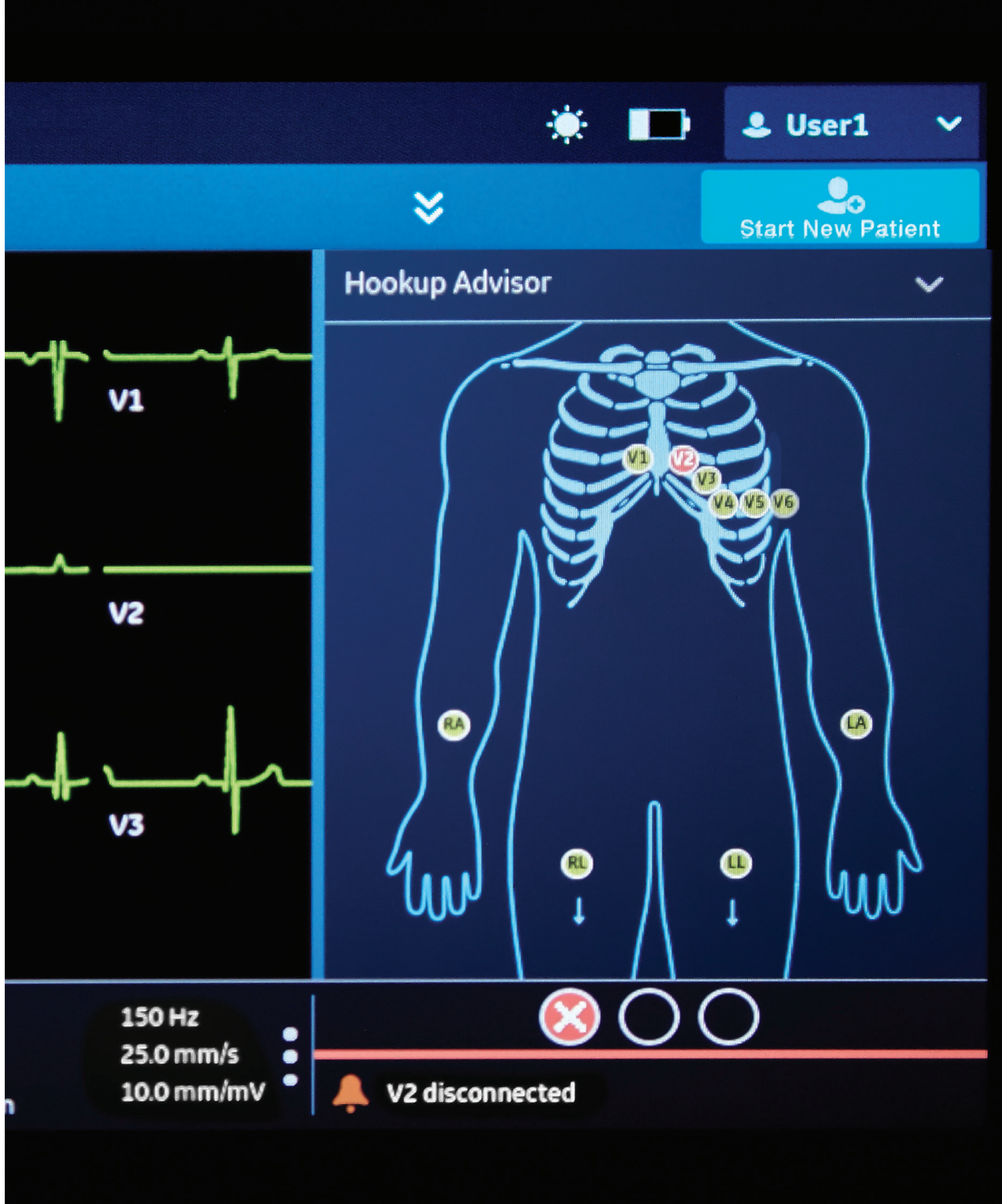
ECG in up to 31% fewer steps[1]
85% of users agree that
they need minimal training[2]

Everything about the MAC 5 experience is designed to keep you moving forward and keep the focus on patient care.

Quickly acquire a quality ECG.

MAC 5 empowers every ECG professional to accelerate the care process.

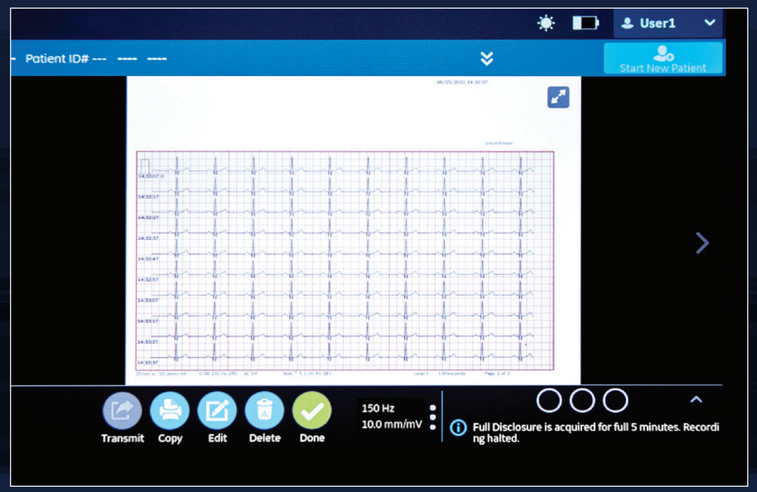
- **Enhanced Hookup Advisor**™ – Even the newest user can be guided to a clean, high-quality waveform in seconds.
- **8.9 inch touchscreen** – We've refined this intuitive platform for ease of use based on thousands of hours of customer testing.



Simple.

Send the results anywhere online, quickly and securely.

MAC 5 supports efficient care and saves your IT team time by connecting easily with existing data systems.



- **Built-in PDF/XML export support**[3]
  – In just a few clicks, send data in your preferred format to a shared folder or SFTP destination of your choice.

- **Bidirectional HL7 and DICOM communication** [4]
  – Connect to your systems with confidence via our MUSE™ cardiology information system or your EMR/ DICOM gateway.

Simple.

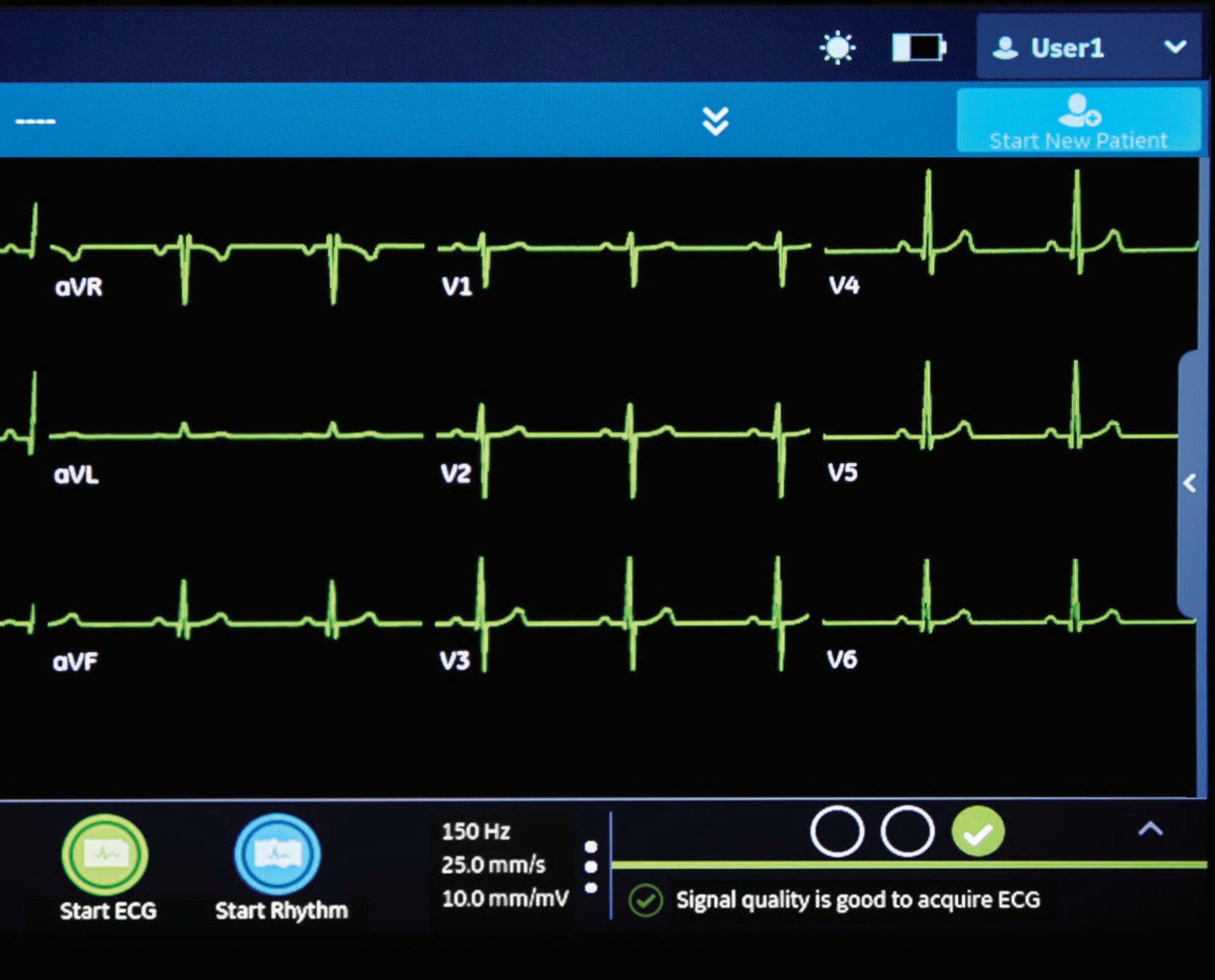
Accommodate your workflow with ease.

MAC 5 drives productivity, helping you and your team quickly handle all your essential ECG tasks.

- **Choice of configuration with or without a printer**[5] – The MAC 5 works the way you work.

- **Easy-clean design** – Wipe down the smooth-surfaced screen in seconds to meet your infection control standards.

- **Optimal mobility** – MAC 5's convenient carry handle and compact design make it easy to move around your facility and between locations.

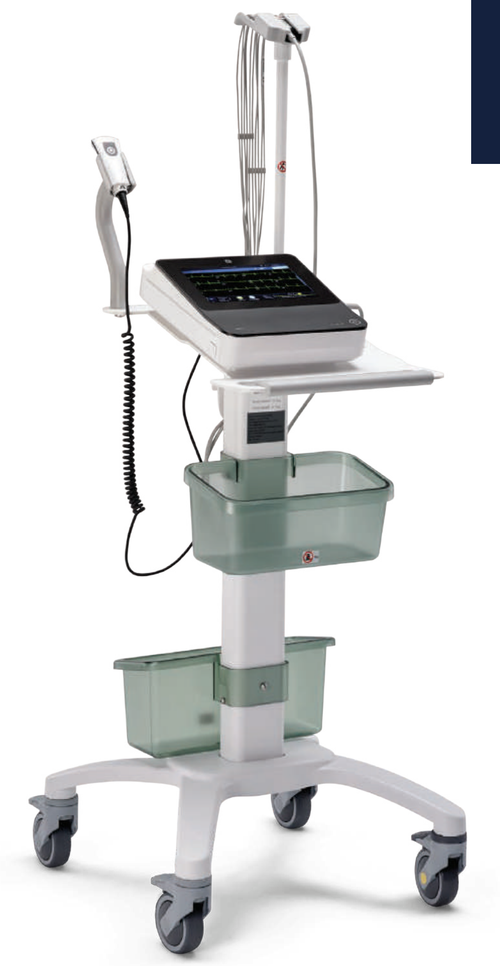


Precise.

Quickly acquire accurate ECGs.

ECG professionals of any skill level can acquire accurate, detailed clinical data to support effective patient care, thanks to MAC 5's proven acquisition architecture and tools.

- **Auto-ECG³ algorithm** – Immediately capture and display the first clean, high-quality ECG.
- **Smart Lead technology** – Automatically detect when a lead has become disconnected.



Precise.

Help make critical diagnoses with speed and confidence.

Enable accurate interpretations aligned with current guidelines, using GE Healthcare's Marquette™ 12SL algorithm, an industry standard that has been continuously improved since 1980.

- **Over 200 scientific references** – Marquette 12SL has been validated extensively against clinically-correlated databases for accuracy.[7]
- **Gender- and pediatric-specific interpretations** – 12SL has been shown to provide a 25% relative improvement in detection of Acute Inferior MI in women under 60 years of age.[8]

Precise.

Provides exceptional clinically validated decision support.

MAC 5 facilitates prompt delivery of accurate data for complex cases.

- **Full disclosure** – Accelerate reading and review with a condensed full-disclosure rhythm report capable of reducing 30 pages to three.[3]
- **Advanced algorithms** – Handle more complex patient cases through access to algorithms such as Critical Values and Acute Coronary Syndrome Analysis.

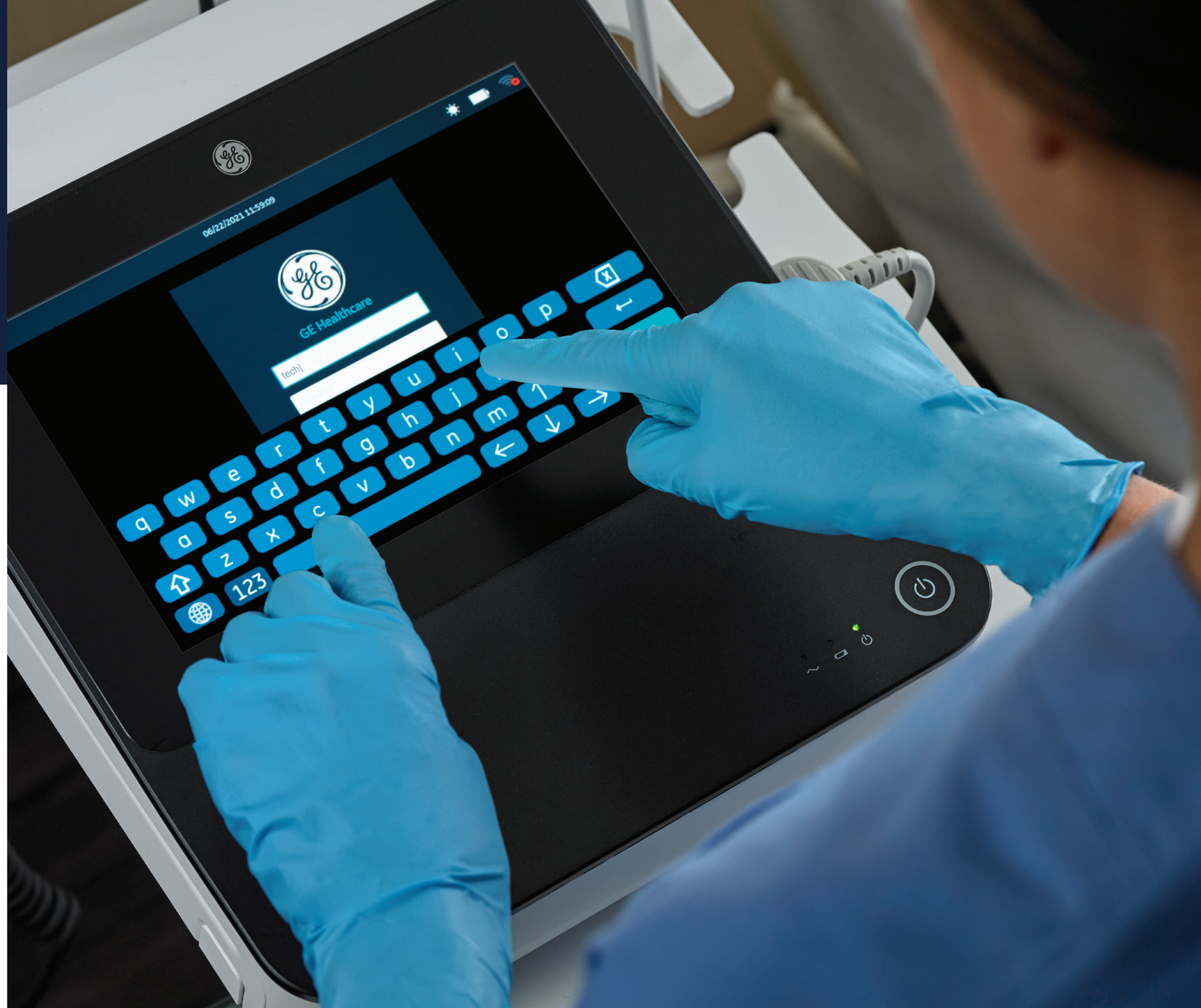
Secure.

Seamlessly connected.
Continuously protected.

Gain peace of mind about patient privacy and data protection with GE Healthcare's ECG security architecture. Security is at the heart of every solution we develop.

- **Minimize vulnerabilities** –
  Providing only the hardware and software needed for optimal ECG workflow, MAC 5 reduces risks by eliminating pathways for breaches or attacks.

- **Control access** –
  Role-based LDAP user authentication, patient data encryption and secure network connections help ensure MAC 5 interacts only with trusted people and systems.

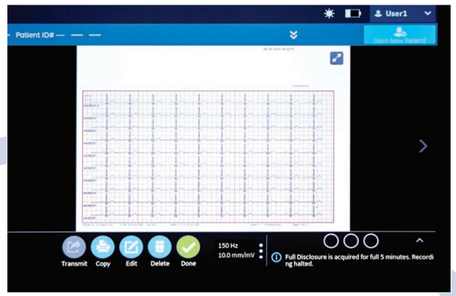


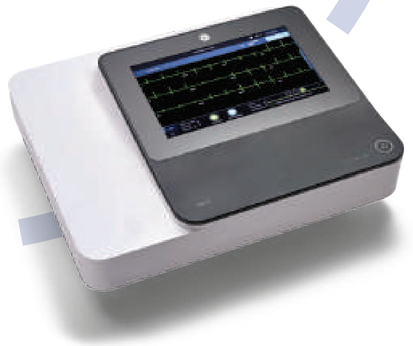
Secure.

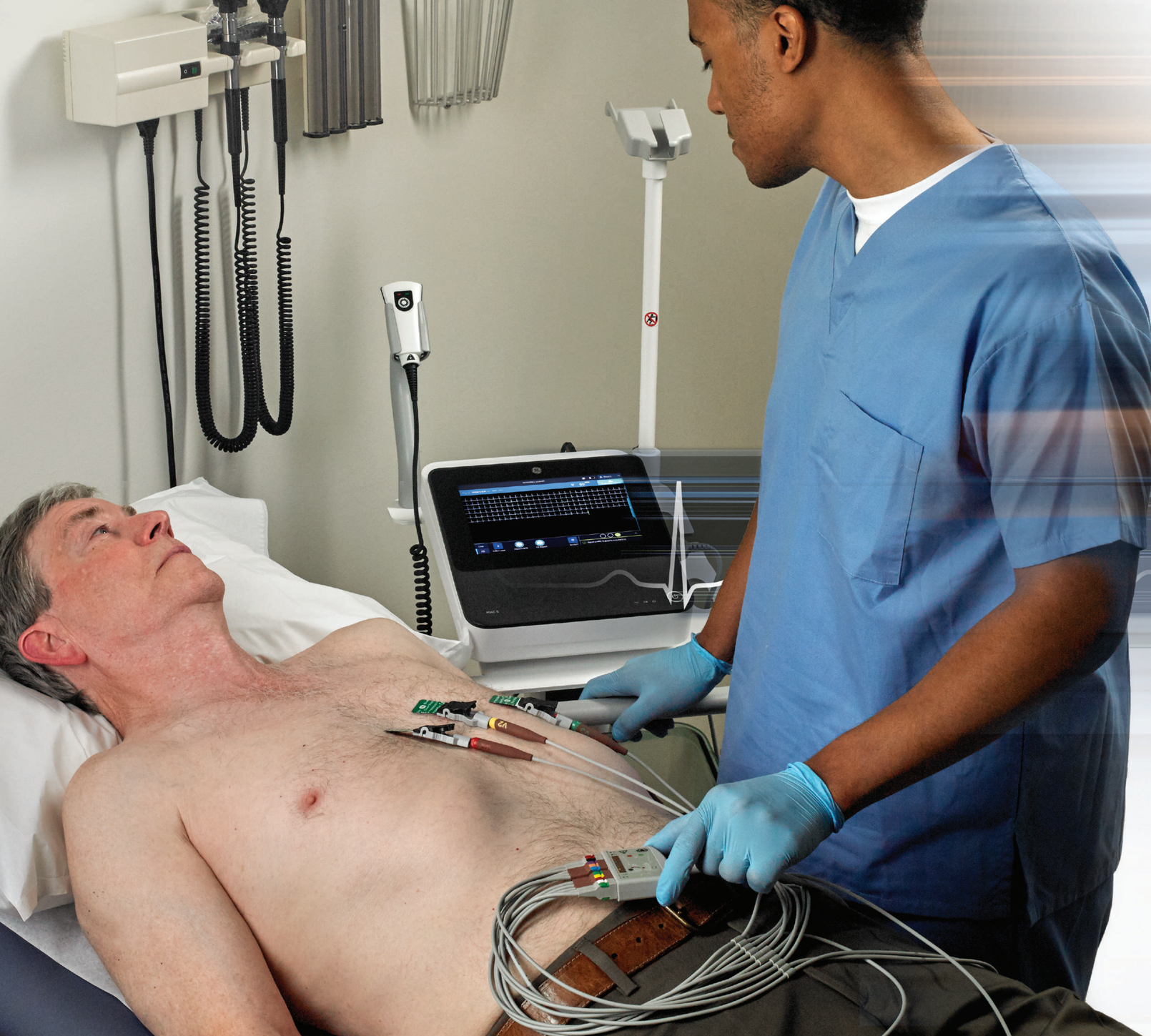
We take a holistic approach to safeguarding data.

Because today's hospital is increasingly interconnected, and threats continue to evolve, we're always working together – across our company, across the healthcare industry and across the cybersecurity field.

- **Mind the unique challenges of medical devices** – We employ a team of experts specialized in medical device cybersecurity.
- **Stay on top of emerging threats** – The GE Healthcare cybersecurity team is constantly monitoring for threats and developing security enhancements for our customers.







Simple.
Precise.
Secure.

MAC 5 keeps you moving forward in cardiac care.

Even when confronting high patient volumes and complex cases, your team now has the power to care for more patients, more efficiently and effectively than ever.

See for yourself.
Contact your GE Healthcare representative for a demonstration today.

Building a world that works

GE Healthcare is a leading global medical technology and digital solutions innovator. GE Healthcare enables clinicians to make faster, more informed decisions through intelligent devices, data analytics, applications and services, supported by its Edison intelligence platform. With over 100 years of healthcare industry experience and around 50,000 employees globally, the company operates at the center of an ecosystem working toward precision health, digitizing healthcare, helping drive productivity and improve outcomes for patients, providers, health systems and researchers around the world. Follow us on Facebook, LinkedIn, Twitter and Insights, or visit our website www.gehealthcare.com for more information.

Not all products or features are available in all markets.

[1] In an observational study comparing the usability of various ECG systems, when participants used GE's new resting ECG interface, they were able to complete the same set of ECG tasks in 31% less steps.

[2] Double-blind study by an independent third party research firm, Healthcare Research & Analytics (HRA) at Smith Research Facility, Chicago.

[3] Optional feature, not available in all regions.

[4] May require a gateway.

[5] Configuration availability depends on region.

[7] For more details please refer to the GE 12SL statement of validation and accuracy

[8] Xue, J. et al. "A New Method to Incorporate Age and Gender into the Criteria for the Detection of Acute Inferior Myocardial Infarction." J Electrocardiol. 34(4) (Part 2) (Oct 2001):229-234

GE Healthcare, a division of General Electric Company.

JB16822XX

GE Healthcare

MAC™ 5 A4/MAC™ 5 A5/MAC™ 5 Lite

Resting ECG Analysis System

Operator Manual

5864335-001-1

Publication Information

The information in this manual applies only to MAC™ 5 Resting ECG Analysis System. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

This product complies with the requirements concerning medical devices from the following regulatory bodies.

Date of first CE mark - 2022.

For more information about compliance, refer to *Regulatory and Safety Information on page 339*.

The document part number and revision are on each page of the document. The revision identifies the document's update level. The revision history of this document is summarized in the following table.

Revision	*Date*	*Comment*
1	18 September 2021	Initial Release

Access other GE Healthcare Diagnostic Cardiology documents at the Customer Documentation Portal. Go to *https://www.gehealthcare.com/en/support/support-documentation-library* and scroll to the bottom of the page.

To access Original Equipment Manufacturer (OEM) documents, go to the device manufacturer's website.

Third-party Licenses

This product includes software developed by:

- Linux Kernel organization (*https://www.kernel.org*)
- NXP Semiconductors (*https://www.nxp.com*)
- Apache Software Foundation (*http://www.apache.org*)
- OpenSSL.org (*http://www.openssl.org*)
- OpenSSH (*https://www.openssh.com/*)
- GNU Foundation packages (*https://www.gnu.org*)
- Gentoo software (*https://packages.gentoo.org*)
- Boost Libraries (*http://www.boost.org*)
- POCO Project (*https://pocoproject.org*)
- Debian packages (*https://packages.debian.org*)
- Yocto project packages (*https://www.yoctoproject.org*)
- Freedesktop.org (*https://www.freedesktop.org*)
- Busybox project (*https://busybox.net*)
- bzip.org (*http://www.bzip.org*)
- FreeType project (*https://www.freetype.org*)
- OpenBSD Project (*https://www.openbsd.org*)
- netfilter.org project (*http://www.netfilter.org*)
- netcat (*http://netcat.sourceforge.net/*)
- OpenLDAP Project (*https://www.openldap.org*)

- ws4d.org (*http://ws4d.org/projects*)
- JS Foundation (*https://js.foundation*)
- ANGULARJS (*https://angularjs.org*)
- QT-labs (*https://github.com/qt-labs*)
- Massachusetts Institute of Technology (*https://web.mit.edu*)
- Cyrus IMAP org (*https://www.cyrusimap.org*)
- rsyslog (*https://www.rsyslog.com*)
- sshpass (*https://sourceforge.net/projects/sshpass/*)
- CUPS (*http://www.cups.org/*)
- cups-filters (*https://openprinting.org/*)

License details of the software used in the product can be viewed in the online help in the *Open Source Licenses* section. Contact GE Service to obtain the source code of the open-source software used in the product, if required.

This document describes the MAC™ 5 Resting ECG Analysis System, also referred to as the" product", "system", or "device". This document is intended to be used by an operator of the MAC™ 5 Resting ECG Analysis System system.

The MAC™ 5 Resting ECG Analysis System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or facility providing patient care.

This document provides information required for the proper use of the system. Familiarize yourself with this information and read and understand all instructions before attempting to use this system. Keep this document with the equipment at all times, and periodically review it.

Illustrations in this document are provided as examples only. Depending on system configuration, screens in the document may differ from the screens on your system. Patient names and data are fictitious. Any similarity to actual persons is coincidental.

Support

GE Healthcare maintains a trained staff of application and technical experts to answer questions and to respond to issues and problems that may arise during the installation, maintenance, and use of this product.

If you require additional assistance, contact your GE Healthcare representative, or GE Healthcare support at one of the following numbers:

- North America: 1-800-558-7044
- Europe: +49 761 45 43 -0
- Asia: +86 21 3877 7888

Training

This document is intended as a supplement to, not a substitute for, thorough product training. If you have not received training on the use of the product, you should request training assistance from GE Healthcare.

To see available training, go to the GE Healthcare training website *www.gehealthcare.com/training*.

For more self-paced course offerings, tools, and reference guides you may find useful, visit the GE Healthcare Education Store at *www.gehealthcare.com/educationstore*.

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1

Product Overview

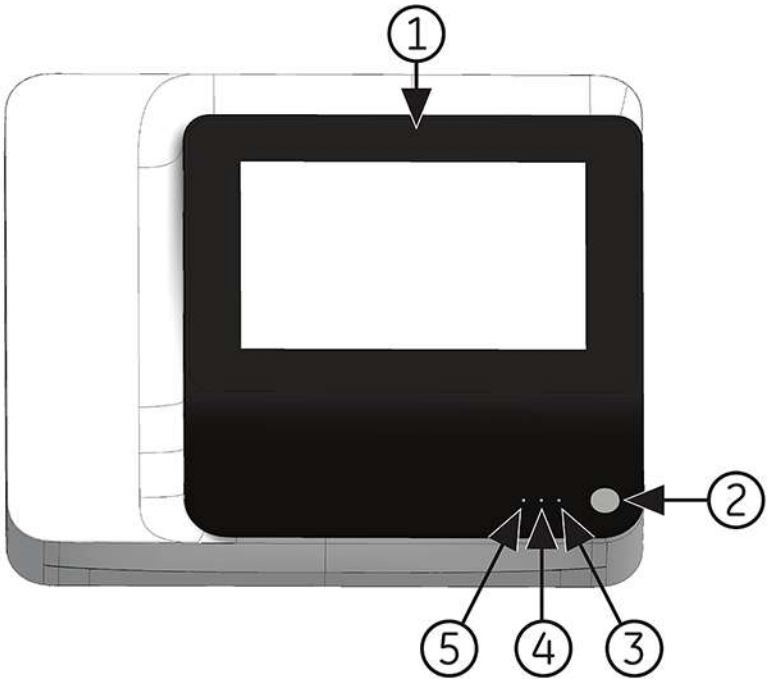
The MAC 5 Resting ECG Analysis System has three modes:

- MAC 5 A4 - This mode includes an A4/Letter paper size thermal printer.
- MAC 5 A5 - This mode includes an A5 paper size thermal printer.
- MAC 5 Lite - This mode does not include a thermal printer.

The MAC 5 Resting ECG Analysis System, (referred to as "the device"), supplies 12-lead ECG measurement and interpretative analysis, prints 12-leads of ECG, and transmits ECG data to and from a central ECG cardiovascular information system.

Front View

The image below is an example of the MAC 5 A4. The information in the table applies to all MAC 5 devices.

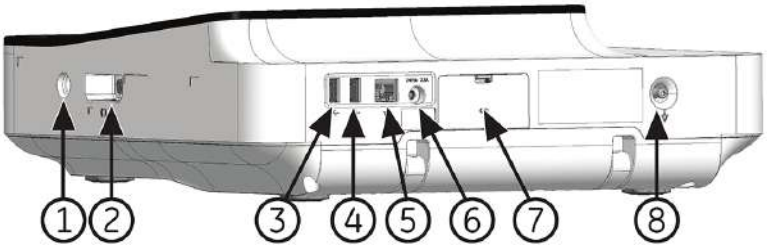


Item	*Name*	*Description*
1	Display and Touchscreen	Displays waveform and text data. The touchscreen enables you to interact directly with the device through touch gestures.
2	Power button	Turns the device on or off.
3	Power on LED	Shows if the device is on or off. • Green light - on. • No light - off. • Flashing green light - standby mode.
4	Battery LED	Battery status: • Flashing amber light at 2 second intervals - battery is charging. • Flashing amber light at a 1 second interval - battery is critically low. • Flashing amber light at a 1/2 interval - battery has a communication failure. • No light - battery is fully charged, not installed, or discharging. The detailed battery status shows on the **Status Bar** of the Acquisition screen, see *Battery Status on page 18*.
5	AC Power LED	AC power status: • Green light - the device is plugged in and receiving power. • No light - the device is not plugged into AC power.

Side and Rear View

Side View

The image below is an example of the MAC 5 A4. The information in the table applies to all MAC 5 devices.

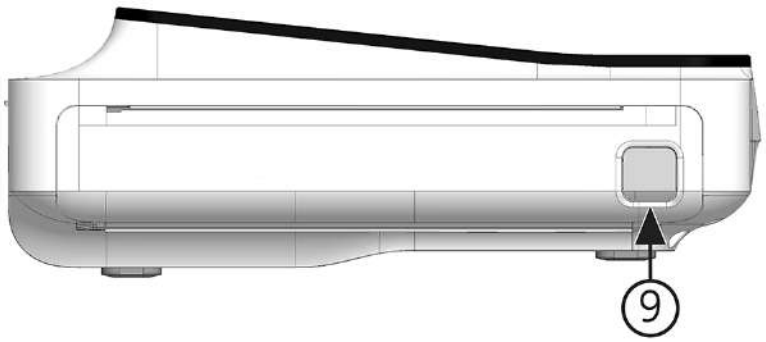


Item	*Name*	*Description*
1	KISS Pump Connector	Use to connect a KISS pump cable.

Item	*Name*	*Description*
2	ECG Patient Cable Connector	D-sub 15–pin female connector for the acquisition cable.
3	USB Slot A	• Use to connect a USB flash drive or USB cable. You can connect a USB flash drive for a software update, backup/restore or export operations, or a barcode reader USB cable. • Standard USB connector for USB devices, for example, the external barcode reader, USB memory stick, USB keyboard, and USB mouse.
4	USB Slot B	• Use to connect a USB flash drive or USB cable. You can connect a USB flash drive for a software update, backup/restore or export operations, or a barcode reader USB cable. • Standard USB connector for USB devices, for example, the external barcode reader, USB memory stick, USB keyboard, and USB mouse.
5	Ethernet/LAN Port	Use to connect an Ethernet cable.
6	DC Power Inlet	Use to connect the DC power cord.
7	Battery Door	Use to insert the battery.
8	Equipotential Grounding Plug	Use to connect non-grounded peripheral devices.

Rear View

The image below is an example of the MAC 5 A4. The information in the table also applies to MAC 5 A5.



Item	*Name*	*Description*
9	Printer Door Button	Use to release the printer door.

Acquisition Screen Overview

The **Acquisition** screen is the main screen that displays when you first log on to the device. You can acquire an ECG from the Acquisition screen.

Table 1: Acquisition Screen

Item	*Name*	*Description*
1	**Patient Information** Banner	Shows **Patient Information** such as the patient first name, surname, and gender. Select anywhere on the banner to add or edit patient information.
2	Date and Time	Current local date and time in the configured date and time format. To configure a date and time format, see *Configure the Date and Time on page 255*.

Item	*Name*	*Description*
3	**Orders/Patients**, **Files**, and **Queue** tabs	• The **Orders** tab displays when you enable order management. Select **Orders** to open the **Orders** list and view a list of the available orders. • The **Orders** tab does not display if you disable order management, the **Patients** tab displays. Select **Patients** to open the **Patients** list. A list of the last 500 patients displays with ECGs that were acquired on the device. If you double click any information in the **Patients** list, the **Patient Information** banner expands and shows the patient information. • Select **Files** to open the **Files** list and view the list of stored patient reports. • Select **Queue** to open the **Queue** list to view the list of reports in the queue to be transmit to a configured destination.
4	Brightness Icon	Select to adjust the screen brightness.
5	Battery or AC Power Icon	Displays the battery status.
6	Network Status Icon	Displays the wireless or LAN connection status.
7	User Menu	Displays the name of the user logged on to the device. When you select the name, the user menu expands and displays the available menu options. You do not have access to some menu options. Your administrator can assign the proper privileges. If you disable user authentication or configure with Technician ID access, the Default user must log on as a user with sufficient privileges to access a menu option.
8	**New Patient** icon	Select to enter patient data for a new patient test. This action will clear all previous patient data.
9	**Expand** icon	Select the tab (**Orders**/**Patients**, **Files**, or **Queue**) that you want to expand, and select the **Expand** icon to open the list.
10	Electrode Placement Picture	Select the arrow to expand and view the picture that shows the placement of electrodes and the electrode quality of each lead. Each lead quality indicator on the picture changes to yellow, red, or green, based on its connection status. You can enable or disable the auto-expansion of the picture. If you enable auto-expansion of the picture: • The picture automatically expands if the **Hookup Advisor** Lead Quality Indicator is yellow or red. • The picture automatically collapses if the **Hookup Advisor** Lead Quality Indicator is consistently green for a few seconds.

Item	*Name*	*Description*
11	Notification Area	Displays messages: • printing status and progress • report transmission status • **Hookup Advisor** lead quality status The messages display one at a time in the sequence of occurrence. The messages do not display when a patient is connected and the hookup advisor is evaluating the waveform.
12	**Hookup Advisor** Lead Quality Status Indicator	Displays the lead quality status indicator in three circles that change to yellow, red, or green, based on the lead quality.
13	Filter, Speed and Gain	Displays the default waveform filter, speed, and gain. Select anywhere around the ellipsis icon and select a different value. You can only make a change before you record an ECG. You can make a change before and during the recording of a rhythm. **NOTE**: A change to the filter, speed or gain is applicable to the current patient. For a new patient, the values are reset to default settings.
14	**Start Rhythm** icon	Select to print or digitally record the rhythm report.
15	**Start ECG** icon	Select to record an ECG.
16	Lead Set and Display Format	Displays the default test type and display format. Select anywhere around the ellipsis icon and select a different value. You can only make a change before you record an ECG. You can make a change before and during the recording of a rhythm. **NOTE**: Any change to the test type and display format only applies to the current patient. For a new patient, the values are reset to the default settings.
NOTE: The items below display only after you purchase and enable **Full Disclosure** in the **Settings** screen.		
17	**Restart** icon	Select to restart the Full Disclosure ECG. A message displays as *The full disclosure data will be cleared. Do you want to proceed?*
18	**Full Disclosure Report** icon	Select to generate a Full Disclosure report. The Full Disclosure report for the selected lead displays for your review.

Item	*Name*	*Description*
19	**Preview ECG** icon	Select anywhere on the Full Disclosure ECG. The 10 seconds of ECG data is selected. Click Preview ECG. A preview of the recorded 10 seconds of data for all leads displays in the configured preview report format in the maximize view. Select the minimize icon to view the report.
20	**Select Lead** icon	Displays the default test type and display format. Select anywhere around the ellipsis icon and select a different value. You can only make a change before you record an ECG. You can make a change before and during the recording of a rhythm. **NOTE**: Any change to the test type and display format only applies to the current patient. For a new patient, the values are reset to the default settings.
21	**Full Disclosure** tab	Displays a full disclosure ECG.
22	Home tab	Displays the live waveform for the current patient connected to the device.

User Menu Options Description

The **User Menu** is located at the top right corner of the Acquisition screen.

Table 2: User Menu Options

Item	*Option*	*Description*
1	**<User>**	Displays the name of the user logged into the device as configured by your administrator. Pre-defined users display as follows: • Admin • STAT • Service • Default
2	**Settings**	Displays the **Settings** screen used to configure the device. The administrator must grant you privileges to access this screen. If the user does not have access to the screen and if user authentication is disabled or configured with Technician ID access, the Default user is prompted to log on as a user with sufficient privileges.

Item	*Option*	*Description*
3	**Service**	Displays the **Service** screen used to service the device. Your administrator must grant you privileges to access this screen. If the user does not have access to the screen and if user authentication is disabled or configured with Technician ID access, the Default user is prompted to log on as a user with sufficient privileges.
4	**Service Snapshot**	The user can get a service snapshot without the **Service** privileges. Complete the snapshot to help identify a problem on the device.
5	**Change Password**	The Admin user or a local user can change their password. Displays only if you enable full user authentication.
6	**Lock**	Locks the device. Displays only if you enable full user authentication.
7	**Log Out**	Logs off the user. Displays only when you are logged on to the device.
8	**Standby**	Puts the device in standby mode to save battery power without turning it off.
9	**Power Off**	Powers off the device. **NOTE**: Pressing the **Power** button on the front panel can also stop the device.
10	**About**	Displays the device software information.
11	**Help**	Displays help information about the device.

Battery Status

The battery icon shows the stored power of the battery. The power levels are shown in 10% increments. The color of the icons change to show the level of battery life.

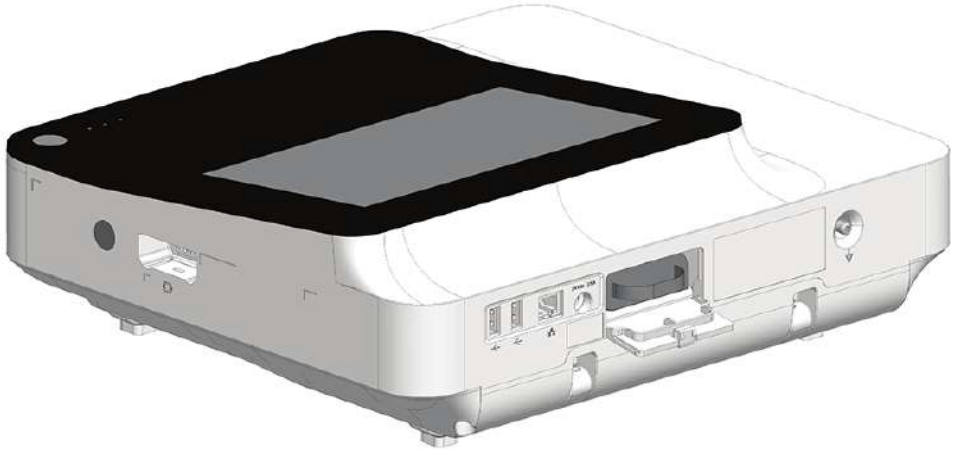
You can operate the device connected to the AC Mains power when the batteries are removed. The device can also operate with a single battery installed to allow hot swapping of the battery without plugging into AC Power.

Table 3: Examples of Battery and Power Icon Status

Icon	*Status*	*Description*
Green 	Connected to AC Mains	The device is connected to the AC Mains power and the battery is charging.
White 	Operating on Battery	The device is only using the battery and the battery is discharging. The device is not connected to the AC Mains power.

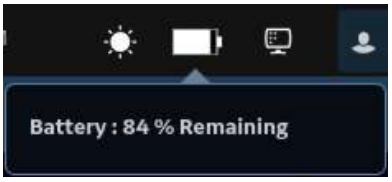
Icon	*Status*	*Description*
White 	Battery – Fully Charged and Disconnected from AC Mains	The battery is fully charged and the device is disconnected from the AC Mains power.
Solid Green 	Battery - Fully Charged and Connected to AC Mains	The battery is fully charged and the device is connected to the AC Mains power.
Red 	Battery – Low or Critically Low	The battery is at low capacity and the device is disconnected from the AC Mains power. If the charge level is below 15%, an error tone sounds. A message opens that tells you the percentage of the remaining battery power. If the charge level is below 10%, the error tone is louder, longer, and sounds every minute. A message opens that tells you the battery is critically low and you should connect to AC power immediately.
No color with red X 	Battery Not Present, AC Mains Power	The battery is not in the device and the AC Mains power is connected. If you select the battery icon, a message opens that tells you the battery is not present.

The image illustrates the battery in the battery compartment.



Show Battery Status

1. Select the battery icon on the **Status Bar** of the Acquisition screen.
2. An image opens showing the battery life.



Show Network Connection Status

When the wireless and wired connection is set to **Enable**, the device uses a wired connection when you connect a Local Area Network (LAN) cable. If you remove the LAN cable, the device uses the wireless connection.

To view the status of your device's connection to your LAN or Wireless Local Area Network (WLAN), perform the procedure as follows:

1. Select the **Network Status** icon on the status bar.
2. Review the tables for the description of the network status icon when connected to a LAN or WLAN network.

Table 4: LAN Icons

Network Status Icon	*Status*	*Description*
	LAN Active	The device is connected to a LAN.
	LAN Connected	The device is connected to a remote server through a LAN and is in the process of obtaining an IP address. If this icon is blinking, the device is acquiring an IP address from DHCP.
	LAN Disconnected	The device is not connected to a LAN; no LAN (Ethernet) cable is attached to the device.

Table 5: WLAN Icons

Icon	*Status*	*Description*
	WLAN Active	The device is connected to a WLAN and has a valid IP address. The icon shows a number of wireless bars to indicate the strength of the wireless signal.
	WLAN Connected	The device is connected to an access point and is in the process of obtaining an IP address. If this icon is blinking, the device is acquiring an IP address from DHCP.

Icon	*Status*	*Description*
	WLAN Disconnected	The device is not connected to a WLAN.

For more information about wireless certificate errors, see *Wireless Network Connectivity Errors on page 284*.

3. Close the **Network Status** window by selecting something on the screen outside of the window.

Change the Brightness of the Screen

To change the brightness of the screen, select the brightness icon on the **Status Bar** of the Acquisition screen.

Follow one of the steps to change the brightness level of the screen from 10% to 100%:

- To increase the brightness of the screen, press **+**.
- To decrease the brightness of the screen, press **-**.

The changes you make are automatically saved to your device and will not change when you turn the device on or off.

2

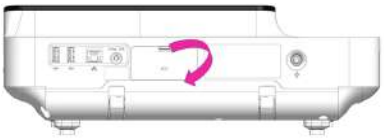
Equipment Setup

Insert the Battery

The device is shipped with one lithium ion battery with minimum charge.

Fully charge the battery before you use the device for the first time. Use the device on AC power while the battery is charging.

1. Place your thumb on the door release tab of the battery compartment door and gently pull it open.



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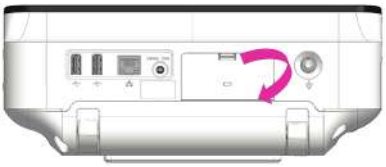

MAC 5 A5

MAC 5 Lite

2. Slide the battery into the battery compartment slots in the correct orientation.

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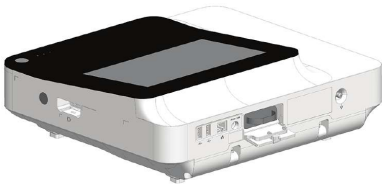
3. Lift the battery compartment door to close it.



MAC 5 A4

MAC 5 A5

MAC 5 Lite

Connect the AC Power

This device can run with AC or battery power. When the device is plugged into an AC outlet, it uses AC power and charges the installed battery.

NOTE:
If the integrity of the protective earth conductor is in doubt, operate the unit from its battery.

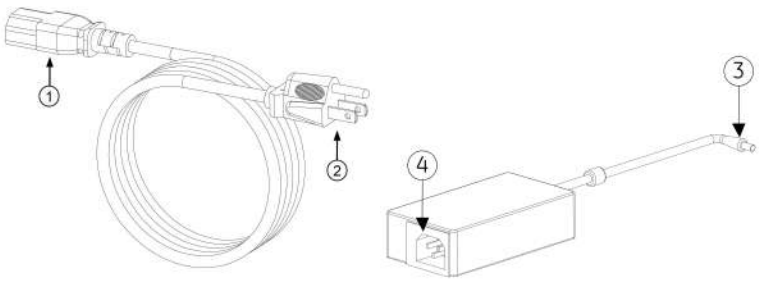


Table 6: Power Cord Parts

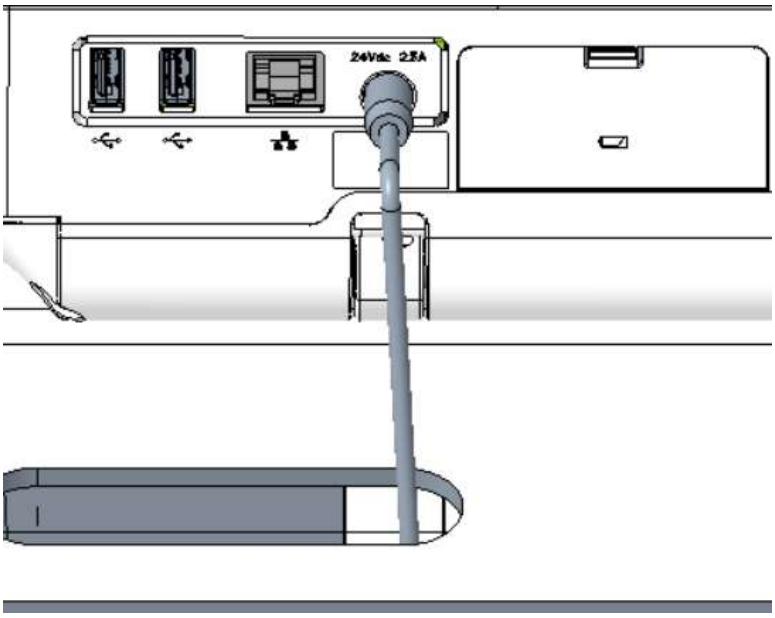
Item	*Description*
1	Female end of the AC power cord connected to the back of the AC/DC adapter.

Item	*Description*
2	Male end of the AC power cord connected to an AC outlet.
3	Female end of the AC/DC adapter cord connected to the back of the device.
4	Male end of the AC/DC adapter connected to the AC power cord.

NOTE:
Before you connect the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit label. If this is not the case, do not connect the system to the power line until you adjust the power source to match the unit power requirements.

1. Connect the female end of the power cord (1) to the AC/DC adapter.

2. Plug the female end of the AC/DC adapter cord (3) to the power connector on the back of the device.



3. Plug the male end of the power cord (2) into an AC outlet.

NOTE:
It is recommended that you connect the device into an uninterruptible power supply (UPS) or a surge suppressor.

4. Check the AC Power LED. If the AC Power LED is green, the device is receiving power from the AC outlet.

Connect the External Barcode Reader

If you purchase the optional barcode reader with the device, connect it to the USB port on the device.

NOTE:
The **BRCD - External Barcode Reader** option is activated at the factory when you purchase the barcode reader with the device. Configure the barcode settings for your site before you use the barcode reader.

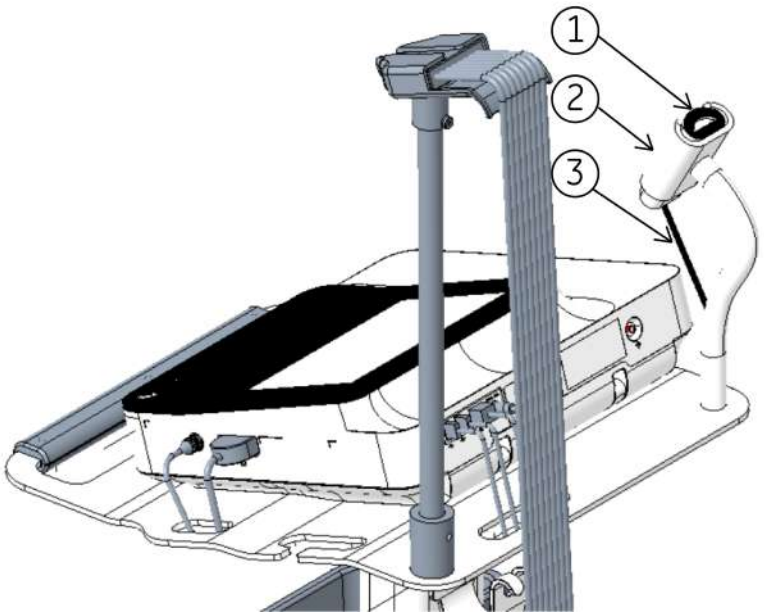


Table 7: Barcode Reader Parts

Item	*Description*
1	Barcode reader
2	Barcode reader holder
3	Barcode reader cable connected to the USB slot

1. Remove the screw cap from the Display rear cover.

2. Remove the screw from the Display rear cover.

3. Attach the cable clamp to the external barcode reader cable approximately 100 mm from the ferrite.


4. Use the M3x10 screw and cable clamp provided along with the external barcode reader kit, to assemble the external barcode reader cable to the Display rear cover.



5. Connect the barcode reader cable connector into the USB slot of the device.

6. If you have a trolley, put the external barcode reader in the barcode reader holder attached to the trolley.

Adjust the Device for Paper Size

MAC 5 A4 printer supports the paper sizes:

- A4 (8.27 x 11.7 inches) - 2104772-001
- Letter (8.4 x 11 inches) - 2104771-001

MAC 5 A5 printer supports the paper sizes:

- A5 (8.27 x 5.9 inches) - 5684683

MAC 5 Lite does not support paper printing.

You can configure the printer module to use the appropriate paper size only on the MAC 5 A4 device. Use the instructions below to change the paper size.

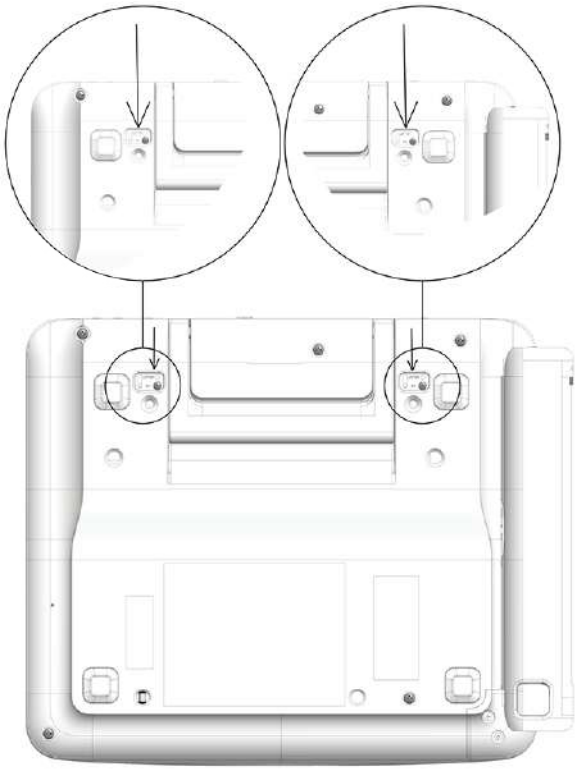
1. Turn off the device.
2. Open the printer door and remove the paper.
3. Apply the paper spacer to the printer module.

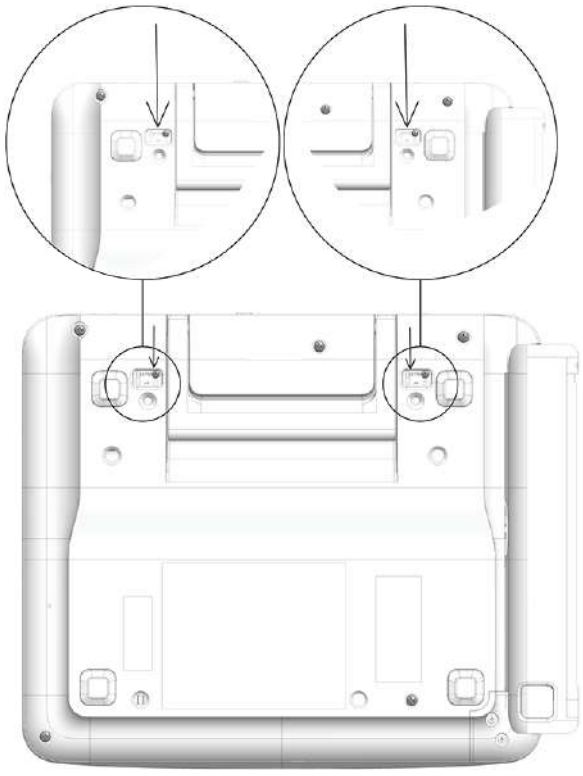
The paper spacer placement depends on the paper size.

If the paper size is	*Then*
A4	Put the paper spacer at the inside slot of the printer head. 
Modified letter	Put the paper spacer at the outside slot of the printer head. 

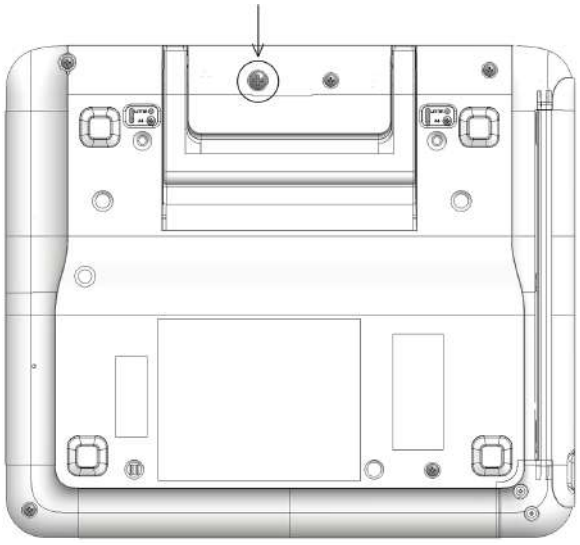
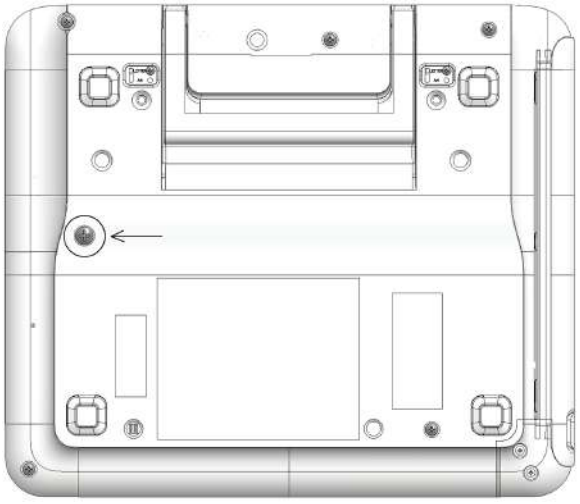
Make sure that the paper spacer is applied at the correct position.

4. Push the printer door to its closed position and verify that the unit is closed.
5. Carefully flip the device to display the bottom.
6. Move the paper latch at the bottom of the device.
   The paper latch placement depends on the paper size.

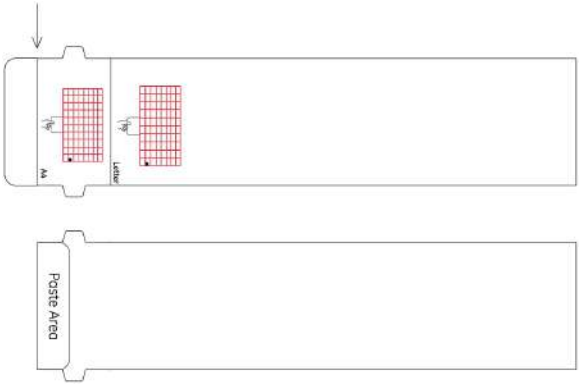
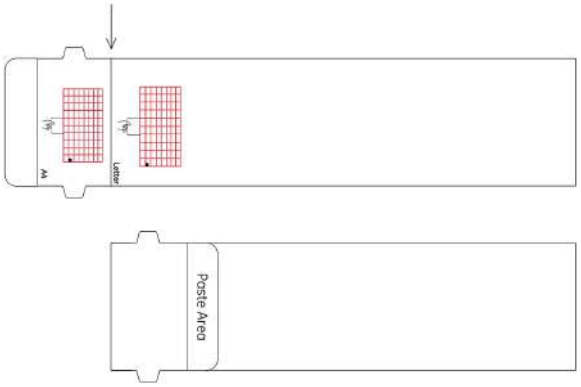
If the paper size is	*Then*
A4	Move the two paper latches to the position of "A4", and fasten the screws using a PH 1x150 mm screwdriver. 

If the paper size is	*Then*
Modified letter	Move the two paper latches to the position of "Letter", and fasten the screws using a PH 1x150 mm screwdriver. 

7. Move the screw at the bottom of the device.
   The screw position depends on the paper size.

If the paper size is	*Then*
A4	Place the screw at below position, and fasten it using a PH 1x150 mm screwdriver. 
Modified letter	Place the screw at below position, and fasten it using a PH 1x150 mm screwdriver. 

8. Adjust the paper film.
   The folding position of the paper film depends on the paper size.

If the paper size is	*Then*
A4	Fold and paste the paper file along the **A4** line. 
Modified letter	Fold and paste the paper file along the **Letter** line. 

Insert the Paper

MAC 5 A4 printer supports the paper sizes:

- A4 (8.27 x 11.7 inches) - 2104772-001
- Letter (8.4 x 11 inches) - 2104771-001

MAC 5 A5 printer supports the paper sizes:

- A5 (8.27 x 5.9 inches) - 5684683

MAC 5 Lite does not support paper printing.

Make sure you put down the handle and place the device on a flat surface. To insert the paper:

1. Press the printer door button to release the printer door.

2. Pull out the paper film and place the paper above it, then slide the paper into the device until it is fully inserted.

   NOTE:

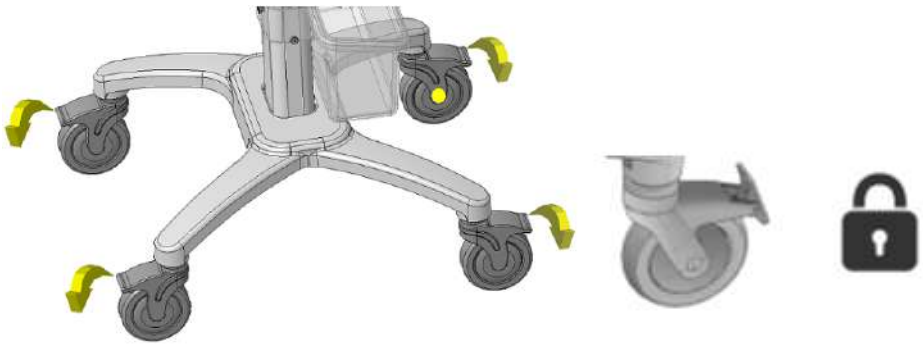
   - If the paper has Q holes, the Q holes must be on the top left side.
   - If the paper has Q marks, the Q marks must be on the bottom left side.

3. Advance the first sheet of paper.

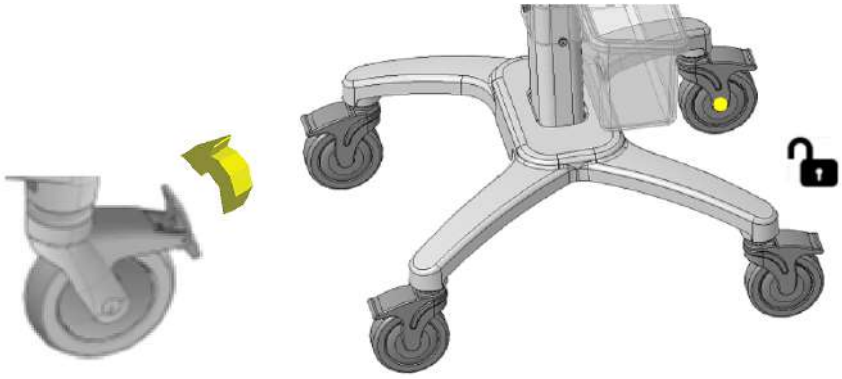
4. Push both ends of the printer door to close it and verify that the unit closes.

Lock and Unlock the Trolley Wheels

1. To lock each trolley wheel, press the wheel brake down.
   Lock the wheels before each use for safety purposes.



2. To unlock the trolley wheel, push the wheel brake up.



Attach the Device to the Trolley

1. Align the positioning holes on the bottom of the device with the positioning pins on the trolley top plate.
2. Gently put the device on the trolley top plate and insert the foot pads on the bottom of the device into the holes on the top plate

MAC 5 A4

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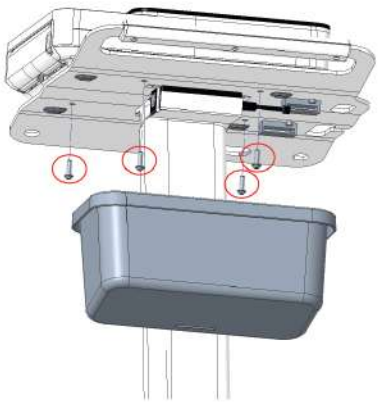
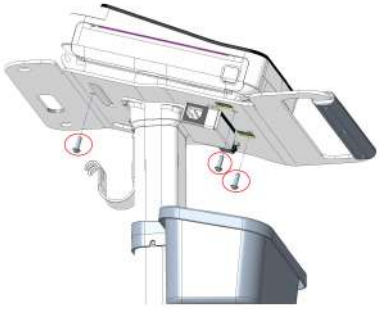
MAC 5 Lite

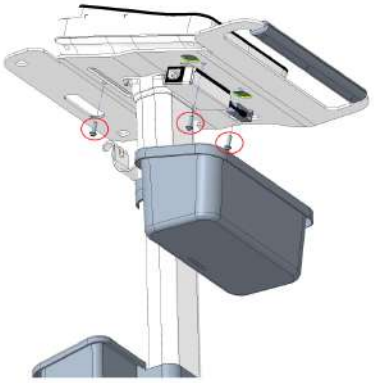
3. Insert the screws (M6x20) and washers (D12xD6.5x1.5) provided with the trolley through the bottom of the top plate into the device, and tighten them with 4mm torque spanner.



MAC 5 A4



MAC 5 A5

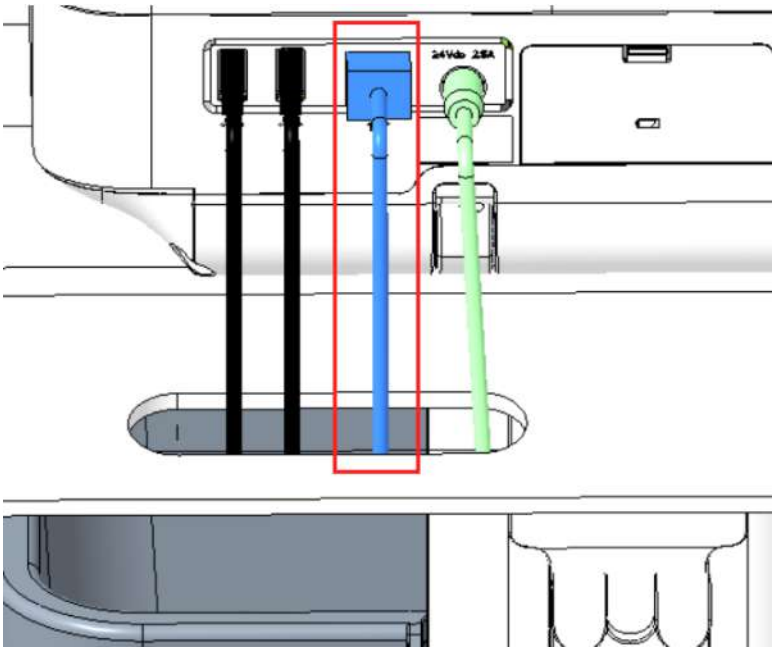


MAC 5 Lite

Connect the LAN Cable

A wireless module is installed in the device before it is shipped from the factory. If you do not configure the device to connect to a wireless network, you can use a wired connection.

1. To connect to a wired network, insert an Ethernet cable to the RJ45 network connector of the device.



NOTE:
This applies only if you use the device as a stationary device. If you use it as a mobile unit, do not connect the device to a LAN until you are ready to import, transmit, or export patient reports.

2. Configure the device to connect to a wired network. See *Configure Wired Network on page 229*.

Configure the Device

When the device is ready for operation, use the information in the manual to configure the system.

If you apply the same settings to more than one device at the site, save the device settings to a USB flash drive to restore them to other devices. See *Save and Restore Configuration Settings on page 248*.

Test the Device

After you set up and configure the device, test the device before you use it with patients. Use the test recommendations as follows:

- Record and print a resting ECG.
- Print a patient report. See *Print a Patient Report on page 85*.

  Delete a patient report. See *Delete a Patient Report on page 87*.

  Transmit a patient report. See *Transmit a Patient Report to a Configured Destination on page 82*.

3

Login and Security

Power On the ECG Device

1. Press the **Power** button on the front panel for a few seconds to start the device.

   The device is powered on. The **Power on** LED on the front panel is green.

   A notification message displays, if it is configured by the administrator.

2. Click **Accept**.
   - If user authentication is enabled, you are prompted to log on to the device.
   - If user authentication is disabled, you are automatically logged on to the device as the **Default User**.
   - If the user authentication mode is **Technician ID**, enter the **Technician ID** to log on as a **Default User**.

Power Off the ECG Device

1. Before you **Power Off** the device, complete pending tasks, for example, acquire an ECG and save configuration settings.
2. Do one of these steps to remove power from the ECG device:
   a) From the **User Menu** on the screen, select **Power Off**.

      The **Power off** window opens and displays a message. Select **Power Off**.

      The device is off. The **Power on** LED on the front panel is off.

   b) Press the **Power** button on the front panel for a few seconds:

      The **Power Options** window opens with **Cancel**, **Standby**, **Log Out**, **Privacy**, and **Power Off** options. Select **Power Off**.

The device is off. The **Power on** LED on the front panel is off.

User Authentication

The device supports different modes of user authentication.

Table 8: Supported User Authentication Modes

User Authentication Mode	*Description*
Full authentication with STAT login	The **Login** screen displays with these fields when the device is powered on or unlocked.  The users below can log on to the device: • Pre-defined users (**Admin**, **Service**) • LDAP users (If LDAP-based user authentication is configured) • Local users (If user profiles are locally managed on the device) • **STAT User** if **STAT** button is selected. The user can configure the text for this button.

User Authentication Mode	*Description*
Technician ID login	The **Login** screen displays when the device is powered on or unlocked.  A technician can access the device by entering the **Technician ID**.
No authentication	A Login screen does not display when you power on the device. You are automatically logged on as the **Default User**. The **Default User** cannot access the device if user authentication is enabled.

Log On to the Device

Enter the user name and password on the **Login** screen to enable User authentication to allow users to log on to the device.

Table 9: Type of Users

Type of User	*Description*
Admin user	The username is **Admin**. The default password to log on as the Admin user is ***admin123***. The Admin user is prompted to change the default password immediately after the first login.
Service user	The username is **Service**. This username is intended for use by Service personnel. A user with the user management privilege can set the password for the **Service** user.
Local users	The local user profiles are managed by the device administrator. Obtain your username and password from the device administrator.
LDAP users	LDAP user authentication is available only if you configure the device to support LDAP. The LDAP server administrator manages the LDAP user profiles. Obtain your username and password from the LDAP server administrator. Your privileges are based on the user role assigned to the LDAP group to which your user profile belongs.

1. Do one of these steps:
   - If the device is shutdown, power on the device. See *Power On the ECG Device on page 39*.
   - If the device is locked, unlock the device. See *Unlock the Device on page 45*.

   The **Login** screen displays.
2. Enter your username and password.
   - If you are an LDAP user and the default domain name is not configured, or your user profile is part of an LDAP server domain which is not the default domain, enter the domain name and username. For example, Domain \Username.
   - To verify that you entered the correct password, select **Show** to view the password.
   - Contact your administrator to reset your password. Log on to the device using the new password. Change the password immediately for security reasons.
   - If you are the Admin user and forgot your password, perform a system reset to reset the password to the default password ***admin123***. For more information, see *Perform System Reset on page 46*.
3. Select **Log In**.
   - If the login credentials are correct, you are successfully logged on to the device. Your username displays on the upper-right corner of all of the screens you have access.
   - If your login fails, see the table below:

Table 10: Login Errors

Symptom	*Cause*	*Solution*
The username or password is incorrect.	You entered your username or password incorrectly.	Re-enter your correct username and password again.
	You are a local user and you forgot your password	Contact your administrator to reset your password, then log on to the device again.
	If you are an LDAP user, the error is caused by: • No connection to the LDAP server. Your username cannot be authenticated against cached LDAP user credentials.	• Wait for the connection to the LDAP server to be restored and log on to the device again.

Symptom	*Cause*	*Solution*
	• You do not belong to any groups authorized access to this device.	• Contact your LDAP administrator to assign your user profile to an LDAP group authorized for this device and log on to the device again.
	• Your current password has expired.	• Contact your LDAP administrator to change your password.
You are prompted to change your password.	You are a local or Admin user and your password has expired.	Perform the procedure *Change the User Password on page 44* and log on to the device again.

Log On the Device as a STAT User

If you enable user authentication **STAT**, a **STAT** user can log on to the device to get a patient ECG in an emergency.

1. On the **Login** screen, select **STAT**.

   The Acquisition screen opens.

2. You can get an ECG or other tasks the administrator has assigned to the **STAT** user role. You are not able to review any report generated by other users.

Access the Device using a Technician ID

Make sure that you enable the user authentication.

1. On the **Login** screen, enter a valid Technician ID to populate the **Technician ID** field.

2. Select **Continue**.

   You are logged on as the **Default User**. The Acquisition screen displays. You can perform tasks with **Default User** or **Technician ID** assigned privileges.

Log Out of the Device

Log out of your user session when you are done using the device. You must enable User authentication.

1. Complete pending tasks, for example, acquire an ECG or save configuration settings, before you log off from your user session.

2. Perform one of these steps to log off of the device:

   - Press the **Power** button. The **Power Options** dialog box opens. Select **Log Out**.
   - From the User Menu on the Acquisition screen, select **Log Out** to log off the device.

If you log off before a task is completed, a message displays that you will lose incomplete data.

3. Perform one of these steps:
   - If you have unsaved data, select **Cancel**.
   - If you want to log off, select **Log Out**.

     You are logged off your user session.

Change the User Password

This procedure applies only to the Admin user and local users. LDAP users must change their password externally as per the instructions provided by their LDAP administrator.

Make sure that the new password follows the password rules:

Password must contain at least:

- One lowercase letter
- One uppercase letter
- One number
- One special character

1. From the User Menu on the Acquisition screen, select **Change Password**.

   The **Change Password** dialog box opens.
2. Enter the current password and new password, and confirm the new password.
3. Select **Change Password**.
   - If the new password meets the password requirements, a message displays that your password was changed successfully.

     Select **OK** to close the **Change Password** window. You are logged into the device.
   - If the new password does not meet the password requirements, an error message displays.

     Follow the password rules for a new password and repeat the steps in this procedure to create a new password.

Activate or Deactivate Privacy Mode

Privacy mode can be activated to prevent the display of confidential information on the screen. During this mode, the screen will be blank. Processes such as ECG acquisition, transmission, and printing continue to work in background, but the device ignores input from a barcode reader.

- To activate privacy mode, press the **Power** button on the front panel.

  The **Power Options** window opens with **Cancel**, **Standby**, **Log Out**, **Privacy**, and **Power Off** options. Select **Privacy**.

  The GE logo displays on the center of the screen with a black background, and a message displays indicating screen privacy is turned on.

- To deactivate privacy mode, tap anywhere on the screen.

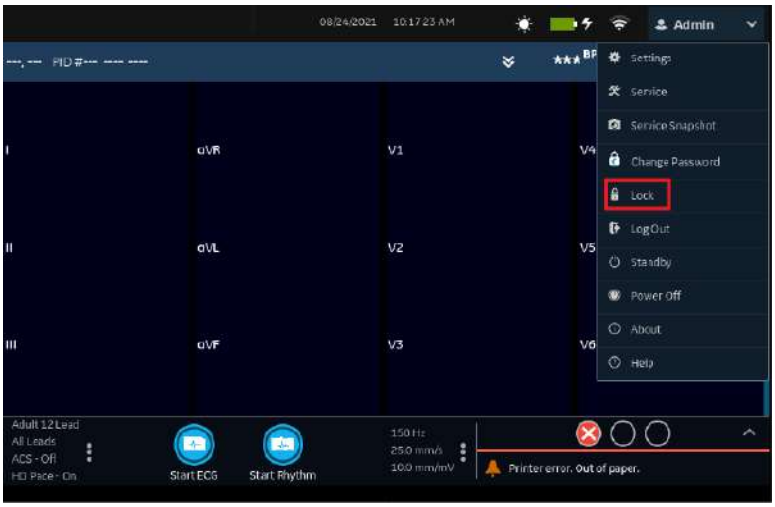
  The screen you were working on before activating privacy mode displays.

Lock the Device

You can lock the device if you enable user authentication. You cannot lock the device while ECG or rhythm acquisition or report printing is in progress.

NOTE:
The **STAT User** cannot lock the device.

1. Complete your tasks.
2. From the User Menu on the Acquisition screen, select **Lock**.



The device is locked. Your username displays on the lock screen.

Unlock the Device

1. Tap the lock icon on the screen.

   A message displays prior to login if one is configured by your administrator. Click **Accept**.

   The **Login** screen displays. The **User Name** field displays the name of the user who is logged on.

2. Enter your password and select **Log In** to log on to the device.

You can also log in as:

- A **STAT User** (if STAT access is enabled)
- A different user

  A message displays that the current user will be logged out and any unsaved data will be lost. Select **Continue** to log into the device.

Put the Device on Standby

Perform one of the steps below to put the device on standby:

- From the User Menu on the Acquisition screen, select **Standby**.
- Press the **Power** button .

  The **Power Options** dialog opens. Select **Standby**.

To exit standby mode, press the **Power** button on the front panel:

- If user authentication is configured, standby mode is off and the lock screen displays. Perform the procedure *Unlock the Device on page 45* to unlock and log in to the device.
- If user authentication is not configured, you return to the last screen displayed when the device was put on standby mode.

Perform System Reset

Before you start this procedure, make sure that:

- You have the serial number of the device.
- You connect the device to AC Power.
- If the authentication mode of the device is **No authentication**, access the **Settings** screen from the user menu to open the **Login** screen.
- If the authentication mode of the device is **Full Authentication with Stat**, power on the device to view the **Login** screen.
- You must log on to the device as the Admin user.

NOTE:
The **System Reset** deletes all data and settings. The system is reset to factory defaults. Use the default admin password to log on to the device. It keeps the previously enabled option codes, serial number, MAC address, and Wireless Country of Operation configuration.

NOTE:
The **Restore to Factory Defaults** resets the settings or section of settings.

Use this procedure as a last solution. **Transfer your data from the system before you start the procedure.**

1. When the **Login** screen displays, press ↑ ↓ ← → ↑ ↓ ← →, consecutively, on the soft keyboard.

   The **System Restore** screen displays a warning that the System Restore will return your system to the original factory shipped configuration. All patient data, system setup changes, logs, and user data will be lost and unrecoverable.

2. Enter the serial number of the device in the **Enter the system serial number** field. The **Restore** button enables after you enter the correct serial number.

3. Select **Restore** to proceed with system restore.

   The system configuration is reset to factory defaults and all patient data records are deleted. The device reboots. You can access the device as the **Default** user without login credentials.

4. To reconfigure the device, access the **Settings** screen from the user menu. A login screen opens. Log on as **Admin** user with the default password *admin123*.

4

Patient Information

Patient Information Screen Overview

Patient information helps you to identify the patient. View and make sure the patient information is complete and correct before you start an ECG.

You can update the patient information on the **Patient Information** screen as follows:

- Attach an order from the orders list (if order management is enabled).
- Attach patient information from the recent patients list (if order management is disabled).
- Read a patient barcode with a barcode scanner.
- Use a software keyboard to enter **Patient Information**.
- Do an Admission, Discharge, Transfer (ADT) query.

WARNING:

INACCURATE PATIENT DATA

Patient data from the last patient may remain in the patient information banner if the last user did not finish and close out of their session. Incorrect patient data can affect diagnosis and treatment. Make sure to check the patient information screen for each patient. Make sure that you enter patient data for the correct patient.

On the Acquisition screen, the **Patient Information** banner is located above the waveform and shows minimal information about the patient.

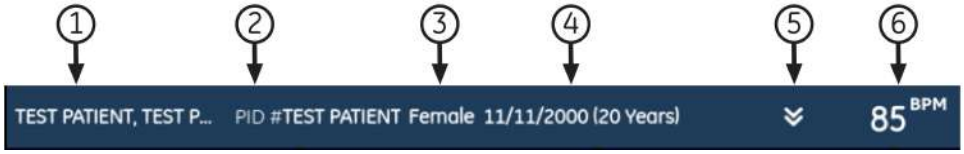


Table 11: Patient Information Banner

Item	*Field*	*Description*
1	**Name**	Shows the last name and first name of the patient.

Item	Field	Description
2	**PID#**	Shows the unique identification number of the patient (patient ID).
3	**Gender**	Shows the patient gender.
4	**DOB (Age)**	Shows the patient date of birth and age. If the **Date of Birth** field is configured to be hidden on the **Patient Information** screen, only **Age** Shows on the bar.
5	Chevron	Select the chevron to collapse or expand the **Patient Information** banner. If the chevron is in a down position, the **Patient Information** banner is collapsed, and if it is in the upward position, the **Patient Information** banner is expanded.
6	**BPM**	Shows the real-time beats per minute (BPM). The heart rate updates whenever the heart rate calculation algorithm reports a change in the heart rate. The heart rate does not display if it drops below 30 bpm, increases above 300 bpm, or the system is not getting ECG data. In cases where the heart rate does not display, three asterisk symbols show instead of the heart rate. 

Select the **Patient Information** banner to expand it into a full screen view. Fields configured by your administrator display in the **Patient Information** screen.

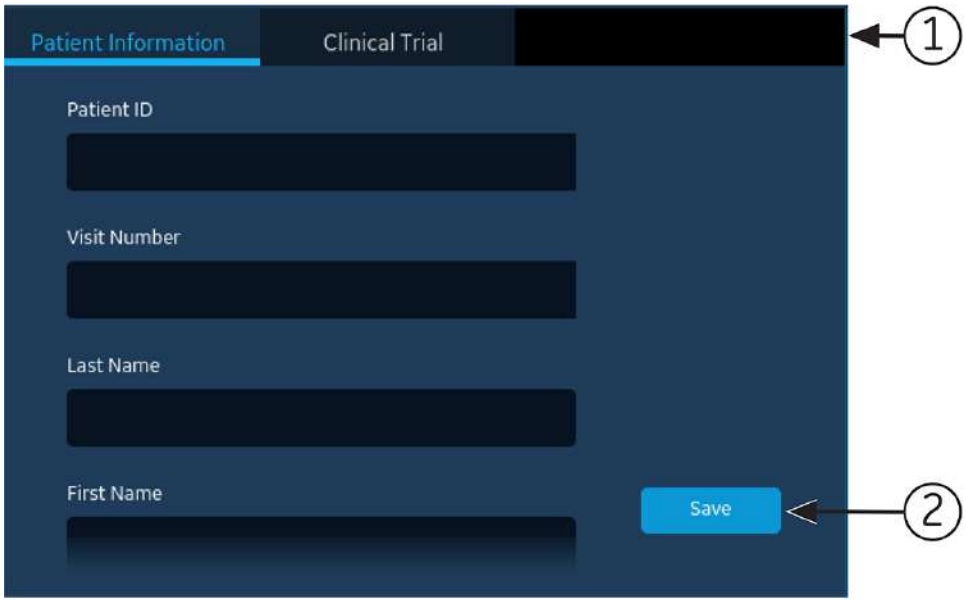


Table 12: Patient Information Screen

Item	Field	Description
1	**Patient Information** tab	Shows patient information, such as patient first name, last name, gender, age, and other configured information.

Item	Field	Description
2	**Save** button	Select **Save** to save the patient information.

If the bottom of the **Patient Information** screen is blurred, it indicates that the configured information does not display completely. Swipe your finger in the upward or downward direction on the screen to scroll through the screen. For information on updating data in the **Patient Information** screen, see *Enter Patient Information on page 51*.

Select the **Patient Information** banner to expand it into a full screen view. Select **Clinical Trial**, fields configured by your administrator display in the **Clinical Trial** screen.

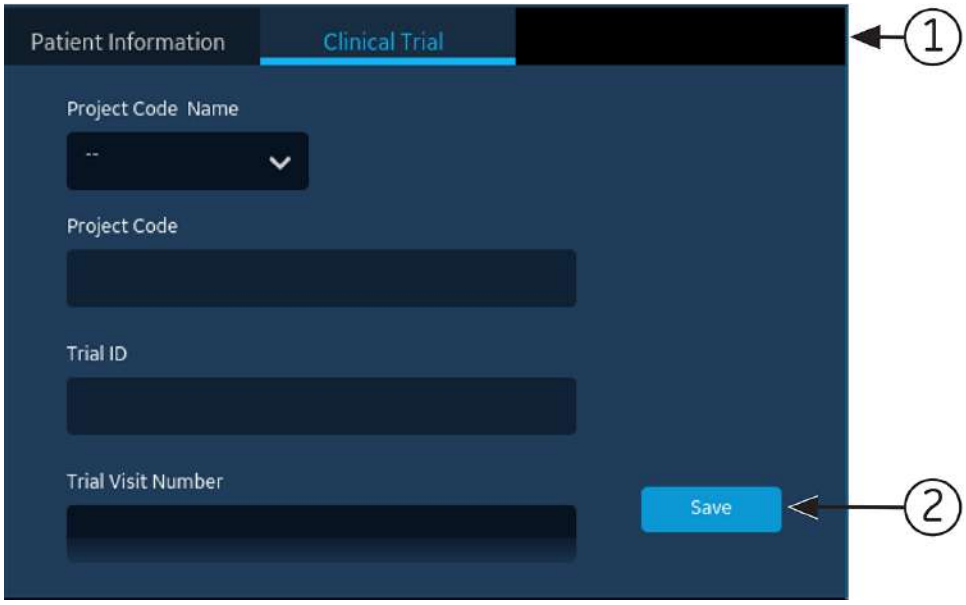


Table 13: Clinical Trial Screen

Item	Field	Description
1	**Clinical Trial** tab	Shows clinical trial information, such as project code name, project code, trial ID, and other configured information.
2	**Save** button	Select **Save** to save the clinical trial information.

If the bottom of the **Clinical Trial** screen is blurred, it indicates that the configured information does not display completely. Swipe your finger in the upward or downward direction on the screen to scroll through the screen. For information on updating data in the **Clinical Trial** screen, see *Enter or Edit Clinical Trial on page 60*.

Start a Test for a New Patient

Start a test for a new patient in the Acquisition screen.

1. Select the **New Patient** icon located in the upper right corner of the Acquisition screen:

If	*Then*
A patient test is open with unsaved data, a message opens that unsaved patient data will be lost.	Select one: • Select **New Patient**, all unsaved patient data is deleted and you can enter new patient data. • Select **Continue with Same Patient**, the patient information on the screen is used for you to continue with the same patient.
Electrodes are put on a patient and then removed or disconnected for more than 30 seconds, a warning message displays when the electrodes are put on a patient again.	Select one: • **Yes, Continue** if you put electrodes on the same patient, then the device will continue a test for that patient. • **No, Clear patient info** if you put electrodes on a new patient, then the device will start a test for the new patient.

2. If there are pending print tasks in the queue, a message opens that pending print tasks will be deleted from the queue.
   - Select **Continue** to delete pending print tasks and start the test for the new patient. The **Patient Information** screen expands.
   - Select **Cancel** to cancel the test for the new patient, and complete the pending print tasks.
3. The **Patient Information** screen opens, enter information for the patient.

Enter Patient Information

Use the methods below to enter or update patient data in the **Patient Information** screen:

- Use a barcode reader, see *Update Patient Information with a Barcode Reader on page 52*.
- Do ADT queries, see *Query Orders or ADT for Patient Demographics on page 53*.
- Open a patient record in the **Patients** list, see *Select a Patient from the Patients List on page 126*.

- Attach an order, see *Work with Orders on page 94*.
- Use a software keyboard, see *Enter or Edit Patient Information Using the Software Keyboard on page 59*.

Update Patient Information with a Barcode Reader

Using a barcode reader can simplify the entry of patient information and reduce the chance of introducing errors. When you scan a patient's barcode, it retrieves the patient information encoded in the barcode. You can then verify and modify the information.

You can scan a patient's barcode using an external barcode reader.

Before you use an external barcode reader, make sure that:

- The BRCD option to use an external barcode reader is activated on the device.
- The barcode reader is connected to the device, and the device is correctly configured to use the peripheral. For more information, see *Update Patient Information with a Barcode Reader on page 52*.
- You are in the **Live** or **Full Disclosure** ECG screen, or when patient demographics banner is open.

An error message displays if you scan a barcode during the acquisition of a Resting ECG, Rhythm ECG or a Full Disclosure ECG for the patient.

Use the procedure below to scan the patient's barcode:

1. Start a test for a new patient. For more information, see *Start a Test for a New Patient on page 51*.

2. Scan the patient's barcode to populate the **Patient Information** screen.

   Hold the button and position the barcode reader 10 cm to 15 cm (4 inches to 6 inches) above the barcode to be scanned.

   The barcode is automatically scanned.

   The barcode reader emits a sound to confirm the barcode scan. The **Patient Information** screen expands and displays the fields populated with patient information.

3. If there is a mismatch between the data scanned from the barcode and existing patient information, a message displays. Perform one of the steps as follows:

- Select **Use Scanned Data** to populate the barcode data into the relevant fields on the **Patient Information** screen, and confirm the data entered from the barcode is accurate.
- Select **Use Current Data** to retain the manually entered information on the **Patient Information** screen, and enter or modify patient information as necessary.

Query Orders or ADT for Patient Demographics

Make sure that:

- You have privileges to see orders and do remote patient query.
- Use orders of ADT data as configured on the device to do remote patient query.
- A barcode reader is connected to the device.

1. Start a test for a new patient. For more information, see *Start a Test for a New Patient on page 51*.
2. Do one of the steps below:
   - Scan the patient barcode.
   - Use the keyboard to enter the **Patient ID** or **Visit Number** on the screen and press **Search** icon on the respective field.

   The device queries
   - orders only
   - or orders and then ADT data
   - or ADT data only

   depending on how the administrator configured the device. Go to:
   - *Order Query Workflow on page 53* if your device queries orders only.
   - *Orders and then ADT Query Workflow on page 55* if your device queries orders and then ADT data.
   - *ADT Query Workflow on page 58* if your device queries ADT data only or if no matching order is found.
3. Enter or change patient information, as necessary.

Order Query Workflow

The device first searches for local orders with the **Patient ID**.

If	*Then*
Multiple local orders are found on the device	The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test.

If	*Then*
One local order is found on the device	The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen.
No local orders are found on the device	A message displays in the notification area that no matching local orders are found.

The device first searches for local orders with the **Visit Number**.

If	*Then*
Multiple local orders are found on the device	The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test.
One local order is found on the device	The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen.
No local orders are found on the device	A message displays in the notification area that no matching local orders are found.

The device then searches for remote orders in the MUSE system with **Patient ID**.

If	*Then*
Multiple remote orders are found on the MUSE system	The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test.
One remote order is found on the MUSE system	The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen.
No remote orders are found on the MUSE system	A message displays in the notification area that no matching remote orders are found.
Remote order query failed on the MUSE system	A message displays in the notification area that remote order query has failed.

The device then searches for ADT data in the MUSE system with **Visit Number**.

If	*Then*
Multiple ADT records are found on the MUSE system	The matching records show on the Acquisition screen, and a message displays in the notification area that matching ADT data is found. The maximum of five records display on the Acquisition screen. Select the ADT record to search the order using that selected record's **Patient ID**.

If	*Then*
Only one ADT record is found on the MUSE system	System searches for the **Patient ID** order found in that ADT record. • If multiple orders are found on the system - The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test. • If only one order is found on the system - The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen. • If no orders are found on the system - A message displays in the notification area that no matching remote orders are found. • If remote order query is failed on the system - A message displays in the notification area that remote order query has failed.
No ADT records are found on the MUSE system	A message displays in the notification area that no ADT data found.
Remote ADT data query failed on the MUSE system	A message displays in the notification area that ADT query has failed.

When local or remote orders are found, and you try to attach the order:

If	*Then*
The selected order matches the patient demographics in the **Patient Information** screen	A warning message displays on the screen: *Are you sure you want to attach this order to the current test?* Select **Yes** to attach the order, **No** to cancel the action.
The selected order does not match the patient demographics in the **Patient Information** screen	A warning message displays on the screen: **Name or Patient ID Mismatch** *Are you sure you want to attach this order to the current test?* Select **Yes** to attach the order, **No** to cancel the action.

Orders and then ADT Query Workflow

The device first searches for local orders with the **Patient ID**.

If	*Then*
Multiple local orders are found on the device	The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test.

If	*Then*
One local order is found on the device	The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen.
No local orders are found on the device	A message displays in the notification area that no matching local orders are found.

The device first searches for local orders with the **Visit Number**.

If	*Then*
Multiple local orders are found on the device	The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test.
One local order is found on the device	The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen.
No local orders are found on the device	A message displays in the notification area that no matching local orders are found.

The device then searches for remote orders in the MUSE system with **Patient ID**.

If	*Then*
Multiple remote orders are found on the MUSE system	The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test.
One remote order is found on the MUSE system	The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen.

If	*Then*

No remote orders are found on the MUSE system	A message displays in the notification area that no matching remote orders are found. The device then searches for ADT data in the MUSE system.
	• If multiple ADT records are found on the MUSE system - The matching records show on the Acquisition screen, and a message displays in the notification area that matching ADT data is found. Select the ADT record to search the order using that selected record's **Patient ID**.
	• If only one ADT record is found on the MUSE system - The device searches for the **Patient ID** order found in that ADT record.
	  • If multiple orders are found on the system - The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test.
	  • If only one order is found on the system - The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen.
	  • If no orders are found on the system - A message displays in the notification area that no matching remote orders are found.
	  • If remote order query is failed on the system - A message displays in the notification area that remote order query has failed.
	• If no ADT records are found on the MUSE system - A message displays in the notification area that no ADT data/remote orders found.
	• If remote ADT data query failed on the MUSE system - A message opens in the notification area that ADT query has failed.

Remote order query failed on the MUSE system	A message displays in the notification area that remote order query has failed.

The device then searches for ADT data in the MUSE system with **Visit Number**.

If	*Then*
Multiple ADT records are found on the MUSE system	The matching records show on the Acquisition screen, and a message displays in the notification area that matching ADT data is found. The maximum of five records display on the Acquisition screen. Select the ADT record to search the order using that selected record's **Patient ID**.

If	*Then*
Only one ADT record is found on the MUSE system	System searches for the **Patient ID** order found in that ADT record. • If multiple orders are found on the system - The orders show on the **Orders** tab in a filtered list. Select the order you will to attach to the patient test. • If only one order is found on the system - The order fills in the **Patient Information** screen, if there is no mismatch with the patient data on the screen. • If no orders are found on the system - A message displays in the notification area that no matching remote orders are found. • If remote order query is failed on the system - A message displays in the notification area that remote order query has failed.
No ADT records are found on the MUSE system	A message displays in the notification area that no ADT data/remote orders found.
Remote ADT data query failed on the MUSE system	A message displays in the notification area that ADT query has failed.

When local or remote orders are found, and you try to attach the order:

If	*Then*
The selected order matches the patient demographics in the **Patient Information** screen	A warning message displays on the screen: *Are you sure you want to attach this order to the current test?* Select **Yes** to attach the order, **No** to cancel the action.
The selected order does not match the patient demographics in the **Patient Information** screen	A warning message displays on the screen: *Are you sure you want to attach this order to the current test?* Select **Yes** to attach the order, **No** to cancel the action.

ADT Query Workflow

The device searches for ADT data in the MUSE system with the **Patient ID** or **Visit Number**.

If	*Then*
An ADT record that matches the **Patient ID** or **Visit Number** is found on the MUSE system	The patient demographics fills in on the **Patient Information** screen.

If	*Then*
Multiple ADT records that match the **Patient ID** or **Visit Number** are found on the MUSE system	The matching records show on the Acquisition screen, and a message opens in the notification area that matching ADT data is found. Select a ADT record, and click **Select** to fill in the patient demographics on the **Patient Information** screen.
No ADT records that match the **Patient ID** or **Visit Number** are found on the MUSE system	A message opens in the notification area that no matching ADT data is found.
The ADT query failed	A message opens in the notification area that ADT query has failed.

NOTE:

If multiple sites are configured on a MUSE system, ADT query is done only on Site 1, if the MUSE system version is MUSE v9 SP5 or earlier. ADT query to the MUSE system for sites other than Site 1 requires MUSE v9 SP6 or later.

Enter or Edit Patient Information Using the Software Keyboard

Below is the software keyboard information:

Item	*Name*	*Description*
1	**Backspace** Key	Deletes inputs.
2	**Enter** Key	Enters inputs.
3	**Save** Key	Saves inputs.
4	**Minimize** Key	Minimizes the keypad from the screen.
5	**Arrow** Keys	Provides movement between columns.
6	**Space** Key	Adds a space between entered characters.
7	**Number** Key	Switches to numbers and symbols.

Item	*Name*	*Description*
8	**Input Method**	Switches between different input methods. **NOTE**: If you use an English user interface, you cannot switch the input methods from English to Chinese Pinyin. If you use the Chinese user interface, you can switch the input methods freely between English and Chinese Pinyin.
9	**Capitalization** Key	Capitalizes a letter during entering.

1. Enter data in the fields displayed in the **Patient Information** screen using the software keyboard. Only fields that are configured to be displayed in the **Patient Information** screen display. See *Patient Information Text Box Names on page 301* for a list of fields that can display on the screen.

   - If the Pinyin input method is configured, when you enter data in the fields, a number list of matching Chinese characters displays in a drop-down menu. Select or enter the number of the desired value in the list to populate the Chinese character in the field.
   - If you enter incorrect data in a field, the field border changes to red.
   - An asterisk (*) displays adjacent to mandatory fields in the **Patient Information**.

   NOTE:
   If you go to the **Settings** or **Service** screen before you complete a patient test, the data entered in the **Patient Information** screen clears when you go back to the **Acquisition** screen.

2. To save your entries, select **Save**.

   The information is saved and the **Patient Information** screen closes.

   Based on the **Mandatory fields apply for Transmission** or **Acquisition** settings, the ECG report will not be accepted, transmitted, or printed until you enter the patient demographic data for any of the mandatory fields. You need to complete the data for the mandatory fields.

Enter or Edit Clinical Trial

1. Enter data in the fields displayed in the **Clinical Trial** screen using the software keyboard. Only fields that are configured to be displayed in the **Clinical Trial** screen display. See *Clinical Trial Text Box Names on page 310* for a list of fields that can display on the screen.

   - If the Pinyin input method is configured, when you enter data in the fields, a number list of matching Chinese characters displays in a drop-down menu.

Select or enter the number of the desired value in the list to populate the Chinese character in the field.

- If you enter incorrect data in a field, the field border changes to red.
- An asterisk (*) displays adjacent to mandatory fields in the **Clinical Trial**.

NOTE:
If you go to the **Settings** or **Service** screen before you complete a patient test, the data entered in the **Clinical Trial** screen clears when you go back to the **Acquisition** screen.

2. To save your entries, select **Save**.

   The information is saved and the **Clinical Trial** screen closes.

   Based on the **Make All Clinical Trial Fields Mandatory** setting, the ECG report will not be accepted, transmitted, or printed until you enter the clinical trial data for any of the mandatory fields. You need to complete the data for the mandatory fields.

5

Record an ECG or Rhythm

Hookup Advisor Overview

The **Hookup Advisor** is a tool to monitor the lead signal quality during ECG acquisition. It can decrease or eliminate the occurrence of poor quality ECGs, by allowing you to view each leadwire signal quality and adjust as necessary.

The **Hookup Advisor** reports the status based on signals from each leadwire. Connect the RA/R leadwire, and then another leadwire to the patient, an electrode placement image expands in the **Hookup Advisor** panel. If all leadwires are disconnected from the patient, the electrode placement image collapses after a few seconds.

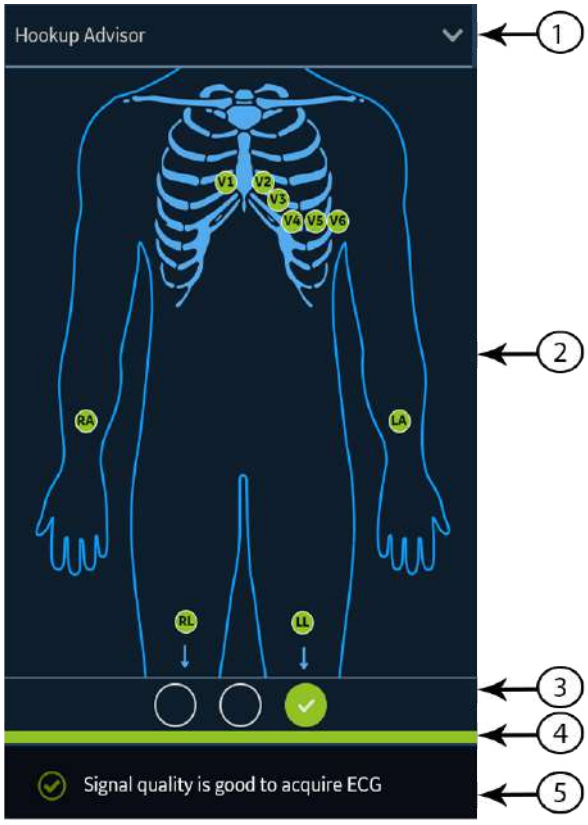


Table 14: Hookup Advisor Panel

Item	*Name*	*Description*
1	**Collapse** arrow	Select the arrow to collapse the electrode placement image.
2	Electrode Placement Image	Displays electrode placement and quality of each lead. Each lead quality indicator changes color to red, yellow or green, based on its connection status. On the Acquisition screen, the image displays the real-time electrode quality of each lead. During review of a patient report, all electrode lead quality indicators are turned off. You can set up a lead condition indicator in settings, if the **Hookup Advisor** level is configured as: • **Yellow**, the image automatically expands when the **Hookup Advisor** status is yellow or red in the Acquisition screen, or during preview of an ECG patient report. • **Red**, the image automatically expands when the **Hookup Advisor** status is red in the Acquisition screen, or during preview of an ECG patient report. The image collapses during review of a patient report, irrespective of the overall **Hookup Advisor** status. • **Never**, the image does not automatically expand when the overall **Hookup Advisor** status is yellow or red. Only the **Hookup Advisor** lead quality status indicator and status messages display in the Notification Area.
3	Lead Quality Status Indicator	Displays three circles that change color to yellow, red, or green, based on the overall lead quality. This indicator does not apply to review of rhythm reports.
4	Status Bar	Displays a solid color bar that matches the same color as the lead quality status indicator. For example, if the lead quality status indicator is green, the status bar displays a solid green color. In the pre-acquisition (refer to *ECG Acquisition Overview on page 69*) mode , when the lead quality status indicator changes from red or yellow to green, the status bar shows a progress bar of acquiring 10 seconds of ECG data with good quality.
5	Notification Area	Displays lead quality status messages indicating the specific problem in each lead. Messages display one at a time. If there are more than one failures, messages for red states display first. When you resolve a problem, the next message displays. Continue to resolve the problems until the indicator is green.

Table 15: Lead Quality Indicators on the Electrode Placement Image

Lead Quality Indicator	*Description*
Green	The leadwire connection is good. The acquisition module is sending a good signal to the device.
Yellow	The leadwire connection is experiencing noise and the signal is not clear.

Lead Quality Indicator	*Description*
Red	The lead is disconnected or not receiving a usable signal.
No color (unlit)	No ECG data is being acquired.

Table 16: Hookup Advisor Lead Quality Status Indicators

Indicator	*Description*
Red 	Shows a lead fail condition or extreme baseline shifts. The red indicator is always the left circle of the indicator. It flashes on and off approximately each second and contains an X symbol. The two circles to the right are black. A message displays with information to help you resolve the problem.
Yellow 	Shows muscle artifact, power line interference, baseline wander, or electrode noise. The yellow indicator is always the middle circle of the indicator and contains a dash. The left and right circles are black. A message displays with information to help you resolve the problem.
Green 	Shows acceptable signal quality. The green indicator is always the right circle of the indicator and contains a check mark. The two circles to the left are black. A message displays showing that the signal lead quality is good to acquire an ECG.

NOTE:

The background color of the **Start ECG** icon is green, when the **Hookup Advisor** status is green. The background color of the **Start ECG** icon is blue, when the **Hookup Advisor** status is red or yellow.

If the **Hookup Advisor** status is red or yellow, check the patient's skin, see *Prepare the Patient's Skin on page 298*.

If a leadwire is disconnected, the overall status shows as failed (red). To determine which leadwire has failed, you need to understand which electrodes are used to form a lead. If RA is the reference electrode and it is not connected, all the electrodes display as failed. If another leadwire is the reference electrode and it is not connected, only that electrode displays as failed.

CAUTION:

ELECTRICAL INTERFERENCE - Electrostatic discharges may interfere with the acquisition of ECG recordings. The acquisition module could be temporarily disconnected with an error message displayed due to an ESD event. The device recovers automatically from this error. ECG recordings need to be restarted after the error message is removed and the acquisition module recovers.

If the device does not recover from the error, troubleshoot the error. Restart the ECG after the error is resolved and the **Hookup Advisor** displays a green status. After you resolve the errors, the electrode placement image collapses after the **Hookup Advisor** status indicator is green for at least four seconds.

The preview or review of a patient report is based on the **Hookup Advisor** status at the time of ECG acquisition, and not the real-time status of a currently connected patient.

Acquire an ECG based on the Hookup Advisor status in Post-Acquisition Mode

In post-acquisition mode (refer to *ECG Acquisition Overview on page 69*), the next 10 seconds of ECG data is acquired when you start to record an ECG.

Review the Hookup Advisor status before you start an ECG. If the Hookup Advisor status is green, it shows that the signal quality is good, you can start to record an ECG that acquires the next 10 seconds of ECG data.

- If the status stays green during the 10 seconds ECG acquisition, you can accept the ECG.
- If the quality of the ECG signal has problems during the 10 seconds ECG acquisition, the status changes from green to yellow or red.

  It is recommended to reject an ECG that is acquired in the post-acquisition mode with poor signal quality.

Acquire an ECG based on the Hookup Advisor status in Pre-Acquisition Mode

In pre-acquisition mode (refer to *ECG Acquisition Overview on page 69*), the previous 10 seconds of ECG data is acquired when you start to record an ECG.

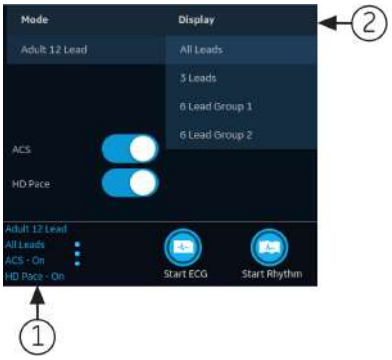
Review the Hookup Advisor status before you start an ECG:

- If the status is green, it shows that the previous 10 seconds of ECG data is good. You can start to record an ECG.
- If the status changes from green to yellow or red, it shows that the quality of the ECG signal is not good. A message displays for the most critical state in the last 10 seconds.
- If the status changes from yellow or red to green, Hookup Advisor displays a message that you need to wait for 10 seconds before you start to record an ECG.

Change Lead Sets and Lead Formats

The Acquisition screen displays the waveform based on the configured lead format, lead set, speed, gain, and filter. After you start a new patient, you can change the lead set or lead format on the Acquisition screen.

1. At the bottom, left-side of the Acquisition screen, select anywhere to the left of the ellipsis icon (1).



The **Mode** and **Display** menus (2) are expanded.

2. Select a different lead set below **Mode**.

   If you change the lead set, it resets the acquisition of data.

   The selected lead set is applied to the waveform.

3. Select a different lead format below **Display**.

   The selected lead format is applied to the waveform. Select anywhere outside the menu to collapse it.

   These changes apply only to the current patient test(s). If you start a new patient, the changes reset to the values configured for the device.

Enable ACS Interpretation

You can enable the ACS option on the Acquisition screen before you record an ECG patient test if the ACS option, which detects Acute Coronary Syndrome, is bought and activated on the device.

This option records a resting ECG with ACS interpretation statements. By default, ACS interpretation statements are disabled for each patient. ACS must be enabled on a per-patient basis.

1. At the bottom, left side of the Acquisition screen, select anywhere to the left of the ellipsis icon (1).

The **ACS** option displays in the expanded menu.

2. Turn the **ACS** option (2) on to enable ACS interpretation statements for the patient report.

If you enable this option, it will stay enabled for the subsequent patient test(s) for that visit. It must be enabled again for the next patient.

If the patient demographics show that the patient is younger than 16 years of age, the device records a pediatric ECG with a standard 12SL analysis. The ACS algorithm is not executed.

Enable HD Pace

The HD Pace option enables or disables the HD Pace Detection, and display the suspected pace annotation for patients with a pacemaker. The pace annotations represent pacemaker pulses. By default, the HD Pace is set as ON.

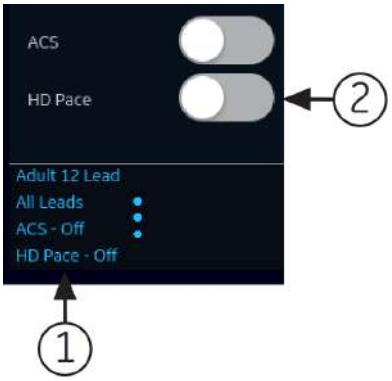
Suspected Pace Annotations

NOTE:
A qualified physician or cardiologist must review and confirm the suspected pace spike displayed.

You can manually disable the HD Pace option on the Acquisition screen before you record an ECG patient test.

The HD Pace option will automatically set back to ON after starting a new patient or rebooting the device.

1. At the bottom, left side of the Acquisition screen, select anywhere to the left of the ellipsis icon (1).



The **HD Pace** option displays in the expanded menu.

2. Turn the **HD Pace** option (2) off to disable the HD Pace Detection.

When **HD Pace** is off, **HD Pace Off** displays on the footer of the report.

When **HD Pace** is on, no additional information displays on the report.

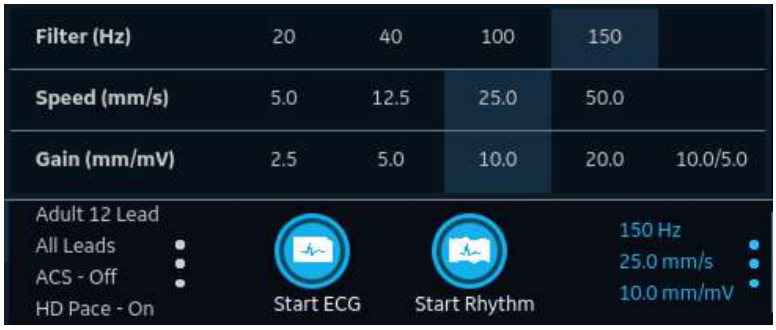
Change Speed, Gain, and Filter

The Acquisition screen displays the waveform based on the configured speed, gain, and filter. After starting a new patient, you can change the speed, gain, or filter on the Acquisition screen.

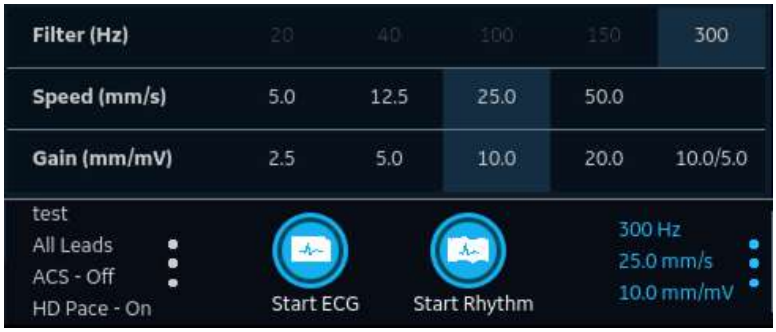
1. At the bottom, right-side of the Acquisition screen, select anywhere to the left of the ellipsis icon.

   The **Filter (Hz)**, **Speed (mm/s)**, and **Gain (mm/mV)** menu expands.

   - If you do not purchase the **F300 - 300 Hz Acquisition** option, the **Filter (Hz)** values are 20, 40, 100 and 150.
   - If you purchase the **F300 - 300 Hz Acquisition** option and the **Acquisition Bandwidth** of the selected lead set is **150Hz**, the **Filter (Hz)** values are 20, 40, 100 and 150.



   - If you purchase the **F300 - 300 Hz Acquisition** option and the **Acquisition Bandwidth** of the selected lead set is **300Hz**, the **Filter (Hz)** value is 300.



2. To adjust the speed, gain, and filter of the waveform, select a different value from the list.

   The selected values are applied to the waveform. Select anywhere outside the menu to collapse it.

These changes apply only to the current patient test(s). If you start a new patient, the changes reset to the values configured for the device.

ECG Acquisition Overview

You can record an ECG in pre-acquisition or post-acquisition modes.

Table 17: ECG Acquisition Modes

Acquisition Mode	*Description*
Pre-acquisition	When you start recording an ECG: • If 10 seconds of ECG data is available, the system records the previous 10 seconds of data for analysis. • If 10 seconds of ECG data is not available, the system continues recording until 10 seconds of ECG data is obtained.
Post-acquisition	When you start recording an ECG, the system records the next 10 seconds of data for analysis.

If the **Auto-ECG** option is enabled on the device, the device automatically records one ECG for each new patient. For more information on automatic ECG acquisition, see *Automatically Acquire an ECG on page 69*.

To record an ECG patient test manually, see *Manually Start an ECG recording on page 70*.

Automatically Acquire an ECG

Start a test for a new patient. For more information, see *Start a Test for a New Patient on page 51*.

Make sure that your administrator enables the **AECG - Auto ECG** option.

The system starts to automatically record an ECG:

- When **AECG - Auto ECG** option is enabled.
- If the **Hookup Advisor** status is green.
- If you are viewing the scrolling waveforms in the **Live** tab.

The automatic acquisition of ECG happens only once per patient connection.

The **Stop Auto ECG** icon displays the count of acquisition progress until you record 10 seconds of data. After acquiring 10 seconds of data with good signal quality, the recording stops and a preview of the ECG patient report displays.

If you record the ECG before you enter patient information in the **Patient Information** screen, you can edit patient information before accepting the preview. For more information, see *Accept or Reject an ECG Patient Report on page 72*.

Automatic ECG acquisition is triggered only one time for the current patient test. Start any new ECG tests for that same patient manually.

When Auto-ECG is in progress, the **Start ECG** button changes to the **Stop ECG** button:

- If you select the **Stop ECG** button, automatic ECG acquisition stops and the **Start ECG** button displays.
- If you select the **Start ECG** button, ECG acquisition starts manually.

If you perform other functions during automatic ECG acquisition, a message displays in the notification area. For example:

- If you perform New Patient - a message displays that *unsaved data will be lost.*
- If you navigate to Settings - a message displays that *cannot perform this action.*

Select **Cancel**, to continue to perform automatic ECG acquisition and retain current patient data. If you select **Continue**, automatic ECG acquisition stops.

The automatic ECG function is aborted and the device will function in manual ECG mode if:

- An automatic ECG acquisition is stopped before 10 seconds of data is acquired.
- The preview of an ECG that was automatically acquired is rejected.

Manually Start an ECG recording

1. Start a test for a new patient. For more information, see *Start a Test for a New Patient on page 51*.

   NOTE:
   If you want to record an ECG for the current patient, do not start a new patient test.

2. Change the lead set or format, gain, speed, or filter, if required. For more information, see *Change Lead Sets and Lead Formats on page 65* and *Change Speed, Gain, and Filter on page 68*.

3. Select the **Start ECG** icon at the bottom of the Acquisition screen to start recording the patient ECG.

   In pre-acquisition mode, the system checks if 10 seconds of ECG data is available.

   - If 10 seconds of ECG data is available, the system records the previous 10 seconds of data for analysis. You cannot stop or cancel the acquisition at this time.
   - If 10 seconds of ECG data is not available, the system continues recording until 10 seconds of ECG data is obtained. The **Start ECG** icon changes to **Stop ECG**, and the count of acquisition progress displays on the icon until

you have recorded 10 seconds of data. You can cancel the acquisition before 10 seconds of data is recorded. For more information, see *Cancel an ECG on page 72*.

In post-acquistion mode, the system starts recording the next 10 seconds of ECG data for analysis. The **Start ECG** icon changes to **Stop ECG**, and the 10 seconds count of acquisition progress displays on the icon. You can cancel the acquisition before 10 seconds of data is recorded. For more information, see *Cancel an ECG on page 72*.

The patient ECG test report starts generating. Based on the print preview mode configuration and the **Hookup Advisor** status, the recorded ECG patient test opens.

If ...	*Then ...*
Print preview mode is configured as **Always**	The ECG patient report preview displays for you to accept or reject the report. For more information on how to accept or reject the report, see *Accept or Reject an ECG Patient Report on page 72*.
Print preview mode is configured as **Yellow** and the Hookup Advisor Status is **Yellow** or **Red**	
Print preview mode is configured as **Red** and the Hookup Advisor Status is **Red**	

If ...	*Then ...*
Print preview mode is configured as **Yellow** and the Hookup Advisor Status is **Green**	The ECG patient report preview does not display. The ECG patient report is automatically accepted, saved in the **Files** list, and displayed for review. For more information, see *Review an ECG Patient Report on page 76*. The report is automatically printed. For more information, see *Automatically Print an ECG Patient Report on page 78*. If a destination is configured for ECG reports to be automatically sent after acquisition, the ECG report is automatically added to the queue of pending reports to be sent to the configured destination. For more information, see *Display the Report Queue on page 121*. **NOTE**: Based on the **Mandatory fields apply for Transmission** settings, the ECG report is not added to the transmission queue until you enter the patient demographic data for the mandatory fields. An error message displays in the notification area. You need to complete the data for the mandatory fields and manually resend the report to a configured destination. **NOTE**: Based on the **Mandatory fields apply for Acquisition** settings, the ECG report is not accepted, transmitted, or printed until you enter the patient demographic data for the mandatory fields. An error message **Unable to accept. Incomplete patient data.** displays on the **Acquisition** screen. You need to complete the data for the mandatory fields to accept the ECG report.
Print preview mode is configured as **Red** and the Hookup Advisor Status is **Yellow** or **Green**	
Print preview mode is configured as **Never**	

Cancel an ECG

You can stop recording an ECG before 10 seconds of data are recorded.

Select the **Stop ECG** icon at the bottom of the Acquisition screen to cancel the ECG acquisition:

The device stops recording the ECG data and the **Start ECG** icon displays.

Accept or Reject an ECG Patient Report

CAUTION:

DELAY IN TREATMENT - Unaccepted ECGs in the preview screen will be automatically rejected and deleted when all patient leads are disconnected and the MAC 5 device is inactive for 2 minutes.

A preview of the recorded 10 seconds of data displays in the configured preview report format if:

- The ECG is recorded in automatic ECG mode.
- Your administrator has configured the preview mode to display the recorded 10 seconds of data.
- The 10 seconds of ECG is selected from the Full Disclosure screen.

NOTE:
The **Full Disclosure** tab displays after you purchase and enable the Full Disclosure option.

You can accept this preview to save the ECG patient report in the **Files** tab, or reject it and start another ECG.

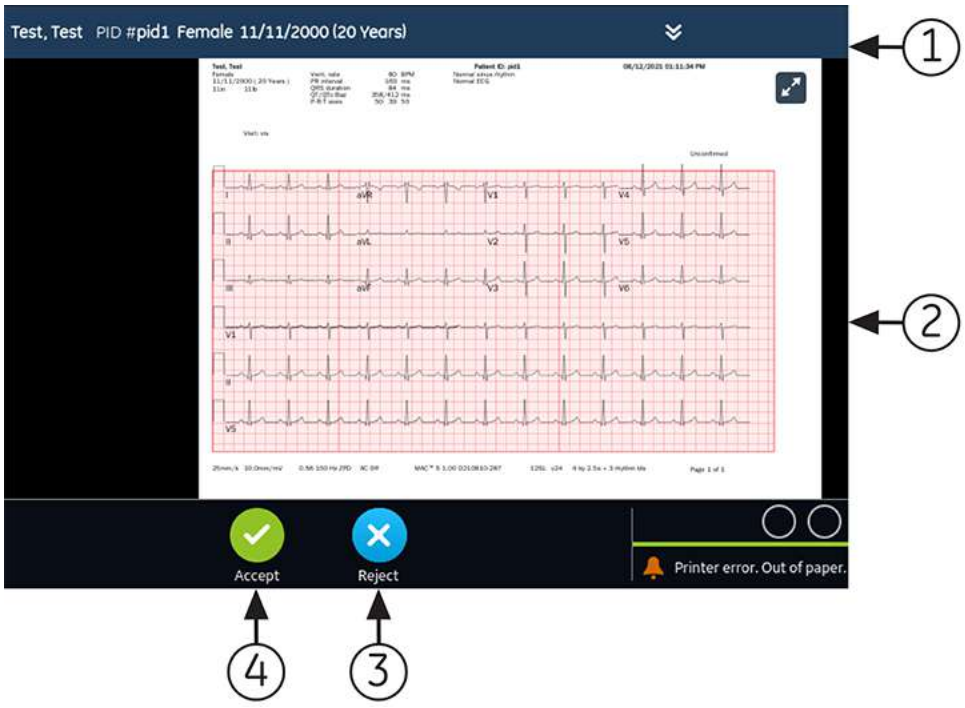


Table 18: Preview of the ECG Patient Report

Item	*Name*	*Description*
1	**Patient Information** Banner	Displays patient information. Select anywhere in the **Patient Information** banner to edit patient information for the patient report. Modify the information by using the software keyboard, attaching an order, scanning the patient barcode, selecting a patient from the **Patients** tab, or performing an ADT query.

Item	*Name*	*Description*
2	Preview of ECG patient report	Displays the preview of the ECG patient report. If a patient report contains multiple pages, a part of another page displays on the right side of the screen. Press the left and right arrows on the screen to navigate from one page to another. For more information on the report formats and the standard layout of the ECG patient report, see *ECG Report Formats on page 287*.
3	**Reject** icon	Select the **Reject** icon to return to the live waveform display in the Acquisition screen.
4	**Accept** icon	Select the **Accept** icon to accept the preview of the ECG patient report and save it in the **Files** list. The accepted ECG patient report is refreshed and displayed for review with additional options.

To accept or reject the ECG preview, perform the steps as follows:

1. Review the patient report and **Hookup Advisor** status.
2. If the **CRIT- Critical Value Notifications** option is enabled on the device, and one or more critical values are detected during ECG acquisition, a window opens on top of the screen displaying critical value notifications in the order in which they are detected.

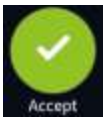
3. Select **Continue** to acknowledge each notification.

   If you try to perform other functions such as accessing the **Settings** or **Service** screen prior to accepting or rejecting the ECG, a message displays indicating that the ECG is not saved, and the preview will be lost if you navigate to the screen.

   Select one of the options as follows:

   - If you select **Continue**, the preview will be lost.
   - If you select **Cancel**, you can proceed to accept or reject the ECG preview.

4. Accept or reject the ECG preview based on the **Hookup Advisor** status.

If ...	*Then ...*	*Next Steps*
Hookup Advisor status is green, the ECG signal quality is good. The **Accept** icon is highlighted in green. The **Reject** icon is not highlighted.	Select the **Accept** icon:  The preview of the ECG patient report is accepted and saved in the **Files** list. The patient report is refreshed and displayed for review with additional options.	• Review the ECG patient report and decide on the next steps. For more information, see *Review an ECG Patient Report on page 76*. • The ECG patient report is automatically printed. For more information, see *Auto-print an ECG Report*. • The patient report is added to the queue of pending reports to be sent to the configured automatic destination. For more information, see *Display the Report Queue on page 121*. **NOTE**: Based on the **Mandatory fields apply for Transmission** settings, the ECG report is not added to the transmission queue until you enter the patient demographic data for the mandatory fields. An error message displays in the notification area. You need to complete the data for the mandatory fields and manually resend the report to a configured destination. **NOTE**: Based on the **Mandatory fields apply for Acquisition** settings, the ECG report is not accepted, transmitted, or printed until you enter the patient demographic data for the mandatory fields. An error message **Unable to accept. Incomplete patient data.** displays on the **Acquisition** screen. You need to complete the data for the mandatory fields to accept the ECG report.

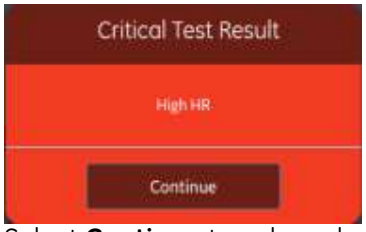
If ...	*Then ...*	*Next Steps*
Hookup Advisor status is yellow or red, there are issues with the ECG signal quality during the recording of this ECG. The **Reject** icon is highlighted in blue to reflect the status of **Hookup Advisor**. The **Accept** icon is not highlighted.	Select the **Reject** icon:  The ECG patient report is discarded. The **ECG Preview** screen closes and returns to the Acquisition screen.	Start a new ECG on the same patient. For more information, see *ECG Acquisition Overview on page 69*.

Review an ECG Patient Report

The reviews of ECG patient reports are automatically closed 2 minutes after disconnecting patient leads and inactivity with the MAC 5 device.

After the 10 seconds ECG is acquired and the ECG preview is accepted, the patient report displays in the configured report format for review.

If the **CRIT - Critical Value Notifications** option is enabled on the device, and one or more critical values are detected during ECG acquisition, a window opens on the top displaying the notifications for the critical values in the order in which they are detected.



Select **Continue** to acknowledge the notification and proceed with other tasks.

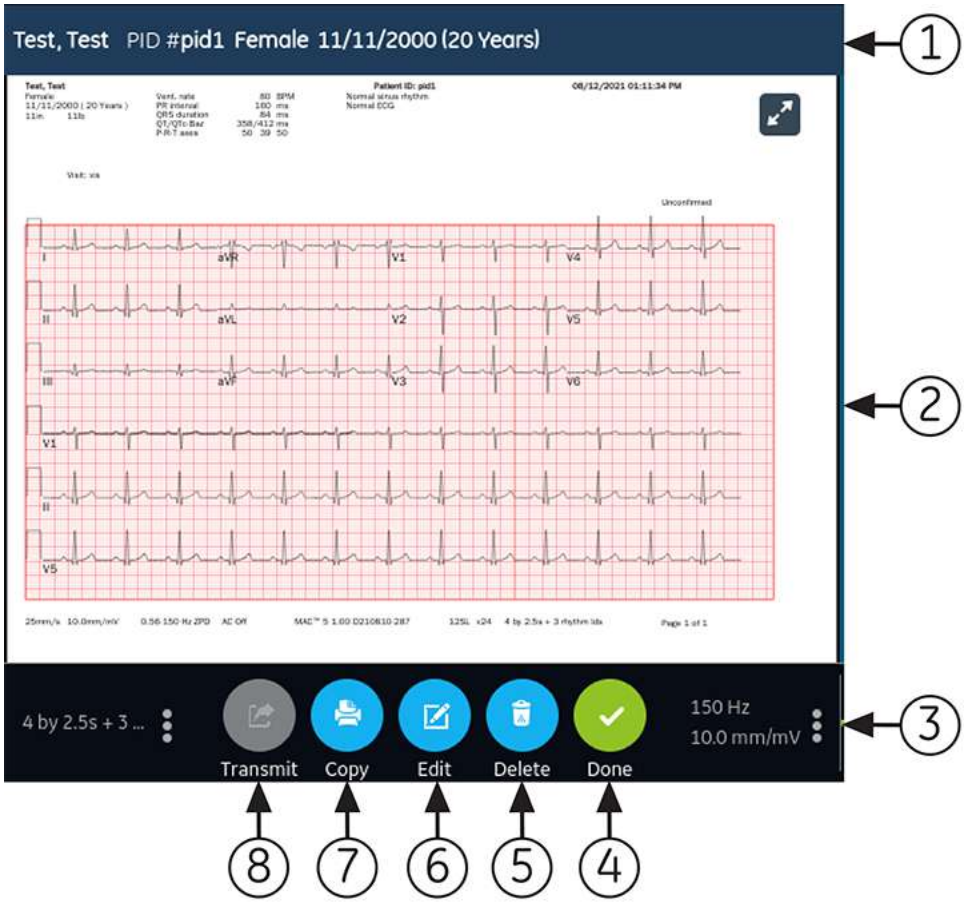


Table 19: Displaying an ECG Patient Report for Review

Item	*Name*	*Description*
1	**Patient Information** Banner	Displays patient information such as patient first name, last name, gender, age, and so on. Select anywhere in the **Patient Information** banner to edit patient information for the patient report.
2	ECG patient report	Displays the ECG patient report. If a patient report contains multiple pages, a part of another page displays on the right side of the screen. Select the left and right arrows on the screen to navigate from one page to another. For more information on the report formats and the standard layout of the ECG patient report, see *ECG Report Formats on page 287*.
3	Gain and Filter	To change the waveform gain or filter, select anywhere around the ellipsis icon next to **Gain** and **Filter** and select a new value from the expanded list. The patient report is refreshed with the selected gain and filter.
4	**Done** icon	Closes the patient report after completing your tasks. For more information, see *Close a Patient Report on page 88*.

Item	*Name*	*Description*
5	**Delete** icon	Deletes the patient report. For more information, see *Delete a Patient Report on page 87*.
6	**Edit** icon	Edits patient information for the patient report. For more information, see *Edit Patient Information in a Patient Report on page 87*.
7	**Copy** icon	Prints a copy of the patient report. For more information, see *Print a Patient Report on page 85*.
8	**Transmit** icon	Transmits the patient report. For more information, see *Transmit a Patient Report to a Configured Destination on page 82*.

To start a new ECG on the same patient, close the review page to return to the live waveform display in the Acquisition screen, and restart the ECG. For more information, see *ECG Acquisition Overview on page 69*.

After you select **Done** on the **Review** screen of an ECG patient report, disconnect patient leads before you select **New Patient** on the MAC 5 device.

To start an ECG for a new patient, select **New Patient**. For more information, see *Start a Test for a New Patient on page 51*.

To start a new 10 seconds ECG on the same patient from the Full Disclosure tab, close the preview page to navigate to the Full Disclosure waveform and application, and select 10 seconds ECG from the Full Disclosure waveform. For more information, see *Record a Full Disclosure ECG on page 90*.

To start a new 10 seconds ECG on the same patient from the Full Disclosure tab, close the preview page to navigate to the Full Disclosure waveform and application, and select 10 seconds ECG from the Full Disclosure waveform. For more information, see *Record a Full Disclosure ECG on page 90*.

Automatically Print an ECG Patient Report

When a patient report is saved in the **Files** list, it is automatically printed in the configured report formats.

The configured report formats determine the following:

- Number of copies printed
- Inclusion or exclusion of 12SL interpretation statements
- Printing of all reports
- Printing of only the reports interpreted by the 12SL analysis as abnormal

The ECG patient report is printed in the order in which it was received. If no other patient reports are printing, the report is printed immediately.

You will see a progress message at the bottom of the screen indicating the printing status.

If the device is configured to print the barcode of the patient ID in the patient reports, the printed patient report includes the barcode. The barcode can be used to perform a query by patient ID in the MUSE system.

If a printer error occurs, the progress message is replaced by the related printer error. The printing restarts automatically after the error is resolved. For more information on printer errors, see *Printing Errors on page 277*.

To stop printing a patient report, select the **Stop** icon in the middle of the screen.

All pending print jobs are cancelled.

Record a Rhythm

Make sure that sufficient paper is available in the paper tray to print a rhythm report.

If the **DRHM - Digital Rhythm** option is purchased and enabled on the device, a rhythm report can be stored in digital form in the **Files** list or printed on paper, depending on how the device has been configured for your site. A digital rhythm report cannot be transmitted to a configured automatic destination.

1. Start a test for a new patient. See *Start a Test for a New Patient on page 51*.
2. Change the lead set or format, gain, speed, or filter, if required. See *Change Lead Sets and Lead Formats on page 65*.
3. Select the **Start Rhythm** icon on the Acquisition screen to start the rhythm for the patient.

   The **Start Rhythm** icon on the Acquisition screen changes to **Stop Rhythm**. A count of the recording progress starting at one-second displays on the icon if the configured rhythm mode is **Digital Only** or **Both**.

   If the **Delay Rhythm Printing** option is disabled, the rhythm for the patient is recorded and/or printed in real-time.

   If the **Delay Rhythm Printing** option is enabled, the rhythm for the patient is recorded and/or printed with the previous 10 seconds data.

If the Rhythm Mode is ...	***Then***
Paper Only	The rhythm is only printed. It is not digitally recorded. Go to step 4 to stop printing the rhythm. If you do not stop printing the rhythm, printing continues until the paper tray is out of paper. **NOTE**: **Paper Only** is available on A4 and A5 devices.

If the Rhythm Mode is ...	*Then*
Digital Only	The rhythm is only digitally recorded in real-time at the configured speed and for the configured duration. When the configured duration is reached, the rhythm stops recording. The digital rhythm report is displayed in a new **Rhythm** tab and saved in the **Files** list. The rhythm is not printed. Go to step 4 if you want to stop recording the rhythm before its configured duration is reached, otherwise go to step 5. **NOTE**: **Digital Only** is available only if you enable the **DHRM - Digital Rhythm** option.
Both	The rhythm for the patient is digitally recorded and printed in real-time at the configured speed and for the configured duration. When the configured duration is reached, the rhythm stops recording and printing. The digital rhythm report is displayed in a new **Rhythm** tab and saved in the **Files** list. Go to step 4 if you want to stop recording and printing the rhythm before its configured duration is reached, otherwise go to step 5. **NOTE**: **Both** is only available on A4 and A5 devices when you enable the **DHRM - Digital Rhythm** option.

If a printer error occurs and rhythm printing is stopped, you need to troubleshoot the error. For more information, see *Printing Errors on page 277*. Digital rhythm continues even if there is a printing error. To restart rhythm printing, you must stop the digital rhythm and then restart both.

4. Select the **Stop Rhythm** icon on the Acquisition screen to stop both digital rhythm recording and printing:

Select the **Stop** icon on the Report Printing screen to stop printing the rhythm report while the digital acquisition of rhythm continues.

5. Review the rhythm report. For more information, see *Review a Digital Rhythm Report on page 80*.

Review a Digital Rhythm Report

If the Digital Rhythm option is purchased and activated on the device, a rhythm report can be stored in digital form.

After the digital rhythm report is recorded, the report displays for your review.

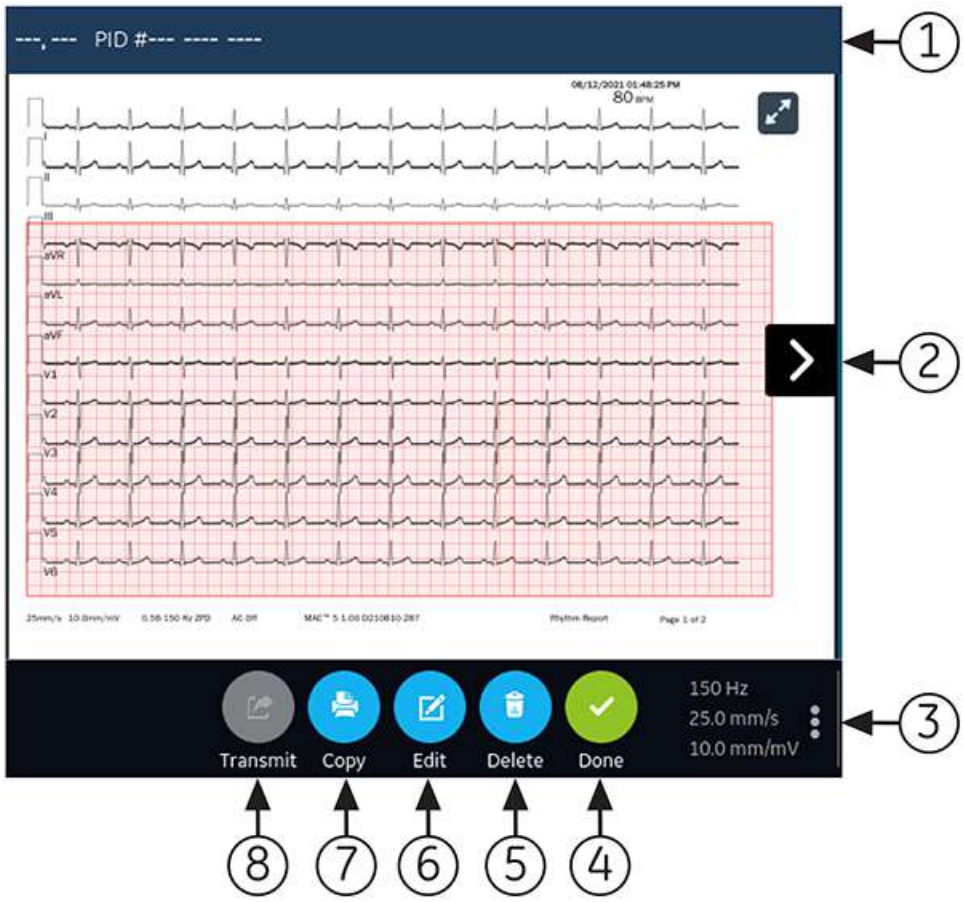


Table 20: Rhythm Tab

Item	*Name*	*Description*
1	**Patient Information** Banner	Displays patient information such as patient first name, last name, gender, age, and so on. Select anywhere in the **Patient Information** banner to edit patient information for the rhythm report.
2	Rhythm report	Displays the rhythm report. If a rhythm report contains multiple pages, press the left and right arrows on the screen to navigate from one page to another. For more information on the rhythm report format, see *Rhythm Report Format on page 291*.
3	Gain, Filter, and Speed	To change the gain, filter, or speed of the waveform, select anywhere around the ellipsis icon on the lower, right corner of the **Rhythm** tab and select a new value from the expanded list. The rhythm report is refreshed with the selected gain, filter, and speed.
4	**Done** icon	Closes the rhythm report after completing your tasks. For more information, see *Close a Patient Report on page 88*.
5	**Delete** icon	Deletes the rhythm report. For more information, see *Delete a Patient Report on page 87*.

Item	*Name*	*Description*
6	**Edit** icon	Edits patient information for the rhythm report. For more information, see *Edit Patient Information in a Patient Report on page 87*.
7	**Copy** icon	Prints a copy of the rhythm report. For more information, see *Print a Patient Report on page 85*.
8	**Transmit** icon	Transmits the rhythm report. For more information, see *Transmit a Patient Report to a Configured Destination on page 82*.

To start a new rhythm for the same patient, close the review screen to return to the live waveform display in the Acquisition screen, and restart the rhythm. For more information, see *Record a Rhythm on page 79*.

To start a rhythm for a new patient, select **New Patient**. For more information, see *Start a Test for a New Patient on page 51*.

Transmit a Patient Report to a Configured Destination

Before you start the procedure, make sure that:

- You have the privilege to transmit patient reports to a configured destination.
- The USB flash drive supports the FAT32 file system.

Select the correct destination for your patient report. For more information, see the table below:

Patient Report Type	*Destination*	*Supported File Format*
Resting ECG	DCP server destination (MUSE v8 SP3 or higher, v9, or MUSE NX and MUSE DICOM Gateway Pro SP1 or higher)	Hilltop format
Resting ECG	USB R/W flash drive	PDF, Hilltop and Sapphire XML (Sapphire XML format is available if you enable the XML format output in the **Option Manager**) formats.
Resting ECG	SFTP server destination with remote directory path	PDF, Hilltop and Sapphire XML (Sapphire XML format is available if you enable the XML format output in the **Option Manager**) formats.
Resting ECG	Shared directory destination with folder path	PDF, Hilltop and Sapphire XML (Sapphire XML format is available if you enable the XML format output in the **Option Manager**) formats.
Digital Rhythm	USB R/W flash drive	PDF format

Patient Report Type	*Destination*	*Supported File Format*
Digital Rhythm	DCP server destination (MUSE v9 SP6 or higher, or MUSE NX and MUSE DICOM Gateway Pro SP6 or higher)	PDF format
Digital Rhythm	SFTP server destination with remote directory path	PDF format
Digital Rhythm	Shared directory destination with folder path	PDF format
Full Disclosure	USB R/W flash drive	PDF format
Full Disclosure	DCP server destination (MUSE v9 SP6 or higher, or MUSE NX and MUSE DICOM Gateway Pro SP6 or higher)	PDF format
Full Disclosure	SFTP server destination with remote directory path	PDF format
Full Disclosure	Shared directory destination with folder path	PDF format

To transmit a patient report to the default or configured destination immediately after acquisition, perform the steps below:

1. Review the patient report to confirm that it can be transmitted to the required destination.

   To review an ECG patient report, see *Review an ECG Patient Report on page 76*.

   To review a rhythm report, see *Review a Digital Rhythm Report on page 80*.

   To review a Full Disclosure report, see *Review a Full Disclosure Report on page 91*.

2. To transmit the report to the required destination, perform one of the steps below:

To transmit the report ...	*Perform the following:*
To the default destination	Select the **Transmit** icon: 

To transmit the report ...	*Perform the following:*
To another configured destination	1. Select anywhere around the ellipsis icon on the left, bottom corner of the tab to view the **Transmit** menu. 2. From the expanded **Transmit** menu, select the destination where you want to transmit the patient report. 3. Select the **Transmit** icon:  One or more destinations must be configured for the **Transmit** icon to be enabled. If no destinations are configured, the **Transmit** icon is disabled.

The selected patient report is added to the **Queue**, processed and transmitted to the selected destination. The **Job Status** in the **Queue** is updated. For information on the status, see *Display the Report Queue on page 121*.

The status of a manually submitted job displays on the notification bar in the lower, right-side of the screen in the format: **<Destination_Name>: <Job_Status>**.

For example, if the destination name is USB, and the job status is **Failed**, the status displays as follows: **USB: Failed**.

A tick mark displays in the **Sent** column of the **Files** expanded list for patient reports successfully transmitted to the default destination.

If	*Then*
The transmission queue has reached its maximum limit of 1000 reports, a message displays in the notification area that the transmission queue is full and no additional reports can be added.	Wait for the reports in the queue to transmit and try again.
The patient report has already been transmitted to the selected destination, a message displays in the notification asking you to confirm if you want to re-transmit the already transmitted report.	Perform one of the actions below: • Select **Continue** to re-transmit the patient report. • Select **Cancel** to cancel the report transmission.

If	*Then*
Patient information is incomplete in the patient report (for example, mandatory fields are blank or contain invalid data), a message displays in the notification area indicating that the patient report cannot be transmitted because of incomplete patient data. **NOTE**: Based on the **Mandatory fields apply for Transmission** settings, the ECG report is not added to the transmission queue until you enter the patient demographic data for the mandatory fields. An error message displays in the notification area. You need to complete the data for the mandatory fields and manually resend the report to a configured destination. **NOTE**: Based on the **Mandatory fields apply for Acquisition** settings, the ECG report is not accepted, transmitted, or printed until you enter the patient demographic data for the mandatory fields. If you manually transmit ECG report, an error message **Unable to transmit. Incomplete patient data.** displays on the **Acquisition** screen. You need to complete the data for the mandatory fields to transmit the ECG report.	Perform the steps below: 1. Edit the patient report to enter missing patient data. 2. Retry transmission.

Print a Patient Report

You can print a copy of a Rhythm, Full Disclosure, or ECG patient report in any configured report format for the selected lead set.

If you purchase the **NETP - Network Printer** option and enable it in the **Option Manager**,

- you can print the copy via thermal printer or send the copy to a network printer on MAC 5 devices with thermal printer.
- you can only send the copy to a network printer on MAC 5 Lite.

See *Configure Network Printer on page 183* for more information.

1. Before printing a copy of the report, review the patient report and verify:
   - The patient information in the patient report is correct.
   - The ECG or Rhythm or Full Disclosure ECG is acquired with the desired gain and filter.
2. Perform one of the steps below:

To print a copy of the patient report ...	*Perform the following:*
In the default or selected report format displayed on the **ECG** or **Rhythm** or **FD Report** tab	Select the **Copy** icon:  A job to print one copy of the patient report in the default report format is sent to the printer.
In a different report format	1. Select anywhere around the ellipsis icon on the left, bottom corner of the **ECG** tab to view the **Copy Format** menu. 2. From the expanded **Copy Format** menu, select the desired report format to be used to print a copy of the report. Only the report formats supported for the lead set used to record the ECG or rhythm are available for selection. For example, if a 12-lead ECG is recorded, only 12-lead ECG patient report formats are available for selection. 3. Select the **Copy** icon:  The patient report is refreshed and displayed in the **ECG** tab in the selected report format. A job to print one copy of the ECG or rhythm in the selected report format is sent to the printer.

The patient report is printed in the order in which it was received. If no other patient reports are printing, the report is printed immediately. The printing status displays at the bottom of the screen.

NOTE:

Based on the **Mandatory fields apply for Acquisition** settings, the ECG report is not accepted, transmitted, or printed until you enter the patient demographic data for the mandatory fields. An error message **Unable to print. Incomplete patient data.** displays on the **Acquisition** screen. You need to complete the data for the mandatory fields and reprint the patient report.

If a printer error occurs, the progress message is replaced by the printer error. The printing restarts automatically after the error is resolved. For more information on printer errors, see *Printing Errors on page 277*.

If the device is configured to print the barcode of the patient ID in the patient reports, the printed patient report includes the barcode. The barcode can be used to perform a query by patient ID in the MUSE system.

3. To stop printing a patient report, select the **Stop** icon in the middle of the screen.

Edit Patient Information in a Patient Report

Make sure that you have the privilege to edit patient reports.

After a test is acquired, you can edit patient information using the software keyboard or by attaching an order. When an order is attached to a patient test, some fields are read-only.

If you try to edit or attach an order to a patient report that is transmitted to the default destination, an error message displays.

You cannot edit patient information by scanning a patient barcode, selecting a patient record from the **Patients** list, or performing ADT queries.

WARNING:

INACCURATE PATIENT DATA - Incorrect patient information can cause patient data mismatch. Data assigned to the wrong patient causes erroneous patient data that can affect diagnosis and treatment.

Be sure to check the patient information screen for each new patient. Make sure that you enter patient data for the correct patient.

1. To edit patient information for the patient report, select the **Edit** icon in the **Report Review** page in the Acquisition screen:

   The **Patient Information** screen opens.

2. Edit the patient information using a software keyboard. See *Enter or Edit Patient Information Using the Software Keyboard on page 59*.

3. Select **Save** to save your changes for this patient and collapse the screen.

   If you select any other icons at the bottom of the tab prior to saving, the **Patient Information** screen collapses and the edited patient information is saved.

   The updated patient information displays on the patient report.

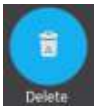
Delete a Patient Report

Make sure that you have the privilege to delete Rhythm, Full Disclosure, or ECG patient reports.

NOTE:

If you do not have the privilege to view patient reports, but you have the privilege to delete patient reports, you can only view and delete patient reports you created in the current session.

1. Select the **Delete** icon in the **Report Review** page on the Acquisition screen to delete the patient report:

   A message displays asking you to confirm if you want to permanently delete the patient report.

2. Select **Delete** to delete the patient report.

   The selected patient report(s) are deleted from the **Files** list.

3. A confirmation message may display if you are trying to delete a patient report that has not yet been transmitted to the default destination (if a message has been configured by your administrator). Perform one of the actions below:

   - Select **Delete** to delete the patient report. The selected patient report is deleted from the **Files** list. Deleting the patient report closes the tab where it was opened for viewing, and returns you to the **Live** tab.
   - Select **Cancel** to cancel the deletion. The selected patient report is not deleted from the **Files** list.

View the Patient Report

You can use the icons in the ECG, Rhythm, or Full Disclosure report tab to view the patient report:

Icon	*Name*	*Description*
	Maximize View	Select this icon or double-tap the patient report to maximize the view of the patient report.
	Minimize View	Select this icon or double-tap the maximized patient report to minimize the view of the patient report.
	Previous	Select this icon to navigate to the previous page of the multiple-page reports.
	Next	Select this icon to navigate to the next page of the multiple-page reports.

Close a Patient Report

1. Review the patient report.

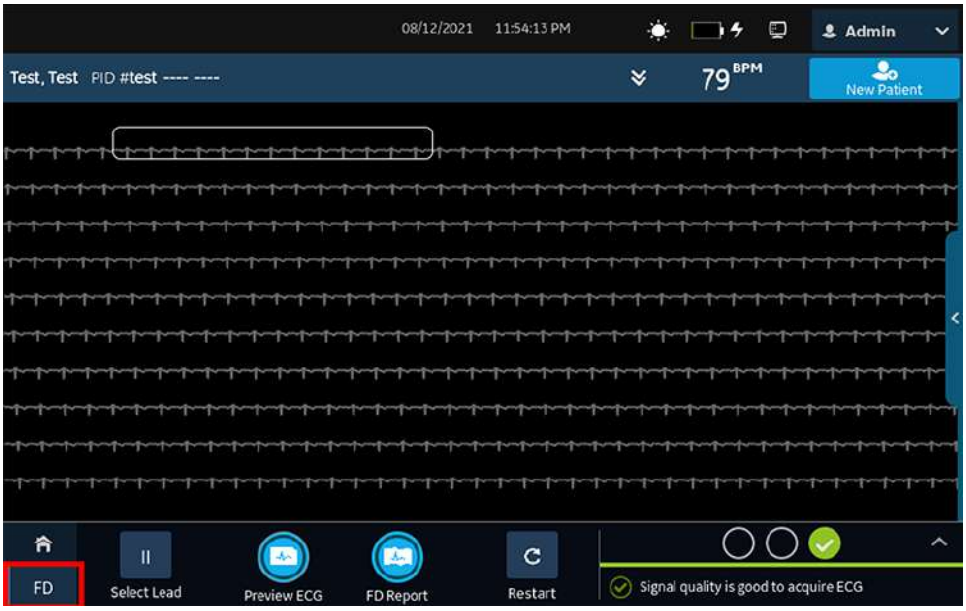
2. After completing your tasks, select the **Done** icon to close the patient report.

A message displays asking you if you want to start a new patient test.

Select one of the options below:

- **New Patient** to start a test for a new patient, see *Start a Test for a New Patient on page 51*. This action will clear the previous patient information.
- **Continue with Same Patient** to start a new test for the same patient. The live waveform for this patient displays on the screen.

Full Disclosure Overview



The Full Disclosure ECG option shows one lead of the patient waveform for a maximum of 5 minutes. From this waveform, you can create a Full Disclosure report (FD Report) or create a 12-lead ECG. It starts after you connect a patient to the acquisition module AND you are viewing the waveforms.

This feature may be helpful for clinicians that need to acquire an ECG on:

- A child that will not sit still or is anxious.
- A patient that is experiencing symptoms or stable arrythmias and would require a 12 lead ECG during those symptoms.

You can acquire a Full Disclosure ECG only if you purchase the Full Disclosure option, and enable it in the **Options Manager**.

Automatic acquisition of ECG does not start while in the **Full Disclosure** tab.

Record a Full Disclosure ECG

Before you start this procedure, make sure:

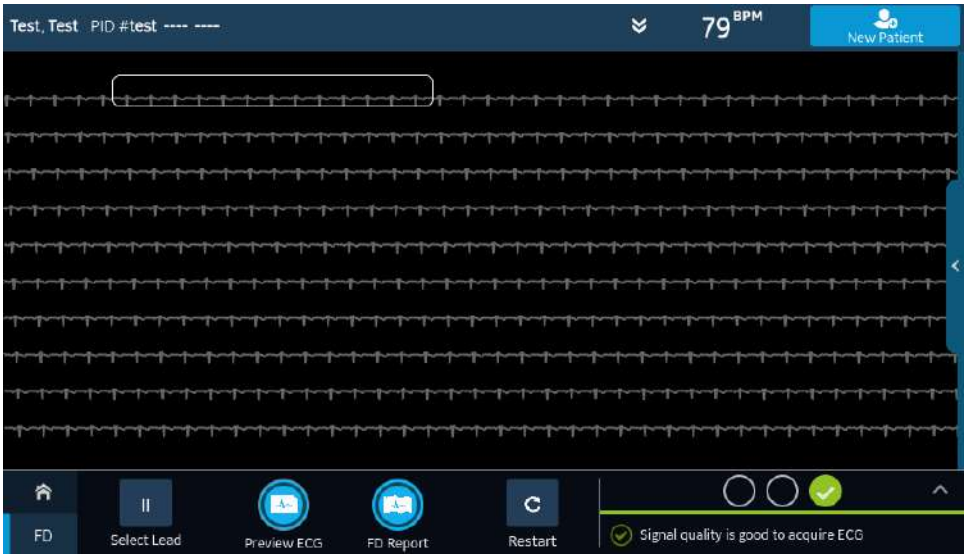
- You purchase and enable the Full Disclosure option in the **Options Manager**.
- You enable the Full Disclosure option in the **Setting** screen.

1. Start a new patient test.
2. To view a Full Disclosure ECG, click the **Full Disclosure** tab on the Acquisition screen.
   - One lead of the Full Disclosure ECG displays. The Full Disclosure shows the waveform from the left to right side of the screen.
   - The Full Disclosure ECG records for a maximum of 5 minutes. The recording stops after the 5 minutes is complete.
   - The Full Disclosure screen displays 10 lines of ECG data and each line is of 30 seconds.
   - A notification message displays on the **Acquisition** screen after the Full Disclosure ECG records for 5 minutes.
   - The Full Disclosure screen displays the previous 5 minutes of Full Disclosure ECG data.
3. To change the lead, click **Select Lead**.

   All the configured leads display. Select the single lead you want to display on the screen and on the printed FD reports. If you connect the leads to a patient after being fully disconnected for at least 30 seconds, all the data will be cleared from the display.

   The ECG recording restarts and the selected lead is applied to the Full Disclosure waveform. All the previous recorded data will be cleared.
4. To restart the Full Disclosure ECG, click **Restart**. All of the current waveform data is deleted.

   The message *unsaved data will be lost. Confirm to proceed* displays.
5. To record a 10 seconds ECG when in the Full Disclosure screen, do the steps that follow:



a) Select anywhere on the Full Disclosure ECG. The 10 seconds of ECG data is selected.

b) Click **Preview ECG**.

A preview of the recorded 10 seconds of data for all leads displays in the configured preview report. Select the minimize icon to view the report.

c) To accept or reject an ECG Patient Report, see *Accept or Reject an ECG Patient Report on page 72*.

d) To review an ECG Patient Report, see *Review an ECG Patient Report on page 76*.

6. To generate a Full Disclosure report, click **FD Report**.

The Full Disclosure report for the selected lead displays for your review.

7. To review the Full Disclosure report, see *Review a Full Disclosure Report on page 91*.

Review a Full Disclosure Report

The Full Disclosure report displays for your review.

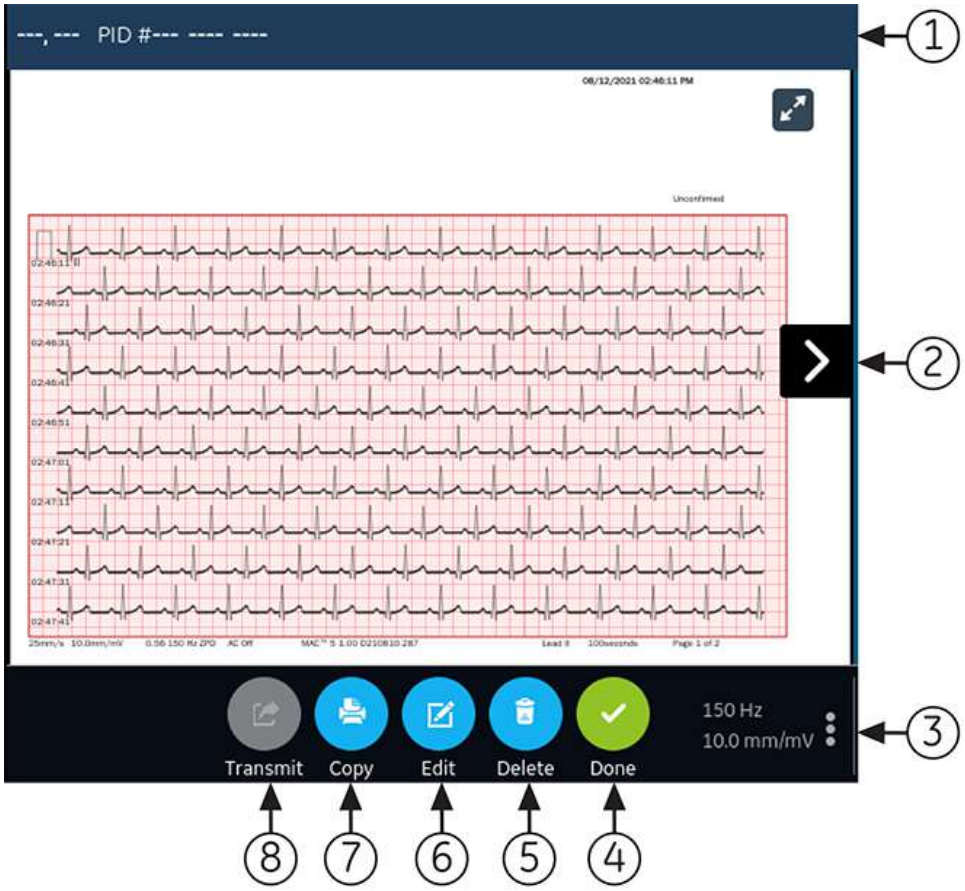


Table 21: Full Disclosure Report Tab

Item	*Name*	*Description*
1	**Patient Information** Banner	The information that displays on the screen for the patient such as first name, last name, gender, age, and so on. To edit the patient information, click anywhere on the **Patient Information** screen.

Item	*Name*	*Description*
2	Full Disclosure Report	Displays the Full Disclosure report. If a Full Disclosure report contains more than one pages, click the left and right arrows on the screen to see the next page. When you record Full Disclosure ECG: • If the acquisition module is disconnected, the Full Disclosure report displays empty space on the screen. • If the lead is disconnected or the ECG waveform does not display, the Full Disclosure report displays a straight horizontal line on the screen, and transforms into square waves on the printed or transmitted FD Report. **NOTE**: Only a FD Report or Rhythm Report can have a single tab. The ECG report will always have a tab, but if you enable a Rhythm tab and select a FD Report, the Rhythm tab will be replaced by the FD tab.
3	Gain, Filter, and Speed	To edit the gain, filter, or speed of the waveform in the report, do the steps as follow: • Click the ellipsis icon that is on the lower right of the **FD Report** tab. • Select a new value from the expanded list. • The Full Disclosure report refreshes with the selected gain, filter, and speed.
4	**Done** icon	Closes the Full Disclosure report. For more information, see *Close a Patient Report on page 88*.
5	**Delete** icon	Deletes the Full Disclosure report. For more information, see *Delete a Patient Report on page 87*.
6	**Edit** icon	Edits the patient information for the Full Disclosure report. For more information, see *Edit Patient Information in a Patient Report on page 87*.
7	**Copy** icon	Prints a copy of the Full Disclosure report. For more information, see *Print a Patient Report on page 85*.
8	**Transmit** icon	Transmits the Full Disclosure report. For more information, see *Transmit a Patient Report to a Configured Destination on page 82*.

To start a new Full Disclosure report for the same patient, click the **Full Disclosure** tab to navigate to the Full Disclosure waveform and application, and restart the Full Disclosure ECG. For more information, see *Record a Full Disclosure ECG on page 90*.

6

Work with Orders

Make sure that the ORDM option is enabled on the device. Contact a GE Healthcare Service Support representative to enable this option.

If order management is enabled, the **Orders** list displays in the Acquisition screen. You can retrieve orders from an order management server (such as a MUSE system) that is connected to your network.

When the orders list is updated, either automatically or manually, new orders are populated in the list.

The figure illustrates the **Orders** collapsed list:

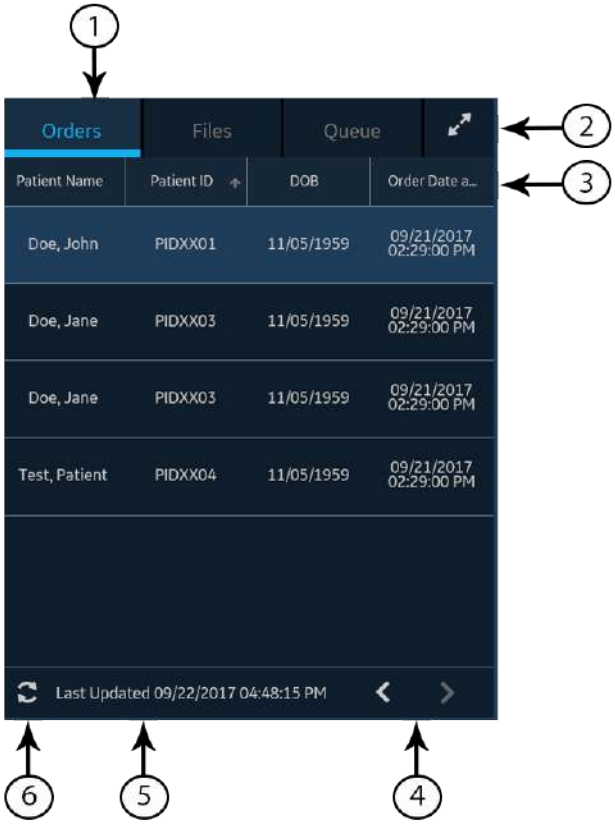


Table 22: Orders Collapsed List

Item	*Name*	*Description*
1	**Orders** tab	Displays a list of orders downloaded from an order management server. A filter icon next to the tab name indicates that the order list is filtered by a location.
2	**Expand** icon	Opens the **Orders** expanded list.
3	**Orders** collapsed list columns	Displays up to four configurable columns that provide information about the orders. This view will include at least one of the columns: **Patient Name**, **Patient ID**, or **Visit Number**.
4	Navigation arrows	Navigates to the previous and next pages in the **Orders** list.
5	**Last Updated** date and time	Displays the date and time the order list was last updated.
6	**Refresh** icon	Downloads the list of orders.

The figure illustrates the **Orders** expanded list:

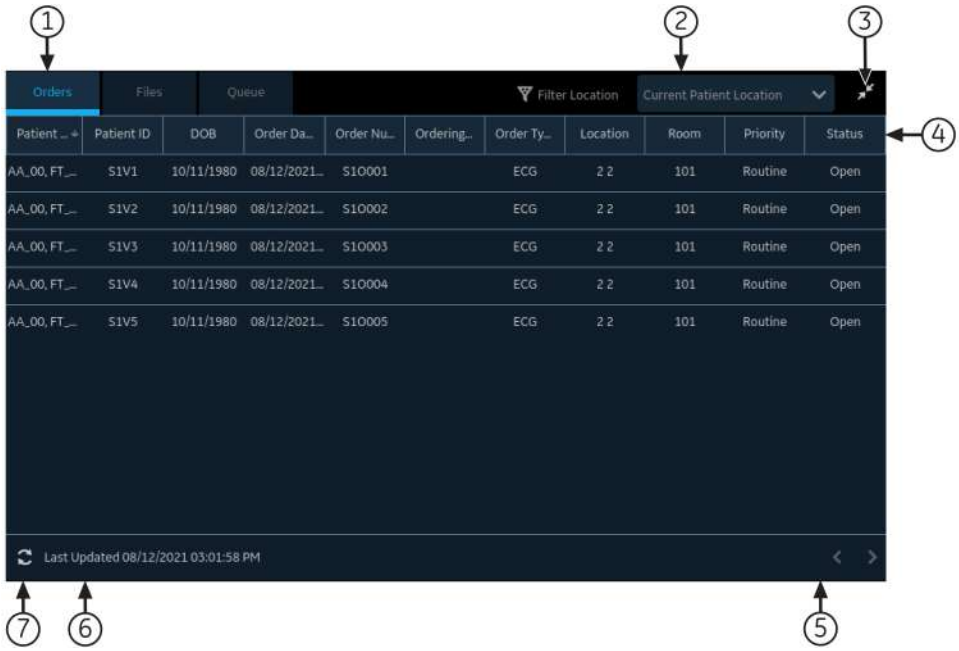


Table 23: Orders Expanded List

Item	*Name*	*Description*
1	**Orders** tab	Displays the **Orders** expanded list. A filter icon next to the tab name indicates that the order list is filtered by a location.
2	**Filter Location** list	Select anywhere on the **Filter Location** field. From the drop-down menu, select the location filter you want to apply to the orders list.
3	**Collapse** icon	Collapses the **Orders** list.

Item	*Name*	*Description*
4	**Orders** expanded list columns	Displays up to eleven configurable columns that provide information about the orders.
5	Navigation arrows	Navigates to the previous and next pages in the **Orders** list.
6	**Last Updated** date and time	Displays the date and time the order list was last updated.
7	**Refresh** icon	Downloads the list of orders.

Only one order can be associated with a patient test at any given time.

Only 12-lead order can be displayed on the device.

Orders cannot be attached to:

- Transmitted patient reports, or
- Digital Rhythm patient reports.

If you do not have permissions to edit patient reports, you cannot attach an order to the patient report.

When an order is attached to a patient test, all fields are read-only except for which can be edited below:

- **Blood Pressure**
- **Room Number**
- **Bed Number**
- **Test Indication**
- **Priority**
- **Comments**
- **Technician**
- **Patient History**
- **Location**
- **<Question>**
- **Attending MD ID**
- **Attending MD First Name**
- **Attending MD Last Name**

WARNING:

INACCURATE PATIENT DATA - Incorrect patient information can cause patient data mismatch. Data assigned to the wrong patient causes erroneous patient data that can affect diagnosis and treatment.

Be sure to check the patient information screen for each new patient. Make sure that you attach the correct order for the correct patient.

Automatically Update the Orders List

The auto-update option must be enabled by your administrator to automatically update orders from the order management server. Orders are automatically updated when:

- The device is powered on.
- A user logs into the device or unlocks the device.
- The **New Patient** button is selected.
- A report is successfully sent to a remote device over the network.

The **Last Updated** date and time is updated. No error messages display if orders are not being automatically updated. You can also manually update the **Orders** list.

Manually Update the Orders List

You can manually update the orders list at any time, even if the auto-update option is enabled.

1. From the Acquisition screen, select the **Orders** tab.

   The **Orders** collapsed list opens.

2. Select the **Refresh** icon to update the orders list .

   The list of orders is refreshed and updated with the latest information. All previous data is overwritten. The date and time when the list was last updated display next to the **Refresh** icon.

   If the device is not connected to the network, a message displays in the notification area indicating that the update has failed because the device is not connected to the network. If the message persists, contact your administrator to resolve the network issue.

   If the device fails to connect to the order management server, a message displays in the notification area indicating that the update has failed because the connection to the order management server could not be established. If the message persists, contact your administrator.

You can download a maximum of 1000 orders. If the number of orders exceeds this limit, an error message displays asking you to restrict the order download filter.

Sort Orders in the Orders List

By default, the **Orders** list is sorted in descending order by the **Location** column, if the **Location** column is configured as one of the display columns.

If the **Location** column is not configured to display in the **Orders** list, the list is sorted in descending order by the column configured to display as the first column.

If you select the **Priority** column header or if the **Priority** column is the first column, the orders list is sorted in the order of priority:

- STAT
- ASAP
- Pre-Op
- Call back
- Routine

If you select the **Priority** column again, the sorting order is reversed.

You can change the sort order by selecting any one of the column headers. The orders list is sorted in ascending order by the selected column. If you select the same column header again, the orders list is sorted in the reverse order. If you select another column header, the orders list is sorted in ascending order by that column.

Changes made to the sort order apply until you log out or shutdown the device.

Filter Orders in the Orders List

The **Orders** list is filtered by **Show All Locations**, **Current Patient Location**, or 1 out of 10 pre-configured filter groups. All of the order lists display based on the location filter you apply.

1. From the Acquisition screen, select the **Orders** tab.

   The **Orders** collapsed list opens.

2. Select the necessary filter location from the drop-down list.

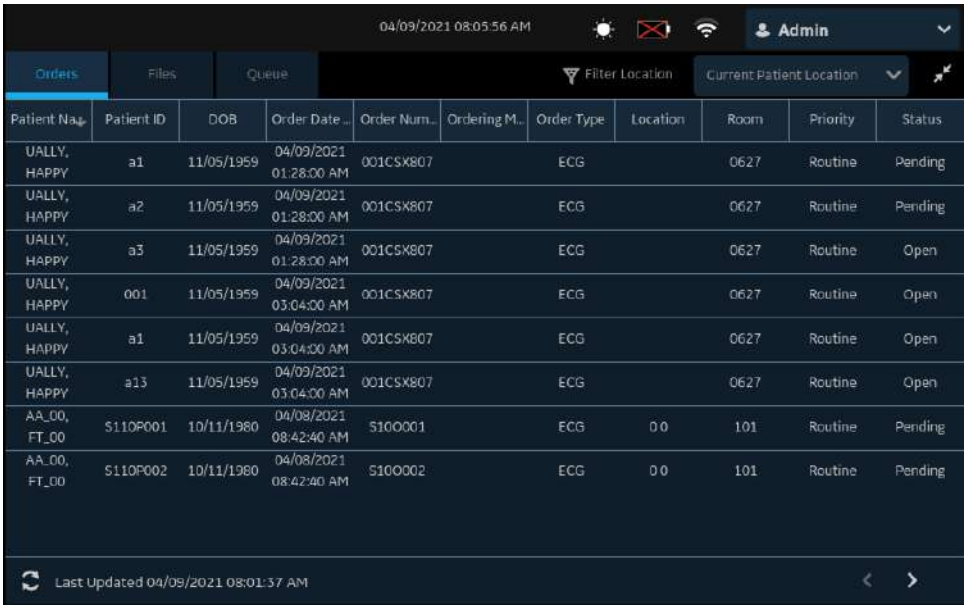
The order list refreshes and displays only the locations in the selected filter. If you select the filter drop-down list, the filter icon changes to . If you apply a location filter in the **Orders** list, the filter icon changes to to indicate that the order list is filtered and does not display all orders.

If you select...	*Then...*
A pre-configured filter group	The orders list displays orders from the locations in the selected filter group.

If you select...	*Then...*
The **Current Patient Location**	The orders list displays only the orders from the current location of the device configured in the device settings.
The **Show All Locations**	The orders list displays the orders from all the locations of the device configured in the device settings.

3. To display an expanded list of **Orders**, select the **Expand** icon.

The **Orders** expanded list opens.



By default, the applied filter is **Current Patient Location** 

, and displays all orders from the current location of the device.

Attach an Order when the Patient Test is Not Started

1. Start a test for the new patient. For more information, see *Start a Test for a New Patient on page 51*.
2. Double-tap the order in the **Orders** list to attach it to a patient test.
   The order number and other details available in the order are populated in the patient test record and the **Patient Information** screen is automatically expanded.
3. Edit patient information and select **Save** to save the patient data.
4. Record the ECG. For more information, see *Manually Start an ECG recording on page 70*.
5. Verify that the status of the order in the **Orders** list is **Attached**.

Attach an Order to a New Patient Test

NOTE:
You cannot attach an order that is already attached to another test. You must first detach the order. See *Detach an Order from a Patient Test on page 104*.

1. Start a test for the new patient. For more information, see *Start a Test for a New Patient on page 51*.
2. Double-tap the order in the **Orders** list to attach it to the current patient test.

If	*Then*
You did not manually enter patient data in the **Patient Information** screen after starting the test	There is no data mismatch upon attaching the order. Therefore, the order number and other details available in the order are populated in the patient test record and the **Patient Information** screen is automatically expanded. The status of the order is changed to **Attached**. Go to step 4.

If	*Then*
You manually entered patient data in the **Patient Information** screen after starting the test	There is a data mismatch between the order data and the manually entered patient data. A warning message displays indicating a mismatch in the patient name or patient ID and asks you to confirm that the selected order can be attached to the patient test, overwriting existing patient data. Go to the step *3*.

3. Select **Yes** to overwrite the patient information with data from the order. The order is attached to the patient report.
   - All patient demographic fields included in the order are populated in the test, overwriting the existing patient data.
   - The status of the order is changed to **Attached**.
4. Update test demographics in the **Patient Information** screen and select **Save**. For more information, see *Enter or Edit Patient Information Using the Software Keyboard on page 59*.
5. Record the ECG. For more information, see *Manually Start an ECG recording on page 70*.

Attach an Order when the Patient Test is Completed

NOTE:
You cannot attach an order that is already attached to another test. You must first detach the order. See *Detach an Order from a Patient Test on page 104*.

1. From the **Files** list, open the stored patient report.
2. Double-tap the order in the **Orders** list to attach it to the current patient test.

If	*Then*
You did not manually enter patient data in the **Patient Information** screen after starting the test	There is no data mismatch, but a message displays asking you to confirm that the selected order can be attached to the patient test, overwriting existing patient data. Go to step *3*.

If	*Then*
You manually entered patient data in the **Patient Information** screen after starting the test	There is a data mismatch between the order data and the manually entered patient data. A warning message displays indicating a mismatch in the patient name or patient ID and asks you to confirm that the selected order can be attached to the patient test, overwriting existing patient data. Go to the step 3.

3. Select **Yes** to update the patient information with data from the order. The order is attached to the patient report.
   - All patient demographic fields included in the order are populated in the test, overwriting the existing patient data.
   - The status of the order is changed to **Attached**.
4. Update test demographics in the **Patient Information** screen and select **Save**. For more information, see *Enter or Edit Patient Information Using the Software Keyboard on page 59*.

Attach an Order that is Attached to a Different Patient Test

NOTE:
Only one patient test can be associated with an order at any given time, regardless of the status of the patient test.

1. Start a new patient test.
2. Double-tap an order attached to a patient test in the **Orders** list.
   A message displays indicating that the order is already attached to a patient test.
3. Perform one of the actions below:
   - Select **Detach** to detach the order from the existing patient test and attach the order to the new patient test.

If	*Then*
The patient test the order is attached to is already transmitted to its default destination	The order cannot be removed from this test. A message displays indicating that the patient test has been transmitted to the default destination and the order cannot be detached. Select **OK**.
If the patient test is not transmitted	A message displays notifying you that the order will be detached from the patient test. Go to step 4.

- Select **View Test** to open the patient test and view it as if the test had been opened from the **Files** list.

4. Select **Continue** to detach the order from the existing patient test and attach the order to the new patient test.

Change the Order Attached to a Patient Test

If an incorrect order is attached to a patient test, use below procedure to detach the order from the patient test and replace it with a different order.

Before you start this procedure, make sure that the patient test is not already transmitted to its default destination. If the test has the **Sent** status of **Yes** (for example, the test was already sent to its default destination), the order can no longer be detached from the test. A message displays indicating that the patient test has been transmitted and the order cannot be detached.

WARNING:

INACCURATE PATIENT DATA - Incorrect patient information can cause patient data mismatch. Data assigned to the wrong patient causes erroneous patient data that can affect diagnosis and treatment.

Be sure to check the patient information screen for each new patient. Make sure that you attach the correct order for the correct patient.

1. Detach the incorrect order from the patient test. See *Detach an Order from a Patient Test on page 104*.

2. Attach the correct order to the patient test. See *Attach an Order when the Patient Test is Completed on page 102*.

Detach an Order from a Patient Test

Before you start this procedure, make sure that the patient test with the incorrect order has not been transmitted to its default destination.

NOTE:

If the patient test to which the order is attached has been transmitted to its default destination, the order cannot be detached from the test. A message displays indicating that the patient test has been transmitted and the order cannot be detached.

1. From the **Files** list, select the patient report with the incorrect order that you want to detach.

2. Expand the **Patient Information** screen and scroll down to the **Order Number** field.

3. Select **Detach** next to the **Order Number** field to clear the field.

A message displays asking you to confirm if you want to detach the order from the selected test.

4. Select **Yes** to detach the order from the current test.
   The order number field is cleared.
5. Select **Save** to save your changes.
   The order is detached from the patient test and moves back to the **Open** status.

Order Status

Each order in the **Orders** list has one of the states below:

- Open
- Pending
- Attached

When an order is downloaded from the order management server, the status of the order can be **Open** or **Pending**. After an ECG has been acquired for an order, or an order has been attached to an existing ECG patient report, the order is moved to the **Attached** state in the **Orders** list.

The table describes various order status changes:

If...	*Then...*
You add an order to a patient test from the **Orders** list	• The order status changes from **Open** to **Attached**. • The MUSE server is notified to change the status of the corresponding order on the MUSE system from **Open** to **Pending**, if the device is connected to the network. If the attempt to notify the MUSE server fails, the status remains as **Open**.
The order number is detached from a patient test before acquiring the ECG	The order status changes from **Attached** to **Open**. The order status changes from **Pending** to **Open** on the MUSE server.
An order attached to an acquired, but untransmitted ECG patient test, is detached	The order status changes from **Attached** to **Open**. The order status changes from **Pending** to **Open** on the MUSE server.

When the order list is updated, the orders attached to completed ECG patient reports transmitted to the MUSE server are cleared from the **Orders** list, and new orders are downloaded from the MUSE server.

NOTE:

The **Attached** order status is not included in the transmitted patient reports.

7

Work with the Files List

The **Files** list displays stored digital rhythm and ECG patient reports.

The figure illustrates the **Files** collapsed list:

Table 24: Files Collapsed List

Item	*Name*	*Description*
1	**Files** tab	Opens the **Files** collapsed list that stores the saved patient reports.
2	**Expand** icon	Opens the **Files** expanded list.
3	**Files** collpased list columns	Displays columns that provide information about the stored patient reports.

Item	Name	Description
4	Navigation arrows	Navigates to the previous and next page in the **Files** list.
5	**Expand** arrow	Expands the **Hookup Advisor** electrode placement image. When expanded, the image overlays the **Files** list.

The figure illustrates the **Files** expanded list:

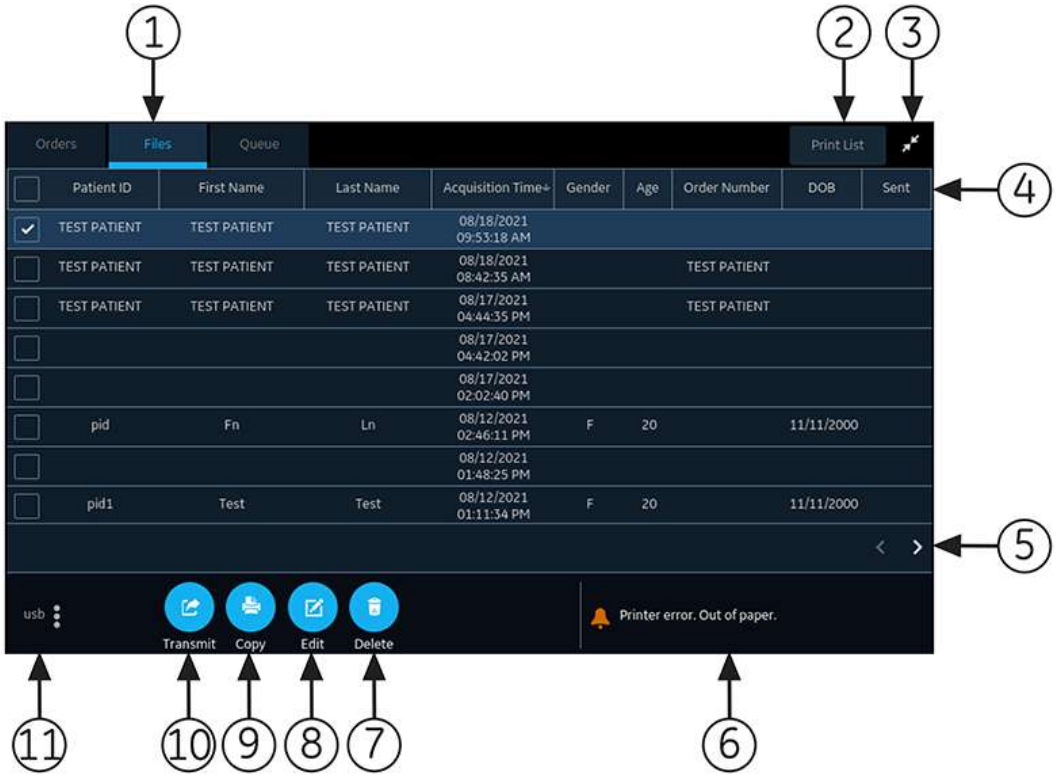


Table 25: Files Expanded List

Item	Name	Description
1	**Files** tab	Opens the **Files** expanded list that stores the saved patient reports.
2	**Print List**	Prints the stored records from the **Files** list. This button is enabled only if the stored records are available.
3	**Collapse** icon	Collapses the **Files** list.
4	**Files** expanded list columns	Displays columns that provide information about the stored patient reports.
5	Navigation arrows	Navigates to the previous and next pages in the **Files** list.
6	Notification status	Shows the progress, error, or successful messages.

Item	*Name*	*Description*
7	**Delete** icon	Deletes the selected patient reports.
8	**Edit** icon	Edits patient information for the selected patient report.
9	**Copy** icon	Prints a copy of the selected patient reports.
10	**Transmit** icon	Transmits the patient reports to the selected destination.
11	**Destination** menu	

Review a Stored Patient Report

Make sure that you have the privilege to view Rhythm, Full Disclosure, or ECG patient reports in the **Files** list. If you do not have the privilege, you can only view the patient reports you created in the current session.

1. From the Acquisition screen, select the **Files** tab.
   The **Files** collapsed list opens.
2. Select the Rhythm or Full Disclosure or ECG patient report that you want to view.
3. Review and make necessary changes to the patient report, before printing a copy of the report or transmitting the report to a configured destination.

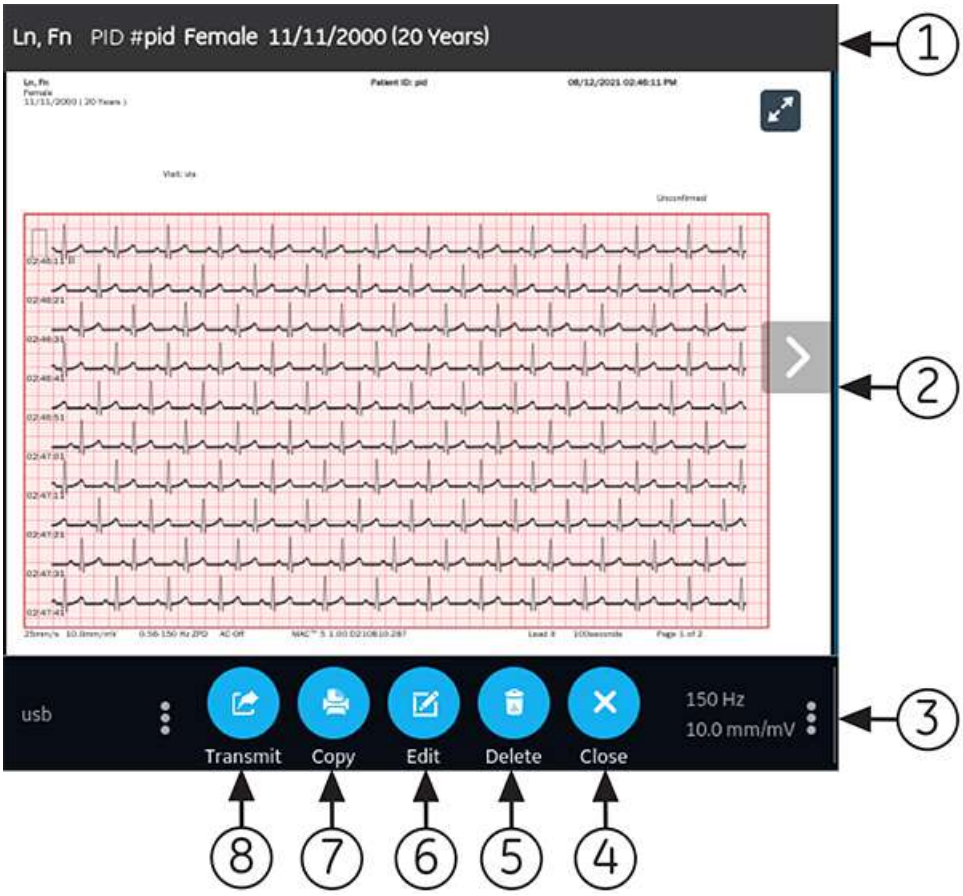


Table 26: Displaying a Stored Patient Report

Item	*Name*	*Description*
1	**Patient Information** Banner	Displays patient information. A grey banner indicates the patient report has been stored in the device. Select anywhere in the banner to expand the screen and edit patient information.
2	ECG patient report, Rhythm report, or Full Disclosure report	Displays the patient report. For more information on the report formats, see *ECG Report Formats on page 287* and *Rhythm Report Format on page 291*.
3	Gain, Filter, and Speed	Allows you to change the waveform gain, filter or speed. Select anywhere around the ellipsis icon next to **Gain**, **Filter** or **Speed** and select a value from the gain, filter, or speed options in the menu. The patient report is refreshed with the selected configurations. **NOTE**: The **Speed** option displays only for the rhythm reports.
4	**Close** icon	Select the **Delete** icon to close the report.

Item	Name	Description
5	**Delete** icon	Select the **Delete** icon to delete the patient report from the **Files** list. Deleting the patient report closes the current tab and displays the **Live** tab. For more information, see *Delete Stored Patient Reports from the Files List on page 117*.
6	**Edit** icon	Select the **Edit** icon to expand the **Patient Information** screen and edit patient information for the patient report. For more information, see *Edit Patient Information in a Stored Patient Report on page 116*.
7	**Copy** icon	Select the **Copy** icon to print a copy of the patient report in the default report format. For more information on printing a copy of the report, see *Print a Stored Patient Report on page 114*.
8	**Transmit** icon	Select the **Transmit** icon to transmit the patient report to the default destination. For more information, see *Transmit a Stored Patient Report to a Configured Destination on page 111*.

4. Select  to close.

Transmit a Stored Patient Report to a Configured Destination

- Make sure that you have the privilege to transmit patient reports to a configured destination.
- Select the correct destination for your patient report.

Patient Report Type	Destination	Supported File Format
Resting ECG	DCP server destination (MUSE v8 SP3 or higher, v9, or MUSE NX and MUSE DICOM Gateway Pro SP1 or higher)	Hilltop format
Resting ECG	USB R/W flash drive	PDF, Hilltop and Sapphire XML (Sapphire XML format is available if you enable the XML format output in the **Option Manager**) formats.
Resting ECG	SFTP server destination with remote directory path	PDF, Hilltop and Sapphire XML (Sapphire XML format is available if you enable the XML format output in the **Option Manager**) formats.
Resting ECG	Shared directory destination with folder path	PDF, Hilltop and Sapphire XML (Sapphire XML format is available if you enable the XML format output in the **Option Manager**) formats.
Digital Rhythm	USB R/W flash drive	PDF format

Patient Report Type	*Destination*	*Supported File Format*
Digital Rhythm	DCP server destination (MUSE v9 SP6 or higher, or MUSE NX and MUSE DICOM Gateway Pro SP6 or higher)	PDF format
Digital Rhythm	SFTP server destination with remote directory path	PDF format
Digital Rhythm	Shared directory destination with folder path	PDF format
Full Disclosure	USB R/W flash drive	PDF format
Full Disclosure	DCP server destination (MUSE v9 SP6 or higher, or MUSE NX and MUSE DICOM Gateway Pro SP6 or higher)	PDF format
Full Disclosure	SFTP server destination with remote directory path	PDF format
Full Disclosure	Shared directory destination with folder path	PDF format

To transmit a patient report to the default or configured destination, perform the steps below:

1. From the Acquisition screen, select **Files**.
   The **Files** collapsed list opens.
2. Perform one of the steps below:

If	*Then*
You want to transmit one patient report	Select the Rhythm or Full Disclosure report or ECG patient report you want to transmit to a configured destination. The selected patient report opens in a new tab (**ECG** or **FD Report** or **Rhythm** tab), depending on the report type.
You want to transmit multiple patient reports	Select the **Expand** icon to expand the **Files** list, and select the check box next to the patient reports to be transmitted. 

3. Perform one of the steps below:

To transmit the report(s) ...	*Perform the following:*
To the default destination	Select the **Transmit** icon: 

To transmit the report(s) ...	*Perform the following:*
To another configured destination	1. Select anywhere around the ellipsis icon on the lower, left-side of the screen to expand the **Transmit** menu. 2. From the expanded **Transmit** menu, select any configured destination to transmit the patient report(s). 3. Select the **Transmit** icon:  One or more destinations must be configured for the **Transmit** icon to be enabled. If no destinations are configured, the **Transmit** icon is disabled.

The selected patient reports are added to the **Queue**, processed and transmitted to the selected destination. The **Job Status** can be viewed in the **Queue**. See *Display the Report Queue on page 121*.

If you select patient reports for transmission from the expanded **Files** list, the message displays on the notification area in the lower, right-side of the screen: **<Count> reports added to the queue**, where **<Count>** is the number of selected reports.

If you select patient reports for transmission from the collapsed **Files** list, the message displays on the notification area in the lower, right-side of the screen: **<Destination_Name>: <Job_Status>**.

For example, if the destination name is USB, and the job status is **Failed**, the status displays as follows: **USB: Failed**.

A tick mark displays in the **Sent** column of the **Files** expanded list for patient reports successfully transmitted to the default destination.

If	*Then*
The transmission queue has reached its maximum limit of 1,000 reports, a message displays in the notification area that the transmission queue is full and no additional reports can be added.	Wait for the reports in the queue to transmit and try again.
One or more patient reports have been transmitted to the selected destination, a message displays in the notification asking you to confirm if you want to re-transmit the already transmitted reports.	Perform one of the actions below: • Select **OK** to re-transmit the patient report. • Select **Cancel** to cancel the report transmission.

If	*Then*
Patient information is incomplete in one or more patient reports selected for transmission (for example, required fields are blank or contain invalid data), a message displays in the notification area indicating that one or patient reports cannot be transmitted because of incomplete patient data.	Perform the steps below: 1. Edit the incomplete patient report to enter missing patient data. 2. Retry transmission.

Print a Stored Patient Report

You can print a copy of a stored ECG patient report in any configured report format for the selected lead set.

If you purchase the **NETP - Network Printer** option and enable it in the **Option Manager**,

- you can print the copy via thermal printer or send the copy to network printer on MAC 5 devices with thermal printer.
- you can only send the copy to network printer on MAC 5 Lite.

For more information of network printer, see *Configure Network Printer on page 183*.

1. From the Acquisition screen, select the **Files** list.

   The **Files** collapsed list opens. You can also select the **Expand** icon to open the **Files** expanded list:

If	*Then*
You are in the **Files** collapsed list	Select the patient report for which you want to print a copy. The patient report opens in a new screen next to the **File** list.
You are in the **Files** expanded list	Select the check box next to the patient report for which you want to print a copy.

2. Select the Rhythm or Full Disclosure or ECG patient report for which you want to print a copy.

   The selected patient report opens in a new screen.

3. Before printing a copy of the report, review the patient report and verify:
   - The patient information in the patient report is correct.
   - The ECG, Full Disclosure, or Rhythm test is acquired with the desired gain and filter.

4. Perform one of the steps below:

To print a copy of the patient report ...	*Perform the following:*
In the default or selected report format displayed on the report screen.	Select the **Copy** icon:  A job to print one copy of the patient report in the displayed report format is sent to the printer.
In a different report format	1. Select anywhere around the ellipsis in the left, bottom corner of the screen. 2. From the expanded **Copy Format** menu, select the report format. For example, if a 12-lead ECG is recorded, you can only select 12-lead ECG patient report formats. 3. Select the **Copy** icon:  The patient report is refreshed and displayed on the report screen in the selected report format. A job to print one copy of the ECG or rhythm in the selected report format is sent to the printer.

The patient report is printed in the order in which it was received. If no other patient reports are printing, the report is printed immediately. You will see a progress message at the bottom of the screen indicating the printing status.

NOTE:

Based on the **Mandatory fields apply for Acquisition** settings, the ECG report is not accepted, transmitted, or printed until you enter the patient demographic data for the mandatory fields. If you manually print, an error message **Unable to print. Incomplete patient data.** displays on the **Acquisition** screen. You need to complete the data for the mandatory fields to print the patient report.

If a printer error occurs, the progress message is replaced by the printer error. The printing restarts automatically after the error is resolved. For more information on printer errors, see *Printing Errors on page 277*.

If the device is configured to print the barcode of the patient ID in the patient reports, the printed patient report includes the barcode. The barcode can be used to perform a query by patient ID in the MUSE system.

Select the **Stop** icon on the Report Printing screen to stop printing a patient report.

Print a List of Stored Records

You can print all the stored records that display in the **Files Manager** on MAC 5 A4 and A5 device. Lite device does not support this function.

1. From the Acquisition screen, select the **Files** list.

   The **Files** collapsed list opens.

2. Select the **Expand** icon  to open the **Files** list.

   The **Files** expanded list opens.

3. Select the **Print List** button  to print the list of stored records.

   The printing starts and a stop icon displays on the screen.

The stored record prints in the order in which it was displayed in the **Files Manager** view.

If a printer error occurs, the printer error message displays. Resolve the error and manually restart the print. For more information on printer errors, see *Table 94: Printing Errors Encountered During Printing of the List of Stored Records on page 278*.

Select the **Stop** icon on the Report Printing screen to stop printing a patient report.

Edit Patient Information in a Stored Patient Report

Make sure that you have the privilege to open stored rhythm, Full Disclosure, or ECG patient reports from the **Files** list and edit patient information.

You can edit patient information using a software keyboard or by attaching an order, but not by scanning a patient barcode, selecting a patient record from the **Patients** list, or performing ADT queries. When an order is attached to a patient test, some fields are read-only.

If you try to edit or attach an order to a patient report that is transmitted to the default destination, an error message displays.

WARNING:

INACCURATE PATIENT DATA - Incorrect patient information can cause patient data mismatch. Data assigned to the wrong patient causes erroneous patient data that can affect diagnosis and treatment.

Be sure to check the patient information screen for each patient. Make sure that you enter patient data for the correct patient.

1. From the Acquisition screen, select **Files**.

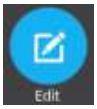
   The **Files** collapsed list opens. You can also select the **Expand** icon to open the **Files** expanded list:

If	*Then*
You are in the **Files** collapsed list	Select the patient report for which you want to edit. The patient report opens in a new screen next to the **File** list.

If	*Then*
You are in the **Files** expanded list	Select the check box next to the patient report you want to edit.

2. Select the **Edit** icon to edit patient information for the stored patient report:



The **Patient Information** screen opens with a grey background indicating that this is a stored patient report.

3. Edit the patient information using a software keyboard. See *Enter or Edit Patient Information Using the Software Keyboard on page 59*.

4. Select **Save** to save your changes for this patient and collapse the screen.

   If you select any other icons at the bottom of the tab prior to saving, the **Patient Information** screen collapses and the edited patient information is saved.

   The updated patient information displays on the patient report.

5. Select  to close.

Delete Stored Patient Reports from the Files List

Make sure that you have the privilege to delete Rhythm, Full Disclosure, or ECG patient reports from the **Files** list.

If you do not have the privilege to view patient reports, but you have the privilege to delete patient reports, you can only view and delete patient reports you created in the current session.

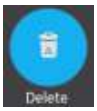
1. From the Acquisition screen, select **Files**.

   The **Files** collapsed list opens.

2. Perform one of the steps below:

If	*Then*
You want to delete one patient report	Select the Rhythm, Full Disclosure, or ECG patient report you want to delete. The selected patient report opens in a new screen.
You want to delete multiple patient reports	Select the **Expand** icon to expand the **Files** list, and select the check box next to the patient reports to be deleted. 

3. Select the **Delete** icon:



A message displays asking you to confirm if you want to permanently delete the selected patient report(s).

4. Select **Delete** to delete the patient reports.

The selected patient reports are deleted from the **Files** list.

An alert may be configured by your administrator to warn you before deletion of untransmitted reports.

If this alert is configured, and one or more patient reports you are trying to delete have not yet been transmitted to the default destination, a message displays asking you to confirm the deletion.

Perform one of the actions below:

- Select **Delete** to delete the selected patient reports. The selected patient reports are deleted from the **Files** list. If the patient report was opened for viewing, deleting the patient report closes the tab, and returns you to the **Live** screen review.
- Select **Cancel** to cancel the deletion. The selected patient reports are not deleted from the **Files** list.

8

Work with the Queue List

The digital rhythm, FD report and ECG patient reports transmitting to a designated location and in-completed network printing jobs are temporarily stored in the **Queue** list.

The successfully transmitted digital rhythm, FD report and ECG patient reports and completed network printing jobs are immediately deleted from the **Queue** list.

The figure illustrates the **Queue** collapsed list:

Table 27: Queue Collapsed List

Item	*Name*	*Description*
1	**Queue** tab	Displays the list of patient reports in the transmission queue.
2	**Expand** icon	Opens the **Queue** expanded list.
3	**Queue** collapsed list columns	Displays columns that provide information about the patient reports in the transmission queue.
4	Navigation arrows	Navigates to the previous and next pages in the **Queue** list.

The figure illustrates the **Queue** expanded list:

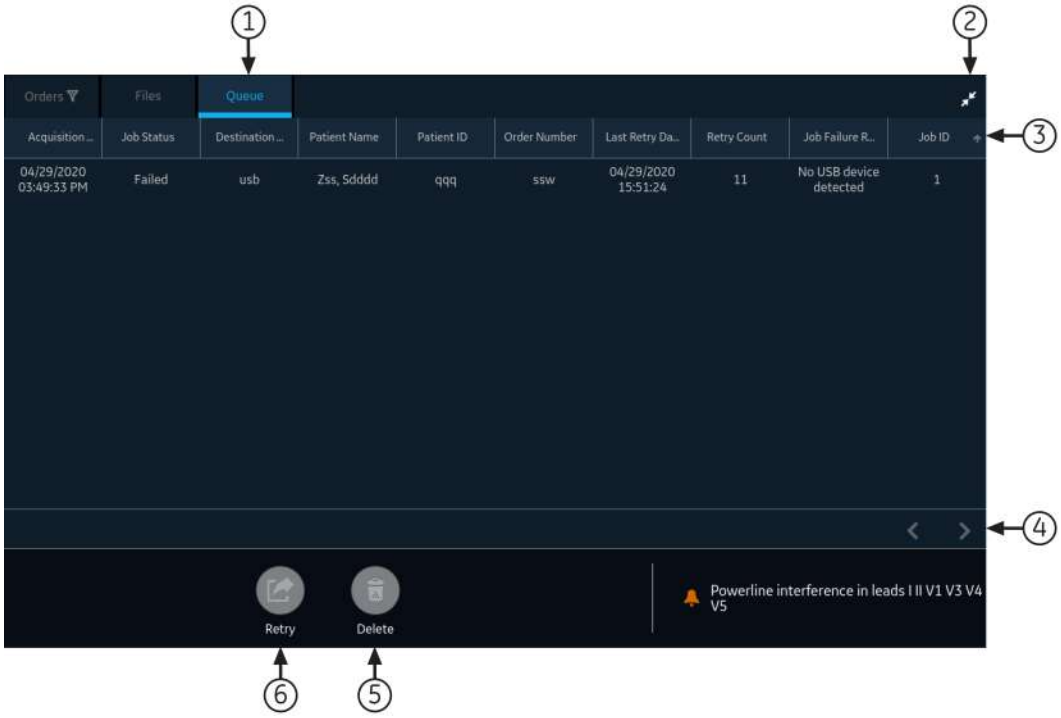


Table 28: Queue Expanded List

Item	*Name*	*Description*
1	**Queue** tab	Displays the list of patient reports in the transmission queue.
2	**Collapse** icon	Collapses the **Queue** list.
3	**Queue** expanded list columns	Displays columns that provide information about the patient reports in the transmission queue.
4	Navigation arrows	Navigates to the previous and next pages in the **Queue** list.
5	**Delete** icon	Deletes the selected transmission or network printing job from the **Queue** list.

Item	Name	Description
6	**Retry** icon	Retries the transmission of an unsuccessful job.

Table 29: Columns in the Queue List

Column Name	Description
Acquisition Date/Time	Displays the date and time of the rhythm, FD report or ECG patient report, in the configured date and time format.
Job Status	Displays the status of the job. Below statuses display: • **In Progress**: The job is currently being processed. • **Failed**: The transmission failed. The reason for failure is provided in the **Job Failure Reason** column. • **Not Sent**: The job is waiting to be processed. When the job is completed, the report is removed from the **Queue** list.
Destination Name	Displays the name of the configured destination.
Patient Name	Displays the name of the patient in the format **First Name, Last Name**.
Patient ID*	Displays the unique ID assigned to the patient.
Order Number*	Displays the order number.
Last Retry Date Time*	Displays the date and time of the last re-tried transmission, in the configured date and time format.
Retry Count*	Displays the re-tried transmission count in numbers. If the device sends the report on the first attempt, the **Retry Count** is 0.
Job Failure Reason*	Displays the reason for the failed transmission. If the device fails to transmit a report, contact your IT department. If the device sent the report successfully, this field is blank. To troubleshoot the errors, see *Report Transmission Errors on page 280*.

Column names suffixed with an asterisk (*) in the table are visible only in the expanded **Queue** list.

Display the Report Queue

This procedure describes how to view the queue for the reports that are ready to be sent, were successfully sent, or failed in transmission.

NOTE:
For auto-transmitted reports, a message **Transmission complete x/y** displays in the notification area indicating that transmission is complete, where *x* is the current count of patient reports being transmitted, and *y* is the total count of reports being transmitted for the current patient.

1. From the Acquisition screen, select **Queue**.
   The **Queue** collapsed list opens.
2. To open the **Queue** expanded list, select the **Expand** icon:

   The **Queue** expanded list opens.
3. Select the **Collapse** icon to collapse the list and return to the Acquisition screen:

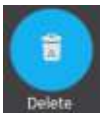
   

Delete Jobs from the Queue

1. From the Acquisition screen, select **Queue**.
   The **Queue** collapsed list opens.
2. To display an expanded list of the **Queue**, select the **Expand** icon:

   The **Queue** expanded list opens.
3. Select the transmission or network printing job you want to delete.
4. Select the **Delete** icon to delete the selected jobs:

   - If the job status is **In Progress**, a message displays indicating that the job is in progress and cannot be deleted.

     You cannot delete the job. Wait until the transmission attempt completes and then try again, if necessary.
   - If the job is in **Not Sent** or **Failed** status, a message displays asking you to confirm the deletion of the selected job.
5. Select **Delete** to confirm the deletion.

   The selected jobs are deleted from the **Queue**. The patient report remains in the **Files** list. You can transmit the patient report to a destination again, if required.

Retry Transmission of a Patient Report

Make sure that you have the privilege to transmit Rhythm, Full Disclosure, or ECG patient reports to a configured destination.

The system automatically tries to transmit a patient report. If you need to re-transmit the patient report before the next automatic attempt, you can use this procedure to transmit the patient report immediately.

1. From the Acquisition screen, select **Queue**.

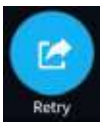
   The **Queue** collapsed list opens.

2. To display the expanded list of the **Queue**, select the **Expand** icon:

   The **Queue** expanded list opens.

3. Select one or multiple patient reports that you want to re-transmit and select the **Retry** icon:

   If no other report transmission is in progress at the time, the selected patient report will be immediately transmitted. If another patient report is in the process of being transmitted, the selected patient report starts transmission as soon as the current patient report is transmitted.

   If a patient report is successfully transmitted, it is immediately deleted from the **Queue**. Review the queue to confirm that the patient report was transmitted. All report transmissions are also logged in the **Report Transmission Log** in the **Service** screen.

   If the patient report is not successfully transmitted (**Job Status** is **Failed**), the reason for the failure is listed in the **Job Failure Reason** field. You can try to re-transmit the report again.

4. Select the **Collapse** icon to close the **Queue** expanded list and return to the Acquisition screen:

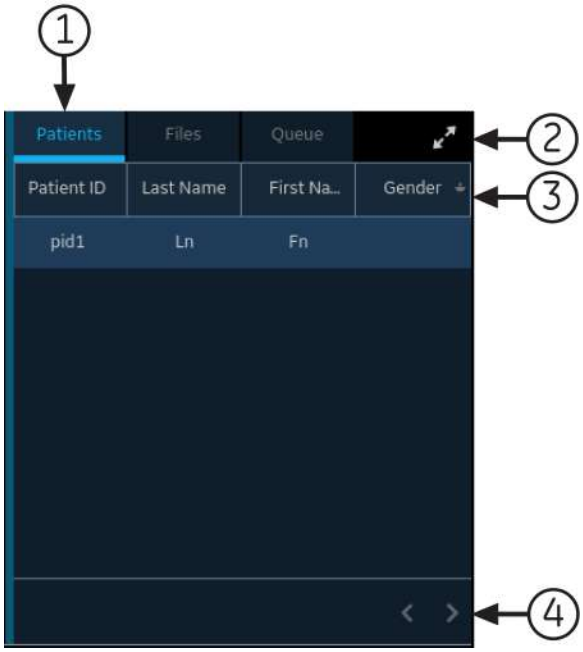
   

9

Work with the Patients List

If the **Order Manager** is disabled in the **Settings** screen, the **Patients** list displays in the Acquisition screen. The information of recent patients is stored in the **Patients** list, and you can view up to 500 recent patient information records.

The figure below illustrates the **Patients** collapsed list:



The figure below illustrates the **Patients** expanded list:

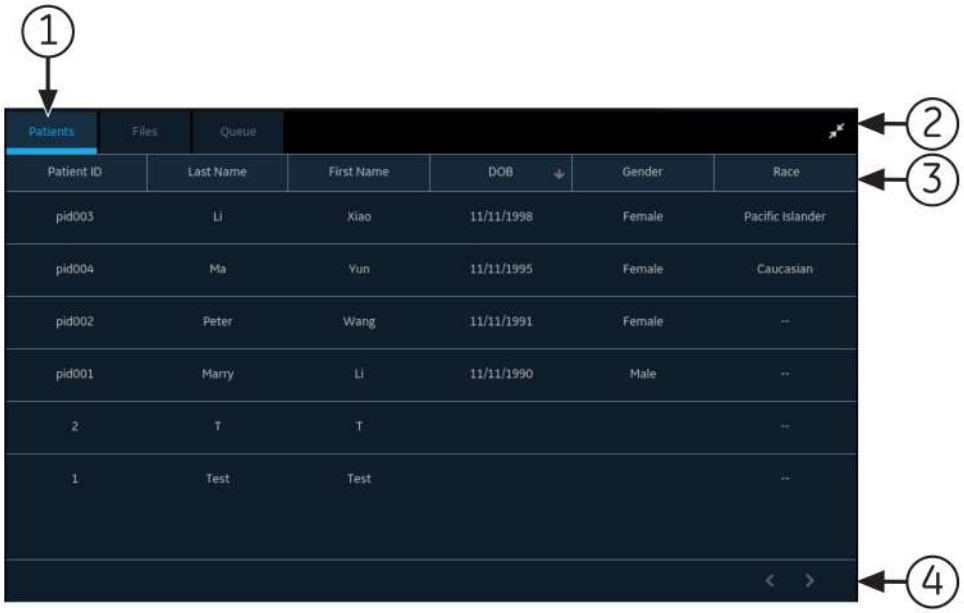


Table 30: Patients List

Item	*Name*	*Description*
1	**Patients** tab	Displays the **Patients** list.
2	**Expand** or **Collapse** icon	Expands or collapses the **Patients** list.
3	**Patients** collapsed and expanded list columns	Displays these four columns in the collapsed list: • **Patient ID** • **Last Name** • **First Name** • **Gender** Displays these six columns in the expanded list: • **Patient ID** • **Last Name** • **First Name** • **DOB** (Date of Birth) • **Gender** • **Race** By default, the list is sorted by **Last Name** in ascending order. You can sort by any column by selecting the column header. Select the same column header again to sort in descending order.
4	Navigation arrows	Navigates to the previous and next pages in the **Patients** list.

Open the Patients List

The **Patients** list displays on the Acquisition screen if order management is disabled.

Make sure that you have the privilege to view the patients lists or an error message will display when you try to view it.

1. From the Acquisition screen, select **Patients**.
   The **Patients** collapsed list opens and displays a list of patients.
2. To display an expanded list of **Patients**, select the **Expand** icon:
   
   The **Patients** expanded list opens.

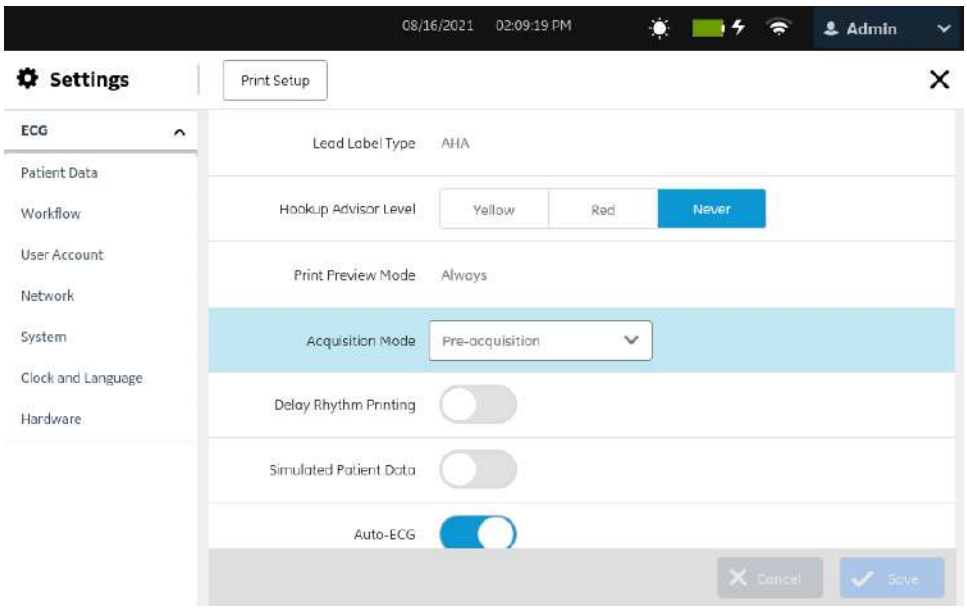
Select a Patient from the Patients List

1. Select **New Patient**. For more information, see *Start a Test for a New Patient on page 51*.
2. Select the **Patients** tab on the right-side of the Acquisition screen.
   The **Patients** collapsed list opens and displays a list of patients.
3. Double-tap the patient record that you want to associate with the patient test.
   If the desired patient record is not visible, select the navigation arrows to navigate to the previous and next pages of the **Patients** list and search for the patient record.
   The patient data from the selected patient record is populated in the **Patient Information** banner and screen, and the screen expands.
4. Edit patient information in the fields. For more information, see *Enter or Edit Patient Information Using the Software Keyboard on page 59*.

10

Configure Settings

Settings Screen Overview



Select the **Settings** screen to set up the features below.

- ECG - *Configure ECG on page 129*
- Patient Data - *Configure Patient Information on page 152*
- Workflow - *Configure Workflow on page 163*
- User Management - *User Account on page 200*
- Network - *Configure Network on page 226*
- System - *Configure System on page 246*
- Clock and Language - *Configure the Clock and Language on page 255*
- Hardware - *Configure Hardware on page 260*

Open the Settings Screen

Select **Settings** from the User Menu on the **Acquisition** screen.

If you have sufficient privileges, the **Settings** screen opens.

If you do not have privileges to access the **Settings** screen, a message displays based on your user profile. Log on as a user with sufficient privileges to access the Settings screen.

User Profile	*Message*
Default User	**You do not have sufficient privileges to view the selected screen. Login as a new user with the required privileges.** **Attention: Logging in as a new user will log out the current user and any unsaved data will be lost.** Log on as a user with sufficient privileges to open the **Settings** screen.
STAT, local or LDAP user	**You do not have sufficient privilege to access the Settings screen.** Log off and log on as a user with sufficient privileges to access the **Settings** screen.

Configure General Tasks

Perform general tasks, as per the information in the table below:

Table 31: Configure General Tasks

Button	*Action*
Print Setup	Select this setting to print the system setup report for the product version. Use this report to configure other devices.
Save	Select this setting to save the system settings. A confirmation message displays: *Saved Successfully.*
Changes	A confirmation dialog displays with a message indicating your changes are not saved and will be lost. Select **Discard Changes** to discard the changes and move to the other screen. Select **Review Changes** to review and save the changes before moving to other screen.

Button	*Action*
Test Connection	Select this setting to test the particular destination is available and online. • If the connection is successful, a success message displays and the **Save** button is enabled. • If the connection fails due to an error, a failure message displays. Troubleshoot the error and test the connection. **NOTE**: This option only tests the destination is available and online. It does not guarantee that the transmit will succeed. At the time of actual connection or transmission, it can fail, even if the test shows **Success**.

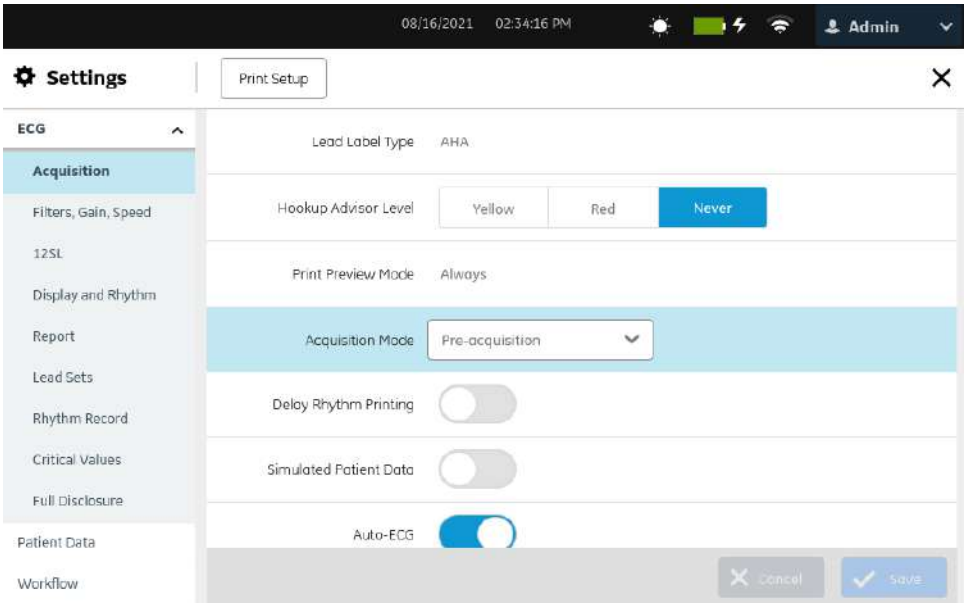
Configure ECG

Select **Settings** > **ECG** menu to configure the following:

- ECG Acquisition - *Configure ECG Acquisition on page 129*
- Filter, Gain, and Speed - *Configure Filters, Gain, and Speed on page 132*
- 12SL Interpretations - *Configure 12SL Interpretations on page 135*
- Display Formats of ECG and Rhythm Leads - *Configure Display Formats of ECG and Rhythm Leads on page 137*
- Patient Reports - *Configure Patient Reports on page 140*
- Lead Sets - *Configure Lead Sets on page 145*
- Rhythm - *Configure Rhythm on page 148*
- Critical Value Notifications - *Configure Critical Value Notifications on page 149*
- Full Disclosure - *Configure Full Disclosure on page 151*

Configure ECG Acquisition

1. Select **Settings** > **ECG** > **Acquisition**.
   The **Acquisition** screen displays.



2. Configure the fields as per the information in the table.

Table 32: Acquisition Settings

Field	*Action*	*Description*
Lead Label Type	Select a value from the drop-down list to configure the lead label type.	The supported lead labels are from the American Heart Association (AHA) and International Electrotechnical Commission (IEC). If the device language is English and the device settings are restored to factory defaults, the lead label type is automatically set as **AHA**. If the device language is Chinese, Danish, Dutch, Finnish, French, German, Italian, Swedish, or Norwegian and the device settings are restored to factory defaults, the lead label type is automatically set as **IEC**.

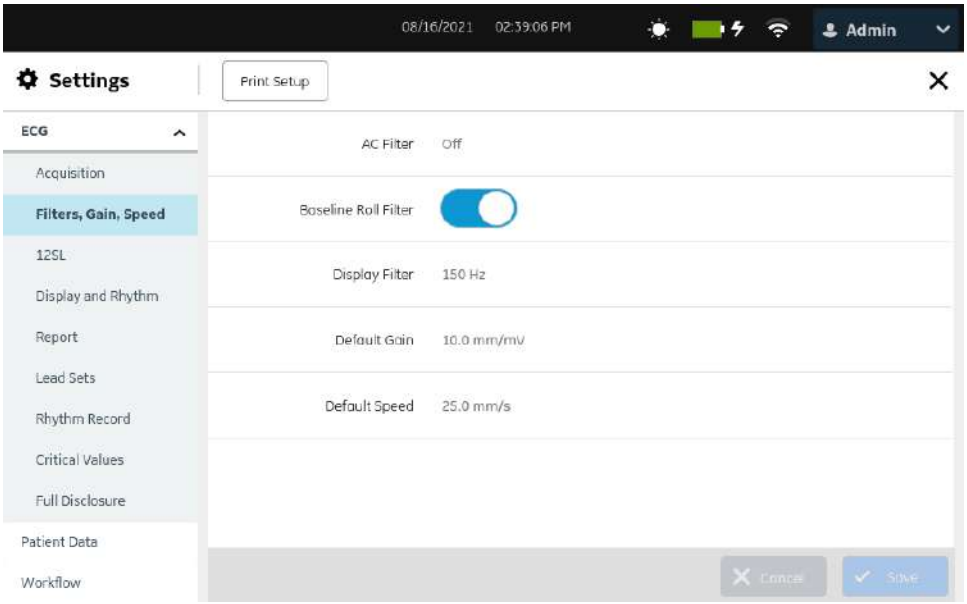
Field	*Action*	*Description*
Hookup Advisor Level	Select a value from the drop-down list to configure when the Electrode Placement Image automatically expands, in case of leadwire failures.	The Hookup Advisor indicator displays yellow or red depending on the severity of the signal failure in a leadwire. • If you select **Yellow**, the Electrode Placement Image automatically expands when the indicator is yellow or red. When the signal turns green, the Electrode Placement Image automatically collapses. • If you select **Red**, the Electrode Placement Image automatically expands when the indicator is red. When the signal turns yellow or green, the Electrode Placement Image automatically collapses. • If you select **Never**, the Electrode Placement Image does not automatically expand or collapse, regardless of the type of signal received. You can manually expand and collapse the Electrode Placement Image at any time. Default value: **Never**
Print Preview Mode	Select a value from the drop-down list to configure the print preview mode.	• If **Always** is selected, a preview of the ECG always displays after ECG acquisition. • If **Yellow** is selected, a preview of the ECG displays after ECG acquisition, if the Hookup Advisor status for the 10-seconds ECG acquired is Yellow or Red. • If **Red** is selected, a preview of the ECG displays after ECG acquisition, if the Hookup Advisor status for the 10-seconds ECG acquired is Red. • If **Never** is selected, a preview of the ECG is never display after ECG acquisition. Default value: **Always**
Acquisition Mode	Select a value from the drop-down list to configure the acquisition mode.	• If **Pre-acquisition** is selected, the system acquires the latest/previous 10-seconds of data for analysis. • If **Post-acquisition** is selected, the system displays the acquisition progress until 10-seconds of ECG data is acquired. Default value: **Pre-acquisition**
Delay Rhythm Printing	Enable or disable this setting.	If this setting is disabled, rhythm printing occurs in real-time. If this setting is enabled, the system waits until 10-seconds of rhythm data is acquired before starting rhythm printing. Default value: Disabled

Field	*Action*	*Description*
Simulated Patient Data	Enable or disable this setting.	If this setting is enabled, you can use simulation patient data for demonstrations or troubleshooting. The system generates and displays simulated ECG waveforms on the Acquisition screen. The label at the top of the screen indicates that the ECG waveform is based on simulated data from the internal simulator, and not actual patient data. If this setting is disabled, the system displays waveforms recorded from a patient attached to the device. Default value: Disabled
Auto-ECG	Enable or disable this setting.	If this setting is enabled, as soon as the ECG signal is good, the device automatically starts recording 10-seconds of ECG data for **only one** ECG per patient connection. Default value: Enabled
Print Preview Auto Full Screen	Enable or disable this setting.	If this setting is enabled, the system automatically displays the ECG preview window in full screen mode. If this setting is disabled, the system displays the ECG preview window in normal mode. This setting is disabled, if the **Print Preview Mode** value is configured to **Never**. Default value: Enabled

3. Click **Save**.

Configure Filters, Gain, and Speed

1. Select **Settings** > **ECG** > **Filters, Gain, Speed**.
   The **Filters, Gain, Speed** screen displays.



2. Configure the fields as per the information in the table.

Table 33: Filter, Gain and Speed Settings

Field	*Action*	*Description*
AC Filter	Select a value from the drop-down list.	The **AC Filter** frequency is set prior to shipping the unit and is based on the country of purchase. The AC filter is used to remove power line interference from the ECG signal. If no power line interference in the ECG signal needs to be removed, it is possible that the AC filter induces noise into the signal. If this is occurring, you can disable the AC filter by changing the setting to **Off**. **NOTE**: The **AC Filter** setting does not change when the system is restored to factory defaults. Default value: Based on country of purchase. Allowed values: • **50 Hz** • **60 Hz** • **Off**

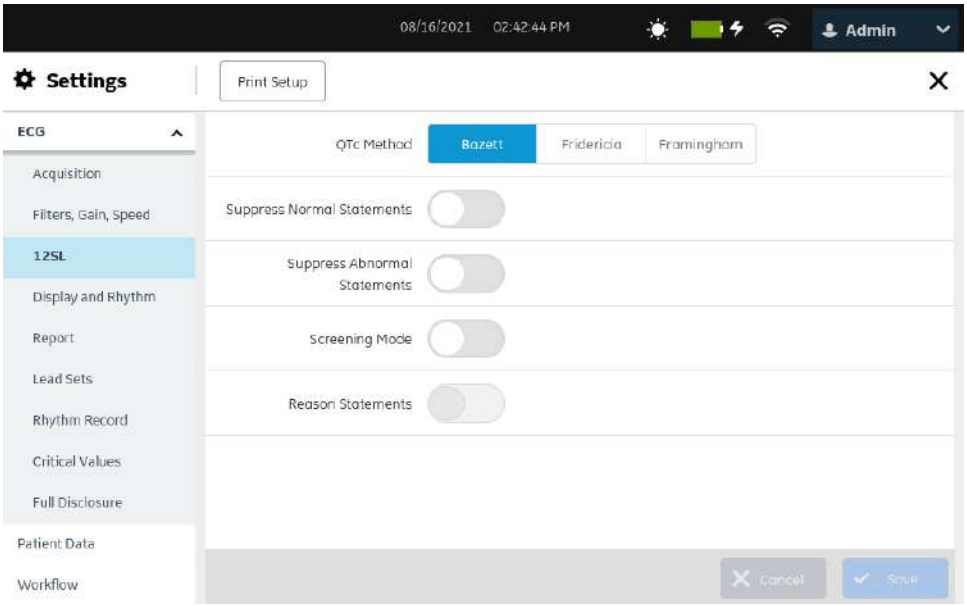
Field	*Action*	*Description*
Baseline Roll Filter	Enable or disable this setting.	If this setting is enabled, the system applies a 0.56 Hz baseline roll filter to the waveforms. Use the baseline roll filter to remove low frequency components such as motion artifact, respiratory variation, and baseline shift. If this setting is disabled, no baseline roll filter is applied. If at any time the ECG configuration settings are restored to factory defaults, the baseline roll filter setting is reset to its default value, enabled. Default value: Enabled
Display Filter	Select a value from the drop-down list to configure the default filter.	This sets the upper frequency limit for the ECG waveform display on the Acquisition screen and the printout. Selecting a filter eliminates signals that exceed the frequency. The smaller the filter selected, the more signal is filtered. For example, a filter of 40 Hz displays only signals at 40 Hz or less; signals greater than 40 Hz are ignored. Default value: **150 Hz** Allowed values: • **20 Hz** • **40 Hz** • **100 Hz** • **150 Hz**

Field	*Action*	*Description*
Default Gain	Select a value from the drop-down list, to configure the default gain of the ECG waveform to display on the Acquisition screen.	Gain indicates how many mm represent 1 mV of sample data on the printout. Changing the gain changes the amplitude of the waveforms. A higher gain makes the amplitude of the waveform appear higher; a lower gain makes the amplitude of the waveform appear lower. The 10/5 mm/mV setting is used to display the limb leads (I, II, III, aVr, aVl, and aVf) at 10mm/mV and chest leads (V1 - V6) at 5 mm/mV. This is sometimes done to reduce or prevent waveform overlap in the chest leads, while avoiding tiny waveforms in the limb leads. The standard grid paper is divided into small squares of 1 mm x 1 mm and large squares of 5 mm x 5 mm. When printing 10 mm/mV, 1 mV of data is represented in 10 mm (2 large squares) on the printout. Default value: **10.0 mm/mV** Allowed values: • **2.5 mm/mV** • **5.0 mm/mV** • **10.0 mm/mV** • **20.0 mm/mV** • **10.0/5.0 mm/mV**
Default Speed	Select a value from the drop-down list, to configure the default speed of the ECG waveform to display on the Acquisition screen.	A faster speed makes the waveform display further apart; a slower speed makes the waveform display closer together. The standard grid paper is divided into small squares of 1 mm x 1 mm and large squares of 5 mm x 5 mm. When printing 25 mm/s, 1 second of data is represented in 25 mm (5 large squares) on the printout. Default value: **25.0 mm/s** Allowed values: • **5.0 mm/s** • **12.5 mm/s** • **25.0 mm/s** • **50.0 mm/s**

3. Click **Save**.

Configure 12SL Interpretations

1. Select **Settings** > **ECG** > **12SL**.
   The **12SL** screen displays.



2. Configure the fields as per the information in the table.

Table 34: 12SL Settings

Field	*Action*	*Description*
QTc Method	Select a value to use a QT Correction Method with the 12SL algorithm.	The name of the QT Correction Method and the QTc value display on the report. Default value: **Bazett** Allowed values: • **Bazett** • **Fridericia** • **Framingham**
Suppress Normal Statements	Enable or disable this setting.	If this setting is enabled, no normal interpretative statements generate or display on the report when you do as follows: • View a report on the preview and review screens • View a stored report in the review screen • Print a report • Send a report to a configured destination. If this setting is disabled, normal interpretative statements display on the report. Default value: Disabled

Field	*Action*	*Description*
Suppress Abnormal Statements	Enable or disable this setting.	If this setting is enabled, no abnormal or borderline interpretative statements generate or display on the report when you do as follows: • View a report in the preview and review screens • View a stored report in the review screen • Print a report • Send a report to a configured destination. If this setting is disabled, abnormal and borderline interpretative statements display on the report. Default value: Disabled
Screening Mode	Enable or disable this setting.	If this setting is enabled, the device runs the 12SL algorithm in high-specificity mode, where you will not see certain lower-acuity statements in the interpretation. If this setting is disabled, the device runs the 12SL algorithm in normal analysis mode and you see the lower-acuity statements. Default value: Disabled
Reason Statements	Enable or disable this setting.	You can select this setting only if you enable the **Screening Mode**. If this setting is enabled, reason statements generate or display on the report when you perform the following: • View a report in the preview and review screens • View a stored report in the review screen • Print a report • Send a report to a configured destination. If this setting is disabled, no reason statements generate or display on the report. Default value: Disabled

3. Click **Save**.

Configure Display Formats of ECG and Rhythm Leads

Table 35: Default Lead Formats for Each Lead Set

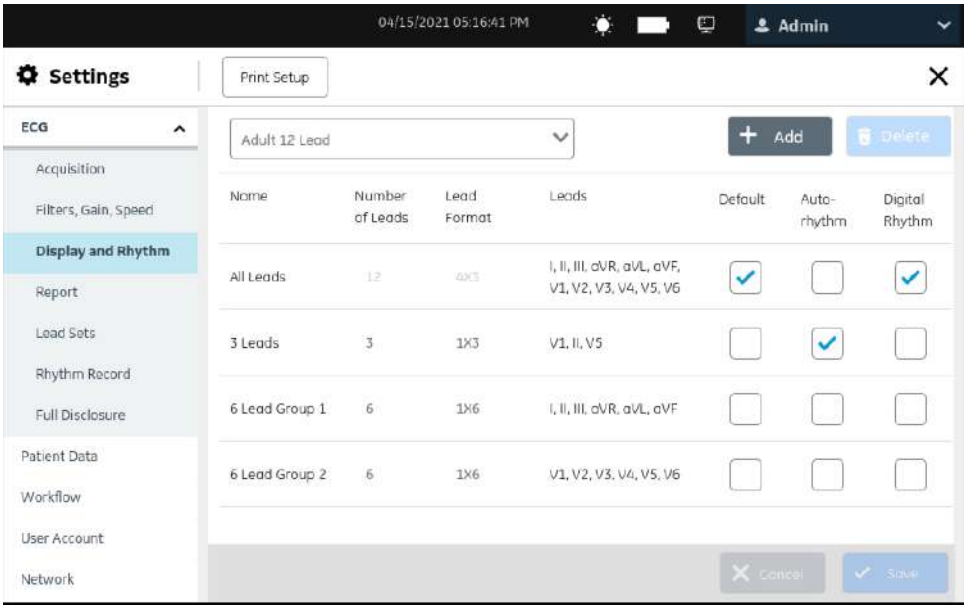
Name	*No. of Leads*	*Lead Format*	*Leads*	*Default*	*Auto-rhythm*	*Digital Rhythm*
Adult 12 Lead						
All Leads	12	4x3	CH1 to CH12: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6	Yes	No	Yes

Name	*No. of Leads*	*Lead Format*	*Leads*	*Default*	*Auto-rhythm*	*Digital Rhythm*
			Swedish standard: CH1 to CH12: aVL, I, -aVR, II, aVF, III, V1, V2, V3, V4, V5, V6			
3 Leads	3	1x3	CH1 to CH3: V1, II, V5	No	Yes	No
6 Lead Group 1	6	1x6	CH1 to CH6: I, II, III, aVR, aVL, aVF	No	No	No
			Swedish standard: CH1 to CH6: aVL, I, -aVR, II, aVF, III			
6 Lead Group 2	6	1x6	CH1 to CH6: V1, V2, V3, V4, V5, V6	No	No	No

The **All Leads** and **6 Lead Group 1** lead formats for all default lead sets are automatically set to the lead channel sequence mentioned in *Table 35: Default Lead Formats for Each Lead Set on page 137* when the device language is set as **Swedish**, and the device is restored to factory default settings.

You can add, edit, and delete user-defined ECG lead formats, except the **All Leads** format.

1. Select **Settings** > **ECG** > **Display and Rhythm**.
   The **Display and Rhythm** formats screen displays.



2. To configure a lead format for a selected lead:
   - To add a user-defined lead format, perform step *3* to step *6*.
   - To edit a user-defined lead format, perform step *7*.
   - To delete a user-defined lead format, perform step *8*.

3. Select the **Add** icon  to add a lead format.
   A new row is added to the lead format table.
4. Configure the lead format as per the information in the table:

Table 36: Display Format Settings for ECG and Rhythm Leads

Field	*Action*	*Description*
Name	Enter a name for your lead format setting.	Allowed values: Up to 20 characters. Allowed values are: • A to Z • a to z • 0 to 9 • All special characters
Number of Leads	Select the number of leads you want to include in the lead format.	Default value: • For 12 leads: 12 Allowed values: • For 12 leads: 3, 6, 12
Lead Format	Select the layout for the leads in columns by rows.	The different types of lead formats are as follows: • 3 Leads: 1x3 • 6 leads: 1x6, 2x3, or 2x3 Simult • 12 leads: 2x6, 2x6 Simult, 4x3, 4x3 Simult **Simult** refers to display all the leads at the same time. You can add up to 10 new format entries. Default value: • For 12 leads: 4x3 Allowed values: • For 12 leads: 4x3, 4x3 Simult, 2x6, 2x6 Simult
Leads	Select the leads in each channel that you want to display in the waveform for the selected lead set.	Default value: Adult 12 Lead: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 Allowed values: Adult 12 Lead: I, II, III, aVR, -aVR, aVL, aVF, V1, V2, V3, V4, V5, V6
Default	Enable or disable this setting.	If this setting is enabled, this lead set format is the default format for ECGs recorded on this device. Default value: Disabled

Field	*Action*	*Description*
Auto-rhythm	Enable or disable this setting.	If this setting is enabled, this lead set format is the default format used for an **Auto Rhythm** report on this device. There can be only one default format used for an **Auto Rhythm** report. If a default format is not selected, the default format for ECGs is used. Default value: Disabled
Digital Rhythm	Enable or disable this setting.	If this setting is enabled, this lead set format is the default format for digital rhythm on this device. There can be only one default format for a digital rhythm recording. If a default format is not selected for digital rhythm, the default format for ECGs is used for digital rhythm. Default value: Disabled

5. Select **Save**.
6. Repeat steps *3* to *5* to add more ECG lead format configurations.
7. To edit an existing ECG lead format configuration:
   a) Select anywhere in the row of the lead format configuration you want to modify to enable the edit mode.
   b) Make changes to the configuration as per the information in *Table 36: Display Format Settings for ECG and Rhythm Leads on page 139*.
   c) Select **Save**.
8. To delete an existing lead format configuration:
   a) Select the **Delete** icon for the lead format configuration you want to delete.

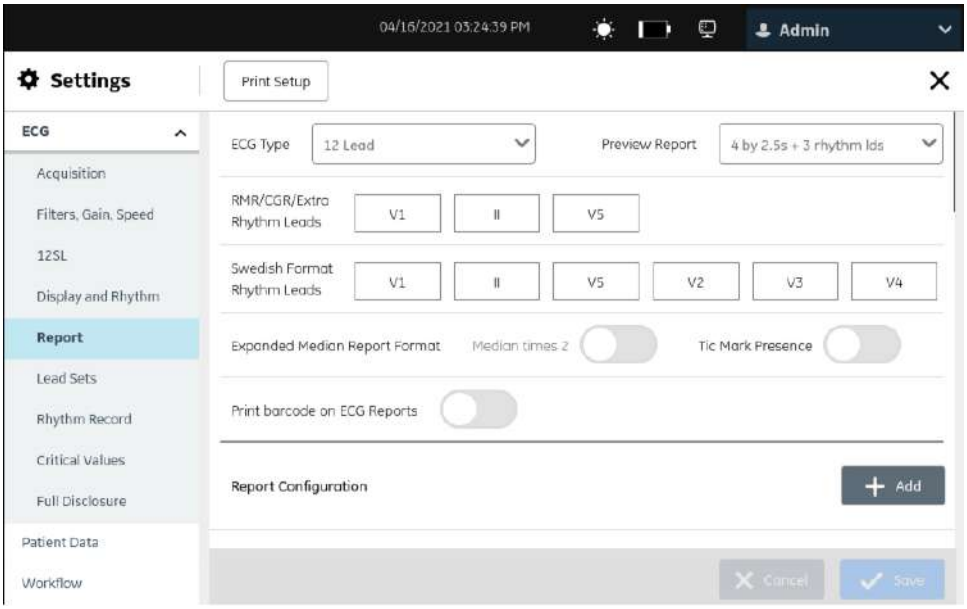
      NOTE:
      You can delete only one lead format configuration at a time. To delete more than one lead format configuration, repeat this step.

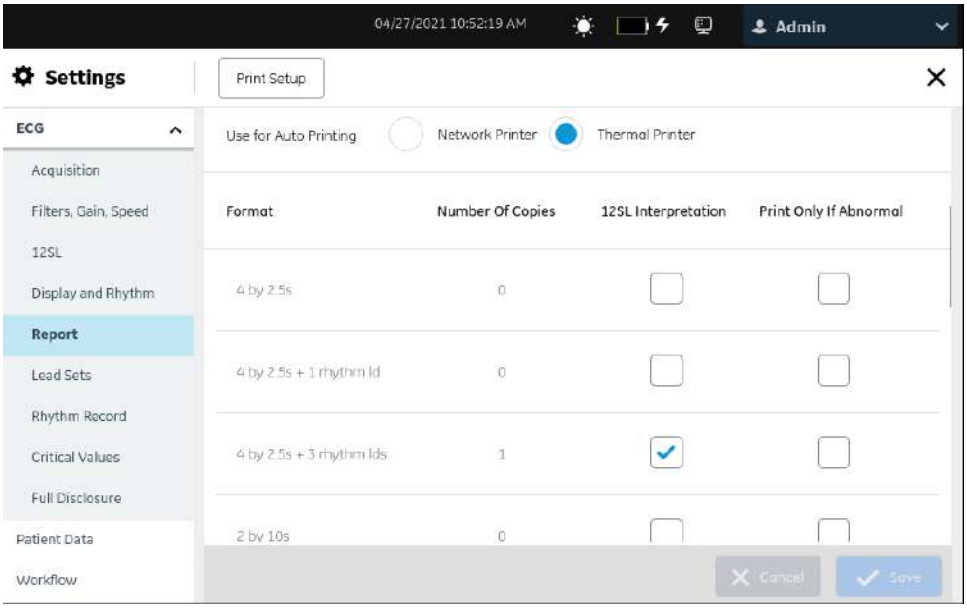
   b) Select **Save**.

Configure Patient Reports

You can configure a report format for each lead set.

1. Select **Settings** > **ECG** > **Report**.
   The **Report** screen displays.





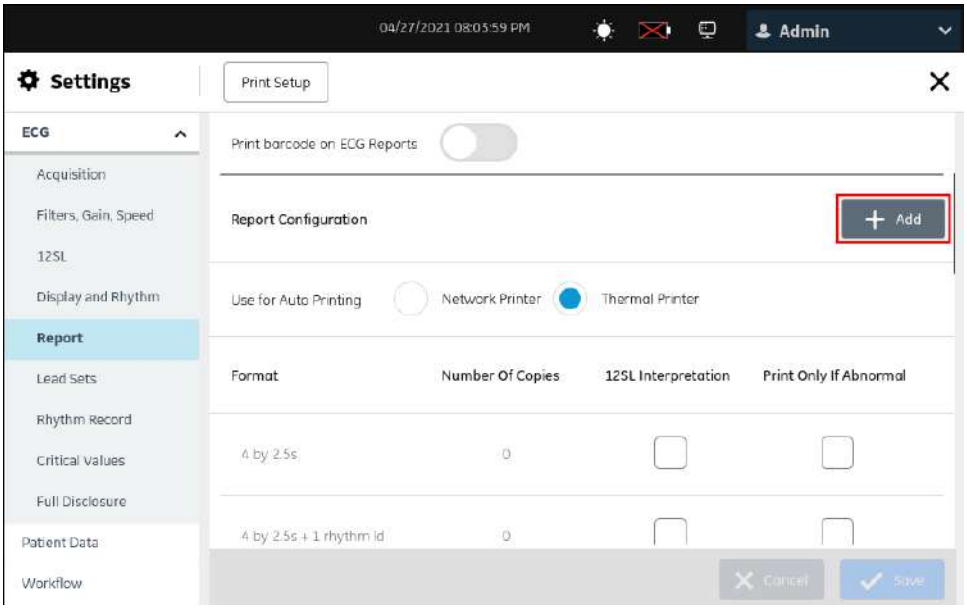
2. Select **12 Lead** as ECG type.
3. Configure the preview report format and leads as per the information in the table:

Table 37: Preview Report Format and Lead Settings

Field	*Description*	*Allowed Values*	*Default Value*
Preview Report	Select a value from the drop-down list to preview the recorded ECG of the selected ECG type before printing. See *ECG Report Formats on page 287* for a list of on ECG report formats.	Supported report formats for 12 lead ECG type	**4 by 2.5s + 3 Rhythm Lds**
RMR/CGR/ Extra Rhythm Leads	Select a value from the first column to configure the first rhythm lead. If the ECG report format to be printed consists of only one line of rhythm data, then this rhythm lead is printed on the ECG report.	**V1 to V6, V3R, I, II, III, aVR, aVL and aVF** leads	**V1** lead
	Select a value from the second column to configure the second rhythm lead.		**II** lead
	Select a value from the third column to configure the third rhythm lead. **NOTE**: The configured rhythm leads are printed on the ECG reports if the report format includes rhythm data.		**V5** lead
Swedish Format Rhythm Leads	Select a value from the first column to configure the first rhythm lead for the Swedish report format.	**V1 to V6, V3R, I, II, III, aVR, aVL and aVF** leads	**V1**
	Select a value from the second column to configure the second rhythm lead for the Swedish report format.		**II**
	Select a value from the third column to configure the third rhythm lead for the Swedish report format.		**V5**
	Select a value from the fourth column to configure the fourth rhythm lead for the Swedish report format.		**V2**

Field	*Description*	*Allowed Values*	*Default Value*
	Select a value from the fifth column to configure the fifth rhythm lead for the Swedish report format.		**V3**
	Select a value from the sixth column to configure the sixth rhythm lead for the Swedish rhythm report.		**V4**
Expanded Median Report Format			
Median times 2	If you enable this setting, the gain of the expanded median report is double the gain set during the acquisition. If you disable this setting, the gain of the expanded median report is the same as the gain set during the acquisition.	• Enabled • Disabled	Disabled
Tic Mark Presence	Displays or hides the tic marks in an expanded median report.	• Enabled • Disabled	Disabled
Print barcode on ECG Reports	If you enable this setting, the barcode of the Patient ID prints on the ECG patient reports. If you disable this setting, the barcode of the Patient ID does not print on the ECG patient reports. **NOTE**: The network printer does not support printing the barcode of the Patient ID on the ECG reports.	• Enabled • Disabled	Disabled
Use for Auto Printing			
Network Printer	If you enable this setting, the patient report prints via the configured network printer. **NOTE**: This setting displays only if the **NETP - Network Printer** option is purchased and enabled in the **Option Manager**.	• Enabled • Disabled	Disabled
Thermal Printer	If you enable this setting, the patient report prints via the thermal printer.	• Enabled • Disabled	Enabled

4. Perform any of the steps below to configure report printing for each supported report format:
   - To add a report printing configuration, perform step *5* to step *8*.
   - To edit a report printing configuration, perform step *9*.
   - To delete a report printing configuration, perform step *10*.
5. Select the **Add** icon + Add to add a report printing configuration.



6. Configure report printing as per the information in the table.

Table 38: Report Printing Settings

Field	*Action*	*Description*
Report Format	Select a report format from the drop-down list to configure the printing settings for this report format.	See *ECG Report Formats on page 287* for a list of report formats. Default value: No default value Allowed values: All supported report formats
Number of Copies	Select the number of copies to print for this print configuration.	Default value: • 1 for **4 by 2.5s + 3 Rhythm Lds** report format • 0 for all other report formats Allowed values: 0 to 10

Field	*Action*	*Description*
12SL Interpretation	Enable or disable this setting.	Displays or hides the 12SL analysis in the ECG report. Default value: • Not applicable for **1 by 10s @25mm/s**, **1 by 10s @50mm/s** and **Expanded media 12ld** formats. • Disabled for all other formats.
Print Only if Abnormal	Enable or disable this setting.	If you enable this setting, an ECG report prints only if the 12SL analysis indicates that it is abnormal. If you disable this setting, all ECG reports print. Default value: • Not applicable for **1 by 10s @25mm/s**, **1 by 10s @50mm/s** and **Expanded media 12ld** formats. • Disabled for all other formats.

7. Select **Add**.
   A new row is added to the report configuration table.
8. Repeat steps *5* to *7* to add more report printing configurations.
9. To edit an existing report printing configuration:
   a) To enable the edit mode, select anywhere in the row of the report printing configuration that you want to modify.
   b) Make changes to the configuration as per the information in *Table 38: Report Printing Settings on page 144*.
   c) Select **Save**.
10. To delete an existing report printing configuration:
    a) Select the **Delete** icon for the report printing configuration you want to delete.

       NOTE:
       You can delete only one report printing configuration at a time. To delete more than one report printing configuration, repeat this step.

    b) Select **Save**.

Configure Lead Sets

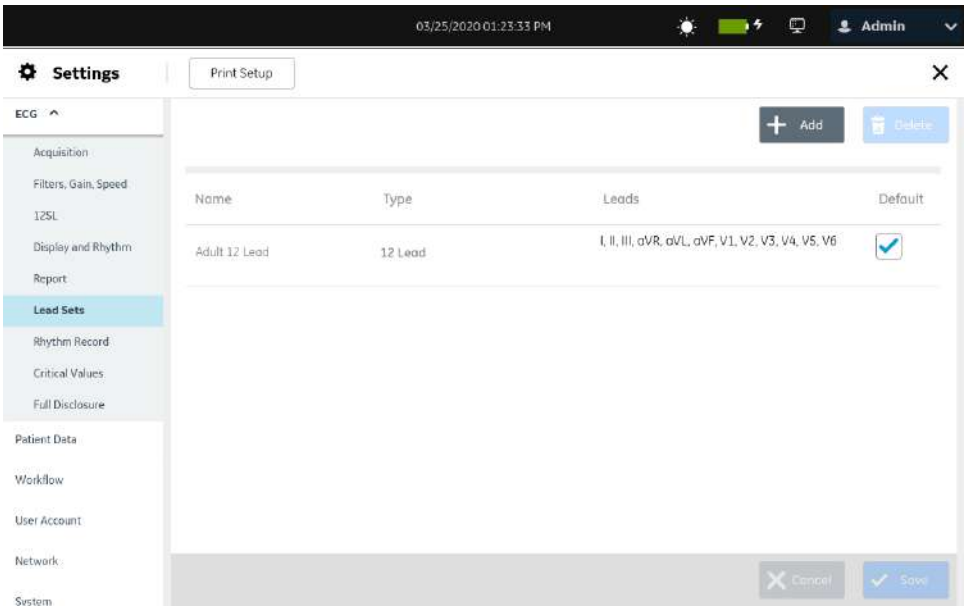
The device includes the default lead set configurations below:

Table 39: Default Lead Set Configurations

Lead Set Name	*Lead Set Type*	*Default*	*Lead Set Channels*
Adult 12 Lead	12 Lead	Yes	CH1 to CH12: I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6

You can edit or delete the default or user-defined ECG lead set configurations by performing the procedure below:

1. Select **Settings** > **ECG** > **Lead Sets**.
   The **Lead Sets** screen displays.



2. Perform any of the steps below to configure a lead set, as applicable:
   - To add a user-defined lead set, perform step *3* to step *6*.
   - To edit a user-defined lead set, perform step *7*.
   - To delete a user-defined lead set, perform step *8*.
3. Select the **Add** icon Add to add an ECG lead set.
   A new row is added to the lead set table.
4. Configure the ECG lead sets.

   NOTE:
   You can configure a maximum of 10 ECG lead sets.

Table 40: ECG Lead Set Configuration

Field Name	*Action*	*Description*
Type	Select the lead set type you want to include in the lead set.	Default value: **12 Lead**
Name	Enter a name for your lead set.	User-defined value up to 15 characters. Allowed values: • a to z • A to Z • 0 to 9 • All special characters
Default	Enable or disable this setting.	If this setting is enabled, this is the default lead set used to display the waveform on the Acquisition screen. You can not delete the default lead set. Default value: Disabled
Leads	Select the leads that you want to display in the waveform for the selected lead set.	Default value: I, II, III, aVR,aVL, aVF, V1, V2, V3, V4, V5, V6 Allowed values: I, II, III, aVR, -aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 If the **F300 - 300 Hz Acquisition** option is enabled, **Acquisition Bandwidth** displays. Default value: 150 Hz Allowed values: 150 Hz, 300 Hz

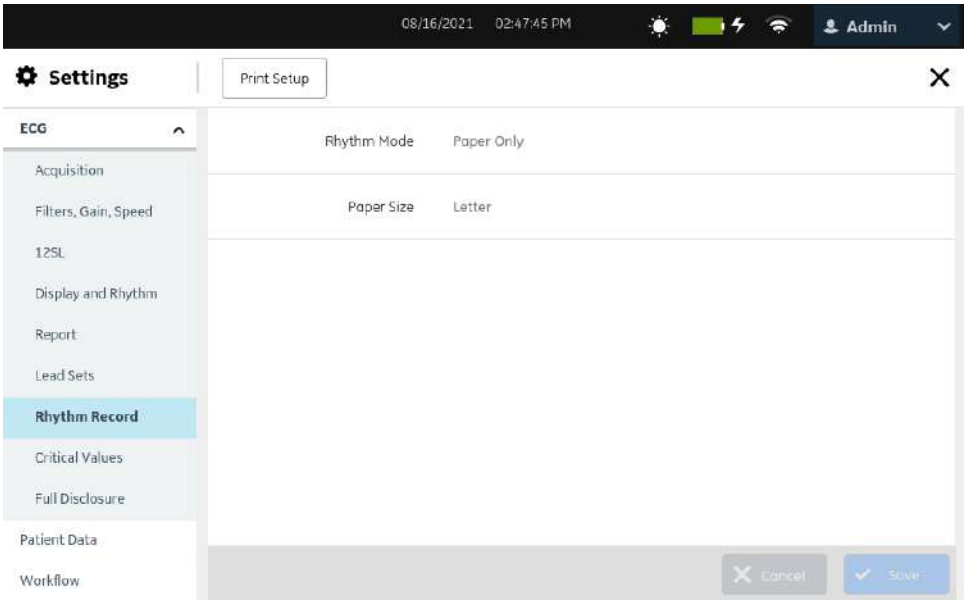
5. Select **Save**.
6. Repeat steps *3* to *5* to add more ECG lead set configurations.
7. To edit an existing ECG lead set configuration:
   a) Select anywhere in the row of the lead set configuration you want to modify to enable the edit mode.
   b) Make changes to the configuration as per the information in *Table 40: ECG Lead Set Configuration on page 147*.
   c) Select **Save**.
8. To delete an existing lead set configuration:
   a) Select the **Delete** icon for the lead set configuration you want to delete.

NOTE:
You can delete only one lead set configuration at a time. To delete more than one lead set configuration, repeat this step.

b) Select **Save**.

Configure Rhythm

1. Select **Settings** > **ECG** > **Rhythm Record**.
   The **Rhythm Record** screen displays.



2. Configure the fields as per the information in the table:

Table 41: Rhythm Settings

Field	*Action*	*Description*
Rhythm Mode	Select a value from the drop-down list to configure the mode of recording a rhythm.	• If you select **Paper Only**, the rhythm report is printed in paper. • If you select **Digital Only**, the rhythm report is recorded and saved in the **Files** view. • If you select **Both**, the rhythm report is recorded and saved in the **Files** view and also printed in paper. • If you select **Digital Only** or **Both**, configure the rhythm speed and duration of acquisition of the rhythm. Default value: **Paper Only**

Field	*Action*	*Description*
Maximum Digital Rhythm Duration	Select a value from the drop-down list to configure the maximum digital rhythm duration.	This field is enabled only when **Rhythm Mode** is configured as **Digital Only** or **Both**. Default value: **300 sec** Allowed values: **10 Sec** to **300 Sec** in multiples of 10.
Rhythm Speed	Select a value from the drop-down list to configure the speed at which the rhythm is recorded.	This field is enabled only when **Rhythm Mode** is configured as **Digital Only** or **Both**. Default value: **25.0 mm/s** Allowed values: • **5.0 mm/s** • **12.5 mm/s** • **25.0 mm/s** • **50.0 mm/s**
Paper Size	Select a value from the drop-down list to configure the paper size for printing.	Default value: **Letter** Allowed values: • **A4** - available on MAC 5 A4 device • **Letter** - available on MAC 5 A4 device • **A5** - available on MAC 5 A5 device

3. Select **Save**.

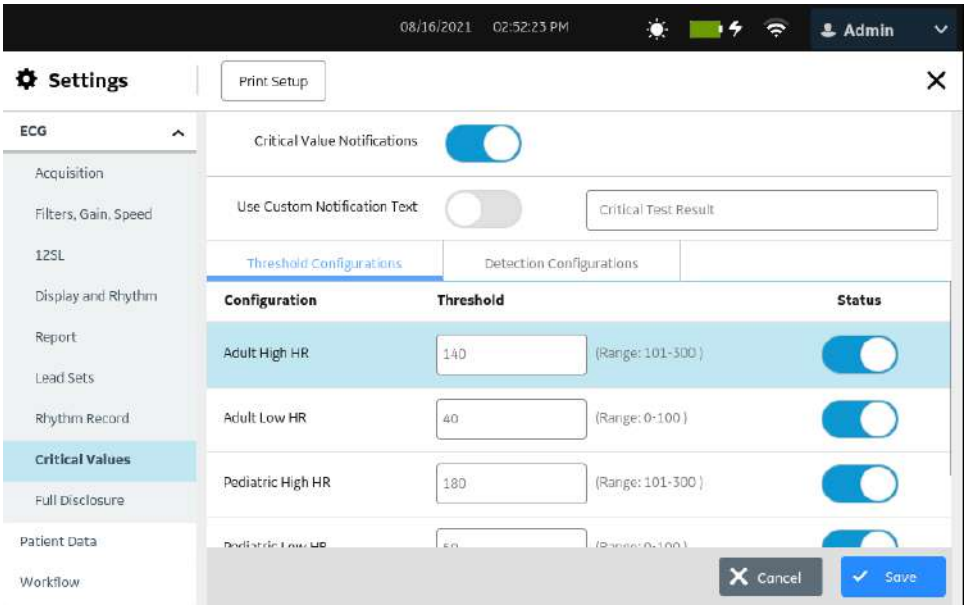
Configure Critical Value Notifications

Before you start this procedure, make sure that:

- The CRIT option is enabled on the device. Contact a GE Healthcare Service Support representative to enable this option.
- Your user role is assigned the privileges to access the **Settings** screen and edit critical value settings. See *Configure User Roles on page 209*.

1. Select **Settings** > **ECG** > **Critical Values**.

   The **Critical Values** screen displays.



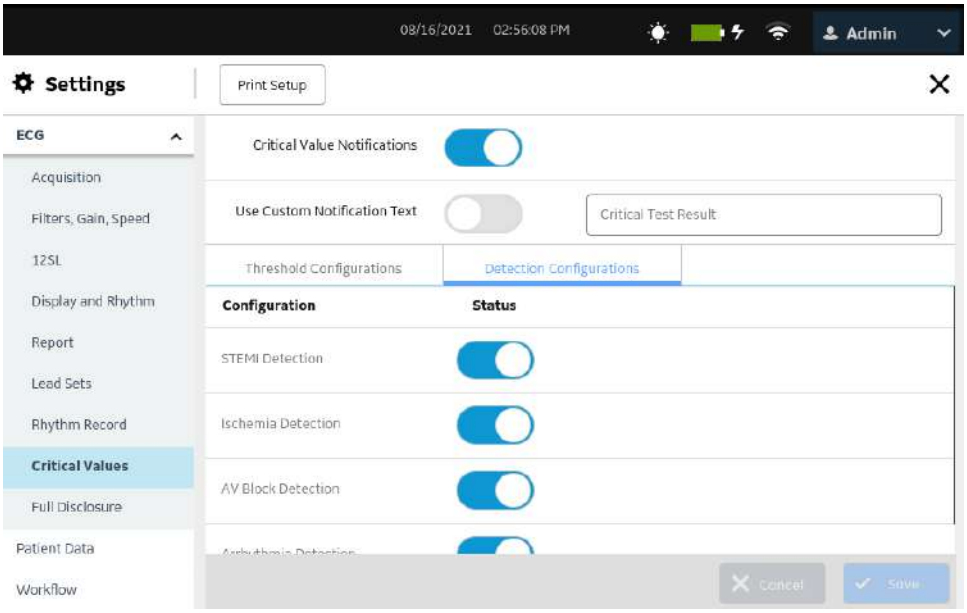
2. Enable the **Critical Value Notifications** setting to configure notifications to display when configured critical value thresholds are met or prescribed critical conditions are detected.
3. Enable the **Use Custom Notification Text** setting to configure custom notification text in the text field.
4. Edit the default phrase *Critical Test Result* in the text field with a customized phrase. The phrase displays on the screen during preview or review of acquired ECG patient reports, when a critical value or condition is detected.
5. Select the **Threshold Configurations** tab to display the threshold configurations for critical values.
6. Select the default critical value to change the threshold value.
   The selected value is now editable.
7. Enter the threshold for the selected critical value as per the information in the table.

Table 42: Threshold Critical Values

Critical Value	*Allowed Threshold Range*	*Default Threshold Value*
Adult High HR	101 to 300	**140**
Adult Low HR	0 to 100	**40**
Pediatric High HR	101 to 300	**180**
Pediatric Low HR	0 to 100	**50**
High QTc	441 to 1000	**550**

NOTE:
By default, critical value notifications are enabled. If you do not want to be notified when a threshold for a specific critical value has been met, disable the **Status** setting for the corresponding critical value.

8. Select **Save** to save the changes.
9. Select the **Detection Configurations** tab to display the detection configurations for critical conditions.



10. Enable or disable notifications when the critical conditions below are detected:
    - STEMI Detection
    - Ischemia Detection
    - AV Block Detection
    - Arrhythmia Detection

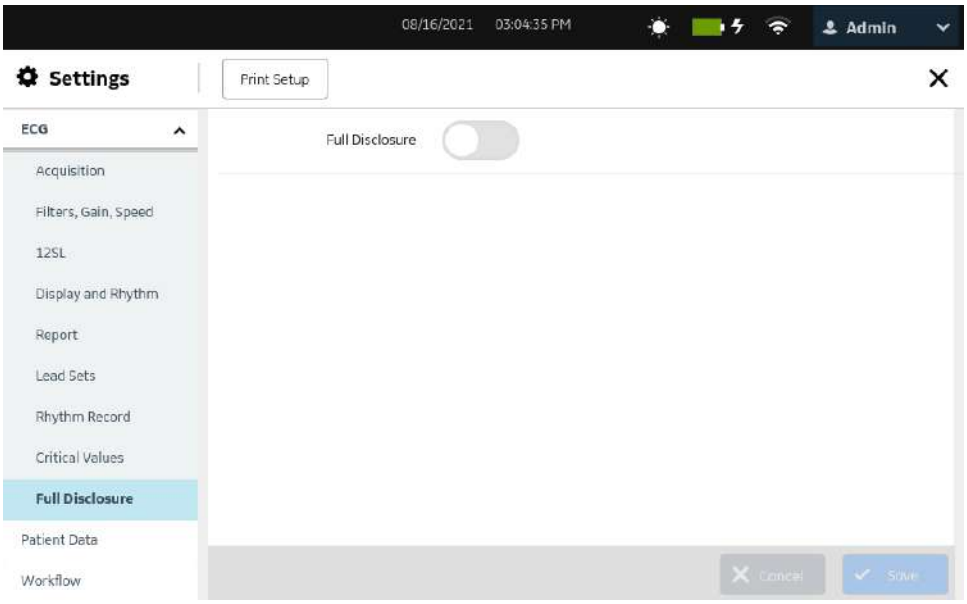
    NOTE:
    By default, notifications are enabled.
11. Save and close the screen.
    The **Acquisition** screen displays.

Configure Full Disclosure

Before you start this procedure, make sure that:

- The **FLDS - Full Disclosure** option is enabled on the device. Contact a GE Healthcare Service Support representative to enable this option.
- Your user role is assigned the privileges to access the **Settings** screen. See *Configure User Roles on page 209*.

1. Select **Settings** > **ECG** > **Full Disclosure**.
   The **Full Disclosure** screen displays.



2. Do one of the below steps.
   - Enable the **Full Disclosure** setting and select **Save** to activate the full disclosure functionality.

     The **Full Disclosure** tab is available on the Acquistion screen.
   - Disable the **Full Disclosure** setting and select **Save** to deactivate the full disclosure functionality.

     The **Full Disclosure** tab is not available on the Acquistion screen.

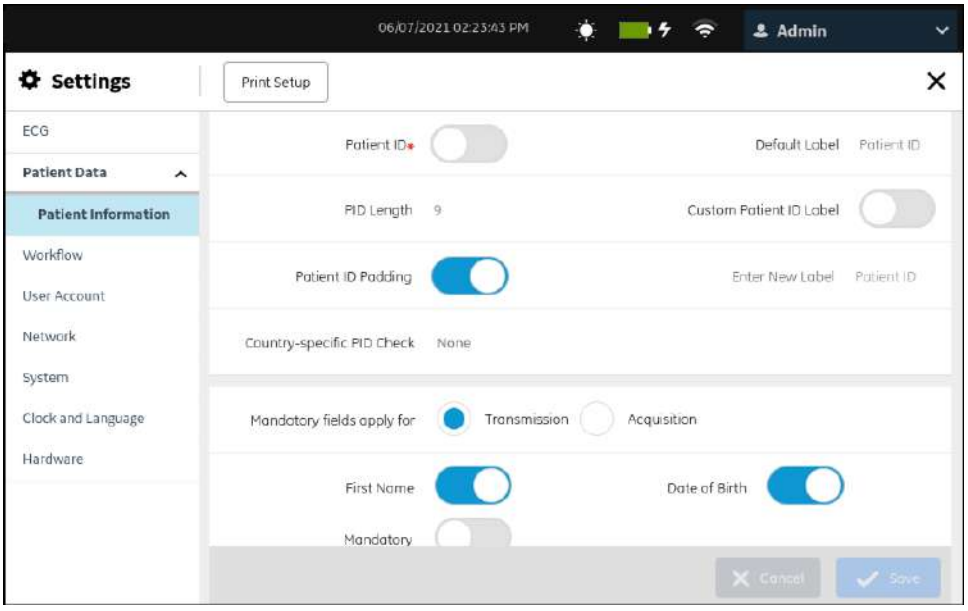
Configure Patient Data

Select **Settings** > **Patient Data** menu to configure the following:

- Patient Information - *Configure Patient Information on page 152*
- Clinical Trail - *Configure Clinical Trial on page 159*

Configure Patient Information

1. Select **Settings** > **Patient Data**.
   The **Patient Information** screen displays.



2. Configure the fields as per the information in the table.

NOTE:

If you enable a field in the **Mandatory** column and **Mandatory fields apply for Transmission** or **Acquisition** option, it becomes a required field or option settings and an asterisk (*) displays next to the field on the **Patient Information** screen.

Table 43: Patient Information Settings

Field	*Action*	*Description*
Patient ID	Patient ID cannot be disabled.	You can enable or disable this field in the **Required** column to make it required or optional in the **Patient Information** screen. Default value: Disabled
PID Length	Enter a value to configure the length of the patient ID in the **Patient Information** screen, if Patient ID is not country-specific. You can edit this field only if **Country Specific PID check** is **None**.	Default value: • **12** for French, German and Italian • **9** for other languages Allowed values: 3 to 16

Field	*Action*	*Description*
Patient ID Padding	Enable or disable this setting.	• If this setting is enabled, the patient ID is padded with the required number of leading zeros as per the configured PID length. • If this setting is disabled, the patient ID is not padded with leading zeros as per the configured PID length. Default value: Enabled
Country-specific PID Check	Select a value from the drop-down list to enable the configuration of the Patient ID according to the country selected.	The value is automatically set as the country specified, when the device language is set to that country and the device is restored to factory defaults. This is applicable for Danish, Swedish, and Norwegian. The value is automatically set as **None** when the device language below is set and the device is restored to factory defaults. • English • Chinese • Dutch • Finnish • French • German • Italian Default value: **None** Allowed values: • **None** • **Danish** • **Norwegian** • **Swedish**
Custom Patient ID Label	Enable or disable this setting.	• If this setting is enabled, the **Enter New Label** field displays. • If this setting is disabled, the default label **Patient ID** displays in the **Patient Information** screen. Default value: Disabled
Enter New Label	Enter the label name to display in the **Patient Information** screen.	Default value: **Patient ID** Allowed values: • A to Z • a to z • 0 to 9 • All special characters

Field	*Action*	*Description*
Mandatory fields apply for	Enable or disble the **Transmission** or **Acquisition** setting.	If the **Transmission** setting is enabled, the mandatory fields need to be set in the **Patient Information** screen. Otherwise the transmission of the ECG report is failed until you set the values for mandatory fields. If the **Acquisition** setting is enabled, the mandatory fields need to be set in the **Patient Information** screen. Otherwise the ECG report will not be saved until you set the values for mandatory fields. Default value: **Transmission**
First Name	Enable or disable this setting.	Displays or hides the field on the **Patient Information** screen. If this field is configured to display, you can enable or disable the field in the **Mandatory** column. Default value: Enabled
Last Name	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. If this field is configured to display, you can enable or disable the field in the **Mandatory** column. Default value: Enabled
Height	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled
Weight	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled
Age	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. **NOTE**: If the **Age** field is enabled, the **Date of Birth** field cannot be enabled, and the **Patient Information** screen will not display the **Date of Birth**. Default value: Disabled
Date of Birth	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. **NOTE**: If the **Date of Birth** field is enabled, the **Age** field cannot be enabled, and the **Patient Information** screen will not display the **Age**. Default value: Enabled
Gender	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled

Field	*Action*	*Description*
Race	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. This setting is automatically enabled when the device language below is set and the device is restored to factory defaults: • English • Chinese • Finnish • French • Italian This setting is automatically disabled when the device language below is set and the device is restored to factory defaults: • Danish • Dutch • German • Swedish • Norwegian
Blood Pressure	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Medications	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled
Referring MD Last Name	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled
Referring MD First Name	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled
Ordering MD First Name	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Ordering MD Last Name	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Referring MD ID	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled

Field	*Action*	*Description*
Bed Number	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Comments	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Test Indication	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled
Location	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. If this field is configured to be displayed, you can enable or disable the field in the **Mandatory** column. Enable this field for **Location ID** to be sent to the MUSE server. Default value: Disabled
Room Number	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Priority	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Patient History	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Technician	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. If this field is configured to display, you can enable or disable the field in the **Mandatory** column. Default value: Enabled
Visit Number	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. If this field is configured to display, you can enable or disable the field in the **Mandatory** column. Default value: Enabled

Field	*Action*	*Description*
Order Number	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. If this field is configured to display, you can enable or disable the field in the **Mandatory** column. Default value: Enabled
Secondary ID	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. If this field is configured to display, you can enable or disable the field in the **Mandatory** column. Default value: Disabled
Ordering MD ID	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Enabled
Attending MD ID	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Attending MD First Name	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Attending MD Last Name	Enable or disable this setting.	Displays or hides the field in the **Patient Information** screen. Default value: Disabled
Question 1 **Question 2** **Question 3** **Question 4**	Enable or disable this setting.	Displays or hides the fields in the **Patient Information** screen. Default value: Disabled
Question	Enter the question to display in the **Patient Information** screen.	This field is enabled if the related **Question** field is enabled. Default value: **Enter the question** Allowed values: 10 characters • A to Z • a to z • 0 to 9 • All special characters

Field	*Action*	*Description*
Answer Type	Select a value from the drop-down list to enable the configuration of the answer type for each question.	This field is enabled if the related Question field is enabled. Default value: **Alphanumeric** Allowed values: • **Alphanumeric** • **Numeric** • **Yes or No or Unknown**

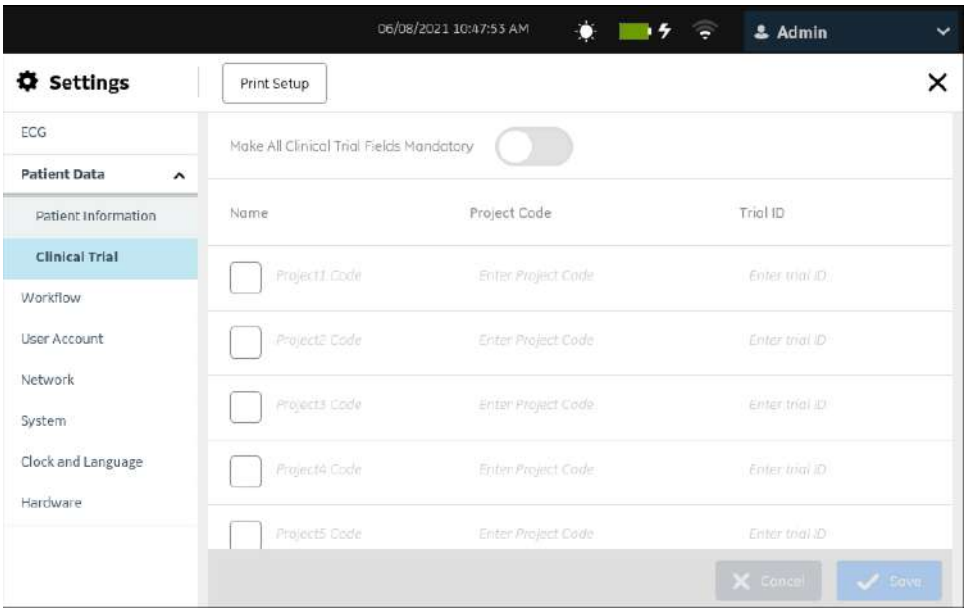
3. Select **Save**.

Configure Clinical Trial

Before you start this procedure, make sure that:

- The **PHAR - Pharmacy** option is enabled on the device. Contact a GE Healthcare Service Support representative to enable this option.
- Your user role is assigned the privileges to access the **Settings** screen. See *Configure User Roles on page 209*.

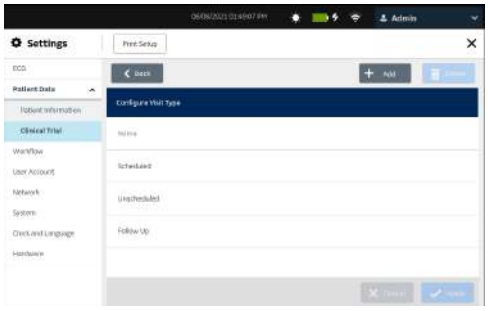
1. Select **Settings** > **Patient Data** > **Clinial Trial**.
   The **Clinial Trial** screen displays.



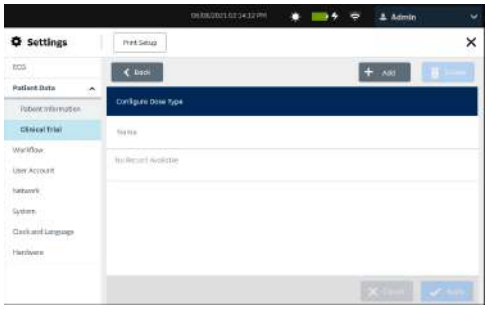
2. Configure the fields as per the information in the table.

Table 44: Clinical Trial Settings

Field	*Action*	*Description*
Make All Clinical Trial Fields Mandatory	Enable or disable this setting.	If you enable this setting, all the configured clinical trial settings are required fields and an asterisk (*) displays next to each field on the **Clinical Trial** screen. If you disable this setting, all the configured clinical trial settings are optional fields on the **Clinical Trial** screen. Default value: Disabled
Name: • **Project1 Code** • **Project2 Code** • **Project3 Code** • **Project4 Code** • **Project5 Code**	Enable or Disable this setting.	If you select one **Name**, the configured **Project Code** displays in the drop down list of the **Project Code Name** field in the **Clinical Trial** screen. Default value: Disabled
Project Code	Enter the information to display in the **Project Code** field on the **Clinical Trial** screen.	This field is enabled if the related **Name** field is selected. Default value: **Enter Project Code** Allowed value:
Trial ID	Enter the information to display in the **Trial ID** field on the **Clinical Trial** screen.	This field is enabled if the related **Name** field is selected. Default value: **Enter Trial ID** Allowed value:
Trial Visit Number	Enable or Disable this setting.	Displays or hides the field in the **Clinical Trial** screen. Default value: Disabled

Field	*Action*	*Description*
Visit Type	Enable or Disable this setting.	Displays or hides the field in the **Clinical Trial** screen. Default value: Disabled If you enable this setting, follow below steps to configure the visit types displaying in the drop down list of the **Visit Type** field in the **Clinical Trial** screen. 1. Select **Configure**. The **Configure Visit Type** screen displays.  Default values: • **Scheduled** • **Unscheduled** • **Follow Up** • **Repeat** • **Early Termination** • **Unknown** 2. Perform any of the below actions to configure a visit type, as applicable: • To add a visit type, select **Add**, then enter the information into the new row. • To edit a visit type, select the text in the row of the visit type you want to modify, then make changes. • To delete a visit type, select the text in the row of the visit type you want to delete, then a massage displays asking you to confirm if you want to delete the visit type. • Select **Yes** to confirm the delete. • Select **No** to cancel the delete. 3. Select **Save**.

Field	*Action*	*Description*

Dose Type	Enable or Disable this setting.	Displays or hides the field in the **Clinical Trial** screen.
		Default value: Disabled
		If you enable this setting, follow below steps to configure the visit types displaying in the drop down list of the **Dose Type** field in the **Clinical Trial** screen.
		1. Select **Configure**.
		The **Configure Dose Type** screen displays.
		 
		Default value: **No Record Available**
		2. Perform any of the below actions to configure a dose type, as applicable:
		• To add a dose type, select **Add**, then enter the information into the new row.
		• To edit a dose type, select the text in the row of the visit type you want to modify, then make changes.
		• To delete a dose type, select the text in the row of the visit type you want to delete, then a massage displays asking you to confirm if you want to delete the dose type.
		  • Select **Yes** to confirm the delete.
		  • Select **No** to cancel the delete.
		3. Select **Save**.

Investigator ID	Enable or Disable this setting.	Displays or hides the field in the **Clinical Trial** screen. Default value: Disabled
Question 1 **Question 2** **Question 3** **Question 4** **Question 5**	Enable or disable this setting.	Displays or hides the fields in the **Clinical Trial** screen. Default value: Disabled

Field	*Action*	*Description*
Question	Enter the question to display in the **Clinical Trial** screen.	This field is enabled if the related **Question** field is enabled. Default value: **Enter the question** Allowed values: 10 characters • A to Z • a to z • 0 to 9 • All special characters
Answer Type	Select a value from the drop-down list to enable the configuration of the answer type for each question.	This field is enabled if the related **Question** field is enabled. Default value: **Alphanumeric** Allowed values: • **Alphanumeric** • **Numeric** • **Yes or No or Unknown**

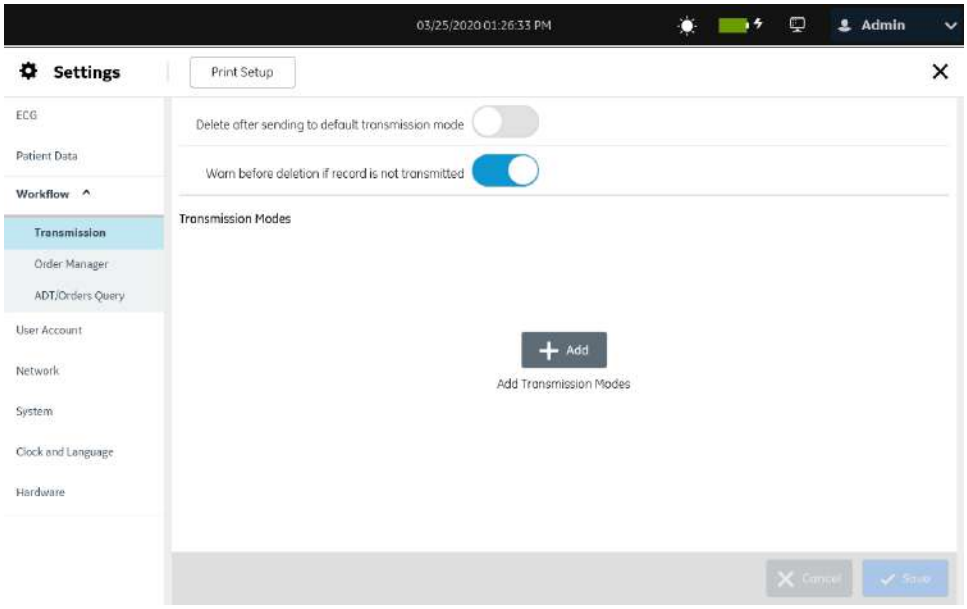
3. Select **Save**.

Configure Workflow

Select **Settings** > **Workflow** menu to configure the following:

- Transmission - *Configure Transmission Settings on page 164*
- Order Management - *Configure Order Management on page 186*
- Patient Query - *Patient Query Overview on page 198*
- Remote Patient Query - *Configure Remote Patient Query on page 199*

Configure Transmission Settings



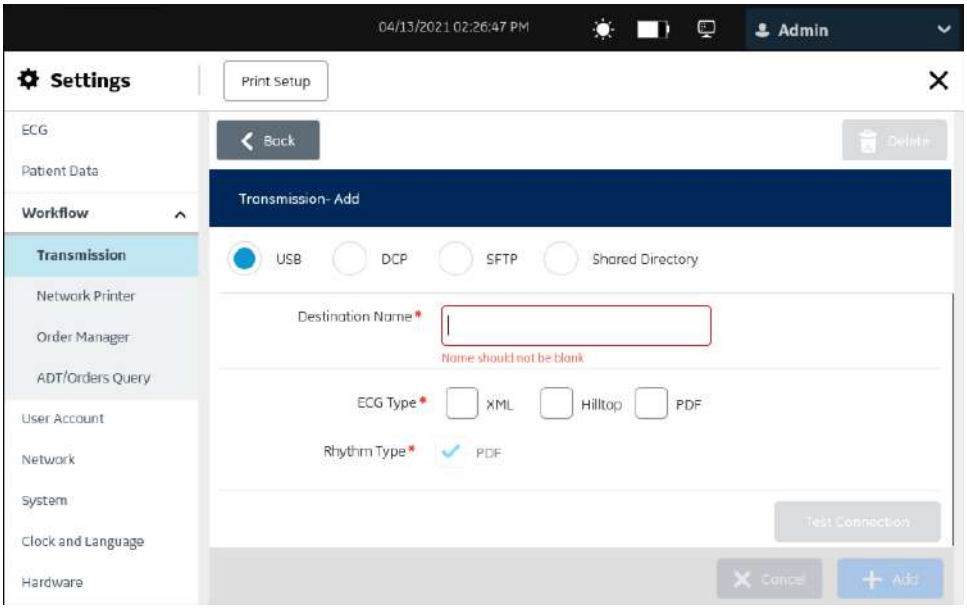
1. Select **Settings** > **Workflow** > **Transmission**.
2. Enable or disable **Delete after sending to default transmission mode** to configure auto-deletion of the ECG patient report from the **Files** list after it is sent to the default destination.

   When **Delete after sending to default transmission mode** is enabled and user does not have **Delete Reports** privilege, the report continues to be deleted after transmission.
3. Enable or disable **Warn before deletion if record is not transmitted** to display a warning message before deletion if the ECG patient report has not been transmitted to the default destination. This setting is enabled by default.
4. Select **Save**.
5. Proceed to configure any of the destinations below for patient report transmission:
   - *Configure a USB Destination to Transmit Reports on page 164*
   - *Configure a DCP Server Destination to Transmit Reports on page 168*
   - *Configure a Shared Directory to Transmit Reports on page 178*
   - *Configure an SFTP Destination to Transmit Reports on page 171*

Configure a USB Destination to Transmit Reports

- Make sure that the setting to allow access to external storage devices is enabled in the **System** > **Storage**. See *Configure External Storage on page 247*.
- Make sure that **USB port** is enabled and the USB flash drive with a key file is inserted into the device. See *Configure the USB Ports on page 261*.

1. Select **Settings** > **Workflow** > **Transmission**.
2. Select the **Add** icon + Add to add transmission modes.
3. Select **USB** to configure a USB server destination.



4. Configure the destination as per the information in the table.

Table 45: Configure a USB Destination to Transmit Reports

Field	*Action*	*Description*
Destination Name	Enter the name of the USB destination where the reports will be sent.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
ECG Type	Select the supported file type of ECG report sent through USB by your facility.	You can select multiple format types. Default available values: • **Hilltop** • **PDF** Allowed values (Option): • **XML** (This type is available only if XML format output is enabled in **Option Manager**). • **Hilltop** • **PDF**

Field	*Action*	*Description*
Rhythm Type	Select the supported file type of rhythm report sent through USB by your facility.	Default and allowed value: **PDF**

5. Select **Test Connection** to test the configured connection.
   - If the test displays **Test Success**, you have a successful connection to that destination.
   - If the test displays **Test Failure**, you do not have a connection to that destination. Troubleshoot the connection failure by confirming that the USB flash drive is firmly seated, test, and add the connection.
6. Select **Save**.
7. Repeat steps 2 to 6 to add more USB destinations.
   - To edit a USB destination, perform step 8.
   - To delete a USB destination, perform step 9.
8. To edit an existing USB destination:
   a) Select anywhere in the row of the destination you want to modify to enable the edit mode.
   b) Make changes to the destination as per the information in the table below.

Table 46: Modify a USB Destination to Transmit Reports

Field	*Action*	*Description*
Destination Name	Modify the name of the USB destination where the reports will be sent, if required	Allowed values: • A to Z • a to z • 0 to 9 • All special characters

Field	*Action*	*Description*
ECG Type	Select the supported file type of ECG report sent through USB by your facility.	You can select multiple format types. Default available values: • **Hilltop** • **PDF** Allowed values (Option): • **XML** (This type is available only if XML format output is enabled in **Option Manager**). • **Hilltop** • **PDF**
Rhythm	Select the supported file type of rhythm report sent through USB by your facility.	Default and allowed value: **PDF**

c) Test the connection as per step 5.

d) Select **Save**.

9. To delete an existing USB destination:

   NOTE:

   You can delete only one destination at a time.

   a) Select anywhere in the row of the destination you want to delete.

   b) Select the **Delete** icon .

   c) Select **Save**.

System Requirements for DCP Communication

The DCAR Communication Protocol (DCP) is used to support LAN and wireless communication between the MAC 5 Resting ECG Analysis System and the MUSE Cardiology Information System or, the CardioSoft system. The DCP requires the static or dynamic IP address for the MAC 5 system.

The following items are required to configure the wireless connection between a MAC 5 system and a MUSE system or the CardioSoft system.

- An enabled communication option: The **WRLS** option if you use wireless data transfer. The **LAN** option is standard if you use wired data transfer.
- A MUSE system running on V8.0 SP4 or later with the DCP communication and MUSEAPI3 service enabled.
- A CardioSoft 7.0 or later system

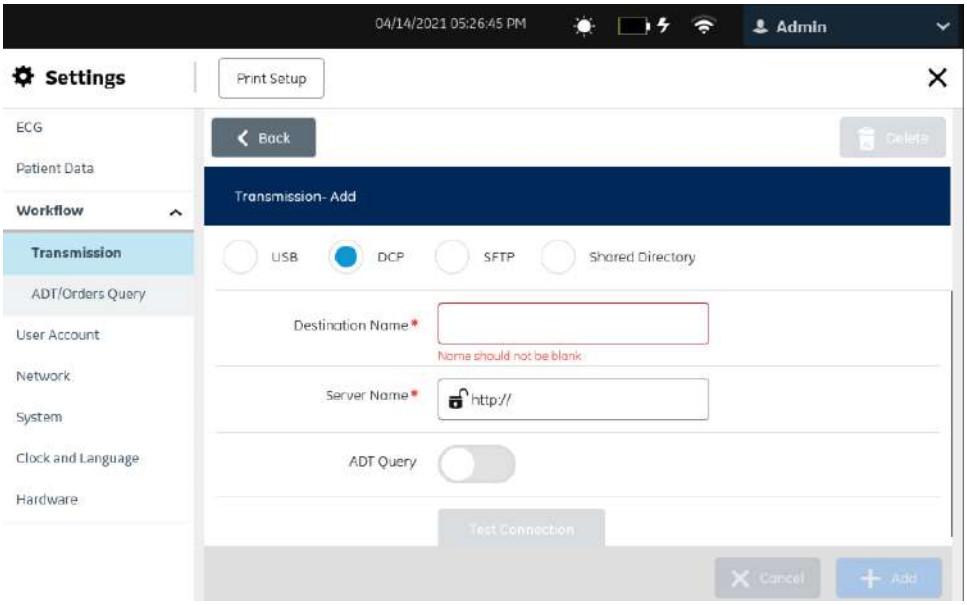
NOTE:

You can secure some communication channels with encryption and authentication. GE Healthcare recommends that you use the encrypted channels, not the unencrypted channels. For example:

- **Upgrade the MUSE server 8.0/9.0 API3 version to the MUSE NX API3 version, to have a secure communication between the MAC 5 system and the MUSE server.**

Configure a DCP Server Destination to Transmit Reports

1. Select **Settings** > **Workflow** > **Transmission**.
2. Select the **Add** icon Add to add transmission modes.
3. Select **DCP** to configure a DCP server destination.



The report is sent to the server using the DCAR Communication Protocol (DCP).

The MUSE server and EMR Gateway use DCP.

- If you configure the DCP server destination to the MUSE system, a Hilltop format report is sent to the server.
- If you configure the DCP server destination to the an EMR Gateway, a Sapphire XML and PDF report are sent to the server.

4. Configure the fields in the table to add a DCP server destination.

Table 47: Configure a DCP Server Destination to Send Reports

Field Name	*Action*	*Description*
Destination Name	Enter the name of the DCP server destination where the reports will be sent.	A user-defined value up to 20 characters. Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Server Name	Enter the URL of the DCP server. **NOTE**: • Make sure that you append '/SendTest' to the URL. For example, *http://<IP_Address> or <Hostname>:<Port>/SendTest*. • Confirm that the URL for the server is correct. • Confirm that the DCP server is running. • Make sure that you enable ADT for DCP communication, configure the same IP address for the DCP destination and the MUSE Orders Server for remote query.	A user-defined value. Allowed values: • A to Z • a to z • 0 to 9 • All special characters
ADT Query	Enable or disable this setting.	If this setting is enabled, the destination is configured to perform ADT query. Default value: Disabled

5. Select **Test Connection**.
   - If the test displays **Test Successful**, you have a successful connection to that destination. Select **Add** to save the destination.
   - If the test displays **Test Failed**, you do not have a connection to that destination. Troubleshoot the connection failure depending on the error, re-test and add the connection.
6. Select **Save**.
7. Repeat steps *2* to *6* to add more DCP server destinations.
8. To edit an existing DCP server destination:
   a) Select anywhere in the row of the destination you want to modify to enable the edit mode.

b) Make changes to the destination as per the information in the table below.

Table 48: Modify a DCP Server Destination to Send Reports

Field Name	*Action*	*Description*
Destination Name	Modify the name of the DCP server destination where the reports will be sent, if required.	A user-defined value up to 20 characters. Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Server Name	Modify the URL of the DCP server, if required. **NOTE**: • Make sure that you append '/SendTest' to the URL. For example, *http://<IP_Address> or <Hostname>:<Port>/SendTest*. • Confirm that the URL for the server is correct. • Confirm that the DCP server is running. • Make sure that you configure the IP address of the DCP destination with ADT enabled and the destination in the MUSE Order Server settings is same for a remote query.	A user-defined value. Allowed values: • A to Z • a to z • 0 to 9 • All special characters
ADT Query	Enable or disable this setting.	If this setting is enabled, the destination is configured to perform ADT query. Default value: Disabled

c) Select **Test Connection**.

- If the test displays **Test Successful**, you have a successful connection to that destination. Select **Update** to save the destination.
- If the test displays **Test Failed**, you do not have a connection to that destination. Troubleshoot the connection failure depending on the error, re-test and add the connection.

d) Select **Save**.

9. To delete an existing DCP server destination:

NOTE:
You can delete only one destination at a time.

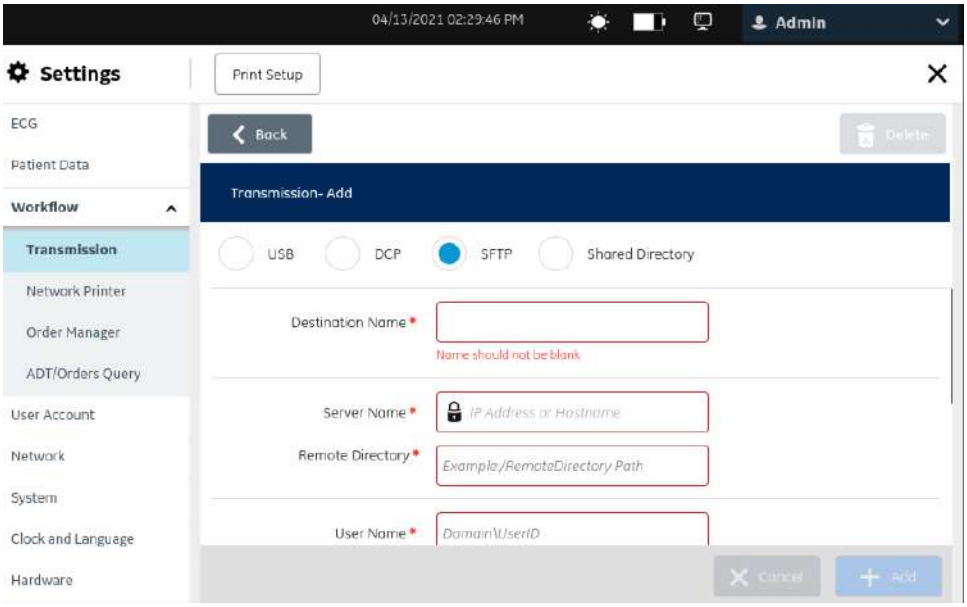
a) Select anywhere in the row of the destination you want to delete.

b) Select the **Delete** icon .

c) Select **Save**.

Configure an SFTP Destination to Transmit Reports

1. Select **Settings** > **Workflow** > **Transmission**.
2. Select the **Add** icon Add to add transmission modes.
3. Select **SFTP** to configure an SFTP destination.



4. Configure the destination as per the information in the table.

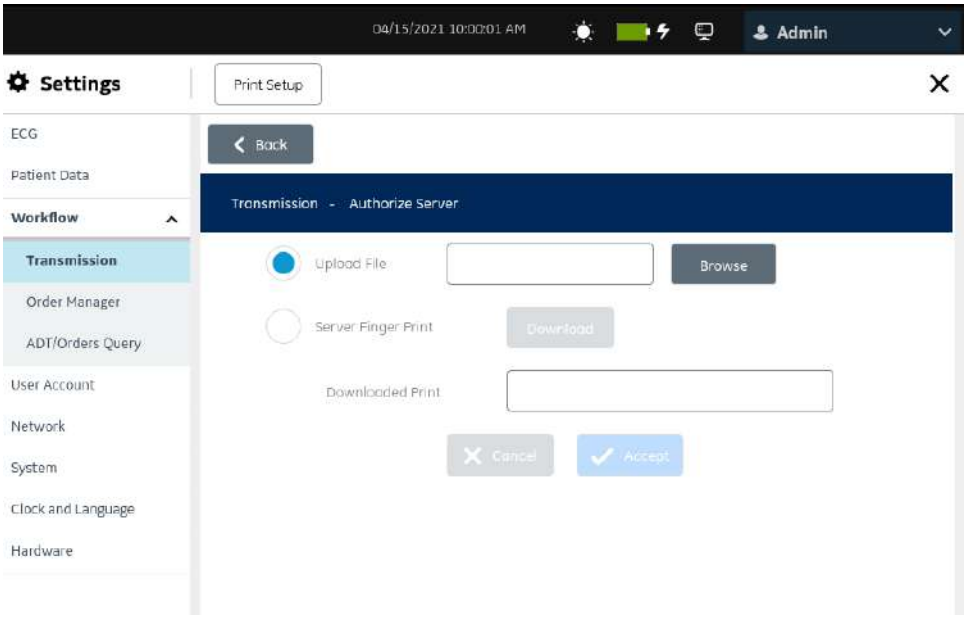
Table 49: Configure an SFTP Destination to Transmit Reports

Field	*Action*	*Description*
Destination Name	Enter the name of the SFTP destination where the reports will be sent.	A user-defined value up to 20 characters. Allowed values: • A to Z • a to z • 0 to 9 • All special characters

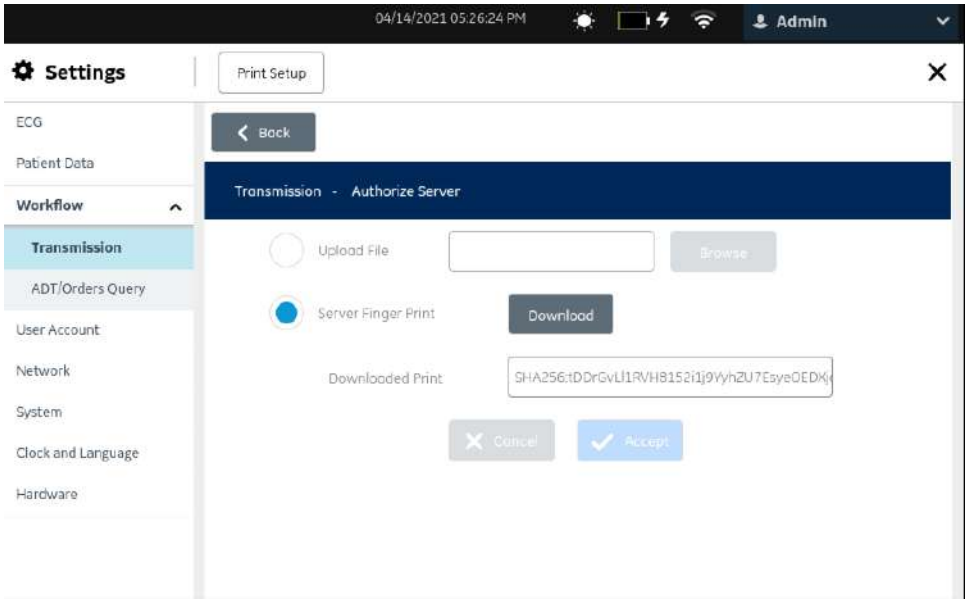
Field	*Action*	*Description*
Server Name	Enter the IP Address or Hostname of the SFTP server where the reports will be sent.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Remote Directory	Enter the path of the remote directory in the SFTP server where the reports will be sent.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
User Name	Enter the user name allowed to access the SFTP server.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Password	Enter the password of the user name allowed to access the SFTP server.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
ECG Type	Select the supported file type of ECG report sent to the SFTP destination by your facility.	You can select multiple format types. Default available values: • **Hilltop** • **PDF** Allowed values (Option): • **XML** (This type is available only if XML format output is enabled in **Option Manager**). • **Hilltop** • **PDF**
Rhythm Type	Select the supported file type of rhythm report sent to the SFTP destination by your facility.	Default and allowed value: **PDF**

Field	*Action*	*Description*
Authorize Server	Select **Authorize** to acknowledge, upload the key file, and download the SFTP server advertised finger print key.	The **Authorize** setting is enabled only after entering the values for **Destination Name**, **Server Name**, **Remote Directory**, **User Name**, **Password**, and **ECG Type** mandatory fields. Default value: Disabled The authorize server is configured through one of the settings below: • **Upload File** • **Server Finger Print**
Upload File	Select **Browse** to upload the public key file that is used to sign the server host certificate from USB. The SFTP server should be configured to use OpenSSH host certificate.	You can select the public key file that is used to sign the server host certificate from the USB to authorize the SFTP server.
Server Finger Print	Select **Download** to download the available finger print from the server.	You can download the finger print from the server to authorize the server.
Test Connection	Select **Test Connection** to test the SFTP server configuration.	You can test the SFTP server configuration.

5. Select **Authorize** to test the configured connection.
   The **Transmission - Authorize Server** screen opens.



6. To authorize a server, perform step 7 or step 8.
7. To authorize the server through a public key file that is used to sign the host certificate:
   a) Select **Upload File** to upload the public key file that is used to sign the host certificate.
   b) Make sure that the USB port is enabled and the USB flash drive with a public key file that is used to sign the host certificate is inserted into the device.
   c) Select **Browse** to choose the public key file that is used to sign the host certificate from the USB.
8. To authorize a server through a finger print:
   a) Select **Server Finger Print** to download and use the available finger print from the server.
      The **Transmission - Authorize Server** for **Finger Print** screen opens.



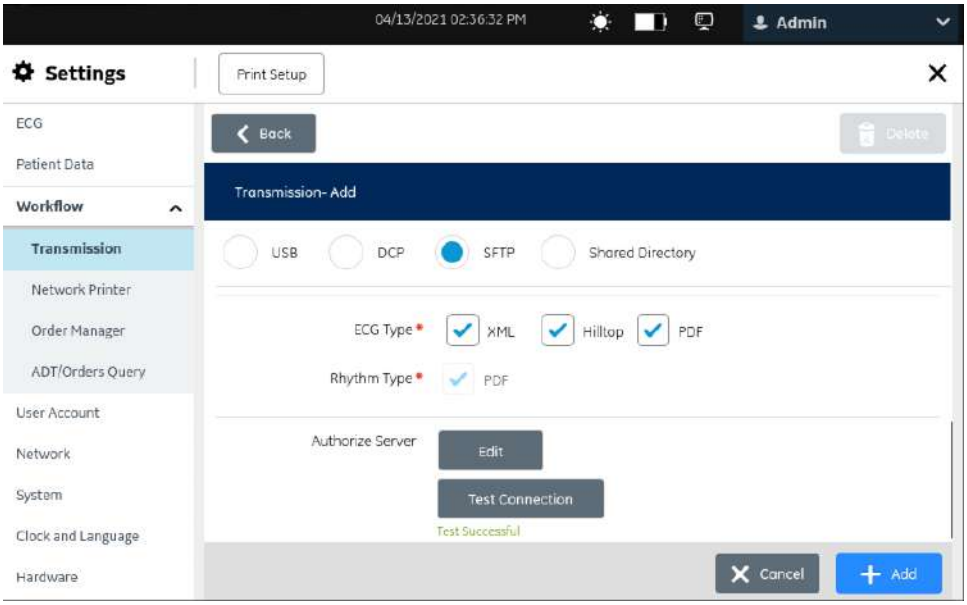
b) Select **Download** to download the finger print.

NOTE:
Make sure that you connect to the correct SFTP server by comparing the displayed finger print against the expected server finger print.

- If the download is successful, the finger print displays in the **Downloaded Print** field.
- If the download is failed, you cannot authorize the server. Troubleshoot the SFTP server configuration.

c) Select **Accept** to accept and close the authorize server settings screen.

9. Select **Back** to view the SFTP server configuration.
The SFTP server **Transmission-Add** screen opens.



10. Select **Test Connection** to test the SFTP server configuration.
    - If the test connection is successful, the SFTP server is configured and you can transmit the reports.
    - If the test connection is failed, the SFTP server is not configured and you cannot trasnmit the reports.
11. Select **Save**.
12. Repeat steps *2* to *11* to add more SFTP destinations.
    - To edit an SFTP destination, perform step *13*.
    - To delete an SFTP destination, perform step *14*.
13. To edit an existing SFTP destination:
    a) Select anywhere in the row of the destination you want to modify to enable the edit mode.
    b) Make changes to the destination as per the information in the table.

Table 50: Modify an SFTP Destination to Send Reports

Field	*Action*	*Description*
Destination Name	Enter the name of the SFTP destination where the reports will be sent.	A user-defined value up to 20 characters. Allowed values: • A to Z • a to z • 0 to 9 • All special characters

Field	*Action*	*Description*
Server Name	Enter the IP Address or Hostname of the SFTP server where the reports will be sent.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Remote Directory	Enter the path of the remote directory in the SFTP server where the reports will be sent.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
User Name	Enter the domain and user ID of the SFTP server where the reports will be sent.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Password	Enter the password of the SFTP server where the reports will be sent.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
ECG Type	Select the supported file type of ECG report sent to the SFTP destination by your facility.	You can select multiple format types. Default available values: • **Hilltop** • **PDF** Allowed values (Option): • **XML** (This type is available only if XML format output is enabled in **Option Manager**). • **Hilltop** • **PDF**
Rhythm Type	Select the supported file type of rhythm report sent to the SFTP destination by your facility.	Default and allowed value: **PDF**

Field	*Action*	*Description*
Authorize Server	Select **Authorize** to acknowledge and download the SFTP server advertised finger print key.	The **Authorize** setting is enabled only after entering the values for **Destination Name**, **Server Name**, **Remote Directory**, **User Name**, **Password**, and **ECG Type** mandatory fields. Default value: Disabled The authorize server is configured through one of the settings below: • **Upload File** • **Server Finger Print**
Upload File	Select **Browse** to upload the public key file that is used to sign the server host certificate from USB. The SFTP server should be configured to use OpenSSH host certificate.	You can select the public key file that is used to sign the server host certificate from the USB to authorize the SFTP server.
Server Finger Print	Select **Download** to download the available finger print from the server.	You can download the finger print from the server to authorize the server.
Test Connection	Select **Test Connection** to test the SFTP server configuration.	You can test the SFTP server configuration.

c) Edit the authorize server as per steps from *5* to *8*.

d) Select **Save**.

14. To delete an existing SFTP destination:

NOTE:
You can delete only one destination at a time.

a) Select anywhere in the row of the destination you want to delete.

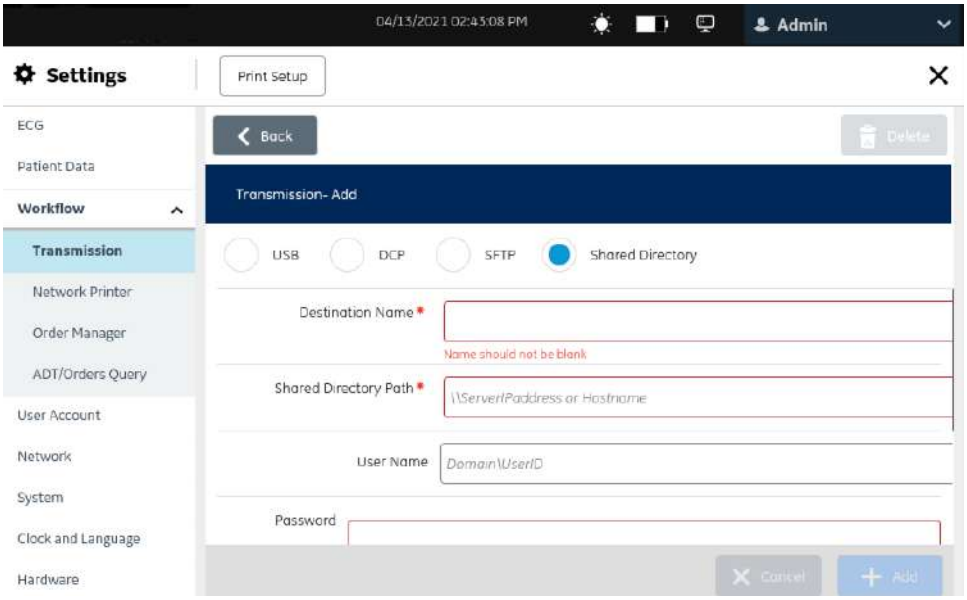
b) Select the **Delete** icon .

c) Select **Save**.

Configure a Shared Directory to Transmit Reports

The shared directory supports only SMB version 2.0.

1. Select **Settings** > **Workflow** > **Transmission**.
2. Select the **Add** icon + Add to add transmission modes.
3. Select **Shared Directory**.



4. Configure a shared directory as per the information in the table.

Table 51: Configure a Shared Directory Destination to Transmit Reports

Field	*Action*	*Description*
Destination Name	Enter the name of the shared directory where the reports will be sent.	A user-defined value up to 20 characters. Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Shared Directory Path	Enter the server IP address or hostname path of the shared directory. For example, ***// ServerIPaddress or Hostname/ sharename***.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters

Field	*Action*	*Description*
User Name	Enter the user name allowed to access the shared directory.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Password	Enter the password of the user name allowed to access the shared directory.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters (a single space)
ECG Type	Select the supported file type of ECG report sent to the shared directory by your facility.	You can select multiple format types. Default available values: • **Hilltop** • **PDF** Allowed values (Option): • **XML** (This type is available only if XML format output is enabled in **Option Manager**). • **Hilltop** • **PDF**
Rhythm Type	Select the supported file type of rhythm report sent to the shared directory by your facility.	Default and allowed value: **PDF**

5. Select **Test Connection** to test the configured connection.
   - If the test displays **Test Successful**, you have a successful connection to that destination.
   - If the test displays **Test Failed**, you do not have a connection to that destination. Troubleshoot the connection failure.
6. Select **Save**.
7. Repeat steps *2* to *5* to add more shared directory destinations.
   - To edit a shared directory destination, perform step *8*.
   - To delete a shared directory destination, perform step *9*.
8. To edit an existing shared directory destination:

a) Select anywhere in the row of the destination you want to modify to enable the edit mode.

b) Make changes to the destination as per the information in the table.

Table 52: Modify a Shared Directory Destination to Transmit Reports

Field	*Action*	*Description*
Destination Name	Enter the name of the shared directory where the reports will be sent.	A user-defined value up to 20 characters. Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Shared Directory Path	Enter the path of the shared directory. For example, ***// ServerIPaddress or Hostname/ sharename***.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
User Name	Enter the user name allowed to access the shared directory.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Password	Enter the password of the user name allowed to access the shared directory.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters (a single space)
ECG Type	Select the supported file type of ECG report sent to the shared directory by your facility.	You can select multiple format types. Default available values: • **Hilltop** • **PDF** Allowed values (Option): • **XML** (This type is available only if XML format output is enabled in **Option Manager**). • **Hilltop** • **PDF**

Field	*Action*	*Description*
Rhythm Type	Select the supported file type of rhythm report sent to the shared directory by your facility.	Default and allowed value: **PDF**

c) Test the connection as per step 5.

d) Select **Save**.

9. To delete an existing shared directory destination:

NOTE:
You can delete only one destination at a time.

a) Select anywhere in the row of the destination you want to delete.

b) Select the **Delete** icon .

c) Select **Save**.

Configure Transmission Modes

Make sure that at least one of the transmission mode is configured in the device.

1. Select **Settings** > **Workflow** > **Transmission**.

2. Configure the transmission modes as per the information in the table below:

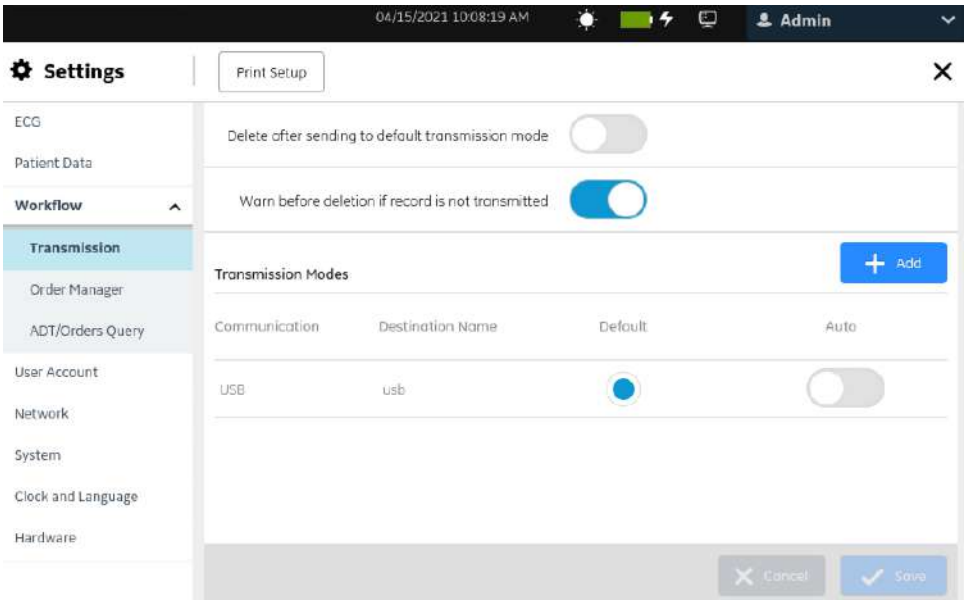


Table 53: Configure Transmission Modes

Field	*Action*	*Description*
Default	Enable or disable this setting.	If this setting is enabled, all generated patient reports are sent to this destination by default. A destination can be both the default and automatic destination. Default value: Disabled
Auto	Enable or disable this setting.	If this setting is enabled, all generated patient reports are automatically sent to this destination. A destination can be both the default and automatic destination. Default value: Disabled **NOTE**: When **Auto** is enabled for transmission and user does not have **Transmit Report** privilege, the report will not be transmitted.

NOTE:
You can configure only one transmission mode at a time.

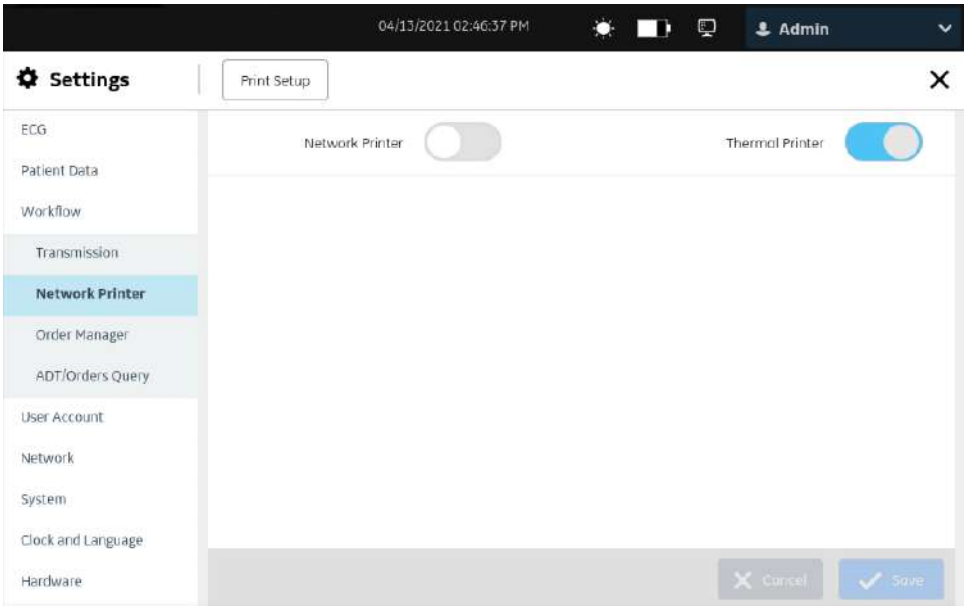
3. Select **Save**.

Configure Network Printer

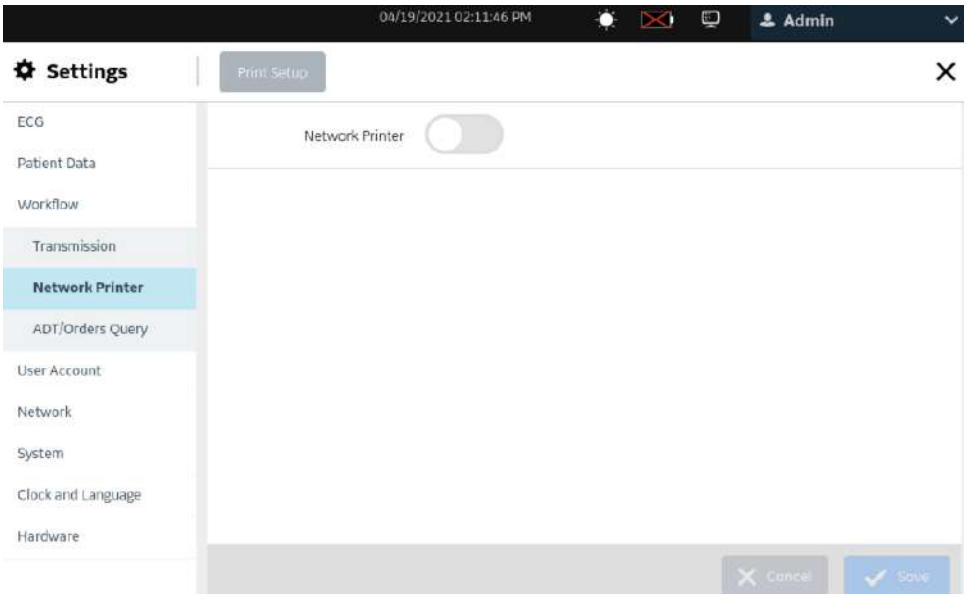
To configure a network printer, make sure the **NETP - Network Printer** option is purchased and enabled in the **Option Manager**.

1. Select **Settings** > **Workflow** > **Network Printer**.
   The network printer setting screen displays.

   User Interface on A4 and A5 devices



User Interface on Lite device



For MAC 5 devices with printer, the default printer is thermal printer.

For MAC 5 Lite device, the network printer is disabled by default.

2. Enable network printer, and configure the network printer per the information in the table below:

NOTE:

Make sure that the device is connected to a LAN or WLAN network, which is the same with the printer you are configuring. See for *Configure Network on page 226* detailed information.

Table 54: Configure Network Printer

Field	*Action*	*Description*
Network Printer	Enable or disable the network printer.	If this setting is enabled, the report can be printed via configuerd network printer.
Thermal Printer	Enable or disable the thermal printer.	If this setting is enabled, the report can be printed via thermal printer.
URL	Enter a valid ipp or ipps URL of the network printer.	A user-defined value. MAC 5 supports both internet printing protocol (ipp) and secured internet printing protocol (ipps). Allowed values: • A to Z • a to z • 0 to 9 • All special characters For example, ***ipp://xxxyyyzzz/ipp/print***
Paper Size	Select a value from the dropdown list to configure the paper size for printing.	Default value: **Letter** Allowed values: • **A4** • **Letter**
User Name	Enter the user name allowed to access the network printer.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Password	Enter the password of the user name allowed to access the network printer.	Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Test Print	Select to test the network printer configuration.	You can test the network printer configuration.

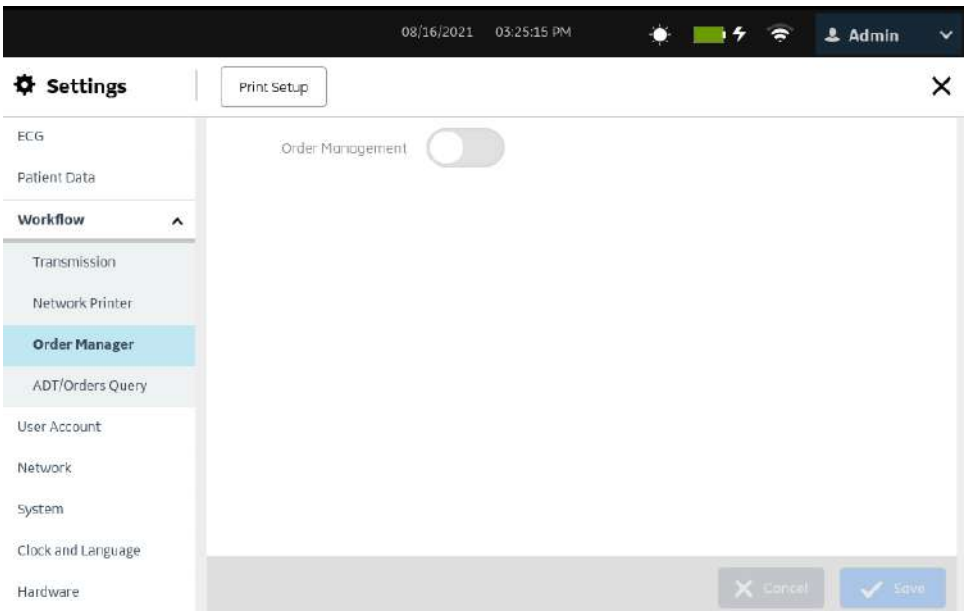
Configure Order Management

Before you start this procedure, make sure that:

- The **ORDM - Order Manager** option is enabled on the device. Contact a GE Healthcare Service Support representative to enable this option.
- Your user role is assigned the privileges to access the **Settings** screen and edit critical value settings. See *Configure User Roles on page 209*.

1. Select **Settings** > **Workflow** > **Order Manager**.

   The **Order Manager** screen displays.



2. Configure order management as per the information in the table.

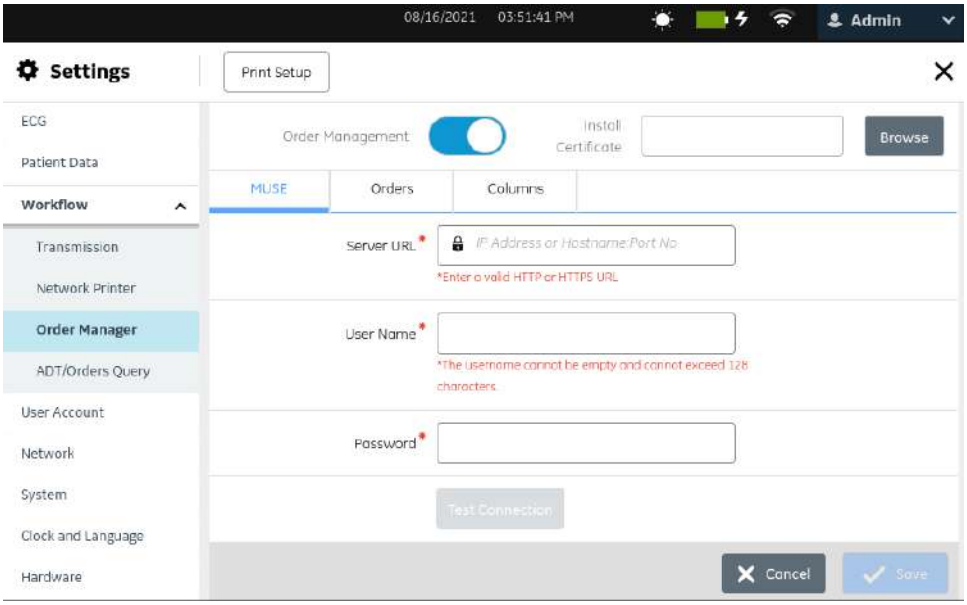
Table 55: Configure Order Management

Field	*Action*	*Description*
Order Management	Enable or disable this setting.	Order management is available on the device when you enable this setting. The **MUSE**, **Orders**, and **Columns** tabs display to configure order management. The **Orders** list displays on the Acquisition screen. Order management is not available on the device if you disable this setting. The tabs do not display on the screen to configure order management. The **Patients** list displays on the Acquisition screen instead of the **Orders** list. Default value: Disabled

Configure the MUSE Server Settings

Make sure that order management is enabled. See *Configure Order Management on page 186*.

1. Select **Settings** > **Workflow** > **Order Manager**.
2. Select **MUSE**.



3. Configure the MUSE server settings as per the information in the table.

Table 56: MUSE Server Settings for Orders

Field	*Action*	*Description*
Server URL	Enter a valid http or https URL of the MUSE server.	**NOTE**: **You can secure some communication channels with encryption and authentication. GE Healthcare recommends that you use the encrypted channels, not the unencrypted channels. For example:** • **Upgrade the MUSE server 8.0/9.0 API3 version to the MUSE NX API3 version, to have a secure communication between the MAC 5 system and the MUSE server.** The URL must correspond to the MUSE system. Allowed values: A valid http or https URL with defined FQDN or IP address and a port number. Use a Fully Qualified Domain Name (FQDN) or IP address. Add the port numeber after the URL with a colon (:) specifier. **NOTE**: Define the port number if it is not defined. • HTTP - 80 • HTTPS - 443 Determine which MUSE version you will connect to and configure the URL: • MUSE system V8/V9: HTTP **NOTE**: MUSE system V8/V9 default port is 8100. • MUSE NX system: HTTPS
User Name	Enter the MUSE account user name.	This field cannot be blank. Default value: No default value **NOTE**: This is a MUSE account, not a Windows account. Allowed values: Up to 128 characters • a to z • A to Z • 0 to 9 • All special characters

Field	*Action*	*Description*
Password	Enter the MUSE account user password.	Default value: No default value Allowed values: Up to 128 characters • a to z • A to Z • 0 to 9 • All special characters (a single space)
Install Certificate	Enable or disable this option to install a valid MUSE CA certificate.	If you configure a https URL, a valid CA certificate is required to authenticate and connect to the MUSE server. Install the CA certificate. See *Install MUSE SSL CA Certificate on page 190*. **NOTE**: The connection to the MUSE server is allowed, if a valid certificate is installed in the system with qualified authentication. To delete the CA certificate, see *Delete MUSE SSL CA Certificate on page 192*. If you configure a http URL, a valid CA certificate is not required to authenticate and connect to the MUSE server. Default value: Disabled

4. Select **Test Connection**.
   - If the connection succeeds, proceed to save the configuration.
   - If the connection fails, the error messages below display:
     - *Certificate validation failed* - the error is due to an invalid certificate.
     - *The username or password is incorrect* - the error is due to an incorrect username or password.
     - *Request timed-out* - the error is due to server request time out.
     - *Cannot connect to the server. Host not found* - the error is due to the host being unavailable.
     - *Authorization failed* - the error is due to incorrect site number set in the ECG acquisition device or an insufficient user privilege for a particular site.
     - *Invalid token* - the error is due to an invalid token exception during test connection.
     - *Test failed* - the error is due to other causes which are not included in the list.

     Rectify the errors and retest the connection.
5. Select **Save**.

If the MAC 5 device is set for LDAP authentication and Order Management with the MUSE system, when a user authenticates through LDAP, the MAC 5 connects to the MUSE server through MUSEAPI3. It checks if any users in MUSE User Setup have a Windows username that matches the user that logged into the MAC 5 device.

- If the users match, the MAC 5 will get the MUSE User ID for that user in the **Technician ID** field on the MAC 5 test entry screen.
- If a matching user is not found, the **Technician ID** field on the MAC 5 test entry screen is not filled.

When a matching user is not found in the MUSE system, the error *No user found for userName="x"*, where **x** is the username entered at the MAC 5 device, logs in the MUSE application log.

If you use the **Default** domain, a user can login to the MAC 5 with the username instead of the **domain\username** format.

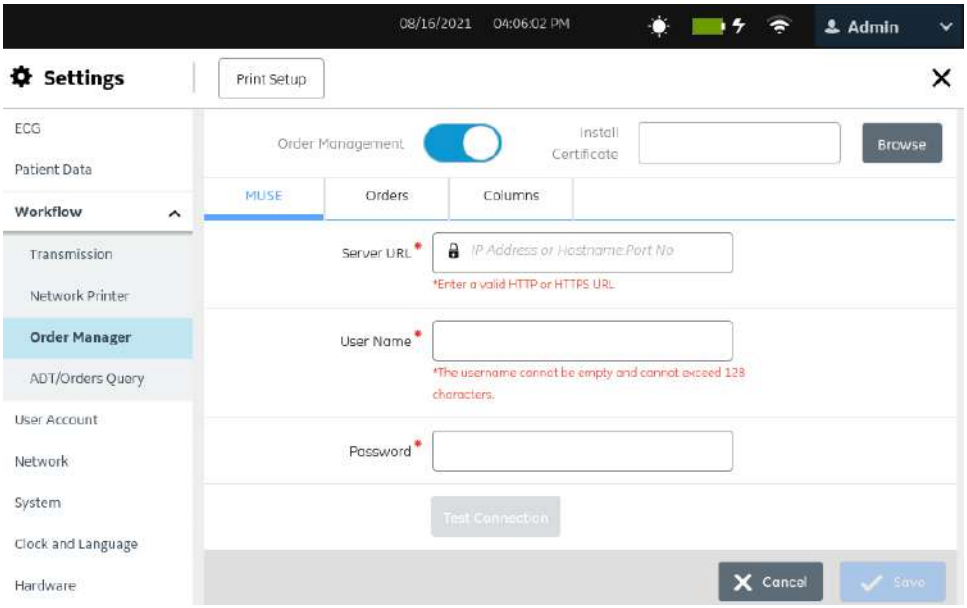
If a user does not enter their username as **domain\username**, the MUSEAPI3 user lookup call will not find the user.

Install MUSE SSL CA Certificate

Before you start this procedure, make sure that:

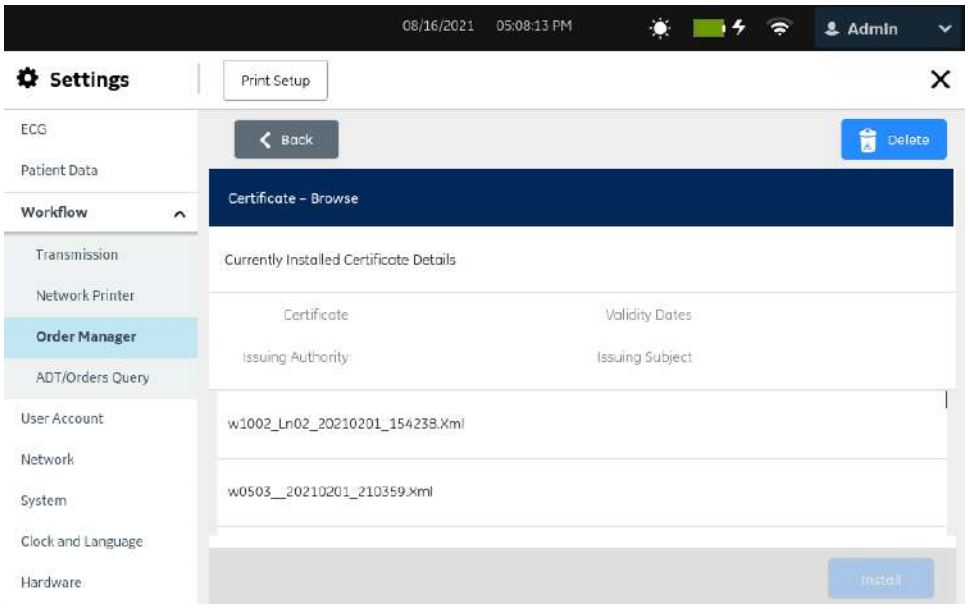
- You obtain the required certificate in the PEM format from your IT department and copy it to the root folder of a USB flash drive for installation.
- The **Enable External USB Storage** is enabled in **Settings** > **System** > **Storage** setting. If this setting is not enabled, access to USB flash drives is blocked.
- You enable at least one USB port in **Settings** > **Hardware** > **USB Port** setting. If this setting is not enabled, the device will not recognize the USB flash drives.

1. Connect the USB flash drive containing the CA certificate to the device.
2. Select **Settings** > **Workflow** > **Order Manager**.
3. Select **MUSE** to view the MUSE server settings.



4. Perform the steps below to install a CA certificate:

   a) Select **Browse** from the **Install Certificate** field and select the CA certificate from the USB flash drive.



   b) Select **Install**.

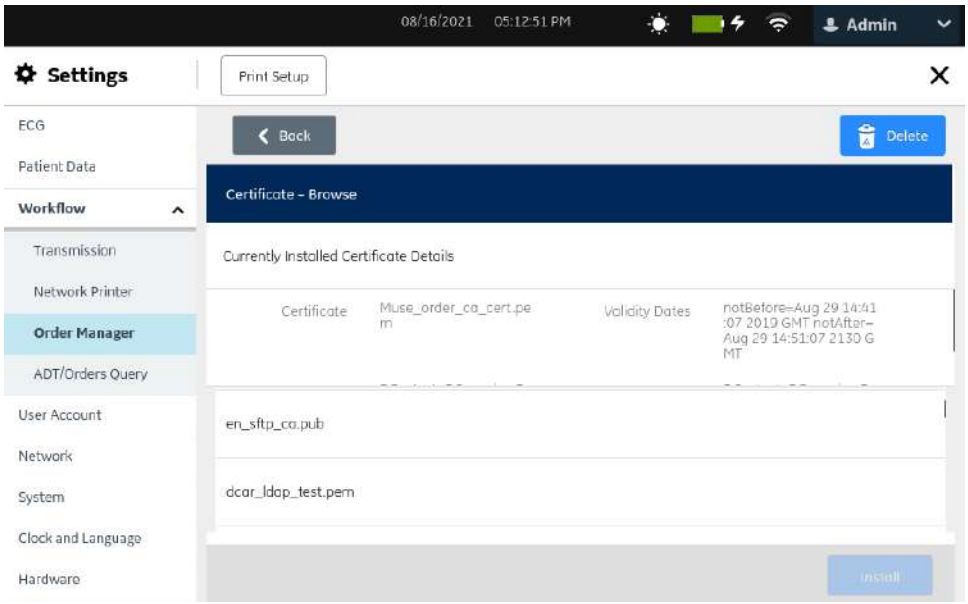
   - If the installation is successful, the CA certificate is saved.
   - If the installation fails because the certificate is in an unrecognized format, an error message displays.

5. Select **Back** to view the MUSE server setting screen.

Delete MUSE SSL CA Certificate

Before you start this procedure, make sure that your user role is assigned with user management privilege.

1. Select **Settings** > **Workflow** > **Order Manager**.
2. Select **MUSE** to view the MUSE server settings.
3. Perform the steps below to delete the currently installed MUSE CA certificate:
   a) Select **Browse** from the **Install Certificate** field.
   The currently installed certificate displays.



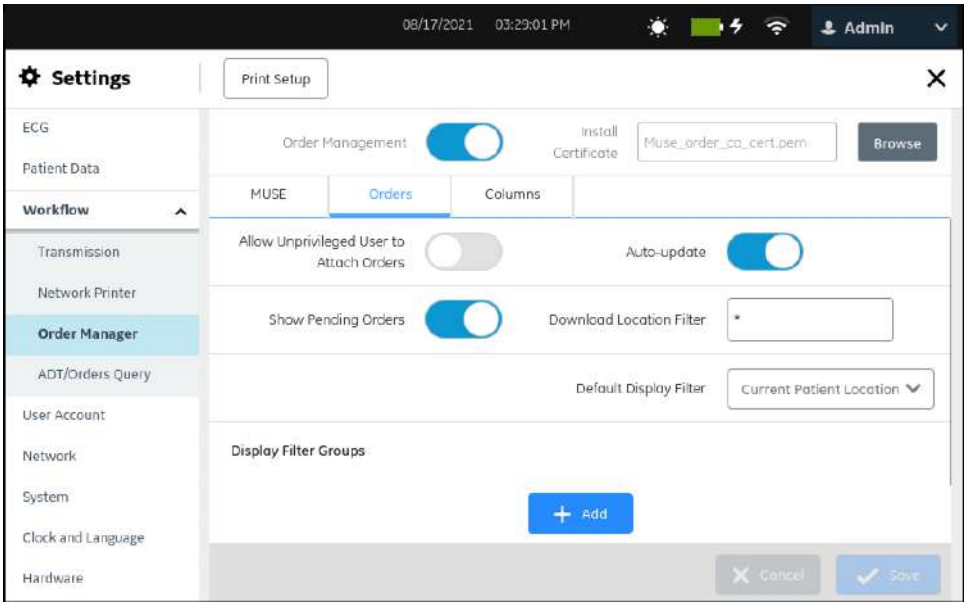
   b) Select **Delete**.
   A message displays asking you to confirm the deletion of the certificate.
   c) Select **OK**. The certificate or key is deleted.
4. Select **Back** to view the MUSE server setting screen.

Configure Display Filter Groups

Make sure that order management is enabled and the MUSE server is configured. See *Configure Order Management on page 186*.

A display filter group displays the configured group of locations at your facility. You can filter the orders in the **Orders** view based on the selected location. You can configure a maximum of 10 display filter groups.

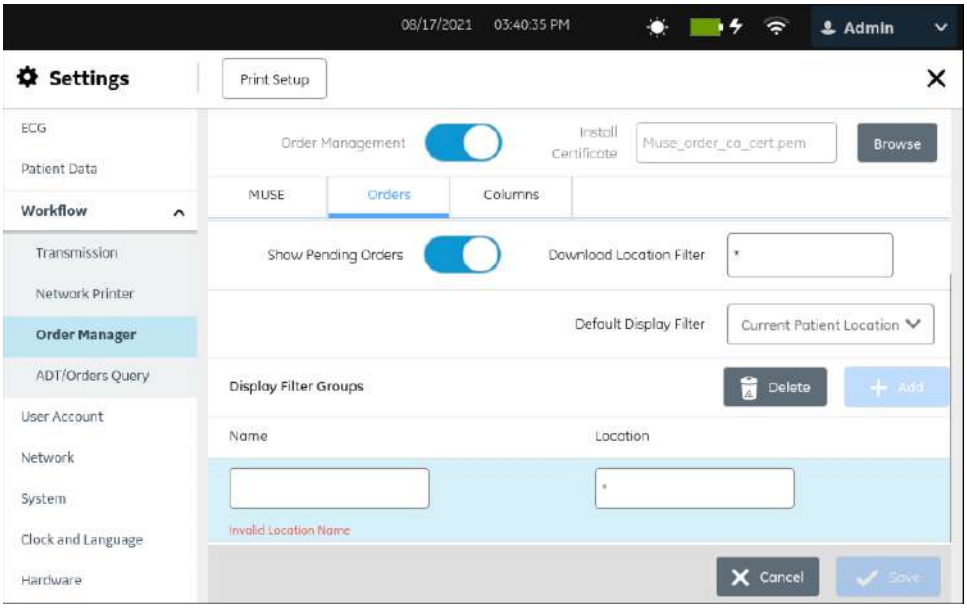
1. Select **Settings** > **Workflow** > **Order Manager**.
2. Select **Orders**.
   The **Order Manager** screen displays.



3. Perform any of the steps below in the **Display Filter Groups** section to configure filter groups.
   - To add a **Display Filter Group**, perform step 4 to step 7.
   - To edit a **Display Filter Group**, perform step 8.
   - To delete a **Display Filter Group**, perform step 9.

4. Select the **Add** icon  to add a display filter group.

   A new row is added to the table.



5. Configure a display filter group as per the information in the table.

Table 57: Configure Display Filter Groups

Field	*Action*	*Description*
Name	Enter a name for the display filter group.	The display filter group name must be unique. No default value Allowed values: Up to 20 characters • a to z • A to Z • 0 to 9
Location	Enter the location(s) you want to include for the display filter group.	• If a location of the display filter group is not configured, an asterisk (*) indicating that orders from all locations display to the device. • If an invalid location of the display filter group is configured, an error message displays. Default value: * Allowed values: • 0 to 65534 • Up to 100 characters Individual numbers and number ranges, are supported. Ranges must have a hyphen in between them. For example, 3-50, 45–*. Multiple locations must be comma-separated. For example, to configure download of orders from locations 0, 3, and 10 through 20, enter 0,3,10-20.

6. Select **Save**.
7. Repeat steps 4 to 6 to add more display filter groups.
8. To edit an existing display filter group:
   a) To enable the edit mode, select anywhere in the row of the display filter group configuration you want to modify in the **Display Filter Groups** section.
   b) Make changes to the configuration as per the information in *Table 57: Configure Display Filter Groups on page 194*.
   c) Select **Save**.
9. To delete an existing display filter group:
   a) Select anywhere in the row of the display filter group configuration you want to delete in the **Display Filter Groups** section.
   b) Select the **Delete** icon 

.

c) Select **Save**.

Configure Order Settings

Make sure that order management is enabled. See *Configure Order Management on page 186*.

1. Select **Settings** > **Workflow** > **Order Manager**.
2. Select **Orders**.
3. Configure order settings as per the information in the table.

Table 58: Order Settings

Field	*Action*	*Description*
Allow Unprivileged User to Attach Orders	Enable or disable this setting.	• If this setting is enabled, any user who does not have the privilege to view orders can search for a matching order on the device or on the MUSE system using the **Patient ID** or **Visit Number**, and attach the order to the patient test. A patient query mode must be configured and the user should be assigned the **Query Remote Patient Data** privilege for automatic patient query. • If this setting is disabled, users who do not have the privilege to view orders cannot attach orders by searching for them. • This does not apply to the default STAT user role. Default value: Disabled
Auto-Update	Enable or disable this setting.	If this setting is enabled, the **Orders** list is automatically updated from the configured order management server. Default value: Enabled
Show Pending Orders	Enable or disable this setting.	• If this setting is enabled, the system displays all pending orders, regardless of the device used to move the order to the pending state. Default value: Enabled

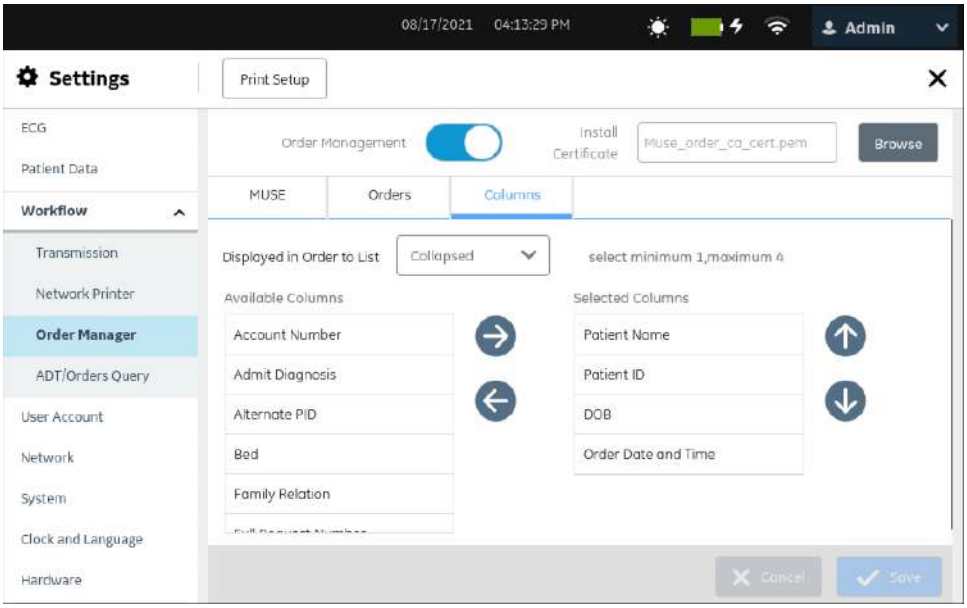
4. Select **Save**.

Configure Columns for the Orders List

Make sure that order management is enabled. See *Configure Order Management on page 186*.

The columns displayed in the **Orders** list on the Acquisition screen are configurable.

1. Select **Settings** > **Workflow** > **Order Manager**.
2. Select **Columns**.



3. Select **Collapsed** or **Expanded** in the **Displayed in Order to List** drop-down list.

Table 59: Column Settings for Orders List

Field	*Number of Columns Supported*	*Default Columns in List*
Displayed in Order to List (Collapsed) **NOTE**: If this list does not include one or more of the columns below: **Patient Name**, **Patient ID**, or **Visit Number**, an error message displays.	1 to 4 columns	• **Patient Name** • **Patient ID** • **DOB** • **Order Date and Time** **NOTE**: Upon a factory reset, these column names display in the same order as in the **Orders** list.

Field	*Number of Columns Supported*	*Default Columns in List*
Displayed in Order to List (Expanded) **NOTE**: This list includes the columns in the collpased list by default.	1 to 11 columns	• **Patient Name** • **Patient ID** • **DOB** • **Order Date and Time** • **Order Number** • **Ordering MD ID** • **Order Type** • **Location** • **Room** • **Priority** • **Status** **NOTE**: Upon a factory reset, these column names display in the same order as in the **Orders** list.

4. Configure the columns to display in each view:

   a) To include columns in the **Orders** collapsed or expanded list, select a column name in the available columns list on the left-side and select the right arrow ➔ to move the column name to the selected column list on the right-side.

   b) To exclude columns from the **Orders** collapsed or expanded list, select a column name in the selected columns list on the right-side and select the left arrow ← to move the column name to the available columns list on the left-side.

   c) Repeat steps *(a)* and *(b)* until the desired list of columns to display in the collapsed and expanded lists are included in the selected columns list on the right-side.

5. To reorder the columns in the **Orders** list, select a column name and use the up arrow ^ or down arrow ⌄.

   NOTE:
   By default, the **Orders** collapsed and expanded lists are always sorted by location, in descending order. If the **Location** field does not display, the orders list is sorted based on the information in the first column, in descending order.

6. Select **Save**.

Patient Query Overview

The patient query results differ depending on the privileges assigned to the user and the configured patient query setting.

When the **View Orders** user privilege or **Allow Unprivileged User to Attach Orders** setting is on and the **Query Remote Patient Data** user privilege is on:

NOTE:
The ADT and Orders can only be retrieved by the Patient ID or Visit Number and not by both.

If the Patient query setting is ...	*Then ...*
Query Orders	Searching by the Patient ID or Visit Number retrieves matching orders on the device or the MUSE system.
Query Orders then ADT	Searching by the Patient ID or Visit Number retrieves matching orders on the device or the MUSE system. If no orders are found, an ADT query is triggered.
Query ADT Only	Searching by the Patient ID or Visit Number triggers an ADT query on the MUSE system.

When the **View Orders** user privilege or **Allow Unprivileged User to Attach Orders** setting is off and the **Query Remote Patient Data** user privilege is on:

If the Patient query setting is ...	*Then ...*
Query Orders	No records are retrieved.
Query Orders then ADT or **Query ADT Only**	An ADT query is triggered on the MUSE system.

If the user does not have the **Query Remote Patient Data** privilege, ADT query cannot be triggered, irrespective of the configured patient query setting. The search results differ depending on the search criterion:

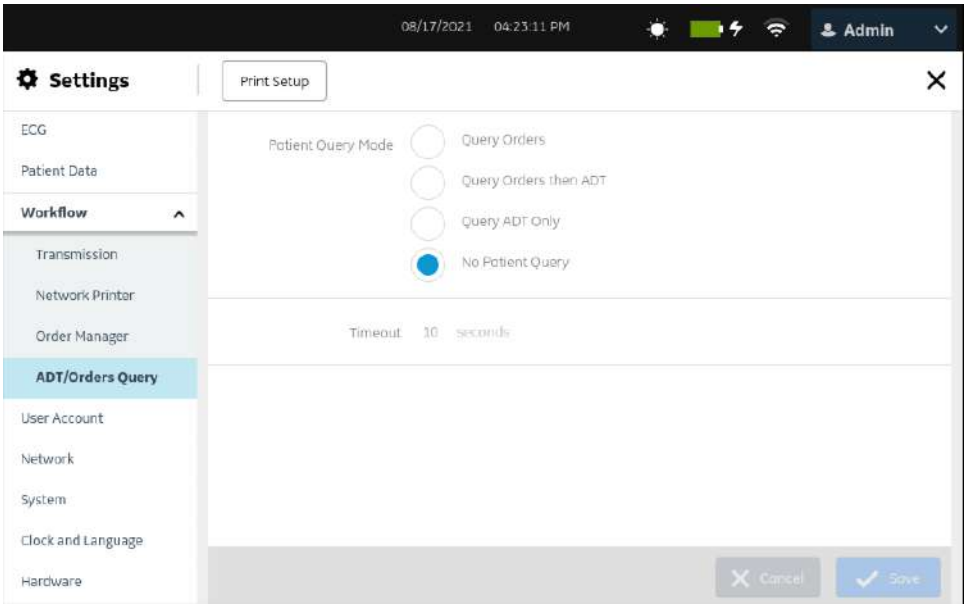
Table 60: Patient Query Result

Search criterion	*Patient query setting*	*DCP destination with ADT enabled and MUSE order server setting*	*Search result*
Patient ID or Visit Number	**Query Orders**	Configure MUSE Order Server settings.	Patient ID search: Matching local or remote orders are retrieved. Visit Number search: Only matching local orders are retrieved.

Search criterion	*Patient query setting*	*DCP destination with ADT enabled and MUSE order server setting*	*Search result*
Visit Number	**Query Orders**	Configure DCP server with ADT enabled corresponding to MUSE Order Server settings and make sure that both IP addresses are same.	Matching local or remote orders are retrieved.
Patient ID or Visit Number	**Query Orders then ADT**	Configure DCP server with ADT enabled corresponding to MUSE Order Server settings and make sure that both IP addresses are same.	Matching local or remote orders are retrieved (if found), otherwise matching ADT data (from remote server) is retrieved.
Patient ID or Visit Number	**Query ADT Only**	Make sure that the DCP server destination is enabled with ADT.	Only matching ADT data is retrieved from remote server.

Configure Remote Patient Query

1. Select **Settings** > **Workflow** > **ADT/Orders Query**.
   The **ADT/Orders Query** screen displays.



2. Configure the fields as per the information in the table:

Table 61: Patient Query Settings

Field	*Action*	*Description*
Patient Query Mode	Select an option to configure the patient query mode.	Default value: **No Patient Query** Allowed values: • **Query Orders** • **Query Orders then ADT** • **Query ADT Only** • **No Patient Query**
Timeout	Enter the duration (in seconds) that the network waits for a response to the ADT query, before a timeout error displays.	Default value: **10** Allowed values: 0 to 1000

3. Select **Save**.

User Account

Make sure that your user role is assigned to the user account privilege.

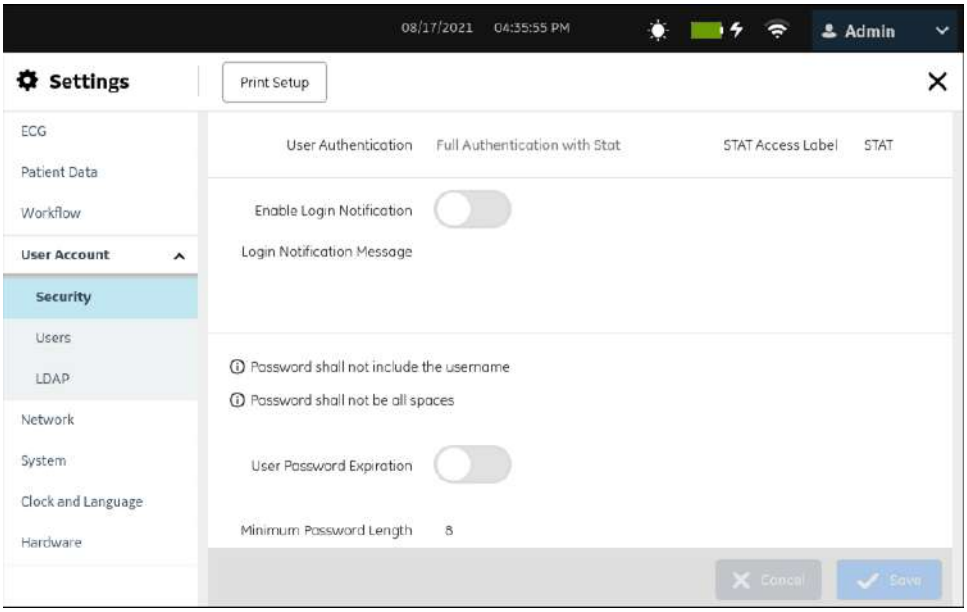
If...	*Then...*
Users are managed locally	Perform the following configurations: • *Configure User Profiles on page 213* • *Configure User Roles on page 209*
Users are managed using LDAP	*Configure LDAP on page 216*.

Select **Settings** > **User Account** menu to configure the following:

- Security - *Configure Security on page 201*
- User Roles:
  - *Types of User Roles on page 206*
  - *Configure User Roles on page 209*
- User Profiles:
  - *Types of User Profiles on page 207*
  - *Configure User Profiles on page 213*
- LDAP - *Configure LDAP on page 216*

Configure Security

1. Select **Settings** > **User Account** > **Security**.
   The **Security** screen displays.



2. Configure the fields as per the information in the table.

Table 62: Configure Security

Field	*Action*	*Description*
User Authentication	Select a value from the drop-down list to configure the type of user authentication for the device.	• If **Full Authentication with STAT** is selected, the device displays a login screen.  The **STAT User** selects the **STAT** button to access the device without any password credentials. All other users need to log on to the device with a user name and password. • If **No Authentication** (default) is selected, the device does not display a login screen. Users access the device without a user name and password. • If **Technician ID** is selected, the device displays a login screen. Users access the device by entering a **Technician ID**.  Default value: **No Authentication** **NOTE**: If you enable user authentication, you are automatically logged off after saving the settings. The login screen displays. You need to log in to the device with the correct login credentials based on the configured mode of user authentication.

Field	*Action*	*Description*
STAT Access Label	Enter the label name to display in the login screen.	This field is enabled only when the **Full Authentication with STAT** setting is selected from the **User Authentication** field. Default value: **STAT** Allowed values: 1 to 20 characters • A to Z • a to z • 0 to 9 • All special characters
Enable Login Notification	Enable or disable this setting.	If this setting is enabled, the **Login Notification Message** field is enabled. You must configure a notification message that displays at the time of login and acknowledged by users who attempt to log in to the device. If this setting is disabled, the **Login Notification Message** field is disabled. Default value: Disabled
Login Notification Message	Enter the login notification message.	No default value Allowed values: Up to 15000 characters • A to Z • a to z • 0 to 9 • All special characters
User Password Expiration	Enable or disable this setting.	If this setting is enabled, set the duration for password expiration in the **Password lifetime duration Minimum and Maximum (days)** fields. The password expires after the configured duration, and the user is prompted to set a new password. If this setting is disabled, the password does not expire. Default value: Disabled

Field	*Action*	*Description*
Password lifetime duration (days)	Set the **Minimum** and **Maximum** password expiration duration in days, if **User Password Expiration** setting is enabled.	**Minimum** duration: This specifies the minimum amount of time a password needs to remain unchanged. • If it is set to one day then the password cannot be changed again until tomorrow. • If it is set to seven days then the password cannot be changed again until next week. • If it is set to zero then there is no minimum duration. The password may be changed immediately. **Maximum** duration: This specifies the maximum amount of time a password can exist before it is required to be changed. If it is set to 90 days then the password must be changed after three months. **NOTE**: The expired password will still work but must be changed when used. Default value for minimum and maximum: **1** and **90** Allowed values for minimum and maximum: 0 to 364 and 0 to 365
Minimum Password Length	Set the minimum number of characters required for a user password.	While adding or modifying a user, if the user password does not meet the minimum number of required characters, the password is not accepted by the system. The password must contain a number of characters equal to or greater than the **Minimum Password Length**. Default value: 8 characters Allowed values: 8 to 14 characters
Prevent reuse of previous password	Select a value from the drop-down list to configure the reuse of previous passwords.	This specifies the number of previously used passwords that a user is not allowed to change their password to. Default value: **10** Allowed values: 10 to 32
Account will be locked out after failed logon attempts	Select a value from the drop-down list to lock the account after failed logon attempts.	This specifies the number of repeated failed login attempts that causes a user account to be temporarily locked. **NOTE**: You can login as a STAT user if your account has been locked. Default value: **5** Allowed values: 3 to 99

Field	*Action*	*Description*
Account lockout duration (min)	Select a value from the drop-down list to set the duration (in minutes) for account to be locked.	This specifies to configure the duration in minutes to lock the account. If it is set to one minute then the account will be locked for one minute. You cannot log in for the next one minute. Default value: **1** Allowed values: 1 to 120
Lower Alphabets	Enable or disable this setting.	If this setting is enabled, the lower alphabet characters are required to be used in the password. If this setting is disabled, the lower alphabet characters are not required to be used in the password. Default value: Enabled
Numeric	Enable or disable this setting.	If this setting is enabled, the numeric characters are required to be used in the password. If this setting is disabled, the numeric characters are not required to be used in the password. Default value: Enabled
Upper Alphabets	Enable or disable this setting.	If this setting is enabled, the upper alphabet characters are required to be used in the password. If this setting is disabled, the upper alphabet characters are not required to be used in the password. Default value: Enabled
Special Characters	Enable or disable this setting.	If this setting is enabled, the special characters are required to be used in the password. If this setting is disabled, the special characters are not required to be used in the password. Default value: Enabled
Auto-Lock	Enable or disable this setting.	If this setting is enabled, the device is automatically locked after a configured duration of inactivity. If this setting is disabled, the device is not locked automatically. Default value: Enabled
Inactivity Duration for Autolock (min)	Enter the duration of inactivity (in minutes) after which the system must be automatically locked, if the **Auto-Lock** setting is enabled,	Default value: **15** Allowed values: 1 to 60

3. Select **Save**.

Types of User Roles

The roles below are pre-defined on the device:

- **System Admin**
- **Clinical**
- **STAT**
- **Service**

Table 63: Pre-Defined User Roles

User Role	*Description*	*Default Privileges*
System Admin	The **System Admin** role has all privileges by default. The Administrator can add roles to the locally managed user role list. The privileges of the user-defined role can be changed.	• Access Settings • Activate ECG Simulator • Access Service • View Audit Logs • View Reports • View Orders • Edit Reports • Delete Reports • Transmit Reports • User Management • Software Update • Edit Critical Value Settings* • View Patient List • Query Remote Patient Data
Clinical	The **Clinical** role is assigned to the **Default User** by default. The privileges of the **Clinical** role can be changed. The role of the **Default User** can be changed.	• View Reports • View Orders • Edit Reports • Delete Reports • Transmit Reports • View Patient List • Query Remote Patient Data
STAT	The **STAT** role is assigned to the **STAT User** by default. The privileges of the **STAT** role can be changed. The role of the **STAT User** can be changed.	• Transmit Reports

User Role	*Description*	*Default Privileges*
Service	The **Service** role is assigned to the **Service** user by default. The privileges of the **Service** role can be changed. The role of the **Service** user cannot be changed.	• Access Settings • Activate ECG Simulator • Access Service • Software Update

NOTE:
Roles suffixed with an asterisk (*) in the table display in the **User Roles** screen even if the required settings are not enabled in the **Service** screen. See the *MAC 5 Resting ECG Analysis System Service Manual* for information to enable the settings.

Types of User Profiles

The users below are pre-defined on the device:

- **Admin**
- **Default User**
- **STAT User**
- **Service**

Table 64: Pre-Defined User Profiles

User Profile	*Description*
Admin	This pre-defined administrator can access the device with password credentials to set up, edit, and delete configurations. The default password to login as the **Admin** user is admin123. The **Admin** user is prompted to change the default password immediately after the first login. Only one local **Admin** user can exist on the device. The Administrator can add users to the locally managed user list or configure LDAP-based user authentication. The password-related fields of the **Admin** user can be modified. See *Configure User Profiles on page 213*. **NOTE**: Safeguard the **Admin** user password and make sure that you do not disclose your password to anyone. Do not use the **Admin** user account for day-to-day activities. If the **Admin** user forgets the password for the **Admin** user account: • A user with the **User Management** privilege can change the **Admin** user password in the **Users** settings screen. • A user can initiate system reset by pressing ↑ ↓ ←→ ↑ ↓ ←→ in the **Login** screen and entering the serial number of the device, when prompted. System reset is used to reset all settings to the factory default (which includes the admin password). ALL DATA is also deleted when you do a system reset. The fields below cannot be modified: • User Name • Display Name • Role (**System Admin**) You cannot add, delete, or disable the **Admin** user.
Default User	When user authentication is disabled and the device is turned on to acquire and print an ECG, this pre-defined user is automatically logged in without entering a password. Only one **Default User** can exist on the device. The **Default User** is assigned the **Clinical** role by default. The role of the **Default User** can be modified. See *Configure User Roles on page 209*. The **Default User** does not have access to the **Settings** or **Service** screens by default, and is prompted to log in as a user with privileges to access these screens. However, if the role of the **Default User** is modified to include these privileges, the user can access these screens without user authentication. You cannot add, delete, or disable the **Default User**.

User Profile	*Description*
STAT User	When user authentication with STAT access is enabled, the **STAT User** can access the device without entering a password to acquire, print, and transmit an ECG. The **STAT User** is assigned the **STAT** role by default. The role of the **STAT User** can be modified. See *Configure User Roles on page 209*. You cannot add, delete, or disable the **STAT User**.
Service	By default, the **Service** user profile is disabled in the device. The **Service** user profile can be enabled by a user with appropriate privileges. If the **Service** user profile is enabled, this user can access the device with password credentials when user authentication is enabled. The password for the **Service** user is set when the **Service** user profile is enabled. The customer specifies the password for the **Service** user. **NOTE**: Once the **Service** user profile is disabled, previously set password will not be valid. When the **Service** user profile is enabled next time, you must set a new password. The **Service** user is assigned to the **Service** role by default. You cannot add or delete the **Service** user profile.

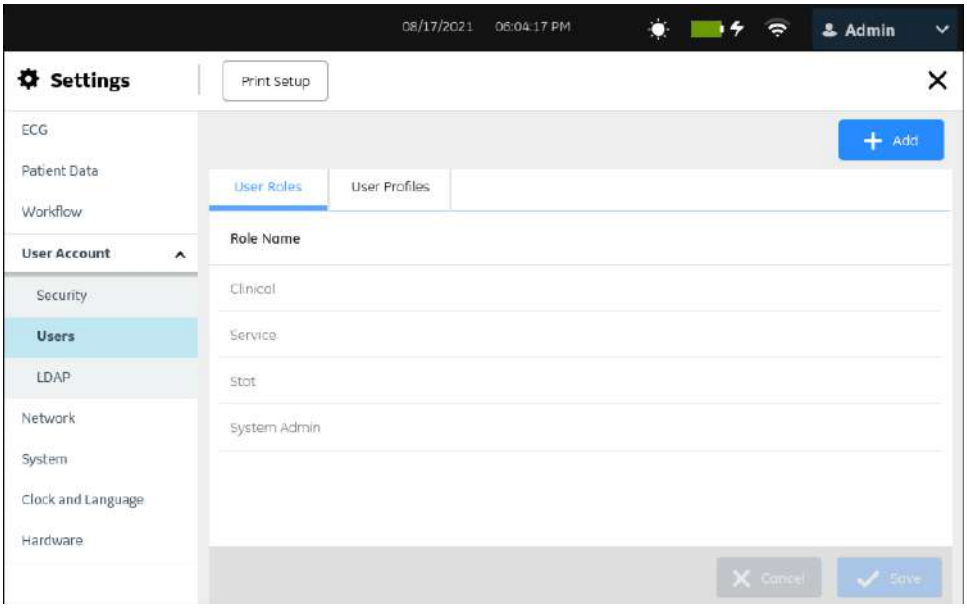
Table 65: User-Defined User Profiles

User Profile	*Description*
Local user	When user authentication is enabled, this locally-added user can access the device with password credentials to perform tasks based on the assigned user privileges. Up to 100 local users can exist on the device. A user with user management privileges can add, modify, delete, or disable a Local user. See *Configure User Profiles on page 213*.
LDAP users	When user authentication is enabled and LDAP-based user authentication is configured, an LDAP user can access the device with password credentials to perform tasks based on the assigned LDAP group role privileges. See *Configure LDAP on page 216*.

Configure User Roles

Make sure that your user role is assigned to the user management privilege.

1. Select **Settings** > **User Account** > **Users**.
2. Select **User Roles**.
   The **User Roles** screen displays.



3. Perform the required procedures to configure user roles, as applicable:
   - To add a user role, perform step 4 to step 7.
   - To edit a user role, perform step 9.
   - To delete a user role, perform step 10.
4. Select the **Add** icon Add to add a user role.
   A new row is added to the user roles table.
5. Configure the user role with the appropriate privileges as per the information in the table.

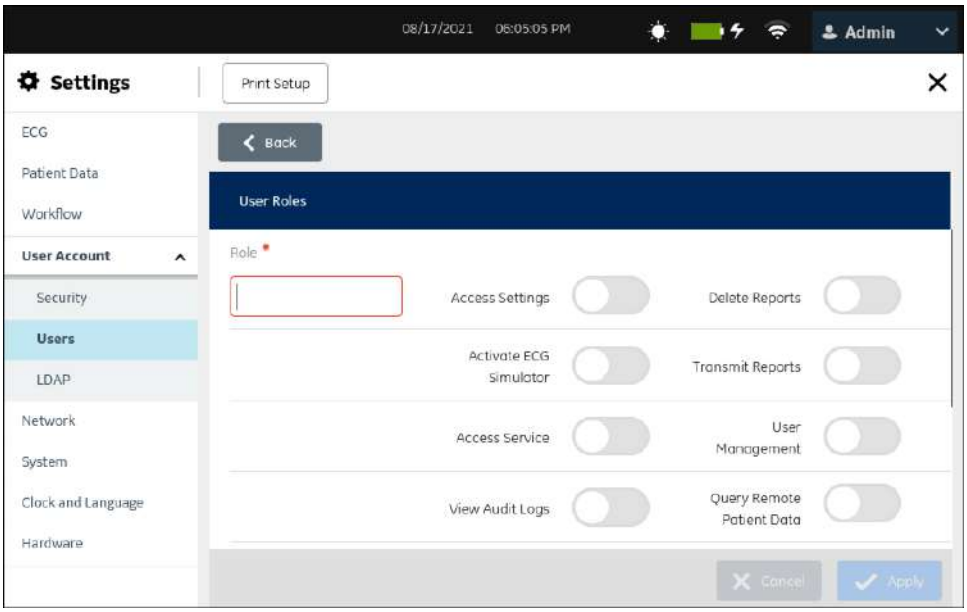


Table 66: Configure User Roles

Field	*Description*
Role Name	Enter the unique name of the user role. Up to 15 characters are allowed.
Access Settings	Access the **Settings** screen and view the newtork parameters upon selecting the network status icon. **NOTE**: If this privilege is disabled: • The **Activate ECG Simulator**, **Edit Critical Value Settings**, and **User Management** privileges are also disabled. • You can only view the network status upon selecting the network status icon, but cannot view the network parameters such as Device Name, IP address, Subnet Mask, MAC address, Gateway address, and DNS.
Activate ECG Simulator	Access to activate the ECG simulator. **NOTE**: If this privilege is enabled, the **Access Settings** privilege is also enabled.
Access Service	Access the **Service** screen. **NOTE**: If this privilege is disabled, the **Software Update** and **View Audit Logs** privileges are also disabled.
View Audit Logs	View audit logs. **NOTE**: If this privilege is enabled, the **Access Service** privilege is also enabled.
View Reports	View patient reports previously stored in the **Files** view. **NOTE**: If this privilege is disabled, a user can only view patient reports that acquired during their current login session.
View Orders	View orders in the **Orders** view.
Edit Reports	Edit stored patient reports. **NOTE**: If the user only has edit patient report privileges and not viewing patient report privileges, they can only edit patient reports they acquired.
Delete Reports	Delete stored patient reports.
Transmit Reports	Transmit patient reports.

Field	*Description*
User Management	Manage the user profiles and user roles. **NOTE**: If you enable this privilege, the **Access Settings** privilege is also enabled.
Software Update	Update the software on the device. **NOTE**: If you enable this privilege, the **Access Service** privilege is also enabled.
Edit Critical Value Settings	Edit the critical values setting. **NOTE**: This privilege displays only if the CRIT option is purchased and enabled. Contact GE Healthcare Service Support to purchase this option. If you enable this privilege, the **Access Settings** privilege is also enabled.
View Patient List	View the patient list.
Query Remote Patient Data	Query a remote patient data.

6. Select **Apply**.
7. Repeat steps *4* to *6* to add more user roles.
8. Select **Save**.
9. To edit an existing user role:
   a) To enable the edit mode, select anywhere in the row of the user role configuration you want to modify.
   b) Make changes to the user role. For a description of privileges, see *Table 66: Configure User Roles on page 211*.
   c) Select **Apply**.
   d) Select **Save**.
10. To delete an existing user role:

    NOTE:
    If the role you are attempting to delete is assigned to a user profile or LDAP Group, the role cannot be deleted.

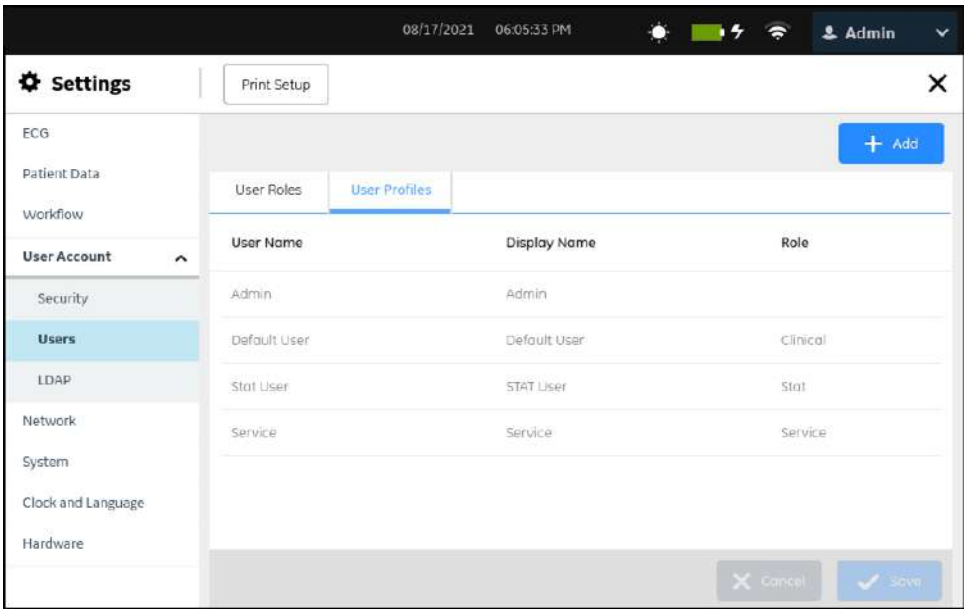
    a) To enable the edit mode, select anywhere in the row of the user role configuration you want to delete.
    b) Select **Delete**.
    A message displays to confirm if you want to delete the user role.
    c) Select **Yes** to confirm the deletion of the user role.

d) Select **Save**.

Configure User Profiles

Make sure that your user role is assigned to the user management privilege.

1. Select **Settings** > **User Account** > **Users**.
2. Select **User Profiles**.
   The configured user profiles are listed in the table *Table 67: Configure User Profiles on page 214*. If no user profile is configured, the table is empty.



3. Perform the required procedures to configure user profiles, as applicable:
   - To add a user profile, perform step *4* to step *7*.
   - To edit a user profile, perform step *9*.
   - To delete a user profile, perform step *10*.
4. Select the **Add** icon

to add a user profile.
   A new row is added to the user profile table.
5. Configure the user profile as per the information in the table.

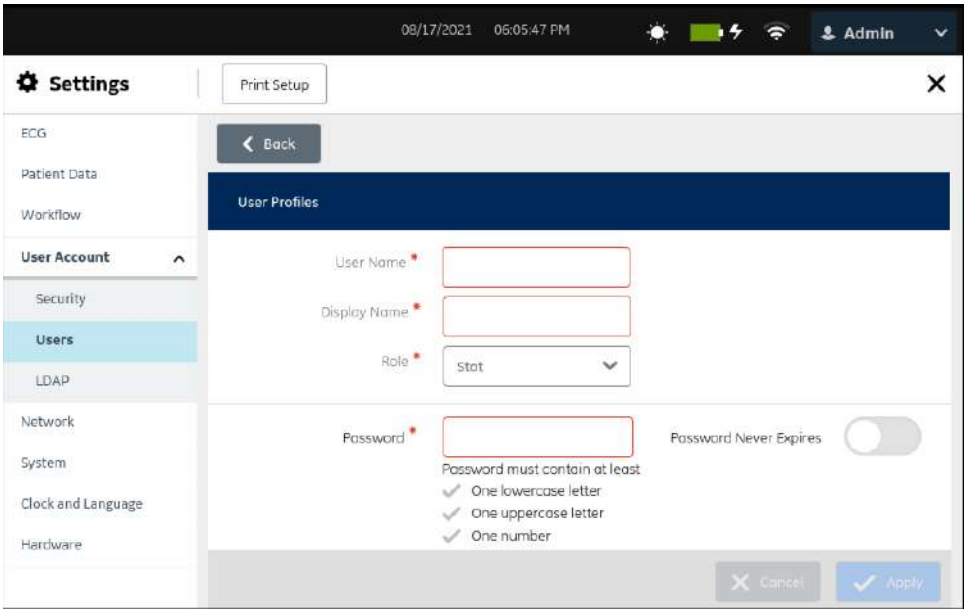


Table 67: Configure User Profiles

Field	*Action*	*Description*
User Name	Enter a unique name for the user.	If a user with the same user name already exists, an error message displays. This is a required field. No default value. Allowed values: User-defined value up to 15 characters
Display Name	Enter a unique display name for the user.	This name displays on the User Menu on the Acquisition screen. This is a required field. No default value. Allowed values: User-defined value up to 50 characters
Role	To assign a user role to the user, select the role from the drop-down list.	Default value: No default value Allowed values: • **System Admin** • **Clinical** • **Stat** • **Service** • All user-defined roles

Field	*Action*	*Description*
Password	Enter the password for the user according to the password rules listed in the Description column.	Each character in the password displays an asterisk (*). If the password rules are not met, the **Password** field display a red box and relevant error messages. Allowed values: • User-defined value up to 126 characters • Minimum number of characters and type of characters allowed is set in the **Security** settings screen. See *Configure Security on page 201*. No default value. **NOTE**: If a local user forgets the user password, a user with the **User Management** privilege can change the password for the user account in the **Users** settings screen. The local user can log into the device with the changed password.
Confirm Password	Enter the exact duplicate entry of the password entered in the **Password** field	Each character in the password displays an asterisk (*). If there is a mismatch with the password entered in this field and the **Password** field, the **Confirm Password** field displays a red box. Re-enter the password to match the **Password** field. No default value.
Technician ID	Enter the Technician ID associated with the user.	This field can be blank. No default value. Allowed values: • a to z • A to Z • 0 to 9 • All special characters User-defined value up to 20 characters.
Password Never Expires	Enable or disable this setting.	• If this setting is enabled, the password of this user does not expire, even if a duration for password expiration for all users of this device is set in the **Password Expiration Duration** field in the **Security** settings screen. • If this setting is disabled, the password of this user expires when the time of the password exceeds the duration for password expiration set in the **Password Expiration Duration** field in the **Security** settings screen. Default value: Disabled

Field	*Action*	*Description*
Disable User	Enable or disable this setting.	• If this setting is enabled, the user is disabled from using the device. • If this setting is disabled, the user is enabled to access the device. Default value: Disabled
Force User to Change Password at Next Login	Enable or disable this setting.	• If this setting is enabled, the user must change the password at the next login. • If this setting is disabled, the user does not need to change the password at the next login. Default value: Enabled **NOTE**: This setting is always disabled for default **Service** user.

6. Select **Apply**.
7. Repeat steps 4 to 6 to add more user profiles.
8. Select **Save**.
9. To edit an existing user profile:
   a) To enable the edit mode, select anywhere in the row of the user profile you want to modify.
   b) Make changes to the user profile as per the information in *Table 67: Configure User Profiles on page 214*.
   c) Select **Apply**.
   d) Select **Save**.
10. To delete an existing user profile:
    a) To enable the edit mode, select anywhere in the row of the user profile configuration you want to delete.
    b) Select **Delete**.
    A message displays to confirm if you want to delete the user profile.
    c) Select **Yes** to confirm the deletion of the user profile.
    d) Select **Save**.

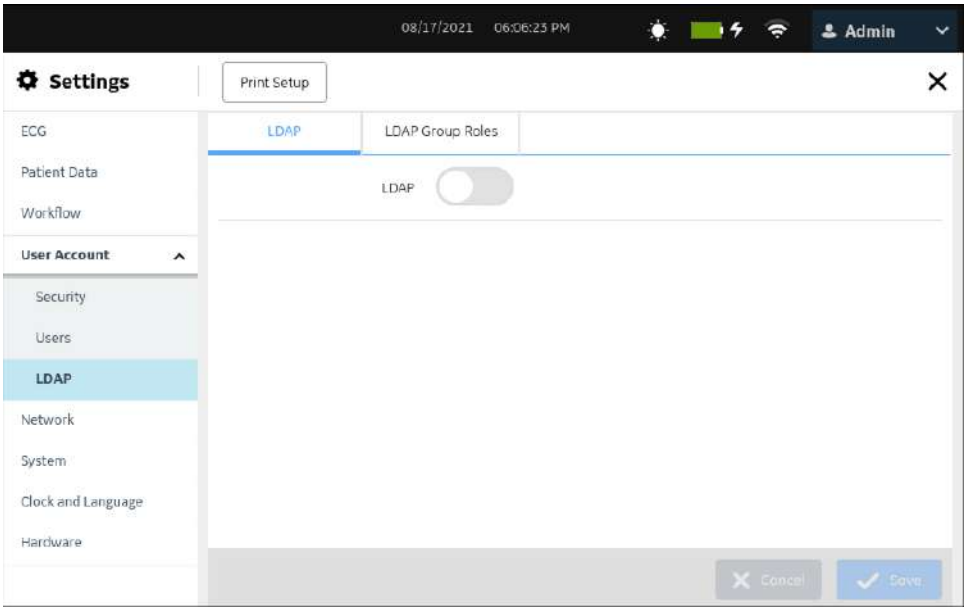
Configure LDAP

Make sure that your user role is assigned the user management privilege.

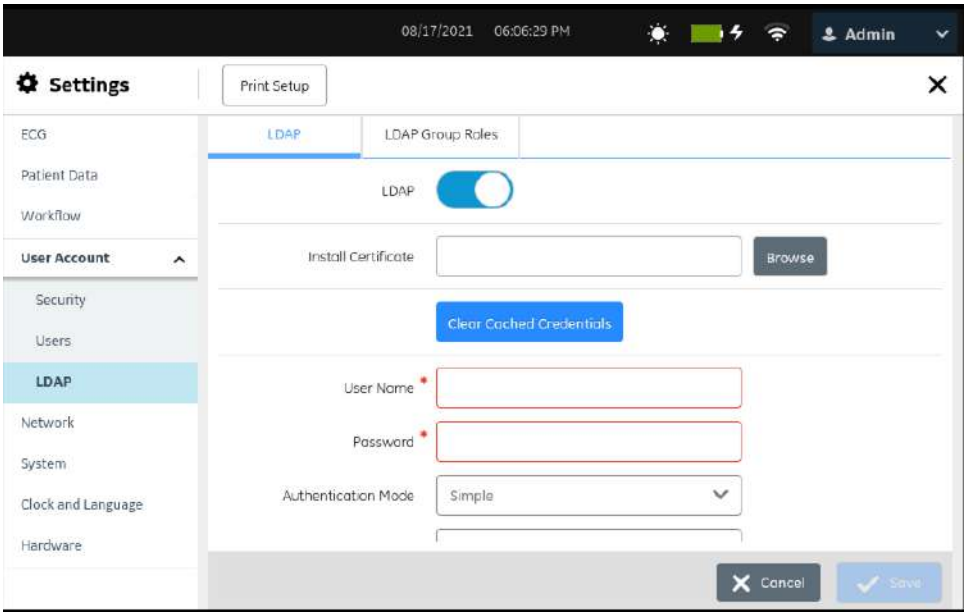
Full Authentication with Stat must be configured for LDAP authentication.

1. Select **Settings** > **User Account** > **LDAP**.

2. Select **LDAP** to view the LDAP settings.
   The **LDAP** screen displays.



3. Enable **LDAP** setting.



4. Configure **LDAP** as per the information in the table.

Table 68: Configure LDAP

Field	*Action*	*Description*
LDAP	Enable or disable this option.	If this option is enabled, technicians can log in to the device remotely using their network credentials. Default value: Disabled

Table 69: Configure LDAP Server

Field	*Action*	*Description*
User Name	Enter the valid username.	This field is enabled if the **LDAP** option is enabled. No default value. The LDAP user profiles are managed by the LDAP server administrator. Obtain your username from the LDAP server administrator. This account has read only access to the LDAP hierarchy that contains the details of all users who logs on to the system. Username can be entered in the formats below: • Name (only) • Domain\Name • Email ID
Password	Enter the valid password.	This field is enabled if the **LDAP** option is enabled. No default value. The LDAP user profiles are managed by the LDAP server administrator. Obtain your password from the LDAP server administrator. There is no limit on the maximum number of characters on the device. Different LDAP servers have their own limit. Allowed values: • A to Z • a to z • 0 to 9 • All special characters
Authentication Mode	From the drop-down list, select the desired Authentication Mode.	This field is enabled if the **LDAP** option is enabled. Default value: **Simple** GE Healthcare recommends that you use **ldaps://** server or TLS encryption certificate if you configure **Simple** authentication mode. Allowed value: • Simple • Digest-MD5 • Kerberos Authentication mode is provided by LDAP server administrator.

Field	*Action*	*Description*
Kerberos Realm	Enter the Kerberos Realm. It must be entered in upper case.	This field displays only if **Kerberos** authentication mode is selected. No default value. Obtain the domain name from the LDAP server administrator.
DC Host	Enter the Distribution Center host name.	This field displays only if **Kerberos** authentication mode is selected. No default value. Obtain the host name from the LDAP server administrator.
DC Port	Enter a valid Distribution Center port number.	This field displays only if **Kerberos** authentication mode is selected. Default port for ldaps:// is 636. Default port for ldap:// is 389. Obtain the DC port number from the LDAP server administrator.
User Login Format	Enter the login format.	This field is enabled if the **LDAP** option is enabled. User Login Format is provided by LDAP server administrator. This is a comma separated list of LDAP user name attributes. For example: ***cn*** and ***sAMAccountName***.
Server Name	Enter the IP Address, hostname, or fully qualified domain name.	This field is enabled if the **LDAP** option is enabled. Default value: **ldaps://** Allowed values: A valid ldap or ldaps URL **NOTE**: • If you configure an ldaps URL, the **Use CA Certificate** option displays. • If you configure an ldap URL, the **Use TLS Encryption** option displays. **NOTE**: **You can secure some communication channels with encryption and authentication. GE Healthcare recommends that you use the encrypted channels, not the unencrypted channels. For example:** • **LDAPS with CA certificate provides encryption and server authentication.** • **LDAPS without CA certificate and LDAP with TLS only provides encryption.**

Field	*Action*	*Description*
Server Port Number	Enter a valid LDAP service port number.	This field is enabled if the **LDAP** option is enabled. No default value. Allowed values: 1 to 65535
Use CA Certificate	Enable or disable this option.	This field displays only if an ldaps URL is configured. If this option is enabled, a CA certificate is required to authenticate and connect to the LDAP server. Install a CA certificate. See *Install LDAP SSL CA Certificate on page 225*. If this option is disabled, a CA certificate is not required to connect to the LDAP server. The data is encrypted regardless of whether a CA certificate is installed. **NOTE**: GE Healthcare recommends that you use a CA certificate when you connect to the LDAP server. If you do not use a CA certificate, the device runs the risk of connecting to an unauthorized LDAP server, potentially enabling an attacker to gain full access to the device and any data that is stored on it. Default value: Disabled
Use TLS Encryption	Enable or disable this option.	This field displays only if an ldap URL is configured. If this option is enabled, the connection to the configured LDAP server is encrypted. If this option is disabled, the connection to the configured LDAP server is not encrypted. Default value: Disabled
Default Domain Name	Enter a valid domain name.	This field is enabled if the **LDAP** option is enabled. This domain name is used if the LDAP user does not enter a domain name to login. If a local user with the same user name exists, then an LDAP user must enter the domain name and user name in the **User Name** field of the Login screen. No default value. Allowed values: • A to Z • a to z • 0 to 9 • All special characters

5. Select **Test Connection** to test the connection to the LDAP server.
   - If the connection is successful, a success message displays.

- If the connection fails due to an error, resolve the error. See *LDAP Configuration Errors on page 286*.

6. Configure the **Name Path to Groups** as per the information in the table. The **Name Path to Groups** limits the available groups used to determine roles to only those groups within the given path.

Table 70: Configure Name Path to Groups

Field	*Action*	*Description*
Name Path to Groups	Enter a valid name path to groups (For example, OU=Groups, OU=Clinical Users, DC=domain, DC=com; CN=Roles, O=GE, C=US).	This field is enabled if the **LDAP** option is enabled. Default value: No default value Allowed values: • A to Z • a to z • 0 to 9 • All special characters

7. Select **Test Connection** to test the connection.
   - If the connection is successful, a success message displays.
   - If the connection fails due to an error, resolve the error. See *LDAP Configuration Errors on page 286*.

8. Configure the **Name Path to Users** as per the information in the table. The **Name Path to Users** limits the possible users that can authenticate to the device to only those users within the given path.

Table 71: Configure Name Path to Users

Field	*Action*	*Description*
Name Path to Users	Enter a valid name path to users (For example, OU=Users, OU=Clinical Staff, DC=domain, OU=Users, DC=com; O=GE, C=US).	This field is enabled if the **LDAP** option is enabled. Default value: No default value Allowed values: • A to Z • a to z • 0 to 9 • All special characters

9. Select **Test Connection** to test the connection.
   - If the connection is successful, a success message displays.
   - If the connection fails due to an error, resolve the error. See *LDAP Configuration Errors on page 286*.
10. Save and close the screen.
    The **Acquisition** screen displays.

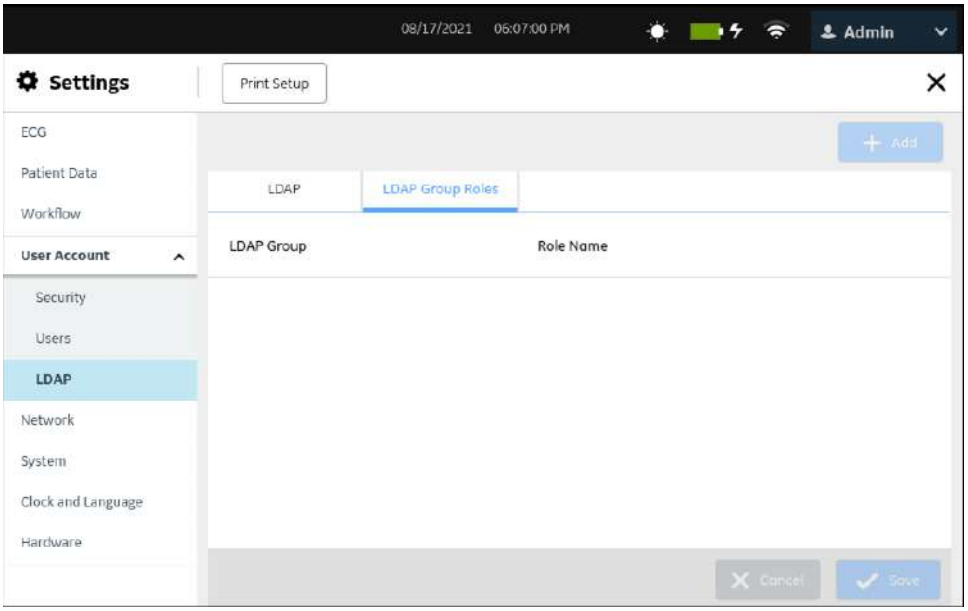
Configure LDAP Group Roles

Make sure that your user role is assigned with user management privilege.

Make sure that the LDAP setting is enabled and configured with a valid distinguished name path to groups. See *Configure LDAP on page 216*.

When you log in to the device as an LDAP user, you will have the privileges of the first LDAP group role that matches a group in your LDAP account in the list.

1. Select **Settings** > **User Account** > **LDAP**.
2. Select **LDAP Group Roles**.
   The configured **LDAP Group Roles** display on the screen.



3. Perform any of the steps below to configure an LDAP group role, as applicable:
   - To add an LDAP group role, perform step *4* to step *6*.
   - To edit an LDAP group role, perform step *7*.
   - To delete an LDAP group role, perform step *8*.
   - To reorder an LDAP group roles, perform step *9*.

4. Select the **Add** icon 

to add an LDAP group role.
The **Add** panel opens on the right-side of the screen.

5. Configure an **LDAP Group Role**:
   a) Enter the search timeout in seconds for the LDAP group search in the **Search Timeout (sec)** field. The default value is 60 seconds. The allowed values are 0 to 999 seconds.
   b) Enter a valid search pattern for the LDAP groups in the **Group Name** field.
      Examples of search patterns: ABC, *ABC, ABC*, *ABC*
      NOTE:
      You can enter part of the name of the group preceded by or followed by *****, or full name of the group and press the **Search** icon to show the configured LDAP groups.
   c) Select the user role from the **Role** drop-down list to map the role to the LDAP group.
   d) Select **Apply** to add the configuration.

The users belonging to the LDAP group are assigned the privileges of the user role mapped to the LDAP group.

6. Repeat steps 4 to 5 to add more LDAP group roles. After adding the LDAP group roles, save and close the screen.
   The **Acquisition** screen displays.
7. To edit an existing LDAP group role:
   a) Select the **Edit** icon next to the LDAP group role you want to edit.
      - When you are logged in as LDAP user and try to edit the group that you are assigned, an error message displays: **This group is assigned to the currently logged in LDAP user and cannot be edited**.
      - If not, the **Edit** panel opens on the right-side of the screen.
   b) Make changes to the LDAP group role as per the information in step 5.
   c) Select **Apply**.
   d) Save and close the screen.
      The **Acquisition** screen displays.
8. To delete an existing LDAP group role:
   a) Select the **Delete** icon next to the LDAP group role you want to delete.
      - When you are logged in as LDAP user and try to delete the group that you are assigned, an error message displays: **This group is assigned to the currently logged in LDAP user and cannot be deleted**.
      - If not, a message displays asking you to confirm if you want to delete the LDAP group.
   b) Select **Yes** to confirm the deletion of the LDAP group role.
   c) Save and close the screen.
      The **Acquisition** screen displays.
9. To reorder the LDAP group roles:
   a) Select the LDAP group role you want to reorder and drag and drop it to the desired order in the LDAP group role table.
   b) Repeat the above step to reorder other LDAP group roles.
   c) Save and close the screen.
      The **Acquisition** screen displays.

Modify LDAP User

Make sure that your user role is assigned with user management privilege.

1. Select **Settings** > **User Account** > **LDAP**.
2. Select **LDAP** to view the LDAP settings.

3. To modify the added LDAP user, see *Configure LDAP on page 216*.
4. When you are logged in as LDAP user and try to configure different LDAP user and server configuration, the error message: **Changes to the LDAP server configuration may affect the added groups** displays.
5. Select **Yes** to confirm.
   The existing LDAP user will be invalid.
6. Save and close the screen.
   The **Acquisition** screen displays.

Clear LDAP Cached Credentials

Make sure that your user role is assigned with user management privilege.

Make sure that the LDAP setting is enabled. For more information, see *Configure LDAP on page 216*.

1. Select **Settings** > **User Account** > **LDAP**.
2. Select **LDAP** to view the LDAP settings.
3. Enable **LDAP** setting.
4. Select **Clear Cached Credentials** to clear the cache of stored LDAP user credentials.
   When a user successfully logs into the system, the user credentials are stored in the cache. If the network is down, the user can sucessfully login when in cache. If the cache is cleared, the user will not be able to login unless the network is connected.
   A message displays asking you to confirm if the cached LDAP credentials can be cleared.
5. Select **Yes**.
   - If the action is successful, a success message displays. The cache of stored LDAP user credentials is cleared.
   - If the action fails, a failure message displays.

Install LDAP SSL CA Certificate

Before you start this procedure, make sure that:

- Your user role is assigned with user management privilege.
- You obtain the required certificate in the PEM format from your IT department and copy it to the root folder of a USB flash drive for installation.
- You **Enable External USB Storage** in **Settings** > **System** > **Storage** setting. If this setting is not enabled, access to USB flash drives is blocked.
- You enable at least one USB port in **Settings** > **Hardware** > **USB Port** setting. If this setting is not enabled, the device will not recognize the USB flash drives.

1. Connect the USB flash drive containing the CA certificate to the device.
2. Select **Settings** > **User Account** > **LDAP**.
3. Select **LDAP** to view the LDAP settings.
4. Enable **LDAP** setting.
5. Perform the steps below to install a CA certificate:
   a) Select **Browse** from the **Install Certificate** field and select the CA certificate from the USB flash drive.
   b) Select **Save**.
      - If the installation is successful, the CA certificate is saved and the **Install Certificate** dialog is closed.
      - If the installation fails because the certificate is in an unrecognized format, an error message displays.

Delete LDAP SSL CA Certificate

Before you start this procedure, make sure that your user role is assigned with user management privilege.

1. Select **Settings** > **User Account** > **LDAP**.
2. Select **LDAP** to view the LDAP settings.
3. Enable **LDAP** setting.
4. Perform the steps below to delete the currently installed CA certificate:
   a) Select the **Browse** setting.
   The currently installed certificate displays.
   b) Select **Delete**.
   A message displays asking you to confirm the deletion of the certificate.
   c) Select **Yes**. The certificate or key is deleted.

Configure Network

You can configure and enable both wired and wireless network connections on the same device. If you enable the wireless and wired connection, the device automatically switches to the wired connection when you connect the LAN cable. If you remove the LAN cable, the device uses the wireless connection.

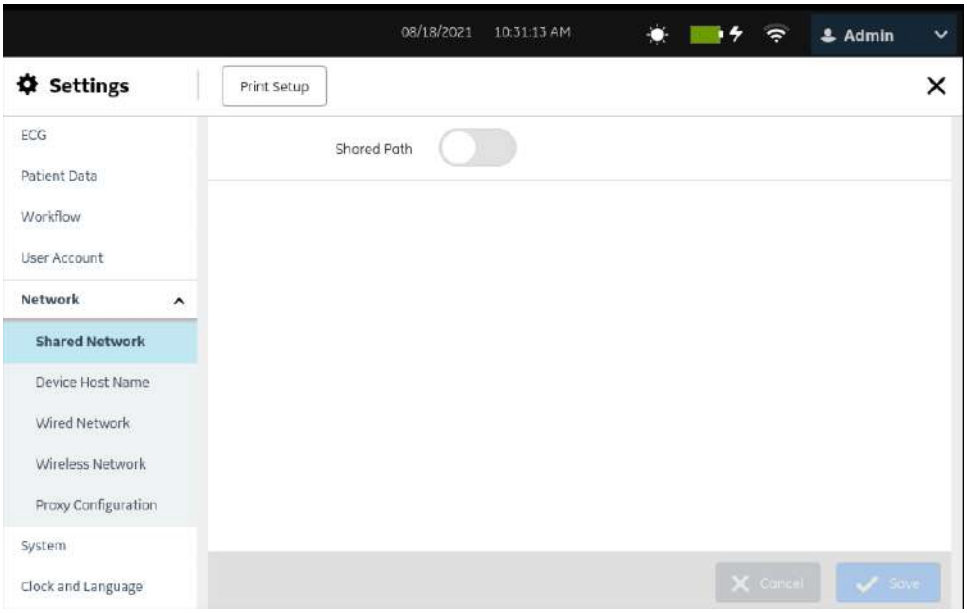
Select **Settings** > **Network** menu to configure the following:

- Shared Network - *Configure Shared Network Settings on page 227*
- Device Host Name - *Configure Device Host Name on page 228*
- Wired Network - *Configure Wired Network on page 229*
- Wireless Network - *Configure Wireless Network on page 231*

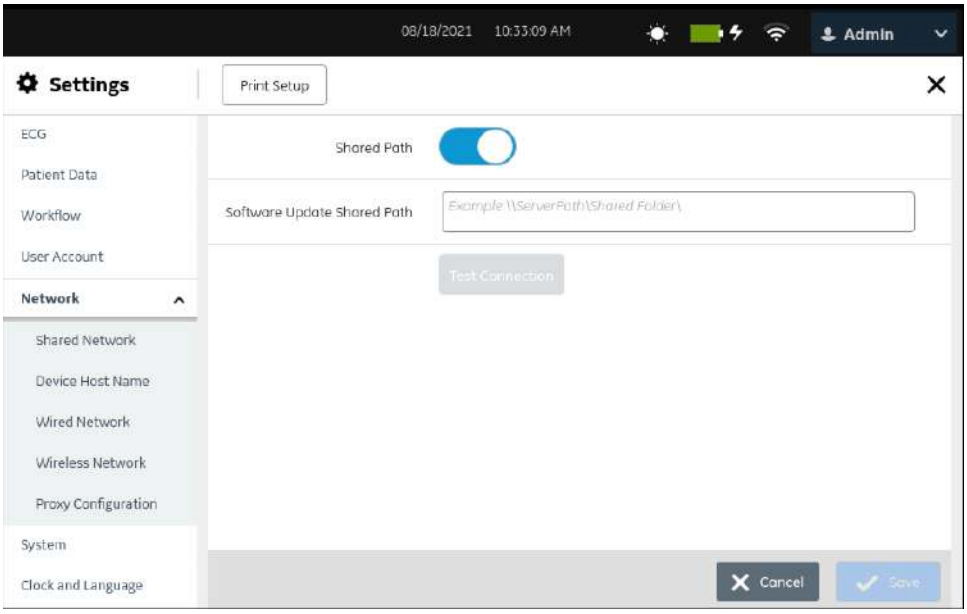
- Wireless Certificates - *Install Wireless Certificates on page 239*
- Proxy Settings - *Configure Proxy Settings on page 243*

Configure Shared Network Settings

1. Select **Settings** > **Network** > **Shared Network**.
   The shared network setting screen displays.



2. Enable **Shared Path**.



3. Configure the fields as per the information in the table.

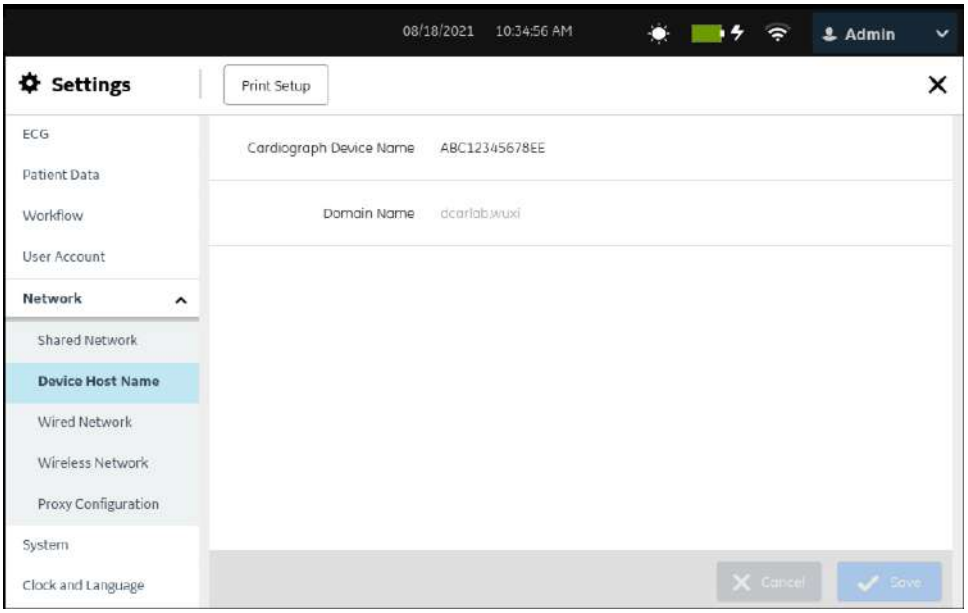
Table 72: Configure Shared Network Settings

Field	*Action*	*Description*
Shared Path	Enable or disable a shared folder in the network to store software files for a software update.	If this setting is enabled: 1. Enter a valid shared path in the text field. Example: ***///<IP address> or <Hostname>/ <Shared Folder>*** 2. Select **Test Connection**. A message displays indicating that the connection has succeeded or failed. In case of failure, see *Shared Network Connection Errors on page 283*. Default value: Disabled

4. Select **Save**.

Configure Device Host Name

1. Select **Settings** > **Network** > **Device Host Name**.
   The device host name setting screen displays.



2. Configure the device host name as per the information in the table.

Table 73: Configure Device Host Name

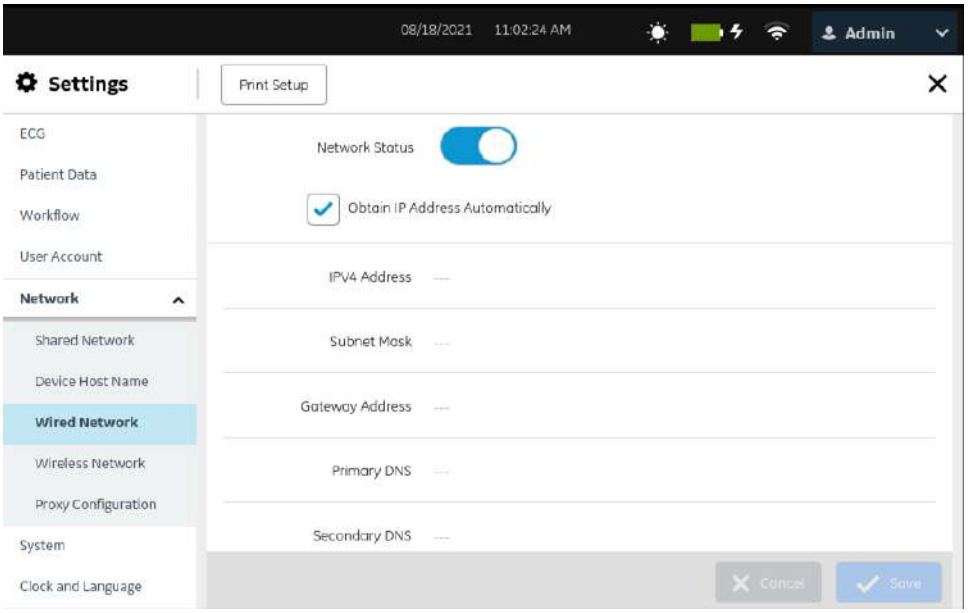
Field	*Action*	*Description*
Cardiograph Device Name	Enter the host name of the device in the **Cardiograph Device Name** field.	The host name cannot start or end with a hyphen. The host name cannot be blank as this is a required field. Octets are used to measure the host name field length, instead of characters. Many Unicode characters consist of more than 1 octet. Default value: Serial number of the device Allowed values: • 1 to 63 octets • ASCII characters a to z (case-sensitive) • digits 0 to 9 • hyphen (-)
Domain Name	Enter the domain name in the **Domain Name** field.	Default value: No default value Allowed values: • Up to 61 characters • ASCII characters a to z (case-sensitive) • 0 to 9 • All special characters If the device is configured to obtain the IP address automatically through DHCP, the domain name is assigned by the network.

A combination of the host name (Device Name) and Domain Name configures the device Fully Qualified Domain Name (FQDN). For example, if you enter *myhost* as the **Device Name** and *example.com* as the **Domain Name**, the configured FQDN of the device is *myhost.example.com*.

3. To edit an existing device name:
   a) Select anywhere in the row of the device name you want to modify to enable the edit mode.
   b) Make changes to the device name as per the information in *Table 73: Configure Device Host Name on page 229*.
4. Save and close the screen.
   The **Acquisition** screen displays.

Configure Wired Network

1. Select **Settings** > **Network** > **Wired Network**.
   The wired network setting screen displays.



2. Configure the wired network settings as per the information in the table.

Table 74: Configure a Wired Connection

Field	*Action*	*Description*
Network Status	Enable or disable this option.	• If this option is enabled, the LAN connection to the device is enabled. • If this option is disabled, the LAN connection to the device is disabled. The remaining fields are disabled. Default value: Enabled
Obtain IP Address Automatically	Enable or disable this option.	Automatically obtains the IP address. • If this option is enabled, the device automatically obtains an IP address (DHCP) to communicate with the LAN. The remaining fields are read-only and the values cannot be changed. • If this option is disabled, the fields to configure the IPV4 Address, Subnet Mask, Gateway Address, Primary DNS, and Secondary DNS, if any, to communicate with the LAN are made active to change the values. Specify these values in the respective fields. Default value: Enabled
IPV4 Address	Enter the static IPV4 address for the device.	This field is enabled to modify if **Obtain IP Address Automatically** is disabled. No default value Allowed values: A valid IPV4 address

Field	*Action*	*Description*
Subnet Mask	Enter the subnet mask identifying the subnet that the device's IPV4 address belongs.	This field is enabled to modify if **Obtain IP Address Automatically** is disabled. No default value Allowed values: A valid subnet mask
Gateway Address	Enter the gateway IP address for the router to use as the default route setting for the device.	This field is enabled to modify if **Obtain IP Address Automatically** is disabled. No default value Allowed values: A valid IPV4 address
Primary DNS	Enter the primary Domain Name Service (DNS) that the device uses.	This field is enabled to modify if **Obtain IP Address Automatically** is disabled. This field is optional. No default value Allowed values: A valid IPV4 address
Secondary DNS	Enter the secondary DNS that the device uses.	This field is enabled to modify if **Obtain IP Address Automatically** is disabled. This field is optional. No default value Allowed values: A valid IPv4 address
Device MAC Address	None	This field is read-only and displays the MAC address of the device. This field displays if **Network Status** is enabled.

3. Save and close the screen.

   The **Acquisition** screen displays.

Configure Wireless Network

To configure a wireless network, make sure WRLS option is purchased and enable them in the **Option Manager**.

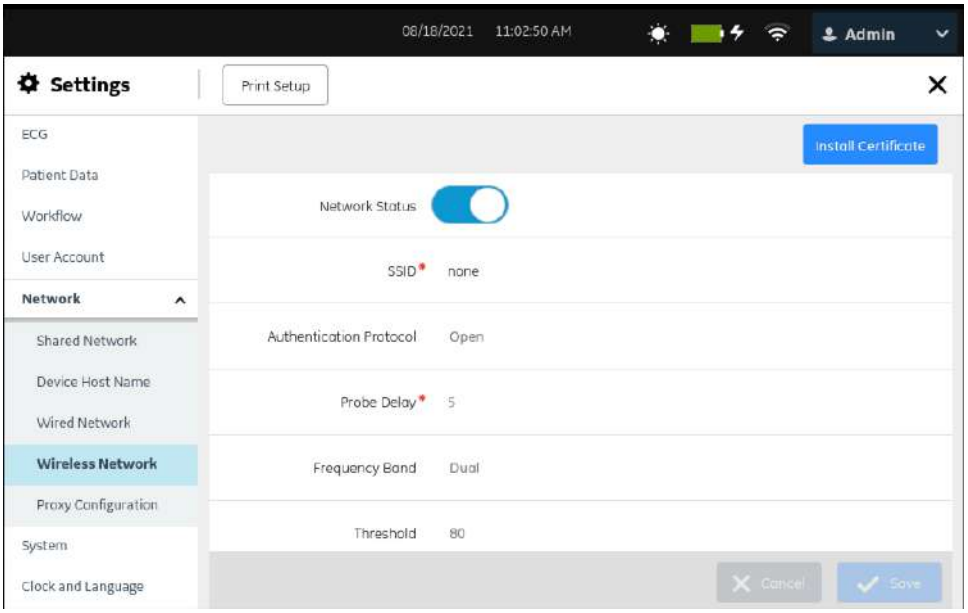
NOTE:

The **VU2** product code is for the **WRLS** wireless option.

Wireless country of operation is configured on the device at the time of shipping. This configuration is required to enable wireless network connectivity on the device. If wireless country of operation is not configured because the expansion board was replaced or the device does not have a wireless certification in the specific country, contact your GE Healthcare Service support representative to configure this setting.

1. Select **Settings** > **Network** > **Wireless Network**.

   The wireless network setting screen displays.



2. Enable wireless and configure the authentication protocol as per the information in the table.

Table 75: Configure Wireless Authentication Protocol

Field	*Action*	*Description*
Network Status	Enable or disable this setting.	• If this setting is enabled, the WLAN connection to the device is enabled. • If this setting is disabled, the WLAN connection to the device and the remaining fields are disabled. Default value: Disabled
SSID	Enter the Service Set Identifier (SSID) for your WLAN.	Default value: No default value Allowed value: Any value (site-specific)
Authentication Protocol	Select a value from the drop-down list to configure the protocol that your site uses to authenticate the transfer of data between the device and other entities on the WLAN.	Different fields display based on the protocol you select. Default value: **Open** Allowed values: • **Open*** • **WEP*** • **WPA*** • **WPA2**

Field	*Action*	*Description*
Probe Delay	Enter the number of seconds for probe delay.	When the timer for this delay starts, the device checks if wireless is enabled and the wireless network is connected. If it is disconnected, the device will try to reconnect to the wireless network. Default value: **5** Allowed values: 5 to 120
Frequency Band	Select a value from the drop-down list to configure the frequency band of wireless operation.	Default value: **Dual** Allowed values: • **Dual** • **2.4 GHz** • **5 GHz**
Threshold (dB)	Select a value from the drop-down list to configure the signal threshold in dB.	To enable the device to roam more frequently, decrease the signal threshold. To prevent the device from roaming frequently, increase the signal threshold. Default value: **80** Allowed values: **50, 55, 60, 65, 70, 75, 80, 85 or 90**

If the configured authentication protocol is:

- **WEP**, go to step *3*.
- **WPA** or **WPA2**, go to step 4.
- **Open**, go to step *7*.

3. Configure WEP authentication as per the information in the table, and then go to step *7*.

NOTE:

You can secure some communication channels with encryption and authentication. GE Healthcare recommends that you use the encrypted channels, not the unencrypted channels. For example, WPA2 for wireless authentication protocol instead of WEP.

Table 76: Configure WEP Authentication

Field	*Action*	*Description*
Active Passkey	Select a value from the drop-down list to configure the Passkey that you want to make active.	The device uses the Active Passkey to encrypt and decrypt data sent to and received from other entities on the WLAN. The active key needs to match the Passkey on the access point that this device connects to. Default value: **Passkey 1** Allowed values: • **Passkey 1** • **Passkey 2** • **Passkey 3** • **Passkey 4**
Passkey 1 **Passkey 2** **Passkey 3** **Passkey 4**	A passkey is an encryption key that prevents an unauthorized user or device from accessing a specific wireless network. Only asterisks display in these fields. The actual value is stored in the encrypted database. Enter a maximum of 4 passkeys for this authentication protocol. • If the length of the passkey is 5 or 13, the allowed values are 0 to 9, a to z, A to Z, ! ," ,# ,$,% ,&,' ,(,) ,* ,+ ,, ,- ,. ,/ ,: ,; ,< ,= ,> ,? , @, [,\ ,] ,^ ,_ ,` ,{, |, }, ~, and <space>. • If the length of the passkey is 10 or 26, the allowed values are 0 to 9, a to f, and A to F. Default value: No default value Allowed values: 5, 10, 13, or 26 characters	

4. Configure WPA or WPA2 authentication as per the information in the table, and then go to step 7.

Table 77: Configure WPA or WPA2 Authentication

Field	*Action*	*Description*
Authentication Mode	Select a value from the drop-down list to configure the authentication mode.	The authentication mode is the client authentication method used to generate unique encryption keys for the device. Default value: **PSK** Allowed values: • **PSK** • **Enterprise**

Field	*Action*	*Description*
Encryption Protocol	Select a value from the drop-down list to configure the encryption protocol.	TKIP is the Temporal Key Integrity Protocol. CCMP is the Counter Mode Ciper Block Chaining Message Authentication Code Protocol. Default value: • **TKIP** for WPA • **CCMP** for WPA2 Allowed values: • **TKIP**: This setting is not available for WPA2. • **CCMP**

If the authentication mode is:

- **PSK**, go to step *5*.
- **Enterprise**, go to step *6*.

5. Configure **PSK** authentication mode as per the information in the table.

Table 78: Configure PSK Authentication Mode

Field	*Action*	*Description*
Passphrase	Enter the passphrase for the authentication mode.	A passphrase is an encryption key that prevents an unauthorized user or device from accessing a specific wireless network. • If the passphrase is 64 characters, the allowed values are 0 to 9, a to f, and A to F. • If the passphrase is 8 to 63 characters, the allowed values are 0 to 9, a to z, A to Z, ! ," ,# ,$,% ,& ,' ,(,) ,* , + ,, ,- ,. ,/ ,: ,; ,< ,= ,> ,? , @,[,\ ,] ,^ ,_ ,` ,{, |, }, ~, and <space>. Default value: No default value Allowed values: 8 to 64 characters

6. Configure **Enterprise** authentication mode as per the information in the table.

Table 79: Configure Enterprise Authentication Mode

Field	*Action*	*Description*
EAP Phase 1	Select a value from the drop-down list to configure EAP Phase 1.	Default value: **PEAP** Allowed values: • **PEAP** • **TTLS** • **TLS**

Field	*Action*	*Description*
EAP Phase 2	Select a value from the drop-down list to configure EAP Phase 2.	This field is available only when EAP Phase 1 is configured as PEAP or TTLS. Default value: **MSCHAPv2** Allowed values: • **MSCHAPv2** • **GTC**
Anonymous Identity	Enter the Anonymous identity.	Default value: No default value Allowed values: Any value (up to 256 characters) **NOTE**: The default industrial standard for wireless networks is anonymous all lowercase unless the user has created a custom **Anonymous Identity**.
User Name	Enter the user name.	Default value: No default value Allowed values: Any value (up to 256 characters)
Password	Enter the password.	This field is available only when EAP Phase 1 is configured as PEAP or TTLS. Default value: No default value Allowed values: Any value (up to 256 characters)
CA Certificate	Enable or disable this setting.	Only PEM encoded certificate is supported. This field must be enabled when EAP Phase 1 is configured as TLS and cannot be disabled, and optional when EAP Phase 1 is configured as TTLS or PEAP. If **CA certificate** is enabled, make sure that the CA certificate is installed. See *Install Wireless Certificates on page 239*. Default value: • Disabled, when EAP Phase 1 is configured as TTLS or PEAP • Enabled, when EAP Phase 1 is configured as TLS
Client Certificate	Enable or disable this setting.	Only PEM encoded certificate is supported. This field must be enabled when EAP Phase 1 is configured as TLS and cannot be disabled, and optional when EAP Phase 1 is configured as TTLS or PEAP. If **Client Certificate** is enabled, make sure that the client private key and client public key are installed. See *Install Wireless Certificates on page 239*. Default value: • Disabled, when EAP Phase 1 is configured as TTLS or PEAP • Enabled, when EAP Phase 1 is configured as TLS

7. Configure the setting to obtain the IP address automatically or manually as per the information in the table.

Table 80: Enable or Disable DHCP

Field Name	*Action*	*Description*
Obtain IP Address Automatically	Enable or disable this setting.	Automatically obtains the IP address. • If this setting is disabled, the fields to configure the IP address, subnet mask, gateway address, primary DNS, and, the secondary DNS, if any, to communicate with the WLAN display. Enter these values in the respective fields. • If this setting is enabled, the device automatically obtains an IP address (DHCP) to communicate with the WLAN. The remaining fields are hidden. Default value: Disabled
IPV4 Address	Enter the static IPV4 address for the device.	This field displays if **Obtain IP Address Automatically** is disabled. Default value: No default value Allowed values: A valid IPV4 address
Subnet Mask	Enter the subnet mask identifying the subnet that the device's IPV4 address belongs.	This field displays if **Obtain IP Address Automatically** is disabled. Default value: No default value Allowed values: A valid subnet mask
Gateway Address	Enter the gateway IP address for the router to use as the default route setting for the device.	This field displays if **Obtain IP Address Automatically** is disabled. Default value: No default value Allowed values: A valid IPV4 address
Primary DNS	Enter the primary Domain Name Service (DNS) that the device uses.	This field displays if **Obtain IP Address Automatically** is disabled. This field is optional. Default value: No default value Allowed values: A valid IPV4 address
Secondary DNS	Enter the secondary DNS that the device uses.	This field displays if **Obtain IP Address Automatically** is disabled. This field is optional. Default value: No default value Allowed values: A valid IPV4 address
Device MAC Address	Display MAC address for the device.	This field is not editable.

8. Save and close the screen.
   The **Acquisition** screen displays.

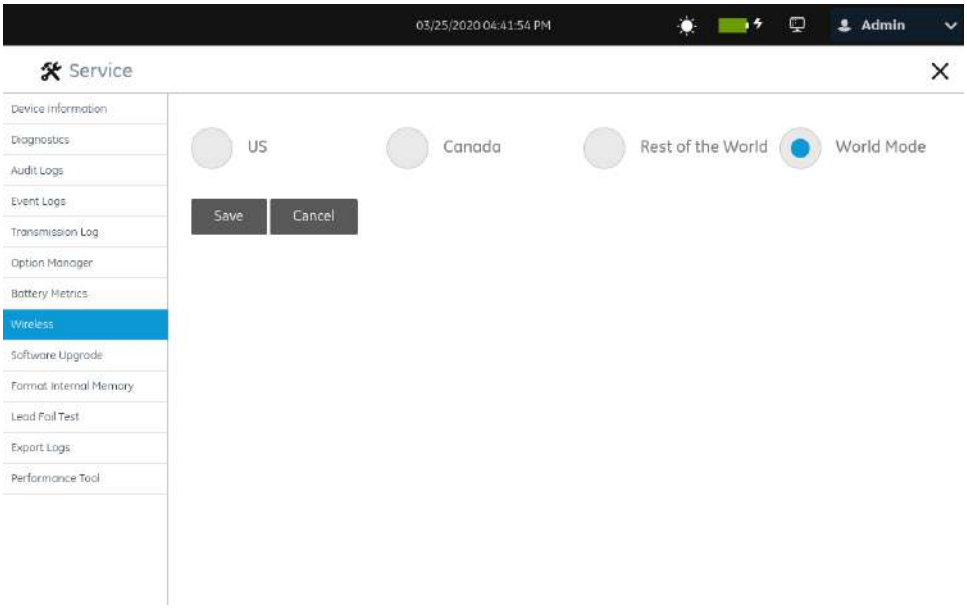
Configure Wireless Country of Operation

NOTE:
The device ships with configured settings for the Wireless Country of Operation option. You can only edit the country code for the **Rest of the World** setting. If the device is set to **US** or **Canada**, you cannot alter the configuration and the **Wireless Country of Operation** option will not be available in the **Service** menu.

Before you start this procedure:

Disable the Network status option in **Settings** > **Network** > **Wireless Network**. If the WLAN is enabled and you try to configure Wireless, an error message displays: **Disable WLAN to set the Wireless Country of Operation**.

1. Open the **Service** screen.
2. Select **Wireless Country of Operation**.
   The **Rest of the World** screen displays.



3. Configure the country code for the **Rest of the World** wireless option as per the information in the table.

To set Wireless Country of Operation in:	*Perform the following steps:*
Rest of the World	The **Country of Operation** option displays. 1. Enter a two-character country code in the text field. The list of possible country codes is available at: *https://www.iso.org/obp/ui/#search/code/*. The allowed values are a to z and A to Z. **NOTE**: You cannot enter US and Canada country codes. 2. Select **Save** to save the configuration. The wireless is set as per the country code you select in *Step 1*. If you enter an invalid country code, an error message displays, and the device is set to **00** for World Regulatory Domain. If you do not enter a country code, the device is set to **00** for World Regulatory Domain.

4. Close the screen.

   The **Acquisition** screen displays.

Install Wireless Certificates

Before you start this procedure, make sure that:

- You obtain the required certificates from your IT department and copy them to the root folder of a USB flash drive for installation.

  NOTE:

  The client certificate must be signed by the CA that is specified in the CA certificate, and you must install the CA certificate prior to installing the client certificate.

  If the client certificate is self-signed, you need to enable the **Self-signed** setting during the installation process, and the installation of CA certificate is not required. If mutual authentication is needed, you can install the server's public key as the CA certificate.

  The certificate must be self-contained. It cannot point to another certificate.

  Accept only PEM format certificates. Make sure that the certificates are in the right format and you import the correct certificate for each tab.

- You enable:
  - **Enable External USB Storage** in **Settings** > **System** > **Storage** setting.
  - At least one USB port in **Settings** > **Hardware** > **USB Port** setting.

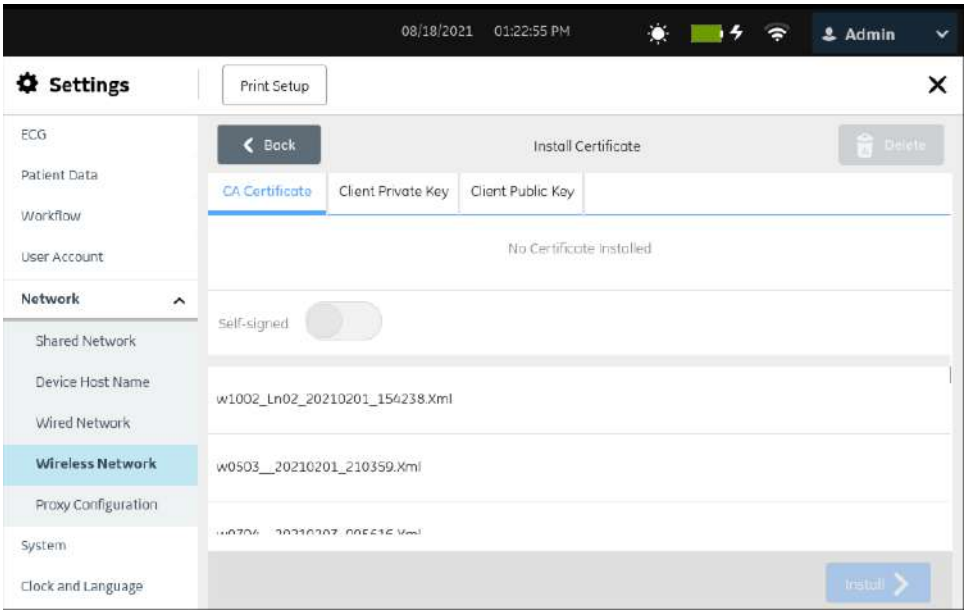
  If these options are not enabled, access to USB flash drives is blocked.

1. Connect the USB flash drive containing the digitally signed CA Certificate, Client Private Key, and Client Public Key to the device.

NOTE:
If the client certificate is self-signed, a CA Certificate is not required.

2. Select **Settings** > **Network** > **Wireless Network**.

3. In the **Wireless Network** section, select **Install Certificate**.
The **Install Certificate** screen opens. By default, the **CA Certificate** tab is selected.



4. If the **CA Certificate** setting is on, perform the steps below to install a CA Certificate:

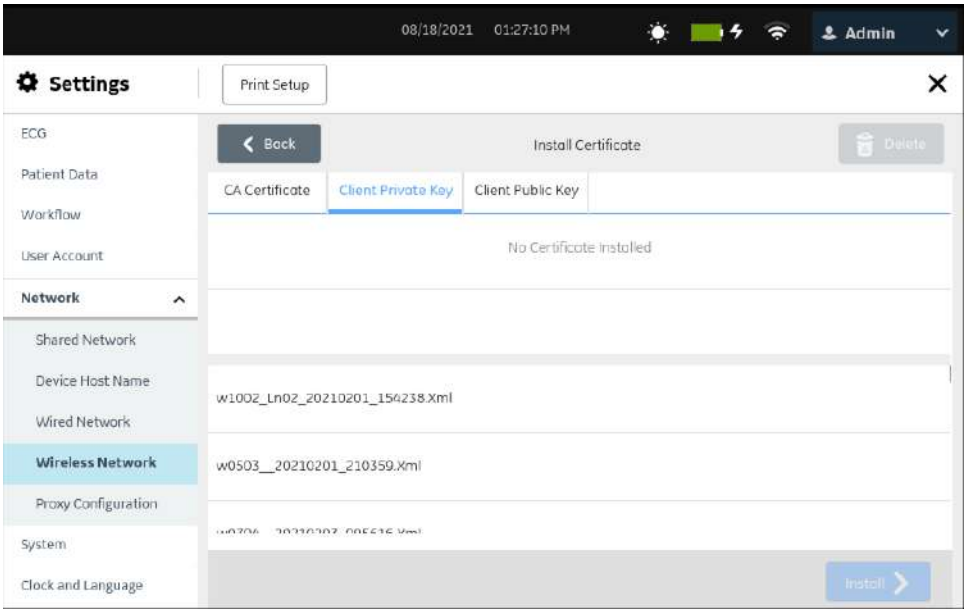
   a) Select the CA certificate from the USB flash drive.

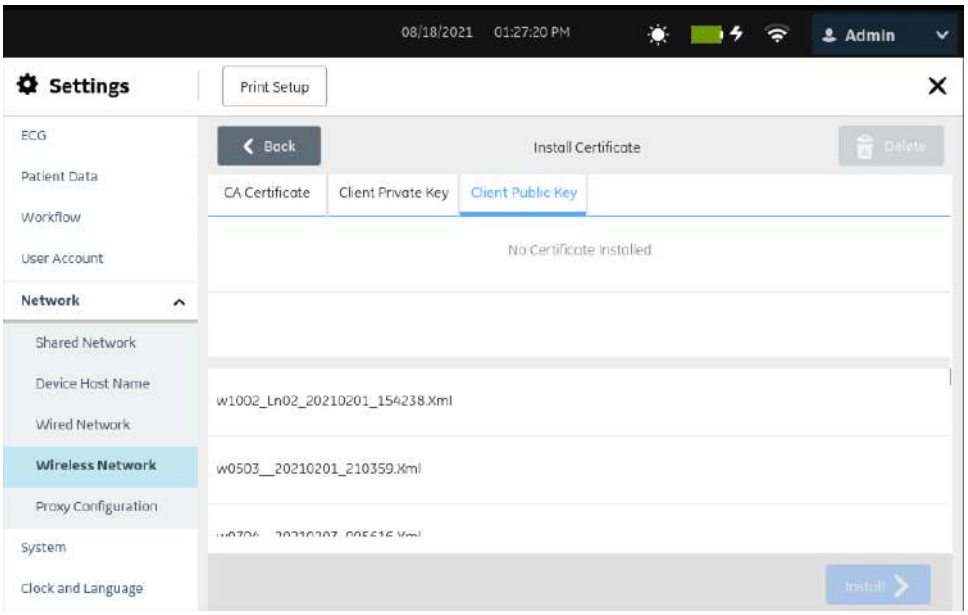
   b) Enable the **Self-signed** button.

   c) Select **Install**.

   - If the installation is successful, the **Installed certificate** status displays on the status bar.
   - The **Certificate** name, **Issuing Authority**, **Validity Dates**, and **Issuing Subject** details displays in the **Currently Installed Certificate Details** section.
   - If the installation fails due to an error, you need to troubleshoot the error. See *Wireless Network Connectivity Errors on page 284* and *Errors while Installing Certificates on page 283*.

5. If the **Client Private Key** is on for the Client certificate, perform the steps below to install the client private key and client public key:





NOTE:

The **Client Private Key** and **Client Public Key** can be in the same certificate.

a) Select **Client Private Key**.

b) Select a valid client private key from the USB flash drive.

c) Enter a valid client private key password in the **Password** field.

d) Select **Client Public Key**.

e) Select a valid client public key from the USB flash drive.

f) Select **Install** to install the selected client private and public keys.

The **Install** button is enabled only after you select client private and public keys.

- If the installation is successful, the **Certificate** name, **Issuing Authority**, **Validity Dates**, and **Issuing Subject** details display in the **Currently Installed Certificate Details** section.
- If the installation fails due to an error, you need to troubleshoot the error. See *Wireless Network Connectivity Errors on page 284* and *Errors while Installing Certificates on page 283*.

6. Perform the steps below to replace or delete the currently installed CA certificate or client public and private keys:

a) Select the tab (**CA Certificate**, **Client Private Key** or **Client Public Key**) where you want to replace or delete the installed certificate or key.

The currently installed certificate or key displays.

b) Select **Delete.**

A message displays asking you to confirm the deletion of the certificate or key.

NOTE:
If you delete the client private key, the client public key is deleted and vice versa.

c) Select **OK**. The certificate or key is deleted.

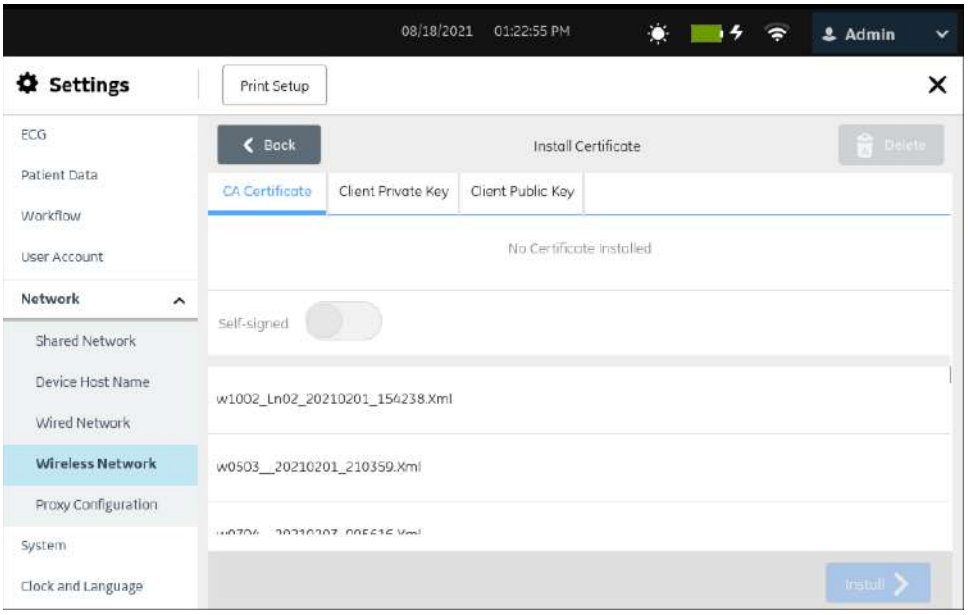
- If you want to replace the CA certificate, perform step 4.
- If you want to replace the client private and public keys, perform step 5.

Intermediate Certificates

If your site uses intermediate certificates, you may need to install both the intermediate and the root certificates. Use the steps below to install the intermediate and the root certificates.

1. Select **Settings** > **Network** > **Wireless Network**.
2. In the **Wireless Network** section, select **Install Certificate**.

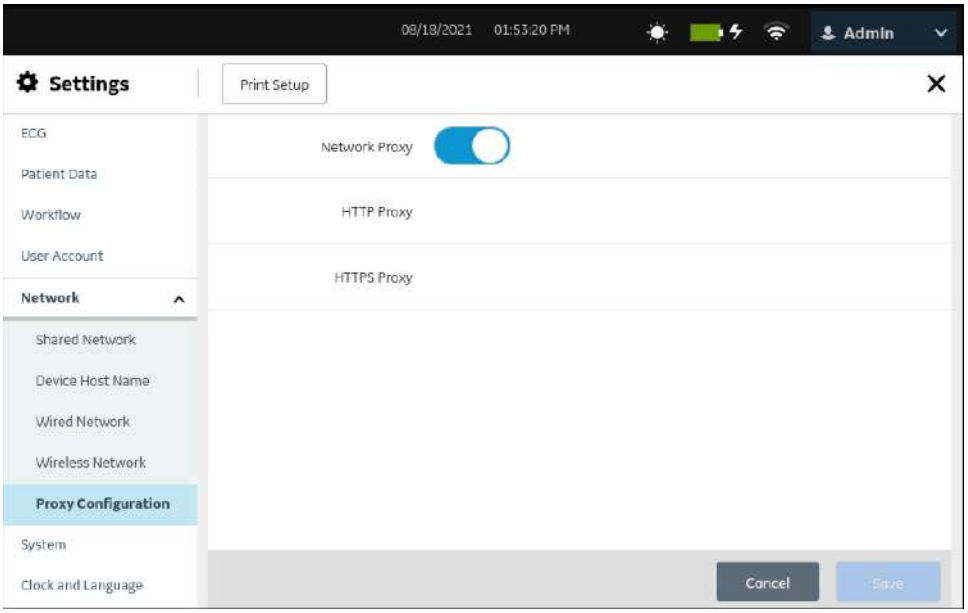
The **Install Certificate** screen opens. By default, the **CA Certificate** tab is selected.



3. If an **Intermediate Certificate** is used, convert the root and intermediate certificates to PEM format.
4. Open the PEM format certificates in a **Notepad** editor.
5. Perform the steps below to create a **Chained CA Certificate**:
   a) Concatenate the root and intermediate certificates as explained in the example below.
   b) Example, if root signed intermediate1 and intermediate1 signed intermediate2 and intermediate2 signed the client public key, the order of certificates in the Chained CA Certificate file should be: **root->intermediate1->intermediate2**.
6. Install the **Chained CA Certificate** created in *Step 6* in the **CA Certificate** tab. See *Install Wireless Certificates on page 239* for more information.

Configure Proxy Settings

1. Select **Settings** > **Network** > **Proxy Configuration**.
   The proxy setting screen displays.



2. Configure the proxy settings as per the information in the table.

Table 81: Configure Proxy Settings

Field	*Action*	*Description*
Network Proxy	Enable or disable this setting.	• If this setting is enabled, the **HTTP Proxy** and **HTTPS Proxy** fields display. You can configure the proxy settings. • If this setting is disabled, the **HTTP Proxy** and **HTTPS Proxy** fields are hidden. You cannot configure proxy settings. Default value: Disabled
HTTP Proxy	Enter the IP address and port number of the HTTP proxy.	Default value: No default value Allowed values: A valid IPV4 address and port number
HTTPS Proxy	Enter the IP address and port number of the HTTPS proxy.	Default value: No default value Allowed values: A valid IPV4 address and port number

3. Save and close the screen.
   The **Acquisition** screen displays.

Show Network Connection Status

When the wireless and wired connection is set to **Enable**, the device uses a wired connection when you connect a Local Area Network (LAN) cable. If you remove the LAN cable, the device uses the wireless connection.

To view the status of your device's connection to your LAN or Wireless Local Area Network (WLAN), perform the procedure as follows:

1. Select the **Network Status** icon on the status bar.
2. Review the tables for the description of the network status icon when connected to a LAN or WLAN network.

Table 82: LAN Icons

Network Status Icon	*Status*	*Description*
	LAN Active	The device is connected to a LAN.
	LAN Connected	The device is connected to a remote server through a LAN and is in the process of obtaining an IP address. If this icon is blinking, the device is acquiring an IP address from DHCP.
	LAN Disconnected	The device is not connected to a LAN; no LAN (Ethernet) cable is attached to the device.

Table 83: WLAN Icons

Icon	*Status*	*Description*
	WLAN Active	The device is connected to a WLAN and has a valid IP address. The icon shows a number of wireless bars to indicate the strength of the wireless signal.
	WLAN Connected	The device is connected to an access point and is in the process of obtaining an IP address. If this icon is blinking, the device is acquiring an IP address from DHCP.
	WLAN Disconnected	The device is not connected to a WLAN.

For more information about wireless certificate errors, see *Wireless Network Connectivity Errors on page 284*.

3. Close the **Network Status** window by selecting something on the screen outside of the window.

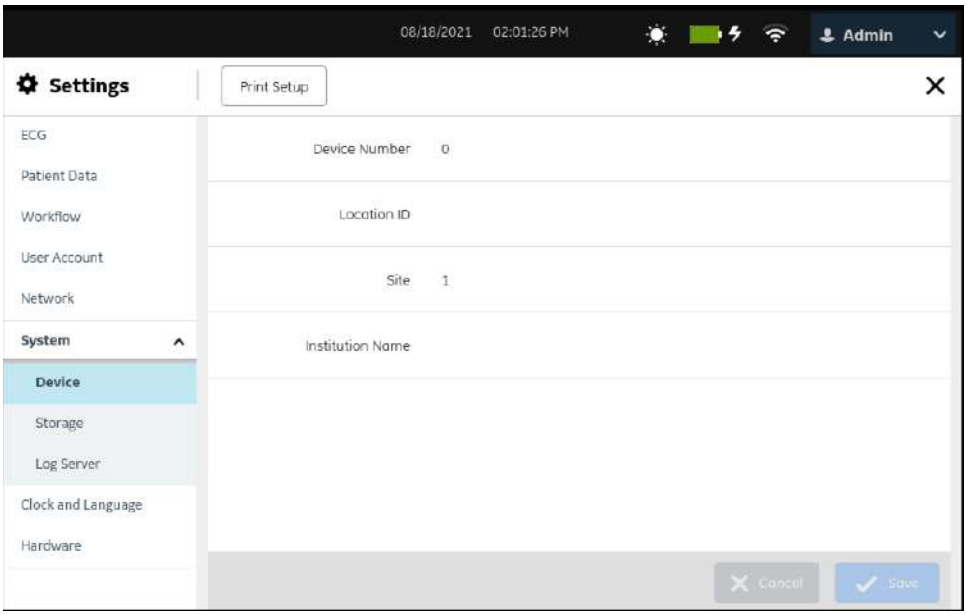
Configure System

Select **Settings** > **System** menu to configure the settings below:

- Device Parameters - *Configure Device Parameters on page 246*
- External Storage - *Configure External Storage on page 247*
- Save and Restore Configuration Settings - *Save and Restore Configuration Settings on page 248*
- Save and Restore User Settings - *Save and Restore User Settings on page 250*
- Restore to Factory Defaults - *Restore to Factory Defaults on page 252*
- Log Server - *Configure Log Server on page 253*

Configure Device Parameters

1. Select **Settings** > **System** > **Device**.
   The device parameter setting screen displays.



2. Configure the fields as per the information in the table.

Table 84: Device Parameters

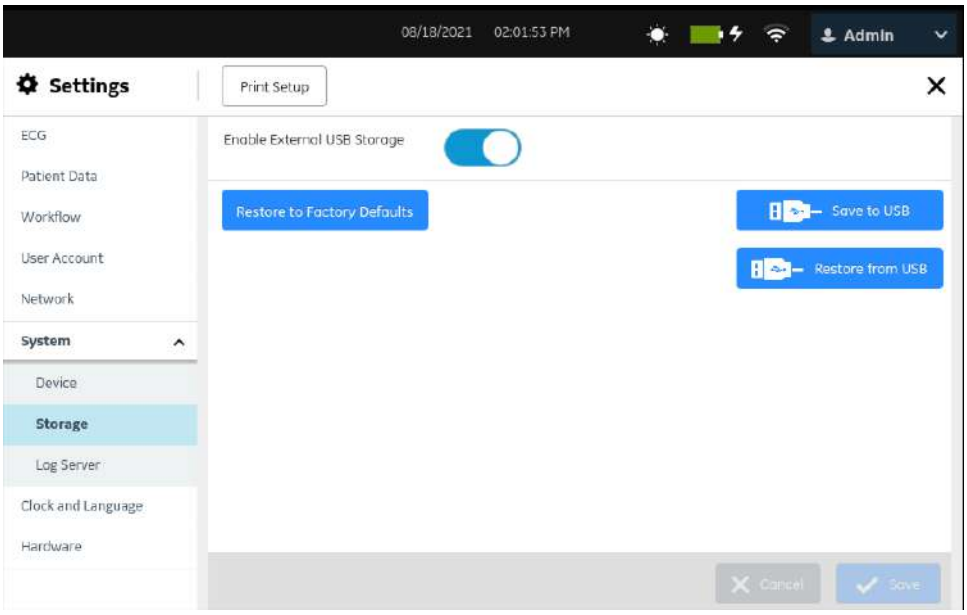
Field	*Action*	*Description*
Device Number	Set the default device number.	The device number is unique for each ECG device. Default value: **0** Allowed values: 0 to 65535

Field	*Action*	*Description*
Location ID	Set the default location ID.	For each patient test, the location ID is populated in the **Location** field of the **Patient Information** screen. No default value Allowed values: 0 to 65535
Site	Set the site number.	Default value: **1** Allowed values: 1 to 255
Institution Name	Set the name of the institution.	The name of the institution displays in the ECG and rhythm reports. No default value Allowed values: 1 to 25 characters • A to Z • a to z • 0 to 9 • All special characters

3. Select **Save**.

Configure External Storage

1. Select **Settings** > **System** > **Storage**.
   The external storage setting screen displays.



2. Configure the fields as per the information in the table.

Table 85: External Storage Settings

Field	*Action*	*Description*
Enable External USB Storage	Enable or disable access to USB flash drives for external data storage.	Only an Admin user or Service user can enable or disable this setting. **NOTE**: If you try to disable this setting, and a USB destination is already configured as a default or auto-destination, a warning message displays notifying you to change the USB destination to a manual destination to disable the **Enable External USB Storage** setting. See *Configure a USB Destination to Transmit Reports on page 164*. Default value: Disabled

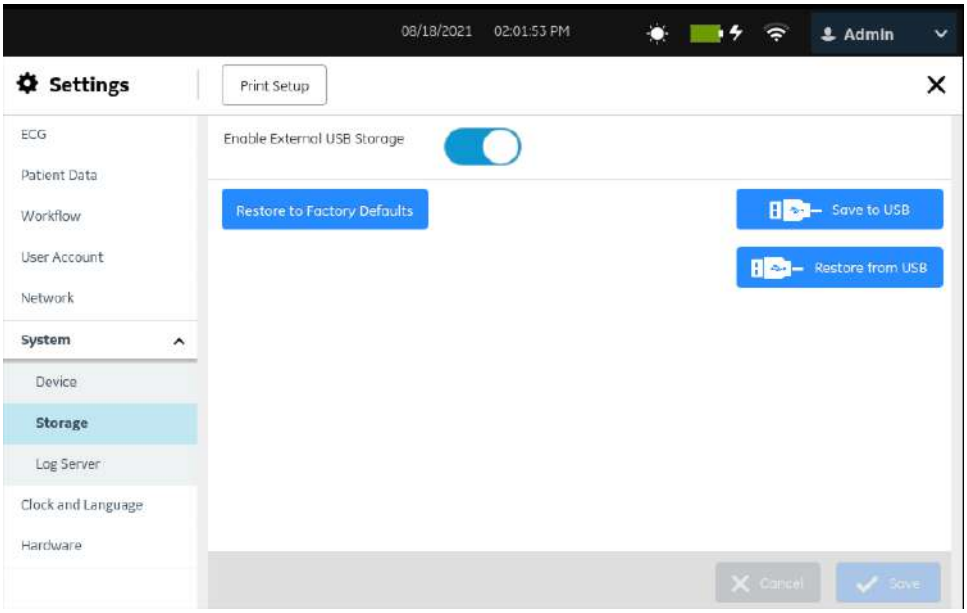
3. Select **Save**.

Save and Restore Configuration Settings

Before performing this procedure, make sure that:

- The USB flash drive is inserted correctly into the drive and has write permissions.
- The **Enable External USB Storage** setting is enabled in the **Settings** > **System** > **Storage** settings.
- The USB ports are enabled in the **Settings** > **Hardware** > **USB Port** setting.
- The USB flash drive supports the FAT32 file system.

1. Select **Settings** > **System** > **Storage**.
   The Storage setting screen displays.



2. Do the steps in the table.

If you want to...	*Then...*
Save the configuration settings to a USB flash drive	1. Select **Save to USB**. A message displays indicating that the selected settings will be saved to an external USB storage. 2. Select the **Select All** check box or select specific check boxes to save required settings to the USB flash drive. **NOTE**: To save user settings, see *Save and Restore User Settings on page 250*. 3. Select **Save**. The configuration file is saved to the root directory of the USB flash drive, and a confirmation message displays. The configuration file name follows the format: ***<product name>_<serial number>.cfg***. If a previously saved file exists, a message displays asking you to confirm overwriting the existing file. Select **OK** to overwrite the file, or insert another USB flash drive to save the file. 4. Remove the USB flash drive and store it carefully for future use.
Restore the configuration settings from a USB flash drive	**NOTE**: • You can restore configuration settings only if you have saved the settings previously to the USB flash drive. • To save critical value settings, make sure that you are assigned the **Edit Critical Values** privilege. If you do not have this privilege, clear the **Critical Values** check box before saving the settings. 1. Select **Restore from USB**. 2. Select the configuration file and proceed. 3. Select the **Select All** check box or select specific check boxes to restore required settings from the USB flash drive. 4. Select **Restore**. If user settings are selected, a message displays indicating that this action will log off the device. 5. Select **Restore** to confirm the action. The settings are successfully restored from the selected file in the USB flash drive. If user settings are selected, the system logs off.

NOTE:

Restore of the configuration settings from the USB flash drive fails, if the source file is imported from the software version less than 1.02 and the target software version is 1.02 or higher.

If there are problems with the USB flash drive or the configuration file, the configuration is not successfully saved or restored.

To resolve errors related to the configuration file, see *Configuration File Errors on page 282*.

To resolve errors related to the USB flash drive, see *USB Flash Drive Errors on page 282*.

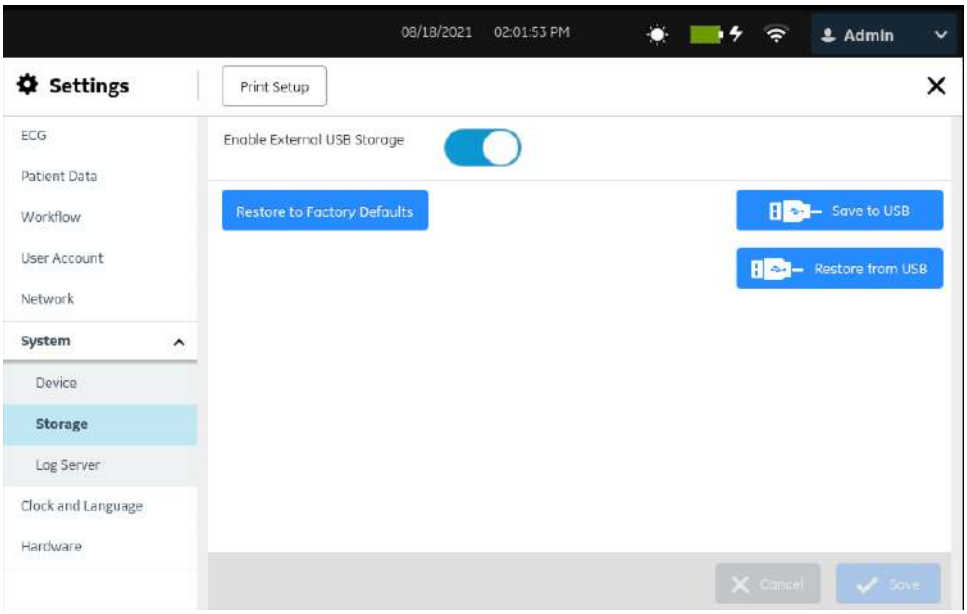
Save and Restore User Settings

Before you start this procedure, make sure that:

- The **Enable External USB Storage** is enabled in **Settings** > **System > Storage** setting.
- The USB ports enabled in **Settings** > **Hardware** > **USB Port** setting.
- The USB flash drive is inserted correctly into the drive and has write permissions. Only one USB flash drive can be inserted to save user settings.
- The USB flash drive supports the FAT32 file system.
- Your user role is assigned the user management privilege.

1. Select **Settings** > **System** > **Storage**.

   The Storage setting screen displays.



2. Save or restore user settings, as per the information in the table.

If you want to...	*Then...*
Save the user settings to a USB flash drive	1. Select **Save to USB**. 2. Select **Select All** to save all the settings to USB flash drive. 3. Select specific check boxes to save the settings below to USB flash drive: • **ECG** • **Patient Data** • **Workflow** • **User Account** • **Network** • **System** • **Clock and Language** • **Hardware** The configuration file is saved to the root directory of the USB flash drive, and a confirmation message displays. The configuration file name follows the format: ***<product name>_<serial number>.usrcfg***. If a previously saved file exists, a message displays asking you to confirm overwriting the existing file. Select **OK** to overwrite the file, or insert another USB flash drive to save the file. 4. Remove the USB flash drive and store it carefully for future use.
Restore the user settings from a USB flash drive	**NOTE**: You can restore user settings only if you previously saved the settings to the USB flash drive. 1. Select **Restore from USB**. If there are multiple configuration files in the USB flash drive, select the correct file. 2. Select the configuration file and proceed. A message displays indicating that this action will log off the device. 3. Select **Yes** to confirm the action. The settings are successfully restored from the selected file in the USB flash drive, and the system logs off.

If there are problems with the USB flash drive or the user configuration file, the configuration is not successfully saved or restored.

To resolve errors related to the user configuration file, see *Configuration File Errors on page 282*.

To resolve errors related to the USB flash drive, see *USB Flash Drive Errors on page 282*.

Restore to Factory Defaults

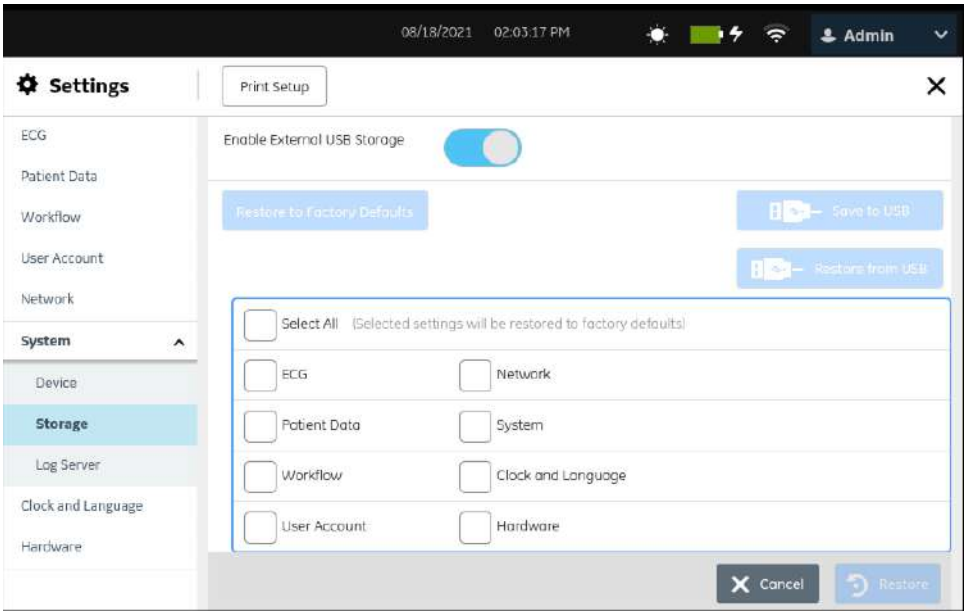
NOTE:
A **System Reset** is used to delete all data including patient data and settings. The system is reset to factory defaults and the default password for the admin user can be used to log in. It retains the previously enabled option codes, serial number, MAC address, and Wireless Country of Operation configuration.

A **Restore to Factory Defaults** is used to reset the settings or section of settings.

- Make sure that you have backed up the current configuration settings, before you reset the settings to factory defaults. See *Save and Restore Configuration Settings on page 248* to back up the current configuration settings.

  If you do not save the current configuration settings prior to restore the settings to factory defaults, you do not have the option of restoring the current settings later. You need to manually re-configure the settings.
- Make sure that your user role is assigned the privileges to access the **Settings** screen.

1. Select **Settings** > **System** > **Storage**.
2. Select **Restore to Factory Defaults**.
   The restore to factory default setting screen displays.



3. Perform *one* of the steps below:
   - Select **Select All** to restore all settings to factory defaults.
   - Select specific settings to restore to factory defaults.
4. Select **Restore**.
   A massage displays.
5. Perform *one* of the steps below:

- Select **Restore** to confirm the action.
- Select **Cancel** to cancel the action.

If you select **Restore**, the selected settings are restored to default values.

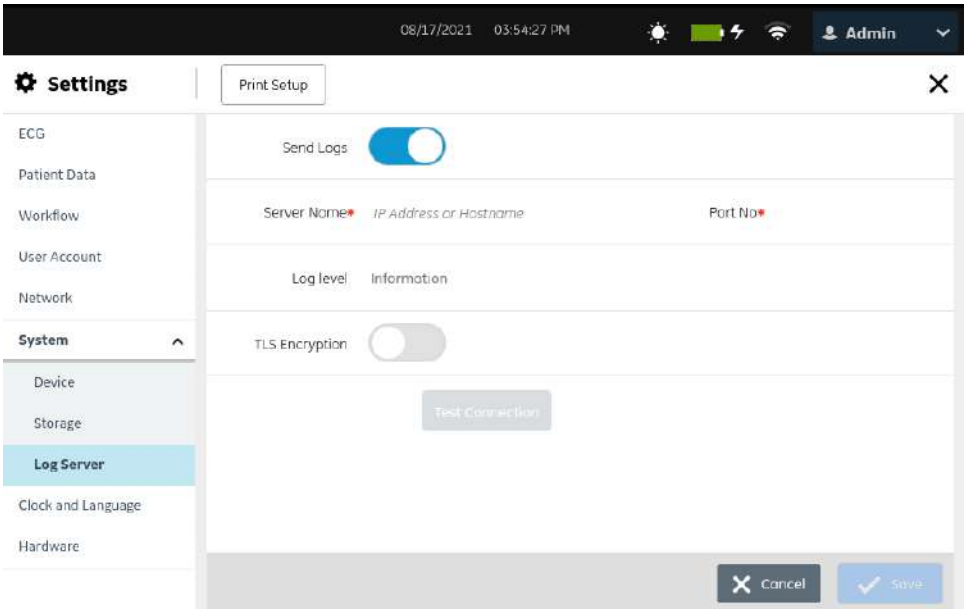
6. Close the screen.
   The **Acquisition** screen displays.

Configure Log Server

Before you start this procedure, make sure that:

- You have access to the **Settings** screen.
- You obtain the required certificate in the PEM format from your IT department and copy it to the root folder of a USB flash drive for installation.
- The **Enable External USB Storage** is enabled in **Settings** > **System** > **Storage** setting. If this setting is not enabled, access to USB flash drives is blocked.
- You enable at least one USB port in **Settings** > **Hardware** > **USB Port** setting. If this setting is not enabled, the device will not recognize the USB flash drives.

1. Connect the USB flash drive thst contains the TLS certificate to the device.
2. Select **Settings** > **System** > **Log Server**.
   The log server setting screen displays.



3. Configure the **Log Server** as per the information in the table:

Field	*Action*	*Description*
Send Log	Enable or disable this setting.	If this setting is enabled, the device transmits the captured system logs and event logs to the configured server location. Default value: Disabled
IP Address	Enter IP address of the configured log server.	Allowed values: A valid IP address Default value: No default value If you enter an invalid IP address, the outline of IP Address field turns red.
Port No	Enter a valid port number of the configured log server.	Allowed values: 1 to 65535 No default value.
Log level	From the drop-down menu, select the desired Log level.	Default value: Information Allowed values: • Information • Warning • Error The information related to selected **Log level** type is transmitted to configured server.
TLS Encryption	Enable or disable this setting.	If this setting is enabled, the connection to the configured server is encrypted. If this setting is disabled, the connection to the configured server is not encrypted. Default value: Disabled

4. If TLS Encryption is enabled, the **Install Certificate** field displays, do the steps that follow to install the TLS certificate:
   a) Select **Browse**.
      The Certificate-Browse window opens and displays the message: **No Certificate Installed**
   b) Select the valid certificate from the list.
   c) Select **Install**. A success message displays.
   d) Select **Back**.
      The **Log Server** window displays. The **Installed** message is shown in the **Install Certificate** field.
5. Select **Test Connection** to test the connection to the configured server.

NOTE:
The maximum time to complete the test connection for **TLS Encryption** is 60 seconds.

- If the connection is successful, a success message displays and the **Save** button is enabled.
- If the connection fails due to an error, an error message displays. Troubleshoot the error and select **Test connection**.

6. Select **Save**, a success message displays.
7. Close the screen.
   The Acquisition screen displays.

Delete TLS Encryption Certificate

Before you start this procedure, make sure that your user role is assigned with user management privilege.

1. Select **Settings** > **System** > **Log Server**.
   The log server setting screen displays.
2. Enable **Log Server** setting.
3. Perform the steps below to delete the currently installed TLS Encryption certificate:
   a) Select the **Browse** setting.
      The currently installed certificate displays.
   b) Select **Delete**.
      A message displays asking you to confirm the deletion of the certificate.
   c) Select **Yes**. The certificate is deleted.

Configure the Clock and Language

Select **Settings** > **Clock and Language** menu to configure the settings below:

- Date and Time - *Configure the Date and Time on page 255*
- NTP - *Configure NTP on page 258*
- Region - *Configure Region on page 259*

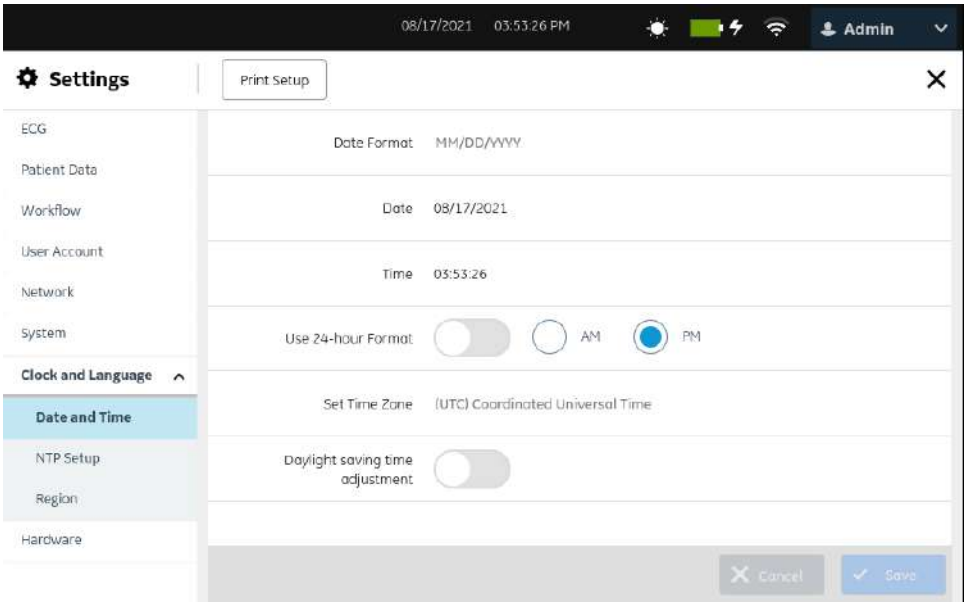
Configure the Date and Time

The items below are set by GE Healthcare before the device is shipped.

- Date and time formats based on the customer's country preferences
- The default time zone (GMT/UTC)

Use this procedure if you want to change the default date and time configurations.

1. Select **Settings** > **Clock and Language** > **Date and Time**.
   The date and time setting screen displays.



2. Configure the fields as per the information in the table.

Table 86: Date and Time Settings

Field	*Action*	*Description*
Date Format	Select the date format.	The date format is automatically set to: • **DD.MM.YYYY** when the device language is set as **Finnish**, or the device is restored to factory defaults settings. • **MM/DD/YYYY** when the device language is set as **English**, or the device is restored to factory defaults settings. • **YYYY-MM-DD** when the device languages are set as **Chinese**, **Danish**, **German**, **Swedish**, or **Norwegian**, or the device is restored to factory defaults settings: • **DD-MM-YYYY** when the device languages are set as **Dutch** or **French**, or the device is restored to factory defaults settings: • **DD/MM/YYYY** when the device language is set as **Italian**, or the device is restored to factory defaults settings. where: • MM = the number of the month. For example, January is 01. • DD = the number of the day of the month. • YYYY = the year Default value: Date format set at factory

Field	*Action*	*Description*
Date	Click anywhere on the **Date** field to populate the **Calendar**. Select the date from the Calendar. Select **Save**. If you select **Cancel**, the calendar closes and your changes are not applied. The **Restore to Factory Defaults** procedure does not change the date. Default value: Date set at factory	
Time	Enter the current time.	• If the **Use 24-hour Format** setting is disabled, you can configure the hour from 1 to 12 and set **AM** or **PM**. • If the **Use 24-hour Format** setting is enabled, you can configure the hour from 0 to 23 with no selection for **AM** or **PM**. The **Restore to Factory Defaults** procedure does not change the time format. Default value: Time set at factory Allowed values: HH:MM:SS, where: • HH = hour • MM = minutes • SS = seconds
AM or **PM**	Enable or disable this setting.	If the **Use 24-hour Format** setting is disabled, select **AM** or **PM**. This setting is not available if the **Use 24-hour Format** is enabled. This setting is automatically enabled when the device language is set as **English**, and the device is restored to factory defaults settings.
Use 24-hour Format	Configure the time format for the device.	• If this setting is disabled, you can configure the hour from 1 to 12 and set **AM** or **PM**. • If this setting is enabled, you can configure the hour from 0 to 23 with no selection for **AM** or **PM**. This setting is automatically enabled when the device language is set as **Chinese**, **Danish**, **Dutch**, **Finnish**, **French**, **German**, **Italian**, **Swedish**, or **Norwegian**, and the device is restored to factory defaults settings. This setting is automatically disabled when the device language is set as **English**, and the device is restored to factory defaults settings.
Set Time Zone	Select the time zone for the device.	Default value: UTC (Coordinated Universal Time) Allowed values: List of time zones representing all areas of the world.

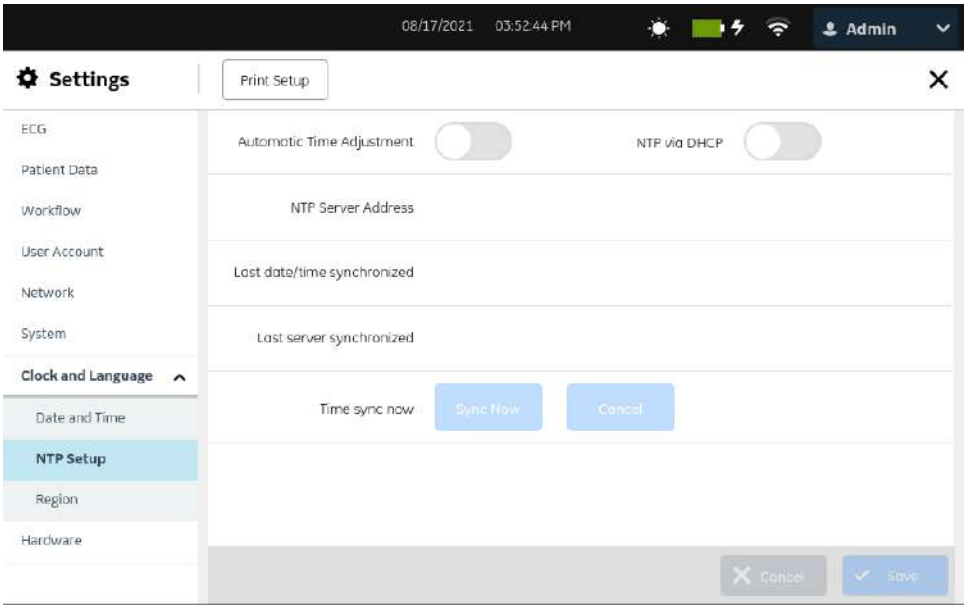
Field	*Action*	*Description*
Daylight saving time adjustment	Enable or disable this setting to automatically adjust the time for daylight savings time according to the selected time zone.	Default value: Disabled

3. Select **Save**.

Configure NTP

Network Time Protocol (NTP) is a networking protocol used for clock synchronization between the device and the configured NTP server.

1. Select **Settings** > **Clock and Language** > **NTP Setup**.
   The NTP setting screen displays.



2. Configure the fields as per the information in the table.

Table 87: NTP Setup

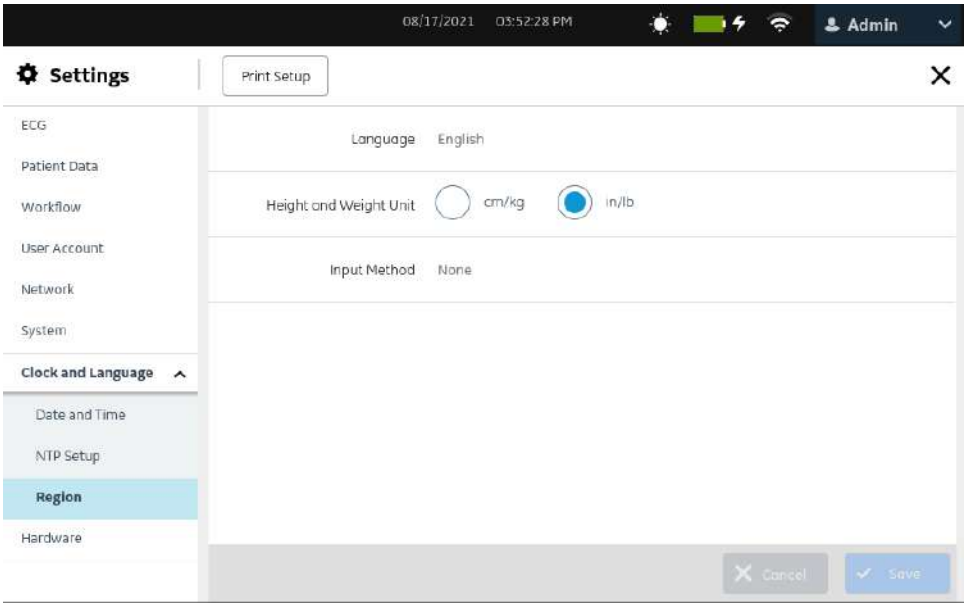
Field	*Action*	*Description*
Automatic Time Adjustment	Enable or disable this setting.	The current date and time is automatically synchronized with an NTP server. If this setting is disabled, the **NTP via DHCP** is also disabled. Default value: Disabled

Field	*Action*	*Description*
NTP via DHCP	Enable or disable this setting.	If this setting is enabled, the device receives the NTP server configuration through DHCP. Default value: Disabled
NTP Server Address	Enter the IP address of the NTP server that synchronizes the current date and time on the device.	Default value: No default value Allowed values : A valid IP address
Last date/time synchronized	Displays the date and time when the device was last synchronized with the NTP server.	
Last server synchronized	Displays the IP address or URL of the NTP server that synchronized the current date and time of the device.	
Time sync now	Select **Sync Now** to synchronize the date and time on the device with the date and time on the NTP server.	

3. Select **Save**.

Configure Region

1. Select **Settings** > **Clock and Language** > **Region**.
   The region setting screen displays.



2. Configure the fields as per the information in the table.

Table 88: Region Settings

Field	*Action*	*Description*
Language	Set the default language of the device.	Default value: **English** Allowed values: List of supported languages
Height and Weight Unit	Select the height and weight unit of measurement to be used on the device.	The configured unit of measurement is applied in the **Patient Information** screen and the ECG patient reports. If the device language is English, Chinese, or Finnish and the device settings are restored to factory defaults, the unit of measurement is automatically set as **in/lb**. If the device language is Danish, Dutch, French, German, Italian, Swedish, or Norwegian and the device settings are restored to factory defaults, the unit of measurement is automatically set as **cm/kg**.
Input Method	Select a value from the drop-down list to configure input method editor for the device.	• If you select **Chinese-Pinyin**, the input method is available to the user to enter Simplified Chinese text. • If you select **None**, no input method is available to the user. Default value: **None**

3. Select **Save**.

Configure Hardware

Select **Settings** > **Hardware** menu to configure the settings below:

- Barcode - *Configure the Barcode on page 260*
- USB Ports - *Configure the USB Ports on page 261*
- Keyboard Tone and KISS Pump - *Configure Keyboard Tone and KISS Pump on page 261*
- Standby Modes - *Configure Standby Modes on page 262*

Configure the Barcode

NOTE:
The device is compatible with the MAC 5 external barcode reader (2030360-018), which supports reading barcodes containing the symbologies below for all supported languages:

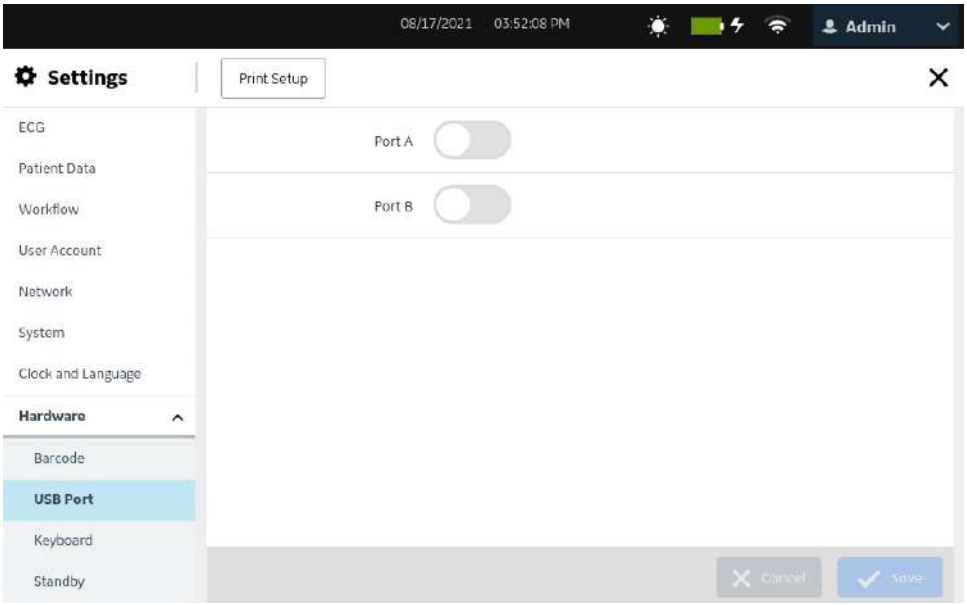
- Code-128
- PDF417
- Code 39
- Interleaved Code 2 of 5

- Data Matrix symbology for characters A-Z (upper case), a-z (lower case), and 0-9

If you are using an external barcode reader, make sure that the barcode reader is connected to this device and the BRCD option is enabled to test the barcode configuration. Before configuring the barcode, perform the Barcode Diagnostics Test described in the *MAC™ 5 Resting ECG Analysis System Service Manual* to make sure that the barcode reader is functioning properly.

Configure the USB Ports

1. Select **Settings** > **Hardware** > **USB Port**.
   The USB port setting screen displays.



2. Configure the fields as per the information in the table.

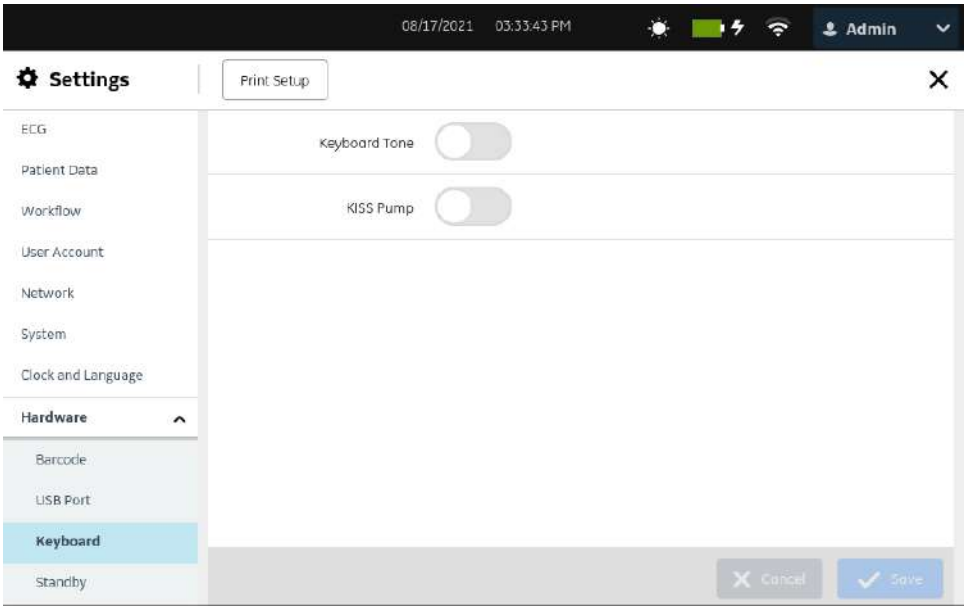
Table 89: Configure USB Ports

Field	*Action*	*Description*
Port A **Port B**	Enable or disable for each USB port.	Default value: Disabled

3. Select **Save**.

Configure Keyboard Tone and KISS Pump

1. Select **Settings** > **Hardware** > **Keyboard**.
   The keyboard setting screen displays.



2. Configure the fields as per the information in the table.

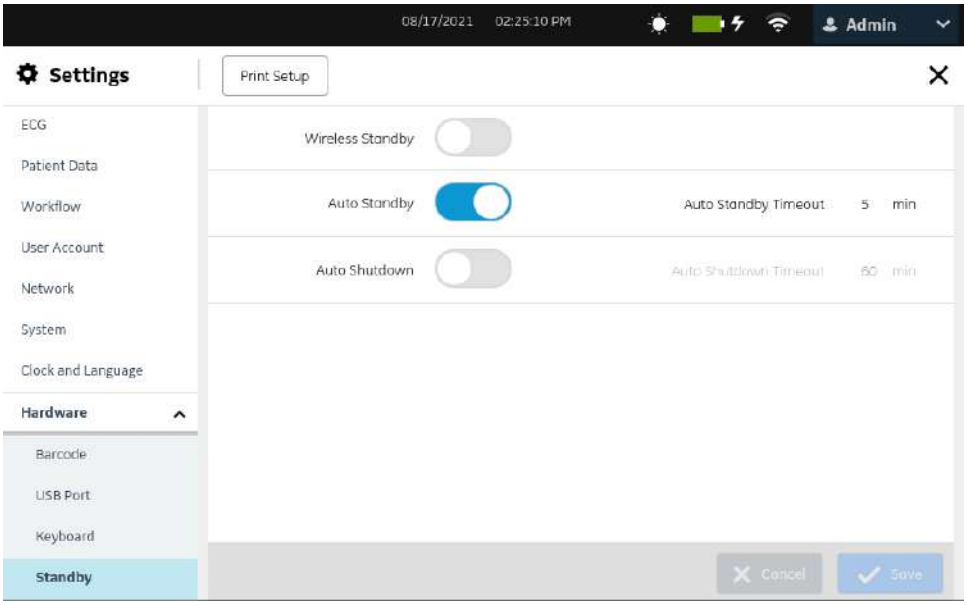
Table 90: Configure Keyboard Tone and KISS Pump

Field	*Action*	*Description*
Keyboard Tone	Enable or disable the keyboard tone.	Default value: Disabled
KISS Pump	Enable or disable this setting.	If this setting is enabled, the power supply to the KISS pump is enabled. If this setting is disabled, the power supply to the KISS pump is disabled. Default value: Disabled

3. Select **Save**.

Configure Standby Modes

1. Select **Settings** > **Hardware** > **Standby**.
   The standby setting screen displays.



2. Configure the fields as per the information in the table.

Table 91: Configure Standby Modes

Field	*Action*	*Description*
Wireless Standby	Enable or disable this setting.	If this setting is enabled: • The wireless connection is put in standby when the device is in standby mode. • The wireless connection is restored to its previous state when the device wakes up. Default value: Disabled
Auto Standby	Enable or disable this setting.	If this setting is enabled, the device is automatically put on standby after a configured duration of inactivity. Default value: Enabled
Auto Standby Timeout (min)	Enter the duration of inactivity, in minutes.	This field is enabled when the **Auto Standby** setting is enabled. After this duration of inactivity, the device is automatically put on standby. Default value: **15** Allowed values: 5 to 120
Auto Shutdown	Enable or disable this setting.	If this setting is enabled, the device is automatically shutdown after a configured duration of inactivity. Default value: Disabled

Field	*Action*	*Description*
Auto Shutdown Timeout (min)	Enter the duration of inactivity, in minutes.	This field is enabled when the **Auto Shutdown** setting is enabled. After this duration of inactivity, the device is automatically shutdown. The shutdown timeout duration must be greater than the standby timeout duration. Default value: **60** Allowed values: 5 to 120

3. Select **Save**.

11

Maintenance

Store Thermal Paper

When imaged and stored properly, ECG tracings resist fading for several years. If your retention requirements exceed five years, consider using GE Archivist paper.

To make sure the tracing is imaged properly, the device must be maintained in accordance with its service and technical manuals.

To make sure the tracing lasts for the paper's expected life span, observe these guidelines when storing your printouts:

- Store in a cool, dark, and dry location.
  - Standard paper

    Temperature must be less than 27°C (80°F).

    Relative humidity must be less than 65%.
  - Archivist paper

    Temperature must be less than 40°C (104°F).

    Relative humidity must be between 40% and 60%.
- Avoid exposure to bright light or UV sources.

  Sources of ultraviolet light include sunlight, fluorescent lights, halogen lights, mercury vapor lamps, and germicidal lamps.
- Avoid contact with cleaning liquids and solvents.

  Solvents to avoid include alcohols, ketones, esters, ether, and so forth.
- Store thermal paper separately in manila folders or polyester or polyimide protectors.

  Plastic document protectors, envelopes, or sheet separators made of polystyrene, polypropylene, or polyethylene do not degrade thermal traces. However, these materials afford no protection against fading from external causes.
- Do NOT store thermal papers with any of the cases below:
  - carbon or carbonless forms

- document protectors, envelopes, and sheet separators containing polyvinyl chloride or other vinyl chlorides

  non-thermal chart papers or any other products containing tributyl phosphate, dibutyl phthalate, or any other organic solvents

  NOTE:
  Many medical and industrial charts contain these chemicals.

- NOT use mounting forms, pressure-sensitive tapes, and labels that use solvent-based adhesives.

  Use only mounting forms and pressure-sensitive tapes made with starch or water-based adhesives.

Clean the Printhead

If the printer does not function, you may need to clean dust and foreign particles from the printhead.

Use below procedure to clean the printhead:

1. Dip cotton swabs in ethyl alcohol and wring out the excess solution.

   NOTE:
   Do not use products that can harm the heating element, such as sandpaper.

2. Open the printer door.

3. Gently wipe the heating element with the cotton swabs.

   NOTE:

   - The printhead gets hot when recording. Do not touch the thermal printhead directly.
   - Avoid unnecessary force when handling the printhead.

4. Re-insert the paper and close the printer door when the heating element is completely dry.

   NOTE:
   Use only original GE Healthcare writer paper. This paper has a special coating that prevents electrostatic buildup and contamination and debris collection on the printhead. Using other paper may result in recordings of poor quality. Use of other papers may wear out the printhead prematurely and may void the warranty.

Charge the Battery

You must charge the battery before initial use and in between acquisitions.

- To make sure a fully charged battery before initial use, charge the device before you use it for the first time.

- To make sure a fully charged battery in between acquisitions, power off the system and connect it to an AC wall outlet until you use the system again. This prolongs battery runtime.

The battery status indicator in the upper-right corner of the Acquisition screen shows how much charge the battery has available, and when the device is charging the battery. For more information on the battery status indicator, see *Battery Status on page 18*.

- When the battery is charging, the color of the battery status indicator on the screen is green. The battery LED on the keyboard flashes the amber light at two-second intervals.
- When the battery is low or critically low, the color of the battery status indicator on the screen is red. If the total charge level drops below 15%, an error tone notifies you and a message displays indicating that the battery is low. If the total charge level drops below 10%, the error tone is louder, longer, and sounds every minute, and a message displays indicating that the battery is critically low and you should connect to AC power immediately. The battery LED on the keyboard flashes the amber light at half-second intervals.
- When the battery is completely discharged, the device powers off. To operate your device, you must connect the system to an AC wall outlet. The battery LED on the keyboard turns off.
- If the battery is fully charged or exceeds safe charging temperature, the device will not charge the battery. The color of the battery status indicator on the screen is:
  - Green, if the device is connected to AC power.
  - White, if the device is not connected to AC power.

  The battery LED on the keyboard turns off.

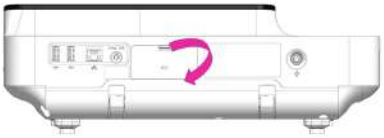
1. Power off the device.
2. Connect the system to an AC wall outlet.
3. Charge the battery for 3 hours or until the battery status indicator displays a full charge.

Replace the Battery

NOTICE:
BATTERY PACK DISPOSAL

Do not dispose of the battery pack by fire or burning. Follow local environmental guidelines concerning disposal and recycling.

1. Place your thumb on the door release tab of the battery compartment door and gently pull it open.



MAC 5 A4

MAC 5 A5

MAC 5 Lite

2. Press the latch beside the battery slot and pull the battery handle in horizontal direction to remove the battery.

MAC 5 A4

MAC 5 A5

MAC 5 Lite

3. Insert the new battery. See *Insert the Battery on page 22*.

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Cleaning and Disinfection

Inspect the Device

Carefully inspect devices between uses to verify proper function.

Evidence of damage and wear on a device may include but is not limited to discoloration, excessive scratches, wear, and cracks. Improperly functioning devices, damaged, and excessively worn devices should not be used.

Care at the Point of Use

Clean instruments as soon as possible after use.

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Preparation for Cleaning

For multi-piece or complex instruments, refer to their disassembly instructions. The disassembly instructions are available in the *MAC™ 5 Resting ECG Analysis System Service Manual*.

Contact your local GE Healthcare service representative for further information. For instruments produced by another manufacturer, reference the manufacturer's instructions for use.

Clean and Disinfect Guidelines

Observe the guidelines while cleaning and disinfecting the device.

- Follow cleaning instructions and observe hazards exactly as issued by GE Healthcare or other suppliers listed.
- Avoid exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion.

- Avoid exposure to highly alkaline conditions (pH > 11), as this can damage products (for example, aluminum parts).
- Never use conductive solutions or solutions that contain wax or wax compounds to clean the equipment.
- Do not immerse the device in any liquid as this may corrode metal contacts and affect signal quality.
- Do not drip or expose the writer assembly to any liquids.
- Do not allow fluid to pool around connection pins. If this happens, blot dry with a soft, lint-free cloth.
- Avoid contact with open vents, plugs, or connectors during the cleaning and disinfecting procedures.
- Never autoclave or steam-clean the device.
- Do not use until thoroughly dry.
- Do not use any of below materials to clean the device, because their use may damage equipment surfaces.
  - Organic solvents
  - Abrasive cleaners or solvents of any kind
  - Acetone
  - Ketone
  - Betadine
  - Sodium salts

Visual Inspection, Cleaning and Disinfection Frequency

The table indicates the frequency of visual inspection, cleaning, and disinfection procedures.

Component	*Visual Inspection*	*Cleaning*	*Disinfection*
Device and Trolley **NOTE**: Trolley is an optional purchase.	Daily, preferably before the equipment's first use each day	Monthly, or more frequently, as needed	Follow the same frequency as cleaning. Disinfection must be performed after cleaning.
Leadwires	Refer to the supplier's instructions for leadwire cleaning and disinfection.		
Reusable electrodes	Refer to the supplier's instructions for reusable electrode cleaning, disinfection and sterilization.		

Clean and Disinfect the Device and Trolley

If you purchase a trolley, the device and trolley are designed to require regular inspection and cleaning to function properly. The cleaning instructions for the device includes the touchscreen.

WARNING:

ELECTRICAL HAZARD - Improper handling during inspection or cleaning could result in electrical shock.

To avoid potential shock, observe the guidelines at all times:

Before inspecting or cleaning the device, turn it off, unplug it from AC power, and remove the battery.

Do not immerse any part of the equipment in water.

Pre-Clean Inspection and Functional Test

Perform a visual inspection to verify that the device meets the minimum conditions:

- The case and display screen are free of cracks and other damage.
- All plugs, cords, cables, and connectors are free of kinks, frays, and other damage.
- All cords and connectors are securely seated.
- All keys and controls operate properly.
- The trolley exterior is free of cracks and other damage.
- The accessory track is functioning properly.
- All cords and connectors are securely seated.
- The actuation lever is functioning properly.
- The castor wheels are functioning properly.

If you notice any items that need repair, contact an authorized service representative to make the repairs. Discontinue using the device until the appropriate repairs can be made.

Clean the Device and Trolley

1. Dispense Super Sani-Cloth® Wipe(s) from the canister.
2. If soil is present, thoroughly wipe the surfaces of the device with a fresh Super Sani-Cloth® Wipe for a minimum of two minutes and until soil and organic matter have been visibly removed.

   Treated surfaces must remain visibly wet for a minimum of two minutes. Use additional fresh disinfectant wipes, if needed, to make sure continuous two minutes contact time. Pay attention to the recessed areas and ridges; use a cotton swab to press onto the wipe for scrubbing these areas.

3. Inspect the device and trolley to make sure the complete removal of soil from surfaces, holes, and moveable parts.

   If soil is still present, re-clean the equipment by repeating step *2*.

4. Allow the device to air dry.

5. Discard wipes to clinical waste.

   Do not reuse wipes.

Post-Clean Inspection

GE Healthcare devices should be visually inspected and functionally tested after cleaning and prior to disinfection for below items:

- Cleanliness.
- Damage, including but not limited to corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear.
- Missing or worn part numbers.
- Proper functioning, including but not limited to the quality of ECGs; correct movement of hinges, joints, box locks, handles, ratchets, and couplings; proper alignment of jaws and teeth; and secure fastening of all locking mechanisms.

Do not use devices that are not functioning properly, that have unrecognizable markings, that have missing or worn part numbers, or that are damaged. Disassembled devices should be reassembled prior to disinfection unless otherwise instructed.

Disinfect the Device and Trolley

Make sure that cleaning is carried out to remove all visible soil and organic matter. See *Clean the Device and Trolley on page 271*.

1. Dispense fresh Super Sani-Cloth® Wipe(s) from the canister.

2. Apply disinfectant to the entire surface using fresh wipes.

   Treated surfaces must remain visibly wet for a minimum of three minutes. Use additional fresh disinfectant wipes, if needed, to make sure continuous three minutes contact time. Pay attention to the recessed areas and ridges; use a cotton swab to press onto the wipe to moisten these areas.

3. Remove disinfectant residue from the device by thoroughly wiping surfaces with a disposable, lint free wipe moistened with 70% Isopropyl Alcohol (IPA) solution.

4. Allow the device to air dry.

5. Discard wipes to clinical waste.

   Do not reuse wipes.

Clean and Disinfect Leadwires and Reusable Electrodes

CAUTION:

IMPROPER FUNCTIONING - Leadwires and electrodes that are not functioning properly could result in ECG distortion or failure.

Carefully inspect instruments between uses to verify proper functioning

Refer to the supplier's instructions for leadwire cleaning and disinfection.

Refer to the supplier's instructions for reusable electrode cleaning, disinfection, and sterilization.

Storage

Store the device in a clean and dry, well-ventilated area protected from dust, moisture, insects, vermin, and extremes of temperature and humidity.

Other Cleaning and Disinfection Agents

Super Sani-Cloth® Wipes is the recommended cleaning and disinfection solution, which has been validated on the device. However, below products are compatible with the device and may be used for cleaning and disinfection.

- PDI Easy Screen Cleaning®
- PDI Super Sani-Cloth®
- PDI Sani-Cloth® Bleach
- Clinell Sporicidal Wipes
- PDI Sani-Cloth® AF3
- PDI Sani-Cloth® Plus
- PDI Sani-Cloth® HB
- Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes
- Oxivir® Tb Wipes
- Clinell Universal Range
- Cleanisept Wipes
- Mikrozid Sensitive Wipes
- Caviwipes
- Phenol 2% (v/v)
- Ethanol (ethyl alcohol) 96% (v/v)
- Hydrogen Peroxide 20% (v/v)

- Sodium Hypochlorite (NaOCl) 5% solution)
- Isopropyl alcohol 70% (m/m)

Additional Information

- GE Healthcare used Super Sani-Cloth® wipes during cleaning and disinfection validation. This cleaning agent is not listed in preference to other available cleaning agents which may perform satisfactorily.
- The cleaning and disinfection information is provided in accordance with ANSI/AAMIST81, ISO 17664. The recommendations provided above have been validated as capable of preparing non-sterile GE Healthcare MAC™ 5 medical devices. It remains the responsibility of the user to make sure that the cleaning and disinfection are performed using appropriate equipment, materials, and personnel and achieves the desired result. This requires validation and routine monitoring of the process. Any deviation from the provided recommendations should be properly evaluated for effectiveness and potential adverse consequences.
- All users should be qualified personnel with documented expertise, competency, and training. Users should be trained on hospital policies and procedures along with current applicable guidelines and standards.
- Users should utilize appropriate Personal Protective Equipment (PPE) when cleaning and disinfecting devices in accordance with the Department of Environmental and Occupational Health and Safety's (OSHA) blood-borne pathogen guidelines or equivalent.

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Troubleshooting

System Errors

The table lists messages that you may encounter while using this device.

Message	*Cause*	*Solution*
WARNING: Approaching <xx>% of ECG storage limit. Transmit and delete reports to free memory.	The device storage capacity is approaching 80% or 90%. This occurs as patient reports are added to the **Files** list.	Transmit patient reports to configured destinations and delete the transmitted reports from the **Files** list to create additional storage space.
Memory is full. Transmit and delete reports to free memory.	The device storage capacity is between 99% and 100%.	Transmit patient reports to configured destinations and delete the transmitted reports from the **Files** list to create additional storage space.
Memory is full. This ECG cannot be saved.	The device storage capacity is full.	Transmit patient reports to configured destinations and delete the transmitted reports from the **Files** list to create additional storage space.
Memory is full. New ECGs cannot be saved.	The device storage capacity is full.	Transmit patient reports to configured destinations and delete the transmitted reports from the **Files** list to create additional storage space.
Battery error. Attach power cord. Contact Service.	• Power sensor failure • Battery capacity sensor failure	Replace the battery. Contact your GE Healthcare Service Support representative if the error persists.
Battery unknown error	An unexpected battery error has occurred.	Replace the battery. Contact your GE Healthcare Service Support representative if the error persists.

Message	*Cause*	*Solution*
Battery not detected	The battery is not detected by the device.	Perform below steps: 1. Remove the battery. 2. Re-insert the battery. If the battery is still not detected, replace the battery. Contact your GE Healthcare Service Support representative if the error persists.
Device date/time is incorrect. Update.	The date and time set on the device is not correct.	Select **Adjust** to set the correct date and time. For more information, se*Configure the Date and Time on page 255*e .
Touchscreen failure	The touchscreen is not working.	Contact your GE Healthcare Service Support representative if the error persists.
Cannot perform action while acquiring ECG data	You have tried to perform below actions while acquiring an ECG or rhythm: • Start a test for a new patient • Enter or edit patient information (available for rhythm) • Change speed, gain, or filter (available for rhythm) • Access User Menu • Access **Orders**, **Files**, or **Queue** list • Start ECG • Power off, lock, log out, standby or privacy mode	Perform only allowed actions.

ECG Acquisition Errors

The table lists messages that you may encounter while acquiring ECG.

Message	*Cause*	*Solution*
Report generation failed	Unknown error	1. Retry the action. 2. If the error persists, power off and power on the device. 3. If the error persists, contact your GE Healthcare Service Support representative.
Cannot open report		
ECG recording failed		

Printing Errors

Table 92: Printer Errors Encountered During ECG Patient Report Printing

Error Message	*Error Condition*	*How to troubleshoot:*
Printer error. Paper jam detected.	Paper is jammed.	Carefully remove the stuck paper from the rollers inside the printer and verify that the remaining papers are loaded correctly in the tray. Printing will restart automatically.
Printer error. Out of paper.	The paper tray is empty.	Insert sufficient paper in the paper tray. Printing will restart automatically.
Printer error. Door is open.	The printer door is open.	Close the printer door. Printing will restart automatically.

Table 93: Printing Errors Encountered During Rhythm Printing

Error Message	*Error Condition*	*How to troubleshoot:*
Printer error. Paper jam detected.	Paper is jammed.	1. Carefully remove the stuck paper from the rollers inside the printer and verify that the remaining papers are loaded correctly in the tray. 2. Select **Start Rhythm** to restart rhythm printing.
Printer error. Out of paper.	The paper tray is empty.	1. Insert sufficient paper in the paper tray. 2. Select **Start Rhythm** to restart rhythm printing.

Error Message	*Error Condition*	*How to troubleshoot:*
Printer error. Door is open.	The printer door is open.	1. Close the printer door. 2. Select **Start Rhythm** to restart rhythm printing.

Table 94: Printing Errors Encountered During Printing of the List of Stored Records

Error Message	*Error Condition*	*How to troubleshoot:*
Printer error. Paper jam detected.	Paper is jammed.	1. Carefully remove the stuck paper from the rollers inside the printer and verify that the remaining papers are loaded correctly in the tray. 2. Select **Print List** from the **Files Manager** to restart printing of the stored records list.
Printer error. Out of paper.	The paper tray is empty.	1. Insert sufficient paper in the paper tray. 2. Select **Print List** from the **Files Manager** to restart printing of the stored records list.
Printer error. Door is open.	The printer door is open.	1. Close the printer door. 2. Select **Print List** from the **Files Manager** to restart printing of the stored records list.
Cannot perform action while printing	You have tried to perform below actions while printing a patient report: • Start a test for a new patient • Delete the patient report • Change speed, gain, or filter • Access User Menu • Access **Orders**, **Files**, or **Queue** lists • Power off, lock, log out, standby, or privacy mode	Perform only the allowed actions.

Table 95: Printer Errors Encountered During Printing via Network Printer

Error Message	*Error Condition*	*How to troubleshoot*
Network printer offline	• The network printer is power off. • The network printer is not connected to network • Network Printer IP address changed	Turn on the network printer, connect it network, and check network printer IP Address is same as configured on MAC 5 device.
Network printer toner low	The cartridge of the network printer is nearly out of use.	Replace the cartridge in the network printer
Network printer media empty	The network printer paper tray is empty.	Insert sufficient paper in the paper tray.
Network printer paper jam	Paper in the network printer is jammed.	Carefully remove the stuck paper from the printer and verify that the remaining papers are loaded correctly in the tray.
Network printer authentication failure	Network printer requires a username and password to accept printing job. • User did not configure username and password in network printer correctly • Network printer username and password changed	Correct username and password on the MAC 5 device.
Network printer unknown error	Unknown error in printer	Restart the system to check if the error is resolved. If the error persists, contact your GE Healthcare Service Support representative.

Table 96: Common Printer Errors

Error Message	*Error Condition*	*How to troubleshoot:*
Low Battery. Printer is disabled. Connect power cord.	Low battery	Connect the power cord.
High printer temperature. Printer disabled. Contact Service.	High printer temperature	Restart the system to check if the error is resolved. If the error persists, contact your GE Healthcare Service Support representative.

Error Message	*Error Condition*	*How to troubleshoot:*
Printer error. Restart system. Contact Service.	Unknown error or hardware failure in printer	Restart the system to check if the error is resolved. If the error persists, contact your GE Healthcare Service Support representative.
Incompatible firmware.	Incompatible printer firmware	Contact your GE Healthcare Service Support representative to upgrade the printer firmware.
Acquisition error. Fix and retry printing.	Printing stopped due to acquisition error	Rectify the error with the acquisition module and retry printing.
Printer error. Retry. If issue persists, restart system.	Unknown error in printer	Retry printing. If the error persists, restart the system.
Printer is recovering. Please wait ...	Printer recovery error	Wait for the printer to recover. If the error persists, restart the system.
Cannot perform action while printing	You have tried to perform below actions while printing a patient report: • Start a test for a new patient • Delete the patient report • Change speed, gain, or filter • Access User Menu • Access **Orders**, **Files**, or **Queue** lists • Power off, lock, log out, standby or privacy mode	Perform only allowed actions.

Report Transmission Errors

Table 97: Errors Encountered During Patient Report Transmission

Error Message	*Error Condition*	*How to troubleshoot:*
Transmission queue is full. Additional reports cannot be added to the queue.	The transmission queue has reached its maximum limit of 1,000 reports.	Wait for the reports in the queue to transmit and try again.

Error Message	*Error Condition*	*How to troubleshoot:*
Unable to transmit. Incomplete patient data.	One or multiple patient reports cannot be added to the transmission queue because required fields in the patient demographics are blank or contain invalid data.	1. Edit the incomplete patient report(s) to enter missing patient data. 2. Retry transmission.
Unable to transmit one or more reports. Incomplete patient data.		
Report transmission is in progress. Delete job from queue to edit.	You are trying to edit a patient report that is being transmitted.	Delete the job from the queue to continue editing the patient report.
Destination unknown	The destination is not found.	Reconfigure the destination. See *Configure Transmission Settings on page 164*
No USB device detected	The USB flash drive is not detected.	Verify that the USB flash drive is firmly inserted into the USB port. If the error persists, verify that external USB storage is enabled and the USB port is enabled. If the error persists, use another USB flash drive.
USB storage is full	The USB storage is full.	Remove this USB flash drive, and insert another USB flash drive with write permissions.
USB unknown error	The USB flash drive has an unknown error.	Remove this USB flash drive, and insert another USB flash drive with write permissions.
Cannot copy to USB	The report cannot be transmitted to the USB flash drive.	Make sure that the USB flash drive is firmly inserted into the USB port.
Hilltop generation unsuccessful	The file generation is unsuccessful.	Retry transmission. Contact your GE Healthcare Service Support representative if the error persists.
PDF generation unsuccessful		
Sapphire generation unsuccessful		
Unknown error	Unknown error	Contact your GE Healthcare Service Support representative if the error persists.
Server not connected	The server connection is unsuccessful.	Retry transmission. Contact your GE Healthcare Service Support representative if the error persists.
DCP not found	The DCP connection is unsuccessful.	

Error Message	*Error Condition*	*How to troubleshoot:*
Unknown server version	The server version is unknown.	
Server is not accepting the test.	The server is not accepting the transmission.	
No network connection	The network connection is lost.	Reconnect to the network.

Configuration File Errors

Table 98: Configuration File Errors

Error Message	*Error Condition*	*How to Troubleshoot:*
Digital signature validation failed	The digital signature in the configuration file used for restoring settings is not valid.	Copy the configuration file with a valid digital signature to the USB flash drive.
Invalid data file format	The configuration file used for restoring settings is invalid.	Copy a valid configuration file to the USB flash drive.
Missing data in data file	The configuration file used for restoring settings was not properly saved.	Copy a valid configuration file to the USB flash drive.

USB Flash Drive Errors

Table 99: USB Device Errors

Error Message	*Error Condition*	*How to Troubleshoot:*
No USB device detected	The USB flash drive is not inserted properly in the USB port.	Make sure that the USB flash drive is firmly inserted into the USB port.
USB unknown error	The USB flash drive has an unknown error.	Remove this USB flash drive, insert another USB flash drive with write permissions.

Shared Network Connection Errors

Table 100: Shared Network Connection Errors

Error Message	*Error Condition*	*How to troubleshoot:*
Network shared path not found	User-specified shared network path is invalid.	Enter a valid path name and select **Test Connection**.
Invalid shared network credentials	User-specified credentials to access shared network path is invalid.	Enter valid credentials and select **Connect**.
Connection to shared network path failed	User-specified IP/URL to access shared network path is invalid.	Enter the correct IP/URL and select **Test Connection**.
Shared network mount path not found	There is no LAN/WLAN connectivity.	Enable LAN/WLAN connectivity and select **Test Connection**.
Username is required	User Name field is empty.	Enter valid username and select **Connect**.
Password is required	Password field is empty.	Enter valid password and select **Connect**.
Username and Password are required	User Name and password fields are empty.	Enter valid credentials and select **Connect**.
Test Successful	The **Test Successful** message displays if you have entered **./** in the User Name field while entering the valid shared directory path.	**Test Connection** can pass if the user does not have a write permission on the server while the actual transmission could fail.

Errors while Installing Certificates

Table 101: CA Certificate Installation Errors

Cause for Error	*Error Condition*	*How to troubleshoot:*
Not in PEM format	The CA certificate is not in PEM format.	Convert the CA certificate to PEM format.
Not a valid CA certificate	The CA certificate is in valid.	Check that the certificate is a valid CA certificate and has the CA certificate flag enabled.
Date not valid	Only a warning and not an error condition.	Check that the CA certificate has a valid date.

Table 102: Client Certificate Installation Errors

Cause for Error	*Error Condition*	*How to troubleshoot:*
Not in PEM format	The client certificate is not in PEM format.	Convert the client certificate to PEM format.
Unrecognized public key algorithm - RSA, DSA, ECDSA.	The client certificate public key algorithm is not recognized.	Check that the client certificate public key algorithm is valid and has the recognizable alorithm including RSA, DSA, and ECDSA.
Signature does not match CA certificate	The client certificate signature does not match with CA certificate.	Verify that the client certificate was signed by the installed CA certificate. Not applicable for **Self-signed** certificate.
Missing link in CA certificate chain	An intermediate certificate in the certificate chain is missing.	Include missing intermediate certificates in the CA certificate. See *Intermediate Certificates on page 242*. Not applicable for **Self-signed** certificate.
Incorrect password for private key	The password is incorrect for private key of the client certificate.	Check that the password is correct for private key of the client certificate.
Incompatible public/ private key pair	The client private key and client public key are not compatible with each other.	Install a compatible public/private key pair for the client certificate.
Date not valid	Only a warning and not an error condition	Check that the client certificate has a valid date.

Wireless Network Connectivity Errors

Table 103: CA Certificate Errors

Error Message	*Error Condition*	*How to troubleshoot:*
CA Certificate PEM Check Failed	The CA certificate format is invalid.	Obtain a PEM-encoded CA certificate.
CA Certificate has expired	The CA certificate has expired.	Obtain a PEM-encoded CA certificate.
CA Certificate is invalid	The CA certificate is invalid.	Obtain a PEM-encoded CA certificate.
Unrecognized certificate format	Certificate format is invalid.	Obtain a PEM-encoded CA certificate.

Table 104: Client Certificate Errors

Error Message	*Error Condition*	*How to troubleshoot:*
Client Public Key Certificate PEM Check Failed	The client certificate format is invalid.	Obtain a PEM-encoded client certificate.
Client Certificate has expired	The client certificate has expired.	Obtain a PEM-encoded client certificate.
Invalid Client Private Key Password	The client private key password is invalid.	Enter a valid client private key password.
Client Certificate is invalid	The client certificate is invalid.	Obtain a PEM-encoded client certificate.
CA Certificate Compatibility Check Failed	The client certificate is not compatible with the CA certificate in the device or the CA certificate is not installed in the device.	Obtain a PEM-encoded client certificate which is compatible with the PEM-encoded CA certificate in the device or turn the **Self-signed** option on.
Unrecognized certificate format	Certificate format is invalid.	Obtain a PEM-encoded client certificate.

Table 105: Errors During Wireless Network Connection

Error Message	*Error Condition*	*How to troubleshoot:*
CA Certificate has expired	The CA certificate has expired.	Obtain a PEM-encoded CA certificate.
Client Certificate has expired	The client certificate has expired.	Obtain a PEM-encoded client certificate.
CA and Client Certificates have expired	The CA and Client certificates have expired.	Obtain valid PEM-encoded CA and client certificates.
CA Certificate is not installed	The CA certificate is not installed in the device.	Obtain a PEM-encoded CA certificate.
Client Certificate is not installed	The client certificate is not installed in the device.	Obtain a PEM-encoded client certificate.
CA and Client Certificates are not installed	The CA and client certificates are not installed in the device.	Obtain valid PEM-encoded CA and client certificates.

Table 106: Errors During Network Connection

Error Message	*Error Condition*	*How to troubleshoot:*
IP address conflict	The user entered an invalid IP address.	Enter the correct IP address.

Error Message	*Error Condition*	*How to troubleshoot:*
Invalid subnet mask	The user entered an invalid subnet mask.	Enter the correct subnet mask.
Invalid default gateway	The user entered an invalid default gateway.	Enter the correct default gateway.
Invalid primary DNS	The user entered an invalid primary DNS.	Enter the correct primary DNS.
Invalid secondary DNS	The user entered an invalid secondary DNS.	Enter the correct secondary DNS.

LDAP Configuration Errors

Table 107: LDAP Configuration Errors

Error Message	*Error Condition*	*How to troubleshoot:*
LDAP Server unavailable	The LDAP server does not exist or the IP address or server name is incorrect.	Verify and update the IP address, server name, or port and test the connection.
LDAP Server failure	The connection to the server fails due to any unknown reasons (for example, the server is down).	Verify that the server is up and test the connection.
LDAP Server connection timed out	The connection to the server times out due to a network connectivity issue.	Check the network connection and test the connection again after network connectivity resumes.
LDAP Server Distinguished Name does not exist	The distinguished name does not exist in the LDAP server.	Verify and update the configured distinguished name and test the connection again.
LDAP authentication failed	User login credentials are invalid.	Enter correct login credentials and test the connection again.

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Report Formats

ECG Report Formats

Table 108: Supported 12-Lead ECG Report Formats

Report Format Name	*Description*	*One Page or Multiple Page Report*
1 by 10s @25mm/s	Shows one column of 12 rows of waveforms. Each column is 10 seconds wide and printed at 25 mm/s.	One page report
1 by 10s @ 50 mm/s	Shows one column of 12 rows of waveforms. Each column is 10 seconds wide and printed at 50 mm/s. 5 seconds are printed on each page. This results in a two page report.	Multiple page report
2 by 5s @25mm/s	Shows two columns of six rows of waveforms. Each column is 5 seconds wide and printed at 25 mm/s.	One page report
2 by 5s @ 50 mm/s	Shows two columns of six rows of waveforms. Each column is 5 seconds wide and printed at 50 mm/s. One column is printed on each page. This results in a two page report.	Multiple page report
2 by 5s + 1 Rhythm Ld	Shows two parts: • The upper part consists of two columns of six rows of waveforms. Each column is 5 seconds wide and printed at 25 mm/s. • The lower part consists of one row of 10 seconds of one lead. The rhythm lead shown in the report is configurable.	One page report
2 by 10s	Shows two columns of six rows of waveforms. Each column is 10 seconds wide and printed at 25 mm/s. One column is printed on each page. This results in a two page report.	Multiple page report
4 by 2.5s	Shows four columns of three rows of waveforms. Each column is 2.5 seconds wide and printed at 25 mm/s.	One page report

Report Format Name	*Description*	*One Page or Multiple Page Report*
4 by 2.5s + 1 Rhythm Ld	Shows two parts: • The upper part shows four columns of three rows of waveforms. Each column is 2.5 seconds wide and printed at 25 mm/s. • The lower part shows one row of 10 seconds of one lead. The rhythm lead shown in the report is configurable.	One page report
4 by 2.5s + 3 Rhythm Ld	Shows two parts: • The upper part shows four columns of three rows of waveforms. Each column is 2.5 seconds wide and printed at 25 mm/s. • The lower part shows three rows of 10 seconds of three leads. The rhythm leads shown in the report are configurable.	One page report
4 by 10s	Shows four columns of 3 rows of waveforms. Each column is 10 seconds wide and printed at 25 mm/s. Three leads are printed on each page. This results in a four page report.	Multiple page report
Pharma	If you purchase the **PHAR - Pharmacy** option, you can select this type for the report. Shows three parts: • The upper part shows four columns of three rows of waveforms. Each column is 2.5 seconds wide and printed at 25 mm/s. • The middle part shows two rows of 10 seconds of three leads. The rhythm leads shown in the report are configurable. • The lower part of the report is text, such as the measurements and patient information.	One page report

Table 109: Additional Supported 12-Lead ECG Report Formats

Report Format Name	*Description*	*One Page or Multiple Page Report*
Computer Graphic Record (CGR)	Shows three columns of four rows of medians at 25 mm/s on the left side and three rows of waveforms printed at 12.5 mm/s on the right side (resulting in 10 seconds of rhythm). The upper part of the report is text, such as the measurements or interpretation. This results in a one page report.	One page report

Report Format Name	*Description*	*One Page or Multiple Page Report*
Swedish Format 1	Shows two columns of six rows of medians at 50 mm/s on the left side and six rows of waveforms printed at 12.5 mm/s on the right side (resulting in 10 seconds of rhythm). The lower part of the report is text, such as the measurements or interpretation. This results in a one page report.	One page report
Swedish Format 2	Shows below parts: • The upper part of the report is six rows of 5 seconds of waveform printed at 50 mm/s. • The lower part of the report is text, such as the measurements or interpretation. Each column (page) is from the first 5 seconds of data. This results in a two page report.	Multiple page report

The figure shows the standard report layout:

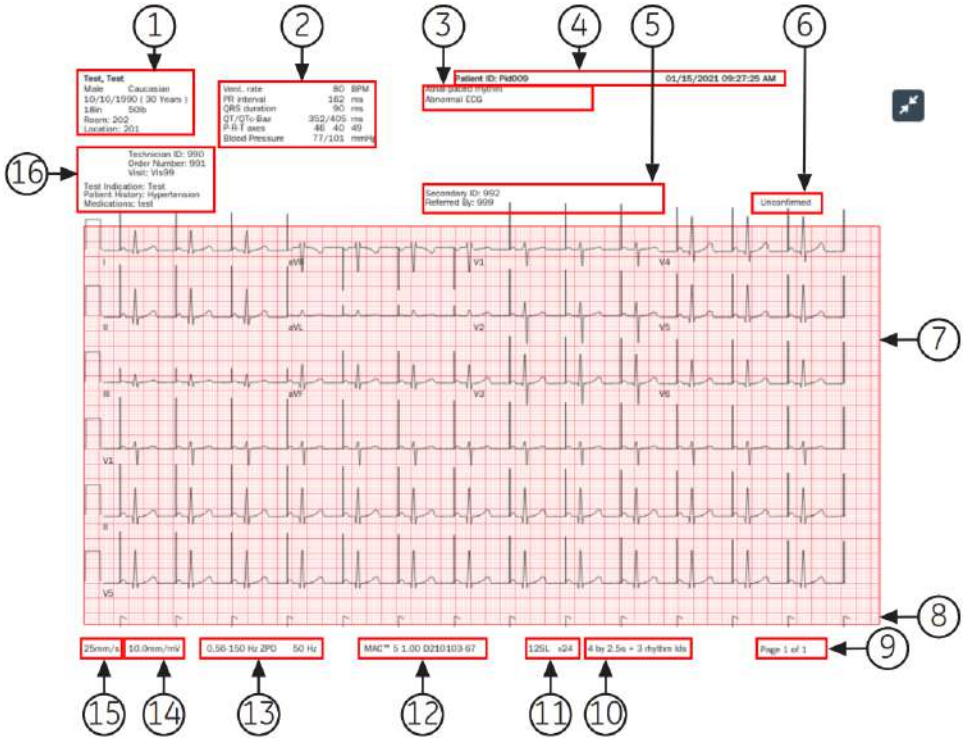


Table 110: Standard Report Layout

Item	*Name*	*Description*
1	**Patient Demographics**	Displays information about the patient, such as: • **First Name** and **Last Name** • **Age** and/or **Date of Birth** • **Gender** • **Race** • **Height** and **Weight** • **Room** • **Location**
2	**Vital Signs**	Displays information about the patient's vital signs, such as: • Heart rate • PR interval • QRS duration • QT/QTc • P-R-T axes • Blood pressure
3	**12SL Interpretation Statements**	Displays automated 12SL interpretation statements if the report format is configured to include 12SL interpretation statements. Clinicians use this information to make decisions about cardiac care for the patient. The patient report includes ACS interpretation statements when the ECG is recorded with the ACS option. The status of **Hookup Advisor** is based on the 12SL analysis of the patient report.
4	**ECG Header**	Displays the **Patient ID**, date and time of ECG acquisition in the configured date and time format, and the name of the institution, if configured.
5	**Physician Information**	Displays the details below: • **Referred by**: Name of the physician who referred the patient • **Secondary ID**: Alternate identification number of the patient
6	**Report Status**	Displays the status of the report.
7	**Waveforms**	Displays the 10 seconds ECG patient report in the configured report format for the selected lead set.

Item	*Name*	*Description*
8	**Pace Annotations**	Displays pace annotaions for patients with a pacemaker. The pace annotations represent pacemaker pulses. Available only when HD Pace option is enabled. See *Enable HD Pace on page 67* for detailed information. **NOTE**: When two pace annotations are detected so close to each other that they cannot be uniquely shown on the report, a single pace flag with two flag tips is printed to indicate this condition. 
9	**Page Number**	Displays the page number of the ECG patient report in the format page *x* of *y*, where *x* is the current page number and *y* is the total number of pages.
10	**Report Format**	Displays the configured report format title used to preview the ECG patient report.
11	**12SL Version**	Displays the 12SL version used to analyze the ECG patient report.
12	**Product Model**	Displays the product model.
13	**Filter Setting**	Displays the filter of the ECG waveform (measured in Hz), with Zero Phase Distortion (ZPD for High Pass filter).
14	**Gain Setting**	Displays the gain of the ECG waveform (measured in mm/mV).
15	**Speed Setting**	Displays the speed of the ECG waveform (measured in mm/s).
16	**Clinical Data**	Displays the clinical data gathered during the ECG test, such as: • **Technician ID** **NOTE**: If the logged-in user has a **Technician ID** associated with their user account, the **Technician ID** is automatically populated in the preview. If the user modifies the value of the **Technician ID** field in the **Patient Information** screen, the preview is refreshed with the updated **Technician ID**. • **Test Indication** • **Priority** • **Visit Number** • **Medical History** • **List of Medications**

Rhythm Report Format

Rhythm reports contain patient information, waveform data, and ECG acquisition data. A rhythm report is a continuous recording of a patient's ECG in a digital format

or in print. A continuous rhythm recording is done for a patient so cardiac events are not missed.

This section describes the information contained in a rhythm report and explains where in the report that the information is located. After generating a rhythm report, it is a recommended best practice to review the report before allowing the patient to leave.

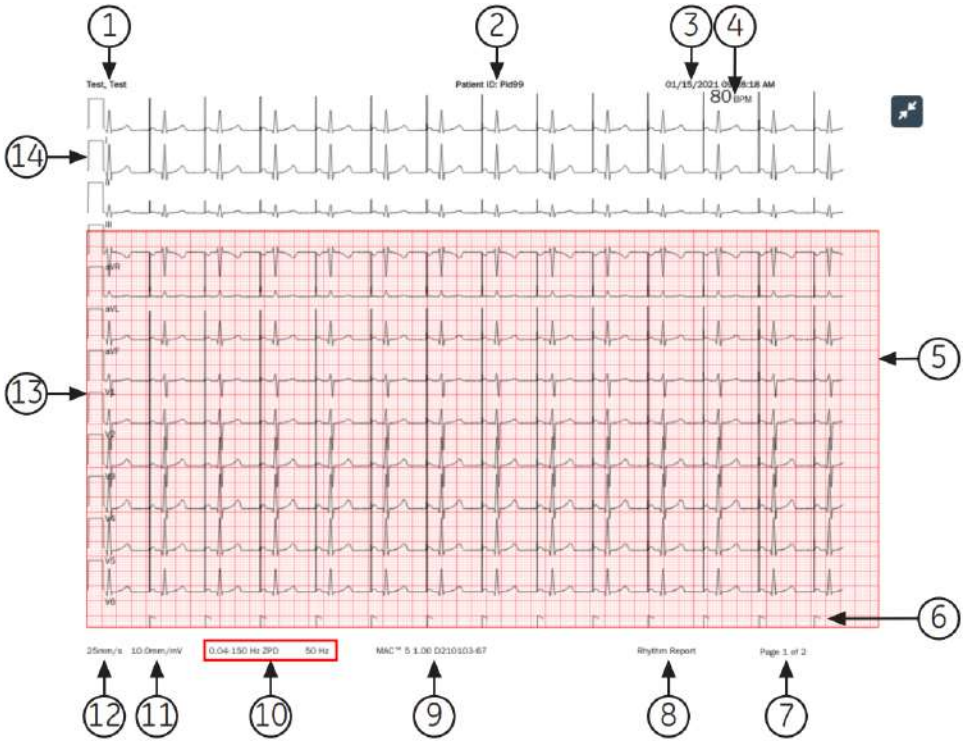


Table 111: Standard Rhythm Report Layout

Item	*Description*
1	Patient name
2	Patient ID and the name of the institution
3	The date and time of acquisition for the report. If the report contains more than one page, the time of acquisition changes on each page to the current time of acquisition.
4	The beats per minute (BPM) for the heart rate of the patient. If the report contains more than one page, the BPM changes on each page of the waveform data.
5	The waveform data The rhythm report contains waveform data for 12 leads configured for the rhythm report.

Item	*Description*
6	Pace channel. Pace annotations display in this channel for patients with a pacemaker. The pace annotations show pacemaker pulses. Available only when HD Pace option is enabled. See *Enable HD Pace on page 67* for detailed information. **NOTE**: When 2 pacemaker pulses are sensed so near each other that they cannot be uniquely shown on the report, a one pace spike with two flag tips is printed to show this condition: 
7	Page number of the report. The page number increments for each page of the rhythm report. For the digital rhythm report, the page number is shown as **Page <x> of <y>**. For the printed rhythm report, the page number is shown as **Page <x>**.
8	The type of report format (rhythm report).
9	The product name.
10	The **Filter** of the ECG waveform (measured in Hz), indicated with ZPD (for High Pass filter). **NOTE**: You can change the filter before or during the recording and/or printing of a rhythm. For the printed rhythm report, the printing stops and restarts at the newly selected filter. A gap is shown on the printed rhythm report where the change occurred. Each time the rhythm printing starts after a change in filter, a calibration pulse is added for each lead that tells which filter on the printed rhythm. For the digital rhythm report, the calibration pulse of the last filter selected during recording is shown on the full report.
11	The **Gain** of the ECG waveform (measured in mm/mV). **NOTE**: You can change the gain before or during the recording and/or printing of a rhythm. For the printed rhythm report, the printing stops and restarts at the newly selected gain. A gap is shown on the printed rhythm report where the change occurred. Each time the rhythm printing starts after a change in gain, a calibration pulse is added for each lead that tells the gain on the printed rhythm. For the digital rhythm report, the calibration pulse of the last gain selected during recording is shown on the full report.

Item	*Description*
12	The **Speed** of the ECG waveform (measured in mm/s). **NOTE**: You can change the speed before or during the printing of a rhythm. For the printed rhythm report, the printing stops and restarts at the newly selected speed. A gap is shown on the printed rhythm report where the change occurred. Each time the rhythm printing starts after a change in speed, a calibration pulse is added for each lead that tells the speed on the is printed rhythm. The digital rhythm report is recorded at the configured rhythm speed.
13	The **Leads**.
14	The **Calibration pulses**. When a rhythm recording is started, a calibration pulse is added at the beginning of each lead in the patient report, which shows the speed and gain at which the rhythm is recorded. Each calibration pulse represents 1 mV of amplitude and 200 ms duration of the waveform. Each time the rhythm recording starts after a change in speed or gain, a calibration pulse is printed for each lead. **NOTE**: The standard grid paper is divided into small squares of 1 mm x 1 mm and large squares of 5 mm x 5 mm. When recording 25 mm/s, 1 second of data is shown in 25 mm (5 large squares) on the rhythm report. When recording 10 mm/mV, 1 mV of data is shown in 10 mm/mV (2 large squares) on the printout.

Full Disclosure (FD) Report Format

Full Disclosure (FD) reports contain patient information, waveform data, and ECG acquisition data in FD buffer at the time of generating report. A FD report is a continuous recording of a patient's ECG in a digital, print, or transmit format for a single lead.

This section describes the information contained in a FD report and explains where in the report that the information is located. After generating a FD report, it is a recommended best practice to review the report before allowing the patient to leave.

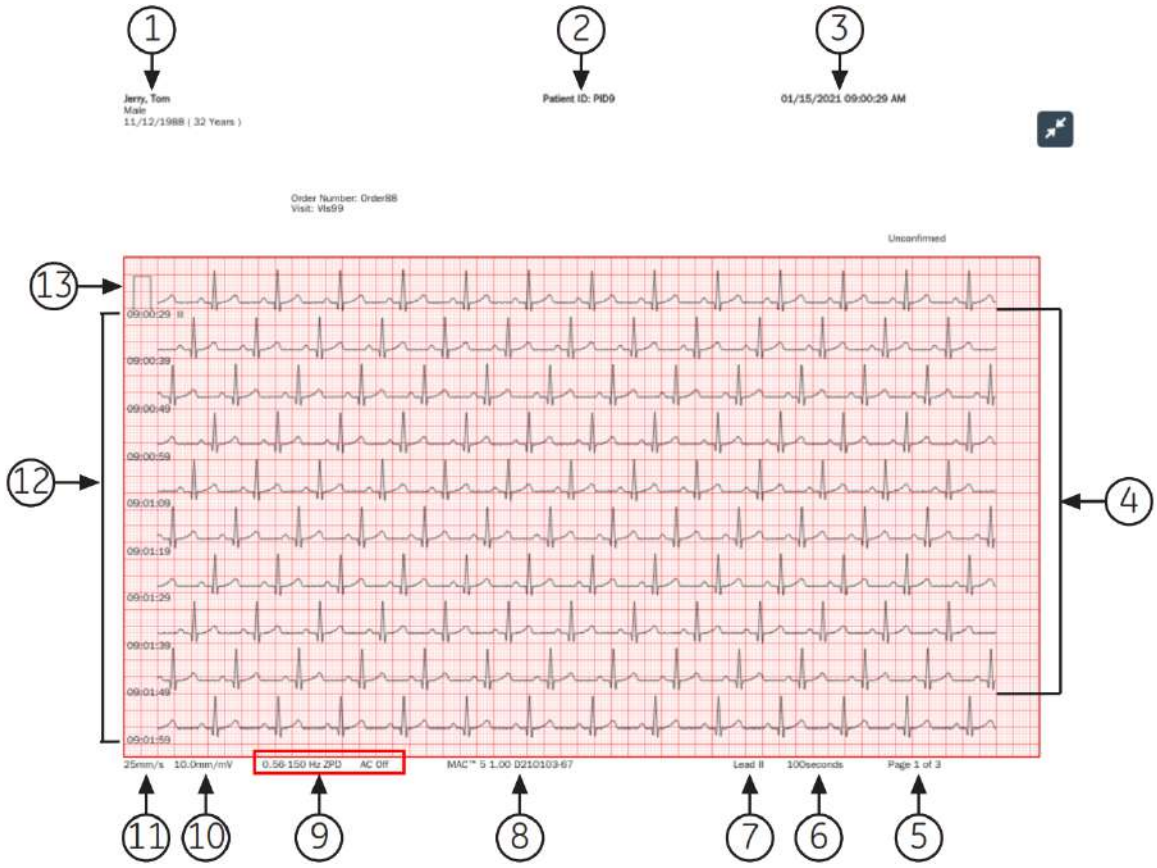
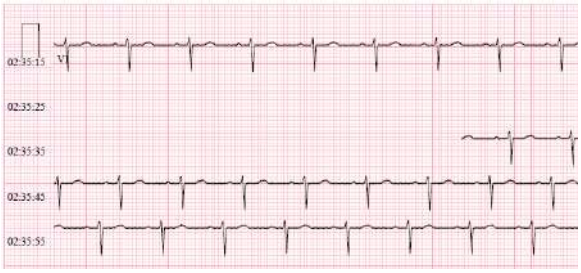
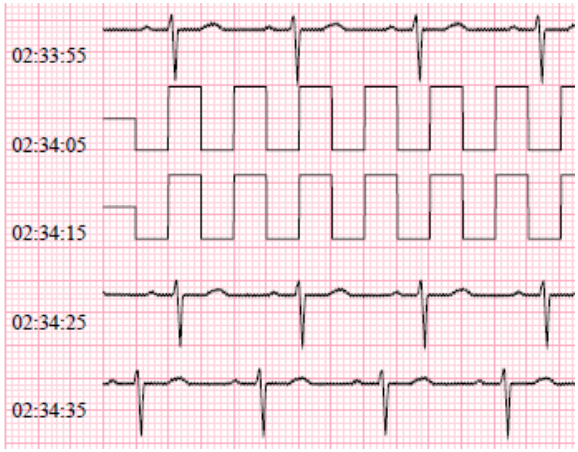


Table 112: FD Report Layout

Item	*Description*
1	Prints the patient name.
2	Prints the patient ID and name of the institution.
3	Prints the date and time of acquisition for the report.

Item	*Description*
4	Prints the waveform. The FD report contains waveform data for a single lead selected in Full Disclosure mode. **NOTE**: A gap is shown on the printed or transmitted FD report when the acquisition module is disconnected.  **NOTE**: A square waves is shown on the printed or transmitted FD report when the lead is disconnected. 
5	Prints the page number of the report. The page number increments for each page of the FD report. For the FD report, the page number is shown as **Page <1> of <3>**.
6	Prints the total number of seconds in the rhythm report on each page.
7	Prints the selected single **Lead** information.
8	Prints the product name.

Item	*Description*
9	Prints the **Filter** of the ECG waveform (measured in Hz), indicated with ZPD (for High Pass filter). **NOTE**: You can change the filter after recording and/or printing of a rhythm. For the printed FD report, the recording stops and restarts at the newly selected filter. Each time the Full Disclosure recording starts after a change in filter, a calibration pulse is added for each lead that tells which filter on the printed rhythm. For the digital FD report, the calibration pulse of the last filter selected during recording is shown on the full report.
10	Prints the **Gain** of the ECG waveform (measured in mm/mV). **NOTE**: You can change the gain after recording and/or printing of a rhythm. For the printed FD report, the recording stops and restarts at the newly selected gain. Each time the Full Disclosure recording starts after a change in gain, a calibration pulse is added for a single lead that tells the gain on the printed FD report. For the digital FD report, the calibration pulse of the last gain selected during recording is shown on the full report.
11	Prints the **Speed** of the ECG waveform (measured in mm/s). **NOTE**: The digital FD report is recorded at the configured rhythm speed.
12	Displays the time stamp for each row. The time stamp corresponds to clock time when the first sample is acquired in that row.
13	Prints the **Calibration pulses**. When a rhythm recording is started, a calibration pulse is added at the beginning of a single lead in the patient report , which shows the speed and gain at which the rhythm is recorded. Each calibration pulse represents 1 mV of amplitude and 200 ms duration of the waveform. Each time the Full Disclosure recording starts after a change in speed or gain, a calibration pulse is printed for a single lead. **NOTE**: The standard grid paper is divided into small squares of 1 mm x 1 mm and large squares of 5 mm x 5 mm. When recording 25 mm/s, 10 rows of data, 10 seconds of data per row is shown in each page on the FD report.

B

Patient Preparation

Prepare the Patient's Skin

Below steps are necessary to properly prepare a patient's skin before acquiring an ECG.

Careful skin preparation is the key to an interference-free ECG. Signal quality is indicated on the device via the **Hookup Advisor** status and messages.

Signal quality is indicated on the device via the **Hookup Advisor** status and messages.

1. Select the electrode placement sites for ECG diagnosis per the protocol specified by the hospital or physician.

   Refer to the electrode placement diagrams and descriptions for the various protocols.

2. Make sure that each site is dry, clean, and free of excessive hair.

   NOTE:

   Do not use solvents to clean the skin; solvents trapped under electrodes may lead to abnormal skin reactions.

3. Apply the electrodes to the prepared sites.

   WARNING:

   ELECTRIC SHOCK - Touching the conductive elements cancels the protection provided by the isolated signal input.

   Make sure that conductive parts of the electrodes or leadwires, including the neutral electrode, do not come in contact with other conductive parts, including earth.

4. Check the **Hookup Advisor** for any indication of lead problems.

   NOTE:

   Use only electrodes and contact agents recommended by GE Healthcare. The signal quality on the **Hookup Advisor** is not indicated until the RA/R electrode is applied. If RA/R becomes disconnected, the system reports that all electrodes are off the patient.

Electrode Placement

This section describes various methods for placing electrodes for resting ECGs on a patient.

WARNING:

INACCURATE DIAGNOSIS - Improper connection of the leadwires to the electrodes will cause inaccuracies in the ECG.

Make sure the leadwires are connected properly to the electrodes. Trace each leadwire to its colored connector to make sure that it is matched to the correct label leadwire connection location.

Standard 12–Lead Electrode Placement

To acquire a standard 12–lead ECG, use the electrode placement shown in the diagram below.

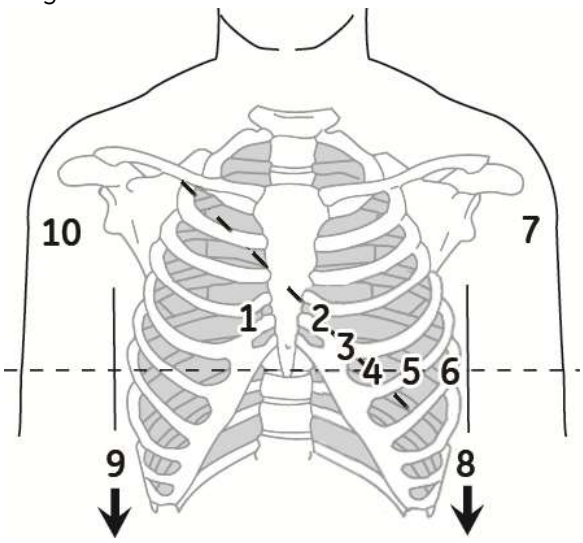


Table 113: Standard 12–Lead Electrode Placement

Item	*AHA Label*	*IEC Label*	*Description*
1	V1 red	C1 red	Fourth intercostal space at the right sternal border.
2	V2 yellow.	C2 yellow	Fourth intercostal space at the left sternal border.
3	V3 green.	C3 green	Midway between location 2 and 4.
4	V4 blue	C4 brown	Mid-clavicular line in the fifth intercostal space.
5	V5 orange	C5 black	Anterior axillary line on the same horizontal level as 4.
6	V6 violet	C6 violet	Mid-axillary line on the same horizontal level as 4 and 5.
7	LA black	L yellow	Left deltoid.

Item	*AHA Label*	*IEC Label*	*Description*
8	LL red	F green	Above the left ankle (alternate placement— upper leg as close to the torso as possible).
9	RL green	N black	Above the right ankle (alternate placement—upper leg as close to the torso as possible).
10	RA white	R red	Right deltoid.

C

Patient Data Fields

Patient Information Text Box Names

When an order is attached to a patient test, all Patient Information text boxes are read-only. The text box names in the table with an asterisk (*) are not.

Table 114: Patient Information text boxs

Name	*Description*	*Length*	*Accepted Values*
Patient ID	Identification number given to the patient. The Patient ID (PID) can be configured by the administrator for a specified country requirement (for example, Denmark, Sweden, or Norway), customize text box names, and add leading zeroes for specified character lengths. If the Patient ID does not agree with the configuration, an error message opens by the Patient ID text box. If the Patient ID agrees with the configuration, the patient **Date of Birth** and **Gender** text boxes are automatically updated.	Standard Patient ID:	
		1 to 16 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
		Danish Patient ID:	

		10 characters	Valid values: '0 to 9' and '-'.
			The PID must be in the format *ddmmyy-exxg* or *ddmmyyexxg*, where:
			• *dd* = patient day of birth
			• *mm* = patient month of birth
			• *yy* = patient year of birth
			• *e* = patient year of birth is calculated as follows:
			  • *e* = 0, 1, 2, 3 or 4, if the patient year of birth is between 1900 to 1999.
			  • *e* = 5, 6, 7, 8 or 9, if the patient year of birth is between 2000 to existent year.
			• *xx* = patient place of birth
			• *g* = patient gender
			  • male = odd number
			  • female = even number

		Swedish Patient ID:	

Name	*Description*	*Length*	*Accepted Values*
		10 (Short) to 12 (Long) characters	Valid values: '0 to 9' and '-' or '+'. The PID must be in one of the below short formats: • *yymmdd+xxgc* • *yymmdd-xxgc* • *yymmddxxgc* or in the long formats as follows: • *yyyymmdd+xxgc* • *yyyymmdd-xxgc* • *yyyymmddxxgc* • *yy* and *yyyy* = patient year of birth • *dd* = patient day of birth • *mm* = patient month of birth • + or - = patient age **NOTE**: If + or - is not before the patient age, the age is less than 100 years. • *xx* = patient place of birth • *g* = patient gender • male = odd number • female = even number • *c* = checksum digit
		Norwegian PID:	

Name	*Description*	*Length*	*Accepted Values*

		11 characters	Valid values: '0 to 9' and '-'.
			The PID must be in the format *ddmmyy-efgxx* or *ddmmyyefgxx*, where:
			• *dd* = patient day of birth
			• *mm* = patient month of birth
			• *yy* = patient year of birth
			• *efg* = patient year of birth calculated as follows:
			  • *efg* = 000 to 499, if patient year of birth is between 1900 to 1999.
			  • *efg* = 500 to 750 and *yy* is more than 49, if the patient year of birth is between 1800 to 1899.
			  • *efg* = 500 to 999 and *yy* is less than 50, if the patient year of birth is between 2000 to current year.
			• *g* = patient gender
			  • male = odd number
			  • female = even number
			• *xx* = patient place of birth

Mandatory fields apply for	The mandatory fields that can be configured for **Transmission** or **Acquisition** of the ECG report. Based on the **Mandatory fields apply for Transmission** settings, the ECG report is not added to the transmission queue until you enter the patient demographic data for the mandatory fields. Based on the **Mandatory fields apply for Acquisition**settings, the ECG report is not accepted, transmitted, or printed until you enter the patient demographic data for the mandatory fields.	Not Applicable	• Transmission • Acquisition

Name	*Description*	*Length*	*Accepted Values*
First Name	Patient first name	1 to 20 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Last Name	Patient last name	1 to 40 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Height	Patient height in inches (in) or centimeters (cm), refer to the configured unit of measurement.	Maximum 3 characters	0 to 127 in 0 to 322 cm
Weight	Patient weight in pounds (lb) or kilograms (kg), refer to the configured unit of measurement.	Maximum 3 characters	0 to 999 lb 0 to 454 kg
Gender	Patient gender	Not Applicable	• Male • Female
Date of Birth	Patient date of birth	Not Applicable	Enter the patient date of birth in the format configured by your administrator. • The date of birth must not be more than the current date. • The date must be less than 127 years from the current date. The date of birth (DOB) also shows in the **Patient Information** bar. The calculated age shows near it.

Name	*Description*	*Length*	*Accepted Values*
Age	Patient age	Not Applicable	If the **Age** text box is on the **Patient Information** screen, the **Date of Birth** text box is not on the screen. 0 to 127 Enter the patient age and select the applicable unit of measurement (hours, days, weeks, months, years). The **Age** also shows in the **Patient Information** bar. The date of birth (DOB) does not.
Race	Patient race	Not Applicable	• Caucasian • Black • Hispanic • American Indian • Eskimo • Hawaiian • Pacific Islander • Asian • Unknown • Other
Order Number	Unique order number given to a patient test. If the order number is given by the computer when an order is attached to the patient test, the order number cannot be edited. **NOTE**: You can clear the order number which removes the number from the patient test. If you enter an order number manually, you can edit the order number.	1 to 22 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Secondary ID	An alternative identification method.	1 to 17 characters	• A to Z • a to z • 0 to 9 • All characters are supported.

Name	*Description*	*Length*	*Accepted Values*
Blood Pressure*	High and Low blood pressures of the patient measured in mmHg.	Maximum 3 characters	0 to 999
Location	Description of where the ECG is to be done. For each patient test, this text box is filled in from the **Location ID** configured in the **System Settings**. You can edit the location.	Maximum 5 characters	0 to 65534
Room Number*	The room number where the ECG is to be done.	Maximum characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Bed Number*	The bed number where the ECG is to be done.	Maximum 32 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Priority*	Priority of ECG patient test.	Not Applicable	• Routine • STAT • PreOp The default is **Routine**.
Comments*	Additional information	Maximum 127 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Medications	Record of the medications the patient uses which is separated by a comma.	Maximum 32 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Ordering MD Last Name	Physician last name who ordered the ECG.	Maximum 40 characters	• A to Z • a to z • 0 to 9 • All characters are supported.

Name	*Description*	*Length*	*Accepted Values*
Ordering MD First Name	Physician first name who ordered the ECG.	Maximum 20 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Ordering MD ID	Physician ID who ordered the ECG	Maximum 5 characters	0 to 65534
Referring MD Last Name	Referring physician last name	Maximum 40 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Referring MD First Name	Referring physician first name	Maximum 20 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Referring MD ID	Referring physician ID	Maximum 5 characters	0 to 65534
Technician*	Technician doing the ECG. • If you are a local user and your user account is configured with a technician name or ID, this text box is filled in with the technician configured to your user account. You can edit this text box. • If you are an LDAP user, this text box is filled in with your HIS user ID, if the HIS server is configured. You can edit the ID.	Maximum 20 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Test Indication*	The ECG is done because of this.	Maximum 64 characters	• A to Z • a to z • 0 to 9 • All characters are supported.

Name	*Description*	*Length*	*Accepted Values*
Patient History*	The patient's medical history	Not Applicable	• Hypertension • CAD • Cardiac Surgery • Unknown
Visit Number	Visit number given to this patient.	Maximum 19 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
<Question 1>* **<Question 2>*** **<Question 3>*** **<Question 4>***	The name of this text box is configured by the administrator. See the accepted values of these text boxes before configuration.	Alphanumeric	
		17 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
		Number	
		10 characters Extra optional one special character (+) or (-) in the beginning	• 0 to 9
		Yes or No or Unknown	
		Not Applicable	• Yes • No • Unknown
Attending MD Last Name*	Attending physician last name	Maximum 40 characters	• A to Z • a to z • 0 to 9 • All characters are supported.

Name	*Description*	*Length*	*Accepted Values*
Attending MD First Name*	Attending physician first name	Maximum 20 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Attending MD ID*	Attending physician ID	Maximum 5 characters	0 to 65534

Clinical Trial Text Box Names

If you purchase and enable the **PHAR - Pharmacy** option on the device, **Clinical Trial** screen displays when you expand the **Patient Information** banner.

NOTE:
If you enable the **Make All Clinical Trial Fields Mandatory** setting in **Clinical Trial** settings screen, all the configured clinical trial settings are required fields and an asterisk (*) displays next to each field.

Table 115: Clinical Trial text boxs

Name	*Action*	*Length*	*Allowed Values*
Project Code Name	Select a value from the dropdown list	Not Applicable	The name you configured in the **Clinical Trial** settings
Project Code	Not Applicable	Not Applicable	This field automatically displays a value if you select a **Project Code Name**.
Trial ID	Not Applicable	Not Applicable	This field automatically displays a value if you select a **Project Code Name**.
Trial Visit Number	Enter the visit number	1 to 22 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
Investigator ID	Enter the investigator ID	1 to 17 characters	• A to Z • a to z • 0 to 9 • All characters are supported.

Name	*Action*	*Length*	*Allowed Values*
Visit Type	Select a value from the dropdown list	Not Applicable	• **Scheduled** • **Unscheduled** • **Follow Up** • **Repeat** • **Early Termination** • **Unknown** • The type you configured in the **Clinical Trial** settings
Dose Type	Select a value from the dropdown list	Not Applicable	The type you configured in the **Clinical Trial** settings
<Question 1>* **<Question 2>*** **<Question 3>*** **<Question 4>*** **<Question 5>***	Enter the answer	Alphanumeric	
		17 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
		Number	
		10 characters Extra optional one special character (+) or (-) in the beginning	• 0 to 9
		Yes or No or Unknown	
		Not Applicable	• Yes • No • Unknown

D

Configure the MUSE System for Network Communication

MUSEAPI3 Installation

This section describes how to install MUSEAPI3 on MUSE v8 or v9 servers.

MUSE v8 ships with MUSEAPI v3.0.

MUSE v9 ships with MUSEAPI v3.1.

For the purposes of this documentation, all references to MUSEAPI3 refer to MUSEAPI v3.0 or v3.1.

Before You Start

Before installing MUSEAPI3, the information below must be obtained to successfully complete the installation. MUSEAPI3 installation is required for order management. If order management is not enabled in the MAC 5 device, you need not install MUSEAPI3.

Table 116: MUSEAPI3 Installation Prerequisites

Action	*Description*
Determining whether MUSEAPI3 is already installed	The MUSE system may already have MUSEAPI3 installed if you are using CV Web 3 or another MUSEAPI3 client. Go to Windows Services on the MUSE server and determine whether the **MUSEAPI3** service is already present. If it is, then MUSEAPI3 is already installed. If MUSEAPI3 is already installed, you may run the ***MUSEAPIServiceConfig.exe*** application located in the MUSE installation folder to determine the communication protocol(s) that MUSEAPI3 is using.

Action	*Description*
Determining the communication protocol MUSEAPI3 uses	You can configure MUSEAPI3 to communicate with MUSEAPI3 clients using http, https, or net.tcp protocols. It is possible to configure MUSEAPI3 for more than one protocol. • HTTP – a non-secure web communication protocol. • HTTPS – a secure web communication protocol that uses an additional encryption layer. Use of HTTPS requires that the customer configure a secure communication channel, such as SSL, and establish any public key certificates. When using HTTPS, you must obtain a thumbprint of the certificate and use it to configure the port MUSEAPI3 uses. The thumbprint is the certificate hash of the public key. See *Obtain the Thumbprint of the SSL Certificate for the MUSEAPI3 Port on page 326* for more information. • Net.tcp – Unless HTTPS is used, this is the preferred communication protocol for MUSEAPI3. Net.tcp uses domain security and requires that the MUSEAPI Client and MUSE Server(s) be on the same domain.
Determining the port assignment for MUSEAPI3	MUSEAPI3 uses the default ports below. If these ports are already in use, you may enter different ports during installation. • HTTP — port 8100 • HTTPS — no default assigned (port 443 is typically used for secure websites using SSL) • net.tcp — port 8101
Locating the MUSE application folder on the MUSE server	You must install MUSEAPI3 files in the MUSE application folder. The list below is the default folder locations: • 32-bit Windows Server Operating Systems: ***C:\Program Files \MUSE***. • 64-bit Windows Server Operating Systems: ***C:\Program Files (x86)\MUSE***.

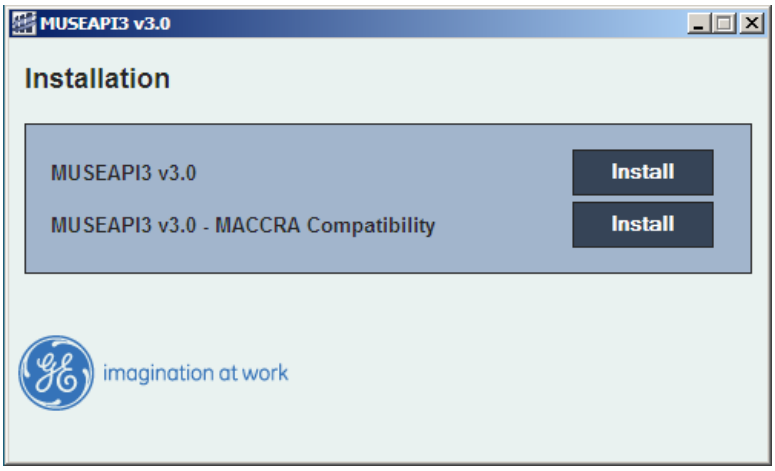
Install MUSEAPI3 on MUSE v8 Server

1. Log into the MUSE application server using an account that has administrator privileges.
2. Have the customer disable any antivirus software during the installation. Re-enable the antivirus software after the installation is complete.
3. Insert the MUSE API 3.0 installation media into the optical drive of the system.

   If an **Autorun** or **AutoPlay** screen displays, close or cancel them.
4. Browse the optical drive in Windows Explorer and execute the **Autorun.exe** application.

   NOTE:
   Be sure to execute **Autorun.exe** and not **Autorun.exe.config**.

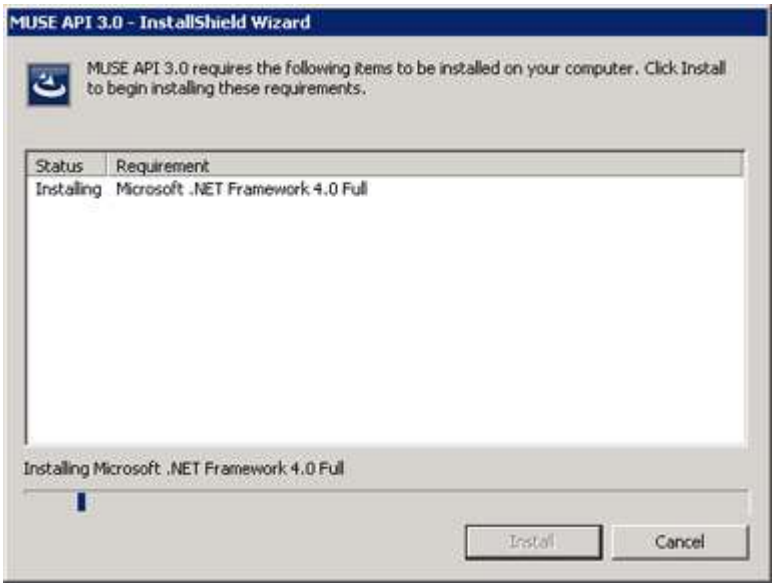
The **MUSEAPI3 v3.0** window opens.



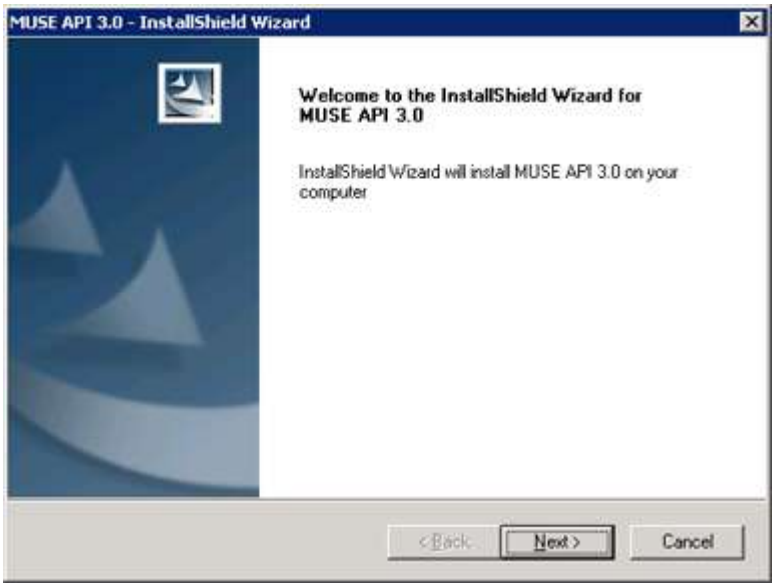
5. Click **Install** next to **MUSEAPI3 v3.0**.

   The installer will check for the Microsoft **.NET Framework 4.0** to complete the installation and install them if necessary. If it is already installed this window will be skipped.

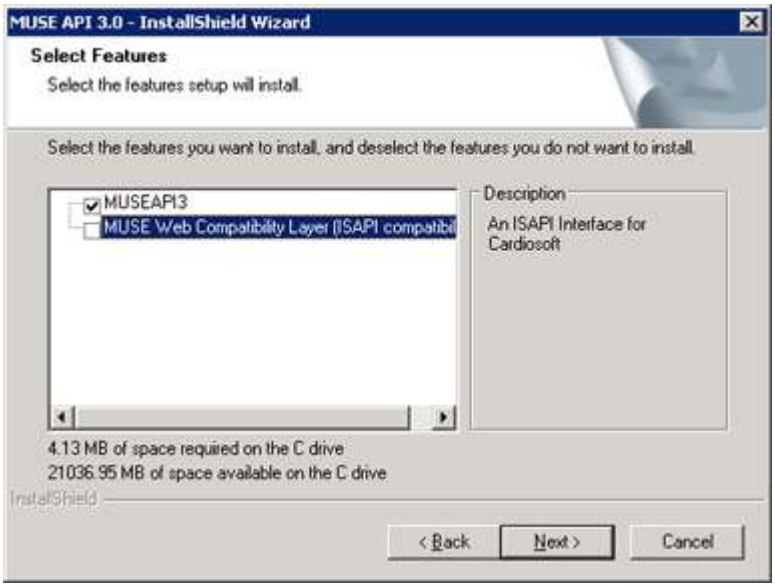
   NOTE:
   Installation of **.NET Framework 4.0** may take several minutes.



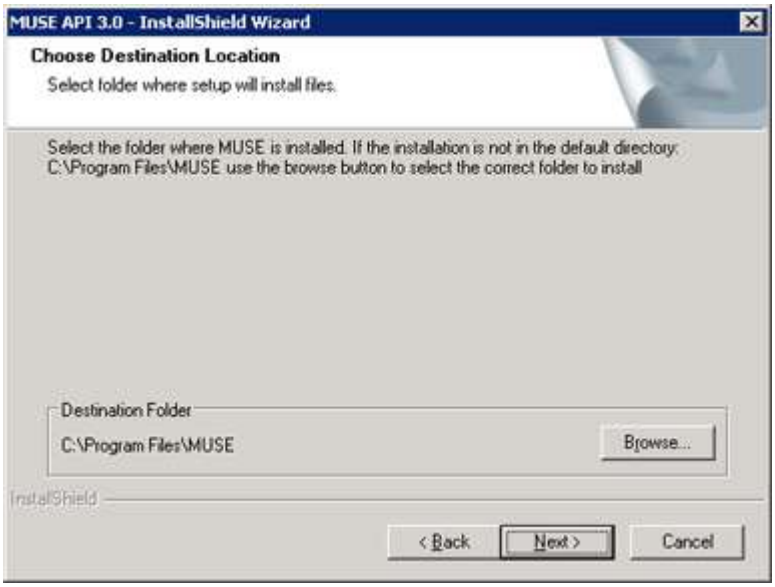
The **MUSE API 3.0 – InstallShield Wizard** window opens.



6. Click **Next**.
   The **License Agreement** window opens.
7. Read and accept the License Agreement.
8. Click **Next**.
   The **Select Features** window opens.

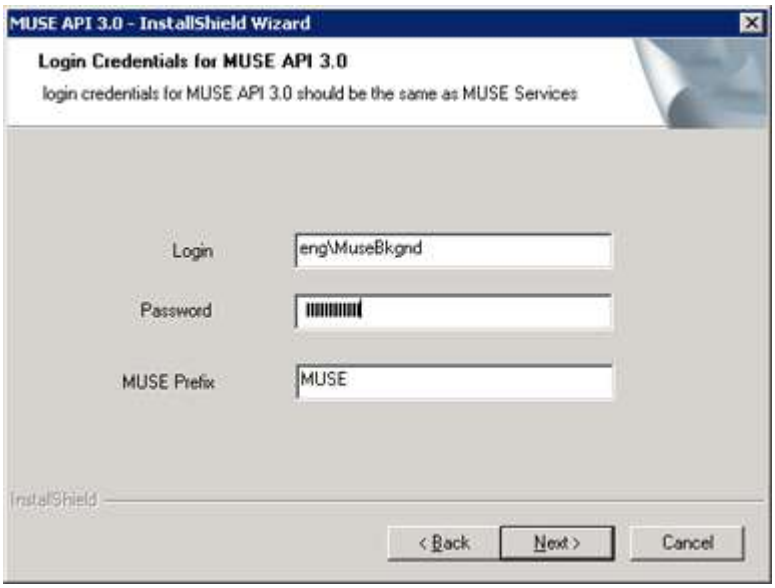


9. Make sure **MUSEAPI3** is selected and click **Next**.
   The **Choose Destination Location** window opens.



10. Make sure that the destination folder for MUSEAPI3 is the same folder in which the MUSE program files are installed, then click **Next**.

    The **Login Credentials for MUSE API 3.0** window opens.



11. Enter the login and password that the **MUSE API 3.0** service uses to communicate with the MUSE Middle Tier.

    This should be the same account used for the MUSE services (typically the domain MUSE Background user).

    NOTE:

    If you are unsure of the account to use for MUSE services, open Windows Services and determine the user account configured to start the other MUSE services. Enter the prefix used by the MUSE services. This is almost always MUSE.

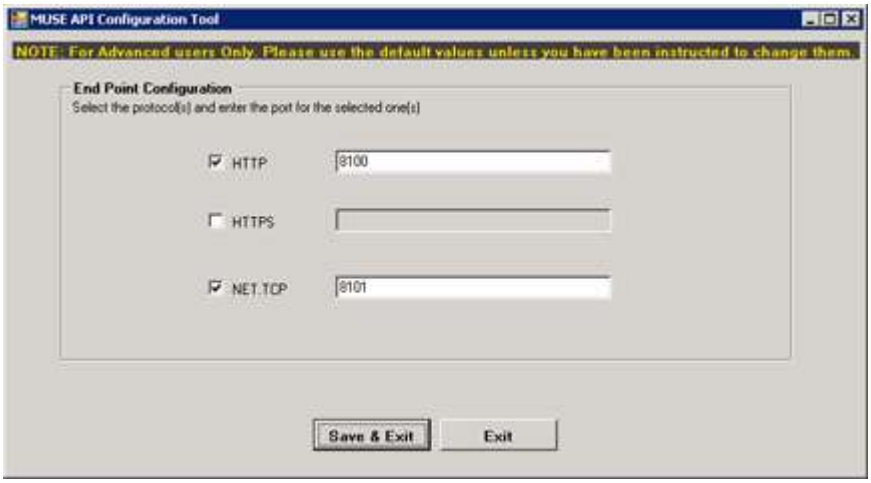
12. Click **Next**.
    The **MUSE API Configuration Tool** window opens.

13. In the **End Point Configuration** area of the window, select the protocol(s) you are using to communicate with MUSEAPI3 and enter the port value(s).

    You must have at least one protocol enabled, and you may have more than one. If any protocols are selected that you do not want, remove the check mark.

    You are advised to use the values below for the ports:

Protocol	*Recommended Port Values*
HTTP	***8100***
HTTPS	The port for SSL, as configured by the customer.
net.tcp	***8101***



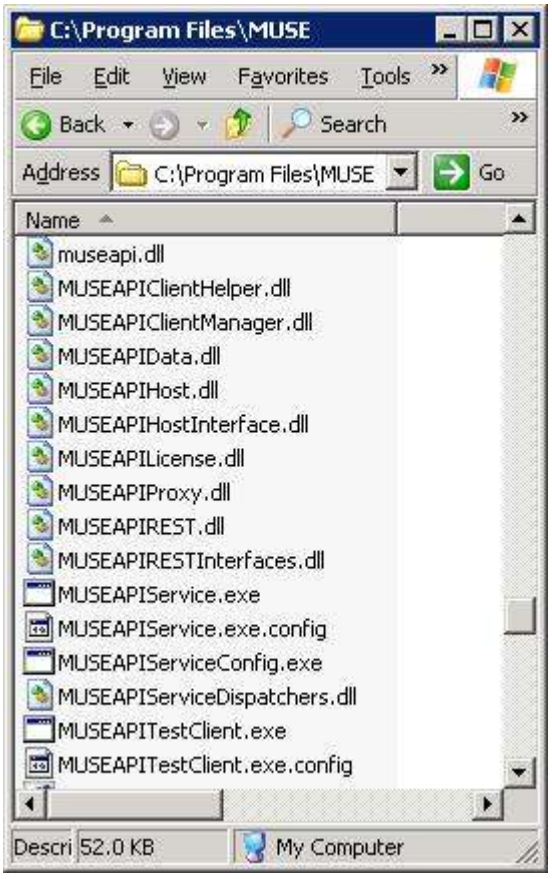
NOTE:
For more information on the available communication protocols, see *Table 116: MUSEAPI3 Installation Prerequisites on page 312*.

14. Click **Save & Exit** to save the changes to the **End Point Configuration**.
    The **InstallShield Wizard Complete** window opens.

15. Click **Finish** to end the installation of MUSEAPI3.
16. Open the install log located in ***C:\MUSEAPI3_Installer_Log_xxx.log*** and verify that the installation completed successfully without any errors.

    A new log is created each time the installer is launched. Look at the log file with the highest number in the sequence to make sure you are looking at the most recent installation. Verify that you complete the installation below:

    - **MUSEAPI3 service** - Verify that the MUSEAPI3 service has started. If the service has not started, manually start it.
    - **MUSEAPI3 program files** - Verify the MUSEAPI3 program files were added to the MUSE installation folder.



Install MUSEAPI3 on MUSE v9 Server

1. Log into the MUSE application server using an account that has administrator privileges.
2. Have the customer disable any antivirus software during the installation. Re-enable the antivirus software after the installation is complete.
3. Insert the MUSE v9 installation media into the optical drive of the system.

   If an **Autorun** or **AutoPlay** screen displays, close or cancel them.
4. Browse the optical drive in Windows Explorer and perform one of the steps below:
   - If the MUSE v9 Application and Support DVD is inserted, navigate to the **MUSE Application** folder and execute the **Autorun.exe** application.
   - If the MUSE v9 Application ISO is being used, navigate to the root folder and execute the **Autorun.exe** application.

     NOTE:
     Be sure to execute **Autorun.exe** and not **Autorun.exe.config**.

The **MUSE v9.0 Installation Options** window opens.

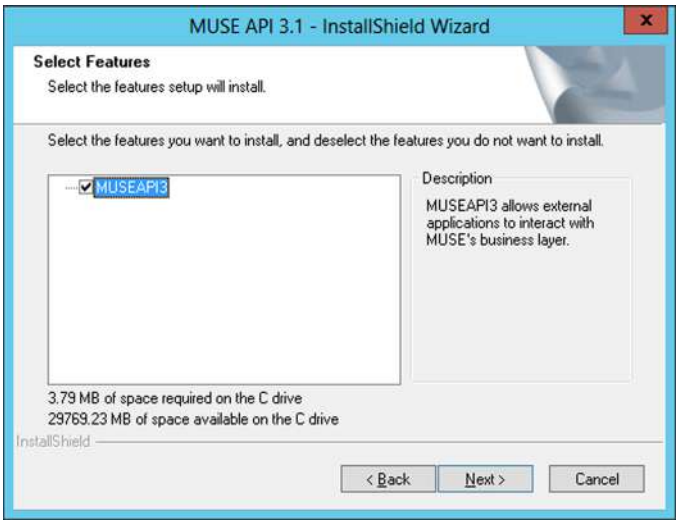
5. Click **Install** next to **MUSEAPI v3.1**.

If a **User Account Control** dialog opens, choose **Yes** or **Allow**.
The **MUSE API 3.1 – InstallShield Wizard** window opens.

6. Click **Next**.
The **License Agreement** window opens.

7. Read and accept the License Agreement.

8. Click **Next**.
The **Select Features** window opens.

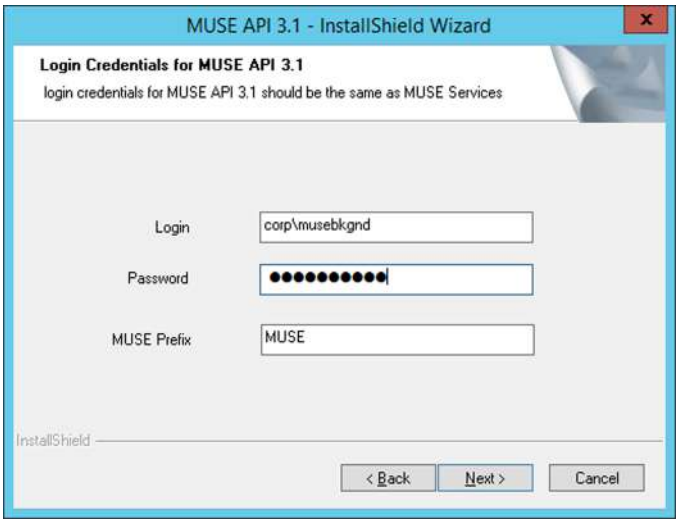


9. Make sure **MUSEAPI3** is selected and click **Next**.

The **Choose Destination Location** window opens.

10. Make sure that the destination folder for MUSEAPI3 is the same folder in which the MUSE program files are installed, then click **Next**.

    The **Login Credentials for MUSE API 3.1** window opens.



11. Enter the login and password that the **MUSEAPI3** service uses to communicate with the MUSE Middle Tier.

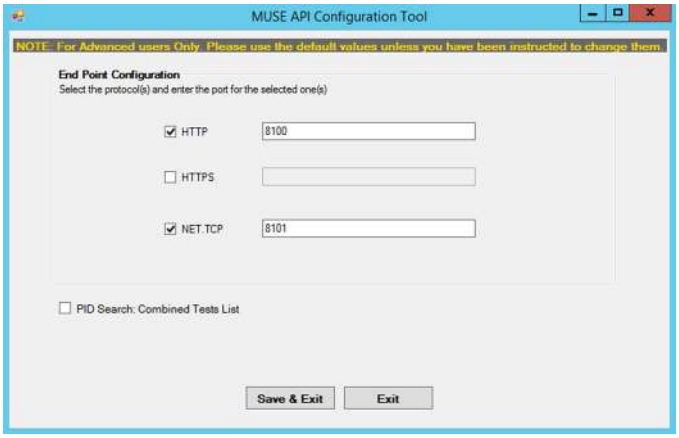
    This should be the same account used for the MUSE services (typically the domain MUSE Background user).

    NOTE:

    If you are unsure of the account to use for MUSE services, open Windows Services and determine the user account configured to start the other MUSE services. Enter the prefix used by the MUSE services. This is almost always MUSE.

12. Click **Next**.

    The **MUSE API Configuration Tool** window opens.



13. In the **End Point Configuration** area of the window, select the protocol(s) you are using to communicate with MUSEAPI3 and enter the port value(s).

    You must have at least one protocol enabled, and you may have more than one. If any protocols are selected that you do not want, remove the check mark.

    You are advised to use the values below for the ports:

Protocol	*Recommended Port Values*
HTTP	***8100***
HTTPS	The port for SSL, as configured by the customer.
net.tcp	***8101***

    NOTE:
    For more information on the available communication protocols, see *Table 116: MUSEAPI3 Installation Prerequisites on page 312*.

14. Determine whether you want to check the box next to **PID Search: Combined Test Lists** to change the Patient Conflict behavior of the MUSEAPI3 and do one of the steps below:

    - Select to enable the **PID Search: Combined Test List**. When performing a Patient ID search while this option is enabled, MUSEAPI3 automatically combines all tests for that Patient ID for the same MUSE site, even if there is a Patient ID/Last Name mismatch.
    - To disable the **PID Search: Combined Test List**, leave the box unselected. When performing a Patient ID search while this option is disabled, MUSEAPI3 includes patient conflicts if there is a Patient ID/Last Name mismatch within the same site.

    This setting can always be changed later.

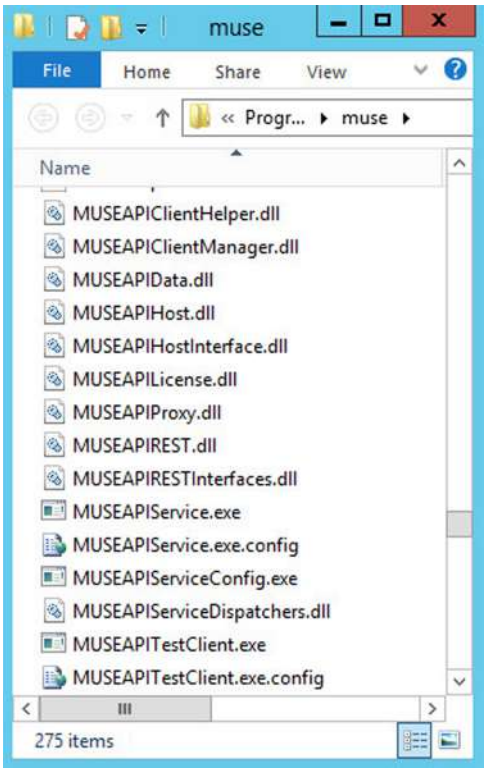
    NOTE:
    MUSEAPI v3.1 handles patient conflicts within the same MUSE site differently than MUSEAPI v3.0. MUSEAPI v3.1 only provides a response that includes

patient conflicts if there is a Patient ID / Last Name mismatch, and that conflict response can be disabled by enabling this option. MUSEAPI v3.1 handles patient ID conflicts across different servers or at different sites the same as MUSEAPI v3.0.

15. Click **Save & Exit** to save the changes to the **End Point Configuration**.
16. Click **Finish** to end the installation of MUSEAPI3.
17. Open the install log located in ***C:\MUSEAPI3_Installer_Log_xxx.log*** and verify that the installation completed successfully without any errors.

    A new log is created each time the installer is launched. Look at the log file with the highest number in the sequence to make sure you are looking at the most recent installation. Verify that you complete the installation below:

    - **MUSEAPI3 service** - Verify that the MUSEAPI3 service has started. If the service has not started, manually start it.
    - **MUSEAPI3 program files** - Verify the MUSEAPI3 program files were added to the MUSE installation folder.



Change the MUSEAPI3 Service Protocol Configuration

1. Run the **MUSEAPIServiceConfig.exe** application located in the MUSE installation folder.

NOTE:
To make changes to the configuration you may need to use **Run as Administrator**.

2. Review the protocol(s) that you are using to communicate with MUSEAPI3 and modify as appropriate.

   You can select more than one protocol.

   You are advised to use the port values below:

Protocol	*Recommended Port Values*
HTTP	***8100***
HTTPS	The port for SSL, as configured by the customer.
net.tcp	***8101***

   NOTE:
   For more information on the available communication protocols, see *Table 116: MUSEAPI3 Installation Prerequisites on page 312*.

3. Determine whether you want to select **PID Search: Combined Test Lists** to change the Patient Conflict behavior of the MUSEAPI3 and do one of the steps below:

   - Select to enable the **PID Search: Combined Test List**. When performing a Patient ID search while this option is enabled, MUSEAPI3 automatically combines all tests for that Patient ID for the same MUSE site, even if there is a Patient ID/Last Name mismatch.
   - To disable the **PID Search: Combined Test List**, leave the box unselected. When performing a Patient ID search while this option is disabled, MUSEAPI3 includes patient conflicts if there is a Patient ID/Last Name mismatch within the same site.

   This setting can always be changed later.

   NOTE:
   MUSEAPI v3.1 handles patient conflicts within the same MUSE site differently than MUSEAPI v3.0. MUSEAPI v3.1 only provides a response that includes patient conflicts if there is a Patient ID / Last Name mismatch, and that conflict response can be disabled by enabling this option. MUSEAPI v3.1 handles patient ID conflicts across different servers or at different sites the same as MUSEAPI v3.0.

4. If any changes were made, restart the **MUSEAPI3** service.

Uninstall MUSEAPI3

If you are going to reinstall MUSEAPI3 at a later date, it is recommended that you copy the **MUSEAPIService.exe.config** file located in the MUSE installation folder, and save it to a location outside of the MUSE installation folder. This file contains

the current settings for MUSEAPI3 and you can use it as reference during the reinstallation or to restore the MUSEAPI3 settings to their original values. Uninstalling MUSEAPI3 removes the MUSEAPI3 service and MUSEAPI files from the MUSE installation folder.

1. Log on to the MUSE application server as an administrator.
2. Stop the **MUSEAPI3** service.
3. Go to Windows **Control Panel** > **Programs and Features**.
4. Right-click on **MUSE API 3.1** and select **Uninstall**.
   The **MUSE API 3.1 - InstallShield Wizard** window opens.
5. Make sure **Remove** is selected and click **Next**.
6. Click **Yes** when you receive the prompt: **Do you want to completely remove the selected application and all its features?**
7. When the **Uninstall Complete** window opens, click **Finish**.

Restore the MUSEAPI3 Configuration

If you saved the MUSEAPI3 configuration file ***MUSEAPIService.exe.config*** as part of the uninstallation process, you can reinstall it and use it to restore the MUSEAPI3 settings.

1. Copy the file ***MUSEAPIService.exe.config*** from the saved location to the MUSE installation folder.
2. Restart the **MUSEAPI3** service.

MUSEAPI Test Client

The MUSEAPI Test Client is installed with MUSEAPI3 and can be used to test and troubleshoot MUSEAPI3.

Run the MUSEAPI Test Client

To run the MUSEAPI Test Client, execute **MUSEAPITestClient.exe** from the MUSE installation folder (default is ***C:\Program Files (x86)\MUSE***).

Use the MUSEAPI Test Client

The steps below provide a high-level example of how to use the MUSEAPI Test Client. This procedure can also be used as a system checkout to verify MUSEAPI3 is installed correctly.

1. Run the MUSEAPI Test Client.
   The **MainWindow** screen opens.
2. Use the table below to complete the configuration of the MUSEAPI Test client.

NOTE:
This configuration will need to be repeated each time the test client is used unless the settings are manually entered in the ***MUSEAPITestClient.exe.config*** file.

Field	*Action*
MUSE Username	Enter the username of a MUSE user whose role includes all privileges in the MUSE system. The default is **museadmin**.
Password	Enter the password of the MUSE user. The default is **maclink**.
License Key	Enter the license key to access MUSEAPI3. A unique key is provided to MUSEAPI3 licensees. GE Healthcare Service has their own license key that they can use here. **NOTE**: GE Healthcare Service must not permanently save the license key in the config file.
Site Number	Enter MUSE **Site Number**. The default is 1.
Base URI	Enter the Endpoint URI for MUSEAPI3. The default is **http://localhost:8100/**.

3. Click **Login**.
4. Select the **Patient** tab.
5. Select **PatientRetrieve.GetTestPatientsByPatientId**.
6. Enter the **Patient Id** of a patient in the MUSE database and click **OK**.
7. Verify the patient is found.
8. Click **Logout**.
9. Close the MUSE API Test Client application.

Obtain the Thumbprint of the SSL Certificate for the MUSEAPI3 Port

This section provides the steps to obtain the thumbprint of the new certificate used to configure the port.

NOTE:
Prior to completing these steps, the customer must obtain a certificate from a Certificate Authority and have it installed on the MUSE application server.

1. To get the thumbprint of your certificate, you need the MMC dialog box open and configured to deal with Certificates:
   a) Run Microsoft Management Console (***mmc.exe***).

b) When the Microsoft Management Console (MMC) opens, press ***Ctrl*+*M*** to add a snap-in.

c) In the **Add or Remove Snap-ins** dialog box, do the steps below:

1. In the **Available snap-ins** list, select **Certificates**.
2. Click **Add**.

d) In the **Certificates snap-in** dialog box do the steps below:

1. Select **Computer account**.
2. Click **Next**.

e) Select **Local computer** and click **Finish**.

f) To close the **Add or Remove Snap-ins** dialog box, click **OK**.

2. Expand the **Certificates** node in the left panel.
3. Expand the **Personal** node in the left panel and click the **Certificates** node.

   The certificate that the customer obtained and installed is listed here.
4. Double-click on the certificate the customer obtained and installed to open it.
5. Select the **Details** tab.
6. In the list box, click **Thumbprint**.

   The bottom window lists the hex values.
7. Select and copy the list of hex values from step *6* into a text editor such as Notepad.
8. Remove all the spaces between the values to make one long string.

   When you are done, it will look similar to the code below:

   `a237052b1a2d52f72c576c5702136802a7bf8804`

   This is your certificate thumbprint.
9. Use **Run as Administrator** to obtain a command-prompt, then run the two commands below:

   - `netsh http add sslcert ipport=0.0.0.0:(port assigned for MUSEAPI3 HTTPS protocol goes here) certhash=[your thumbprint] appid={3df9aba0-cbd8-4dbe-b3c7-daf47b8a015b}`
   - `netsh http add sslcert ipport=[::]:(port assigned for MUSEAPI3 HTTPS protocol goes here) certhash=[your thumbprint] appid={3df9aba0-cbd8-4dbe-b3c7-daf47b8a015b}`
10. Run the command below to show the SSL Certificate bindings and verify that the IP:port, Certificate Hash, and Application ID match those entered in step *9*:

```
netsh http show sslcert
```

NOTE:
IF the SSL Certificate bindings were entered incorrectly, the SSL Certificate bindings must be deleted and recreated using the commands below:

```
netsh http delete sslcert ipport=0.0.0.0:(port
assigned for MUSEAPI3 HTTPS protocol)
```

```
netsh http delete sslcert ipport=[::]:(port assigned
for MUSEAPI3 HTTPS protocol)
```

After deleting the bindings they can be re-created using the information in step 9.

Set Up DCP Inbound Communication for MUSE v8.x or v9.x

Use the procedures below to set up a MUSE v8.x or v9.x server for DCP communication.

Verify that the MUSE DCP Inbound service and DCP Communication options are installed and perform one of the steps below:

- If the options are not installed, go to *Add the DCP Service and DCP Communication Option to the MUSE System on page 328*.
- If the options are installed, go to *Set Up the DCP Server Configuration in the MUSE System on page 329*.

NOTE:
Installation of the DCP services restarts all MUSE services. If the MUSE system is currently in use, before installing the DCP services, perform an Automatic Shutdown of the MUSE system to notify MUSE users that the system is shutting down.

Add the DCP Service and DCP Communication Option to the MUSE System

Use the procedures below to verify, and if necessary, add the MUSE DCP services and DCP communication option to the MUSE system.

1. Log on to the MUSE application server as an administrator.
2. Select **Control Panel** > **Add or Remove Programs or Programs and Features**.
3. Select **MUSE 8.x** or **MUSE 9.x** and click **Change**.
   The **Welcome** window opens.
4. Choose **Modify** and click **Next**.
   The **Select Features** window opens.
5. Go to **Server** > **Services**.
6. Verify that **DCP** is selected.

If it is not selected, select it now.

When selecting DCP, both **DCP inbound** and **DCP outbound** are also selected.

7. Continue to click **Next** on each window until you reach the **Choose MUSE Options** window.
8. Verify that the **DCP communication** option is selected.
   If it is not selected, select it now.
9. Click **Next**.
   The **MUSE Serial Number** window opens.
   - If you added the DCP communication option in the previous step, you need to enter the **Options Configuration Password**.
   - If you do not know the password, contact GE Healthcare Technical Support.
10. Click **Next** through the remaining screens until your changes are applied and the **Maintenance Complete** window opens.
11. Click **Finish**.

    NOTE:
    When communicating with a MUSE system via DCP communication, a modem cannot be defined for the MAC system.
12. Verify the installation.
    See *System Checkout on page 332*.

Set Up the DCP Server Configuration in the MUSE System

By default, the **DCP Inbound** service has a **Device Friendly Name** of MUSE and listens on port 9240 of all network interfaces on the MUSE application server.

Perform the steps below to modify these defaults:

1. Log on to the MUSE system as a user with privileges to modify settings in **MUSE Setup**.
2. Go to **System** > **Setup**.
3. In the **Navigation** pane, select **System**.
4. Right-click on the MUSE entry and choose **Properties**.
   The **System Properties** window opens.
5. Select **DCP Configuration**.
6. Modify the fields using the information in the table below.

Field	*Description/Action*
Device Friendly Name	This is the name the compatible device will see when searching for the DCP server. The default is MUSE. Change this if desired.
Server Port	This is the port on which the **DCP Inbound** service is listening for inbound connections. The default is 9240. Change this if necessary.
Network Interfaces	This is where you can specify which network interface the DCP Server should listen on. This field is blank by default so it will listen on all network interfaces on the MUSE application server. To configure the DCP Server to listen only on a single network interface, for example IPv4, you can type the IPv4 IP address into this field.
Server Addresses (MUSE v9 only)	This is a read-only output indicating the Server Address(es) that the **DCP Inbound** service is currently listening on. This is the full DCP URL that can be used to define this MUSE system on a compatible DCP client device such as a MAC 2000. Multiple server addresses may be listed if the **Network Interfaces**' field is blank.

7. Click **OK** to save your changes or **Close/Cancel** to ignore your changes.
8. If any configuration changes were made, restart the MUSE **DCP Inbound** service on the MUSE Application server.

E

Configure the CardioSoft System for Network Communication

CardioSoft V7 Installation

For CardioSoft installation instructions, refer to the Cardiosoft Software Installation and Upgrade Guide.

Set Up DCP Port in CardioSoft V7.0

Set up a CardioSoft v7.0 server for DCP communication.

Configure the port in connectivity server tab of server computer and then configure the same port in the client computer to establish DCP connection from the client computer.

Steps as follow to establish DCP connection:

1. Open server computer.
2. Click **Connectivity Server** tab.
3. Enter the DCP server details such as **Friendly Name**, **IP Address**, **Copy Location**, and **Port number** (for example, 9240 or 9280).
4. Click **OK**.
5. Open client computer.
6. Click **DCP** tab.
7. Enter **Server Address** with same port as in server computer (for example: http://X.X.X.X:9240/SendTest).
8. Click **Test Connection**.
9. Click **OK**.

F

System Checkout

Complete these verification procedures to make sure that the device can successfully transmit tests to the MUSE system and CardioSoft system and download orders from the MUSE system.

DCP Transmission to the MUSE System

1. Transmit an ECG test from the MAC 5 to the MUSE system using the DCP protocol.
2. Verify the test is successfully acquired into the MUSE system.

DCP Transmission to the CardioSoft System

1. Transmit an ECG test from the MAC 5 to the CardioSoft system using the DCP protocol.
2. Verify the test is successfully acquired into the CardioSoft system.

MUSE Order Download

1. From the MAC 5 device, download an order from the MUSE system.
2. Verify the order is successfully downloaded to the MAC 5 device.

G

Technical Specifications

System Specifications

Table 117: Device Physical Specifications

Item	*Description*
Device type	Microprocessor augmented automatic electrocardiograph; 12-leadwire acquisition with programmable lead configuration A4: Integrated unit with display and printer A5: Integrated unit with display and printer Lite: Integrated unit with display
Height	A4: 12.4 in (31.5 cm) A5: 12.4 in (31.5 cm) Lite: 12.2 in (30.9 cm)
Width	A4: 14.2 in (36 cm) A5: 10.2 in (26 cm) Lite: 10.2 in (26 cm)
Depth	A4: 4.5 in (11.4 cm) A5: 4.3 in (10.8 cm) Lite: 3.3 in (8.4 cm)
Weight	A4: 3.6 kg A5: 3.0 kg Lite: 2.0 kg
USB Port	2 USB 2.0 ports supplying 0.5 Amps of current each
Mechanical design	Housing with fixed angle graphics display Software on mainboard

Table 118: Display Specifications

Item	*Description*
Display	22.6 cm (8.9 in) diagonal graphics LED backlit full HD
Touchscreen	Projected Capacitative (PCAP) multipoint touch input that works while wearing medical exam gloves
Resolution	892 X 558 pixels, with waveform enhancement
Data	Heart rate, patient name, patient ID, date and time, battery power indicator, scrolling waveforms, lead labels, speed, gain and filter settings, warning messages, prompts, hookup advisor, and help messages.

Table 119: Printer Specifications

Item	*Description*
Technology	Integrated thermal dot array
Writer speed	5, 12.5, 25, and 50 mm/s
Number of traces	3, 6 and 12
Sensitivity/gain	2.5, 5, 10, 20 mm/mV, and 10/5 mm/mV split gain
Speed accuracy	5, 12.5 mm/s at ±5% 25, 50 mm/s at ±2%
Amplitude accuracy	±5%
Horizontal resolution	40 dots/mm at 25 mm/s
Vertical resolution	8 dots/mm
Paper type	Z-fold thermal with pre-printed grid and perforation
Paper size	A4: 215 mm x 280 mm (8.5 in x 11 in) (modified letter) 210 mm x 297.5 mm (8.27 in x 11.7 in) (A4) A5: 148 mm x 210 mm (5.83 in x 8.27 in) (A5)
Paper tray capacity	Holds up to 150 sheets

Table 120: Electrical Specifications

Item	*Description*
Power supply	AC mains or battery operation
Input voltage	100–240 VAC ±10%

Item	Description
Input current range	A @100V to 625mA @240V 780 mA @100V AC to 110 mA @240V AC
Input frequency	50/60 Hz ± 3 Hz

Table 121: Battery Specifications

Item	Description
Type	Replaceable and rechargeable internal battery
Charge time	Approximately 240 minutes from total discharge when device is off (standby).
Battery capacity	The system shall be able to acquire and print a single page 12-lead Resting ECG report every fifteen minutes for a minimum of three hours when the battery is installed and the battery is fully charged (with five minutes auto standby enabled and all accessories on except KISS), without AC connection.

Table 122: Other Input Device Specifications

Item	Description
External USB barcode reader	Fixed and variable length types Symbologies: Code-128, PDF417, Code 39, Interleaved Code 2 of 5, and Data Matrix symbology for characters A-Z (upper case), a-z (lower case), and 0-9 for all supported languages.

ECG Specifications

Table 123: ECG Data Acquisition Specifications

Item	Description
Signal input	Type CF, Defibrillation-Proof Defibrillation protection: Per IEC 60601-2-25:2011
Dynamic range	AC Differential ± 10mV, DC offset ± 600 mV
Common mode rejection	>125 dB (>100 dB with AC filter disabled)
Input impedance	>50 MΩ @ 10 Hz, defibrillator protected
Patient leakage current	<10 µA
Detection of pacemaker pulse	Duration: 0.2 ms to 2.1 ms Amplitude: 2 mV to 700 mV Separation: 1 ms or greater

Item	*Description*
Pace Annotation	Dedicated pace channel on display and printed reports
Pace digital sampling rate	75,000 samples/second per channel

Table 124: ECG Data Processing Specifications

Item	*Description*
ECG Interpretation	Marquette 12SL ECG Analysis Program for Adults and Pediatrics
Computerized measurements	12-lead analysis
Heart rate meter	30 to 300 beats per minute (BPM) with an accuracy of ±10% or 5 BPM, whichever is greater. Heart rates outside this range will not display.
ECG data formats	GE Hi-Fidelity ECG, XML
Pre-acquisition	Provides 10 seconds of instantaneous ECG acquisition
Digital rhythm	Up to 5 minutes of continuous rhythm storage (exportable as a PDF)
Storage	300 records consisting of 10 second Resting ECG records and Digital Rhythm records on the device internal memory
External storage	USB-compliant flash drive supporting the FAT32 file system
Downsampled ECG waveform	Bandwidth: 0.04 to 300 Hz Sample rate: 2 ksps Resolution: 1.22 µV
Analyzed ECG waveform	Bandwidth: 0.04, 0.56 ZPD to 300 Hz Sample rate: 500 and 1000 sps Resolution: 4.88 µV
Additional report filters	20 Hz, 40 Hz, 100 Hz, 150 Hz or 300 Hz
Channels	Up to 12 channels, skew between channels: < 100 µS

Environmental Specifications

Table 125: Environmental Specifications

Item	*Description*
Operating Conditions	
Temperature	10°C to 40°C (50° F to 104° F)
Relative Humidity (RH)	20% to 95% (non-condensing)

Item	*Description*
Atmospheric Pressure	70 to 106kPa
Transport/Storage Conditions	
Temperature	-20°C to +60°C (–4° F to 140° F)
Relative Humidity (RH)	15% to 95% (non-condensing)
Atmospheric Pressure	50kPa to 106kPa

Safety Specifications

Table 126: Safety Specifications

Item	*Description*
Certification marks	 The medical device has a lifetime of 7 years with respect to the Council Regulation EU 2017/745 Annex I, Requirement 6.
Certification	CAN/CSA-C22.2 No. 60601-1, ES60601-1 IEC 60601-1 IEC 60601-1-2 IEC 60601-2-25 IEC 60601-2-51
Type of Protection Against Electrical Shock	Class 1, internally powered
Degree of Protection Against Ingress of Liquids	IP 20
Patient Mode of Operation	Continuous
Patient Leakage Current	<10 µA Normal Condition (NC), <50 µA Single Fault Condition (SFC)
Degree of Protection Against Electrical Shock	Type CF defibrillation-proof applied part

Network Specifications

Table 127: Network Specifications

Item	*Description*
Frequency bands of transmission	2.401 – 2.461 GHz 5.180 – 5.825 GHz
Maximum radiated power in frequency bands	2.4 GHz: 18.5 dBm 5 GHz: 18.0 dBm
Antenna	Support 2.4G and 5G
Modulation	DSSS, CCK, OFDM, BPSK, QPSK, QAM
Supported certificate key lengths	1024/2048/4096-bit encryption
Supported certificate digest algorithms	SHA1, SHA2
Wireless specifications	
Wireless Standards	802.11a/b/g/n WLAN interfaces Configured manually or via DHCP
Authentication Protocols	• Open • WEP • WPA • WPA2
Authentication Methods	• PSK • PEAP-MSCHAPV2 • PEAP-GTC • EAP-TLS • TTLS-MSCHAPV2 • TTLS-GTC
Wired Specifications	
Ethernet interface	802.3 Ethernet interface via RJ45 connector
Wired Standards	10Base-T and 100Base-T LAN x 1 port Configured manually or via DHCP

H

Regulatory and Safety Information

This section provides information about the safe use and regulatory compliance of this system. The system software is considered medical software. As such, it was designed and manufactured to the appropriate medical regulations and controls.

Intended Use

The MAC 5 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult or pediatric populations. Basic system delivers 3, 6, or 12 lead ECG's and interpretive analysis. Transmission and reception of ECG data and other clinical data to and from a central clinical information system is optional.

The MAC 5 ECG Analysis System is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital, medical professional's facility or wherever ECG testing is performed.

Indications for Use

The MAC 5 Resting ECG Analysis System is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric (birth through 21 years of age) populations.

Contraindications

This MAC 5 Resting ECG Analysis System is not intended in the manners below:

- During patient transport
- With high-frequency surgical units
- As an intra-cardiac application
- As a sole means of diagnosis
- As a vital signs physiological monitor

Clinical Benefits

The clinical benefits of the MAC 5 Resting ECG Analysis System include: analysis of ECG data (QRS Complex) for diagnostic interpretation by the clinician/physician to assist with clinical decision making in the care of patients with heart disease. These clinical benefits follow the devices' intended uses and indications for use.

Prescription Device Statement

CAUTION:

United States federal law restricts this device to sale by or on the order of a physician.

Safety Conventions

This section describes the safety conventions used in the documentation for the product.

A Hazard is a source of potential injury to a person, property, or the system.

The manuals for this system use the terms DANGER, WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the definitions below and their significance.

Table 128: Definitions of Safety Conventions

Safety Convention	*Description*
DANGER	Indicates an imminent hazard, which, if not avoided will result in death or serious injury.
WARNING	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in death or serious injury.
CAUTION	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in moderate or minor injury.

Safety Convention	*Description*
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data.

Safety Hazards

The safety messages below alert you to potentially hazardous conditions that could arise during the normal use of this product and recommend steps that can be taken to avoid those conditions. Safety messages pertaining to hazardous conditions that may arise during specific actions may also be provided during the discussion of those actions in this or other manuals for this product.

CAUTION:

EQUIPMENT MALFUNCTION - Any attempt by unauthorized personnel to service the device could result in equipment malfunction and void the warranty. This equipment contains no user-serviceable parts.

Please contact the authorized service personnel to service the device.

NOTICE:

EQUIPMENT COMPATIBILITY - Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

WARNING:

PERSONAL INJURY-STUMBLING HAZARD - Patients can become entangled in the cables and leadwires connected to the device, which could cause the patient to stumble or trip.

Route cables and leadwires in a way to avoid creating a stumbling hazard: keep them off the floor, and route leadwires away from the patient's legs and the healthcare provider's work area.

WARNING:

MAGNETIC AND ELECTRICAL INTERFERENCE - Magnetic and electric fields can interfere with the acquisition of ECG readings.

Make sure that all peripheral components operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems (cellular phones) and so forth, are possible sources of interference because they may emit higher levels of electromagnetic radiation. Verify the performance of the system before use.

WARNING:

EXPLOSION HAZARD - Using this device in the presence of anesthetic vapors or liquids can cause explosions.

Do not use this device in the presence of anesthetic vapors or liquids. Only persons with adequate training in the correct use of this device may use this device.

CAUTION:

EQUIPMENT FAILURE - Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge blocks acquisition of the ECG signal.

Whenever patient defibrillation is a possibility, use non-polarizing electrodes (silver-silver chloride construction) for ECG monitoring.

WARNING:

PERSONAL INJURY - Contact with patients during defibrillation can cause serious injury or death.

Do not contact patients during defibrillation. Patient signal inputs labeled with the CF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only GE Healthcare recommended cables and leadwires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

CAUTION:

EXPLOSION HAZARD - Do NOT use in the presence of flammable anesthetics vapors or liquids.

WARNING:

INTERPRETATION HAZARD - Results of the automated QT analysis are not considered a diagnosis.

A qualified physician or cardiologist must review and confirm the measurements and waveforms recorded by the system. It should be used only as an adjunct to the clinical history, symptoms, and results of other tests.

WARNING:

INTERPRETATION HAZARD - Computerized interpretation is only significant when used in conjunction with clinical findings.

A qualified physician must overread all computer-generated tracings.

WARNING:

IMPROPER USE - This is a prescriptive device.

This equipment is intended for use by or under the direct supervision of a licensed healthcare practitioner.

NOTICE:

BATTERY EXPLOSION HAZARD - Batteries may explode in fires.

Do not dispose of the battery by fire or burning. Follow local environmental guidelines concerning disposal and recycling.

WARNING:

ELECTRIC SHOCK HAZARD/SYSTEM MALFUNCTION - Liquids inside a device can cause electric shock or system malfunction.

Do not allow liquids to enter the device. If liquids enter the device, turn it off and inform your service technician. Do not use the device until it is checked by a service technician.

WARNING:

ELECTRIC SHOCK - Improper connection of this equipment may cause electric shock.

To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth.

WARNING:

EQUIPMENT MALFUNCTION/INTERFERENCE - Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Do not use portable phones or other electronic equipment that may emit radio frequency (RF) near this system.

WARNING:

EQUIPMENT MALFUNCTION/INTERFERENCE - Do not use the equipment or system adjacent to, or stacked with, other equipment.

If adjacent or stacked use is necessary, test the equipment or system to verify normal operation in the configuration in which you are using it.

WARNING:

ACCESSORIES/COMPONENTS - Adding accessories or components, or modifying the medical device or system, may result in increased EMISSIONS or decreased IMMUNITY of the device or system.

CAUTION:

ACCESSORIES (SUPPLIES) - To ensure patient safety, use only parts and accessories manufactured or recommended by GE Medical Systems *Information Technologies, Inc*. Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards and essential performance standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

CAUTION:

ACCESSORIES (EQUIPMENT) - The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include: Use of the accessory in the PATIENT VICINITY; and Evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

NOTICE:

DATA LOSS - Formatting the device's internal flash drive erases all the data in memory and returns the device to its factory settings.

If possible, back up or record any data that you do not want to lose before formatting the device's internal flash drive.

WARNING:

ELECTRIC SHOCK HAZARD - The conductive parts of electrodes and associated connectors for leadwire, including the neutral electrode, should not contact any other conductive parts including earth.

WARNING:

ELECTRIC SHOCK HAZARD - Devices which connected to the same Ethernet/LAN with MAC 5 should comply with IEC 60950/IEC60601 or equivalent safety standard.

CAUTION:

DISPOSAL HAZARD - At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with local, state, or federal guidelines regulating the disposal of such products.

If you have questions concerning disposal of the product, please contact GE or its representatives.

CAUTION:

INTERCONNECTED DEVICES - When several items of medical equipment are interconnected, summation of leakage current must meet the leakage current as per IEC 60601-1.

Connect the device only to the GE approved supplies and accessories.

CAUTION:

ISOLATION FROM SUPPLY MAINS - Do not position the device so that it is difficult to operate the disconnection of the AC power supply of the device.

Classification of Medical Device

The device is classified as follows according to IEC 60601-1.

Table 129: Medical Device Classifications

Category	*Classification*
Type of protection against electrical shock	Class I, internally powered
Degree of protection against electrical shock	Type CF defibrillation-proof applied part
Degree of protection against harmful ingress of solids and liquids	The Ingress Protection (IP) code for this device is IP 20.

Category	*Classification*
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable
Mode of operation	Continuous operation

Certification Information

Table 130: Certification Information

CE 0197	This system bears CE mark 0197 indicating it conforms with the provisions of Council Regulation EU 2017/745 concerning medical devices, and it fulfills the requirements of Annex I of this regulation. The system is in radio-interference protection class B in accordance with EN 55011. The country of manufacture is indicated on the equipment labeling. The product complies with the requirements of standard EN 60601-1-2 “Electromagnetic Compatibility – Medical Electrical Equipment”. The medical device has a lifetime of 7 years with respect to the Council Regulation EU 2017/745 Annex I, Requirement 6.
TÜVRheinland C US	**Medical Equipment** With respect to electric shock, fire, and mechanical hazards only in accordance with IEC 60601-1, and CAN/CSA C22.2 NO. 601.1.

Recording ECGs during Defibrillation

This equipment is protected against the effects of cardiac defibrillator discharge to ensure recovery, as required by test standards. The patient signal input of the acquisition module is defibrillation-proof. It is not necessary to remove the ECG electrodes prior to defibrillation.

When using stainless steel or silver electrodes, a defibrillator discharge current may cause the electrodes to retain a residual charge causing a polarization or DC offset voltage. This electrode polarization blocks acquisition of the ECG signal. To avoid this condition, if there is a situation where a defibrillation procedure is necessary, use non-polarizing electrodes such as silver/silver-chloride types, which do not form a DC offset voltage when subjected to a DC current.

If you use polarizing electrodes, GE Healthcare recommends disconnecting the leadwires from the patient before delivering the shock.

Electrode defibrillation recovery is the ability of the electrode to allow the ECG trace to return after defibrillation. GE Healthcare recommends using non-polarizing disposable electrodes with defibrillation recovery rating as specified in AAMI EC12.5.2.2.4. AAMI EC12 requires that the polarization potential of an electrode pair does not exceed 100 mV 5 seconds after a defibrillation discharge.

Refer to the supplies and accessories guide for this system for a list of approved electrodes.

Modulating Effects in Digital Systems

This section describes the modulating effects that may occur in digital systems of the product.

This device uses digital sampling techniques that may produce some variation in amplitudes of Q, R, and/or S waves from one heart beat to the next, which may be particularly noticeable in pediatric recordings. If you observe this phenomenon, be aware that the origin of amplitude variations is not entirely physiological. For measuring voltages of Q, R, and S waves, GE Healthcare advises using the QRS complexes with the largest deflection of the particular waves.

Electromagnetic Compatibility (EMC)

Before installing or using the device or system, be aware of the proximity of known radio frequency (RF) sources, such as:

- Radio and TV stations
- Portable and mobile RF communication devices (cell phones, two-way radios)
- X-ray, CT, or MRI devices

  These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

WARNING:
EQUIPMENT MALFUNCTION OR INTERFERENCE - Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

WARNING:
EQUIPMENT MALFUNCTION OR INTERFERENCE - Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the ECG device, including cables specified by the manufacturer. Degradation of the performance of this equipment could result.

WARNING:

PATIENT SAFETY/EQUIPMENT FAILURE - Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Guidance and Manufacturer's Declaration—Electromagnetic Emissions

The system described in this document is intended for use in the specified electromagnetic environment below. It is the responsibility of the customer or user to make sure that this system is used in such an environment.

Table 131: EMC Emissions Test

Emissions Test	*Compliance*
RF emissions (Radiated) EN 55011	Group 1 Class B
RF emissions (Conducted) EN 55011	Group 1 Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies

Guidance and Manufacturer's Declaration—Electromagnetic Immunity

The system described in this document is intended for use in the specified electromagnetic environment below. It is the responsibility of the customer or user to make sure that this system is used in such an environment.

Table 132: EMC Immunity Test

Immunity Test	*EN60601 Test Level*	*Compliance Level*
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air
Electrical Fast Transient/burst (EFT) IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth

Immunity Test	*EN60601 Test Level*	*Compliance Level*
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% Ut (> 95% dip in Ut) for 0.5 cycles < 40% Ut (> 60% dip in Ut) for 5 cycles < 70% Ut (> 30% dip in Ut) for 25 cycles < 5% Ut (> 95% dip in Ut) for 5 s	< 5% Ut (> 95% dip in Ut) for 0.5 cycles < 40% Ut (> 60% dip in Ut) for 5 cycles < 70% Ut (> 30% dip in Ut) for 25 cycles < 5% Ut (> 95% dip in Ut) for 5 s
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
Conducted RF IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	3 V/m at 80 to 2700 MHz, AM Modulation 9 to 28 V/m at 385 to 6000 MHz, FM or Digital Modulation	3 V/m at 80 to 2700 MHz, AM Modulation 9 to 28 V/m at 385 to 6000 MHz, FM or Digital Modulation

NOTE:

- Do not use portable or mobile RF communications equipment closer to any part of the system, including the cables, than the recommended separation distance calculated for the equation applicable to the frequency of the transmitter.
- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot, theoretically, be predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, consider conducting an electromagnetic site survey. If the measured field strength in the location the system is used exceeds the applicable RF compliance level listed in this table, observe the system to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by the reflection from structures, objects, and people.

Essential Performance

The essential performance of the system may be lost or degraded because of electromagnetic disturbances. For expected degradations and instructions of the basic safety and essential performance maintance in the case of electromagnetic disturbances, see the table below:

Essential Performance	*Degradation Caused by Electromagnetic Disturbances*	*Essential Performance Maintainance*
Defibrillation Protection	No degradation.	Not applicable.
ECG Measurements *	Temporary function loss during Electrostatic Discharge (ESD) and Electrical Fast Transient/ Burst (EFT) disturbances.	The device resumes normal operation within 10 seconds after the disturbance is removed: • No operator setting or stored data loss; • Will continue to perform its intended functions; • Will maintain the essential performance.
FILTERS (Including Line Frequency Disturbance FILTERS)	No degradation.	Not applicable.
* Essential performance is amplitude measurement accuracy as defined by IEC 60601-2-25 Section 202.6.2. The difference for each amplitude measurement shall not deviate from the reference value by more than ± 50 µV for reference values ≤ 500 µV, or by more than 5 % or ±100 µV (whichever is greater) for reference values > 500 µV.		

Biocompatibility

The parts of the system described in this manual that come into contact with the patient during the intended use, including all accessories, fulfill the biocompatibility requirements of the applicable standards. If you have questions in this matter contact your GE Healthcare representative.

Legal Notice

GE Healthcare software contains several fields that can be populated before performing an ECG. Some of these fields are required, others are optional and left to the user to assess whether they are needed to perform the exam. The field **Race** is one of these optional fields. Race has been acknowledged by the medical profession as useful to analyze some pathologies. You should be aware that, in some jurisdictions, the processing of data revealing an individual's racial origin is subject to legal requirements, such as obtaining the patient's prior consent. If you elect to collect this type of data, it is your responsibility to make sure that you comply with all applicable legal requirements.

Supplies and Accessories

This section is in regard to the supplies and accessories you may purchase for your product.

You should use only supplies and accessories recommended by GE Healthcare. For a list of recommendations, refer to the supplies and accessories guide for this system.

Contact GE Healthcare before using anything that is not recommended for this system.

Responsibility of the Manufacturer

This section describes the responsibility of GE Healthcare as the manufacturer of your product.

GE Healthcare is responsible for the safety, reliability, and performance of hardware supplied by GE Healthcare only if the conditions below are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are performed by persons authorized by GE Healthcare.
- The electrical installation of the room where the device is used complies with the requirements of the appropriate local, state, and other government regulations.
- The equipment is used in accordance with the instructions for use.

Responsibility of the Purchaser/Customer

The customer is responsible for providing appropriate desks, chairs, electrical wall outlets, network connections, and analog phone lines, and for locating any of the system components described in the manuals in compliance with all local, state, and national codes.

Lack of data security may compromise patient privacy. GE Healthcare recommends that you take appropriate steps to secure the privacy of communication on your network when using this product.

Notification to Member States

The user and/or patient should report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Warranty Information

This device is considered GE Healthcare-supplied hardware. Only authorized GE Healthcare service personnel should service the device. Any unauthorized attempt to

repair equipment under warranty voids that warranty. It is the user's responsibility to report the need for service to GE Healthcare or to one of their authorized agents.

Product and Packaging Information

The illustrations and tables in this section describe the labels and their location on your device and its packaging.

Contact your local GE Healthcare service representative, if the device packaging is:

- Damaged.
- Accidentally opened.
- Exposed to an environment that does not meet the prescribed conditions.

MAC 5 A4 Hardware Label Locations

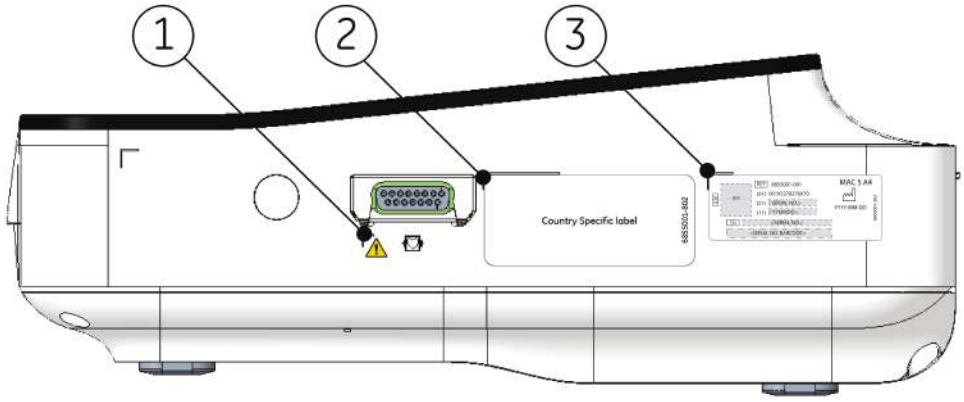


Table 133: Label Descriptions on the Right Side of the Device

Item	*Label*	*Description*
1	General Warning Symbol	See *Symbol Descriptions on page 366* for an explanation of the label.
2	Country-specific Label	Country registration information.
3	Serial Number Label	Device identification. See *Serial Number Label on page 364* for a description of the label contents.

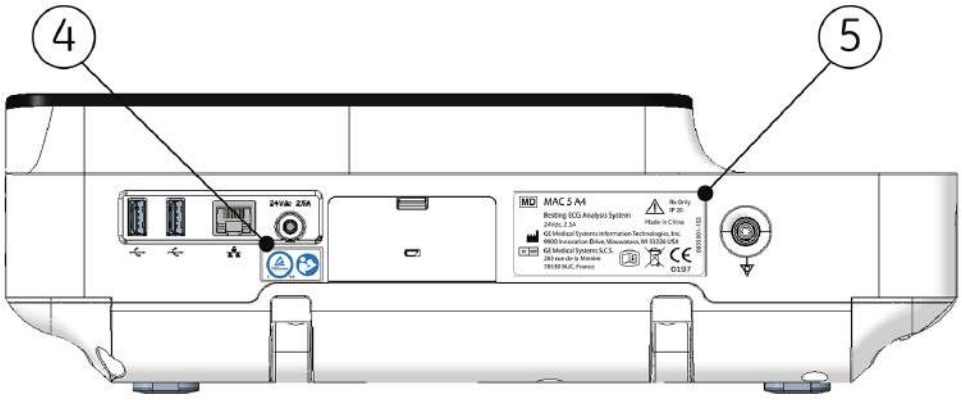


Table 134: Label Descriptions on the Back Side of the Device

Item	*Label*	*Description*
4	TUV and IFU Symbol Label	See *Certification Information on page 345* and *Symbol Descriptions on page 366* for a description of the label contents.
5	Product and Rating Label	Regulatory and cautionary information. See *Device Address Label and Rating Plate on page 365* for an explanation of the label.

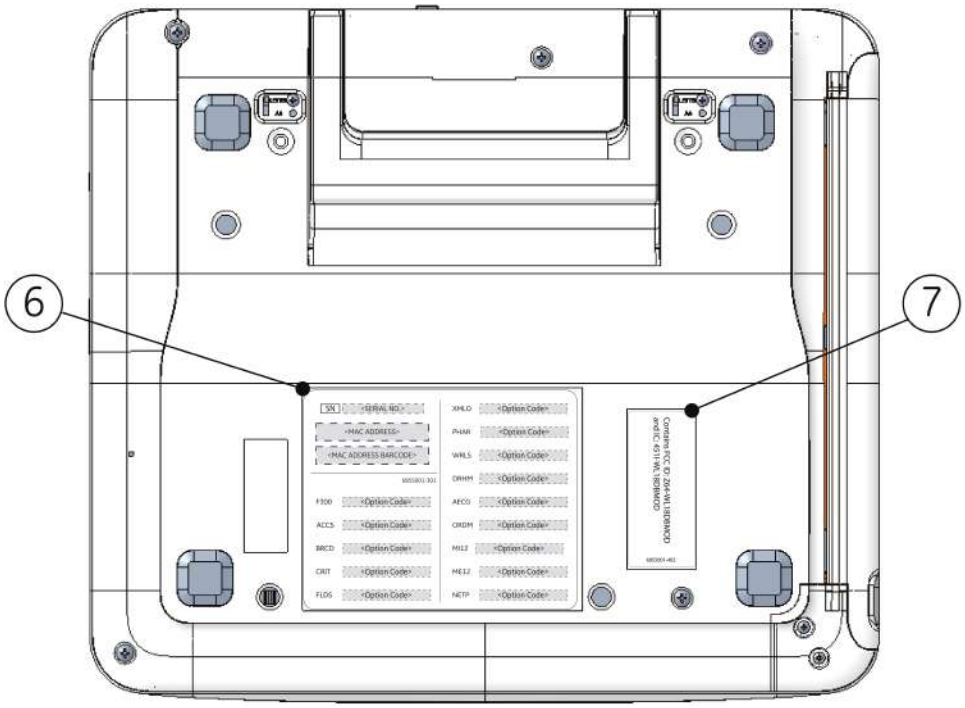
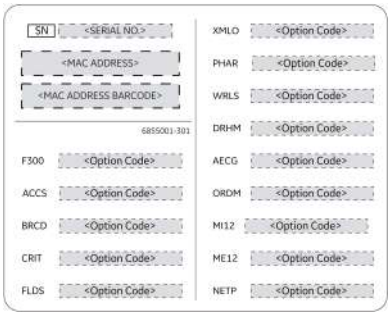


Table 135: Label Descriptions on the Bottom of the Device

Item	*Label*	*Description*
6	Option Code and MAC Address Label	The MAC address of the wired network card. Use the option codes to set up the purchased options in your system. 
7	Wireless Label	The wireless registration information. 

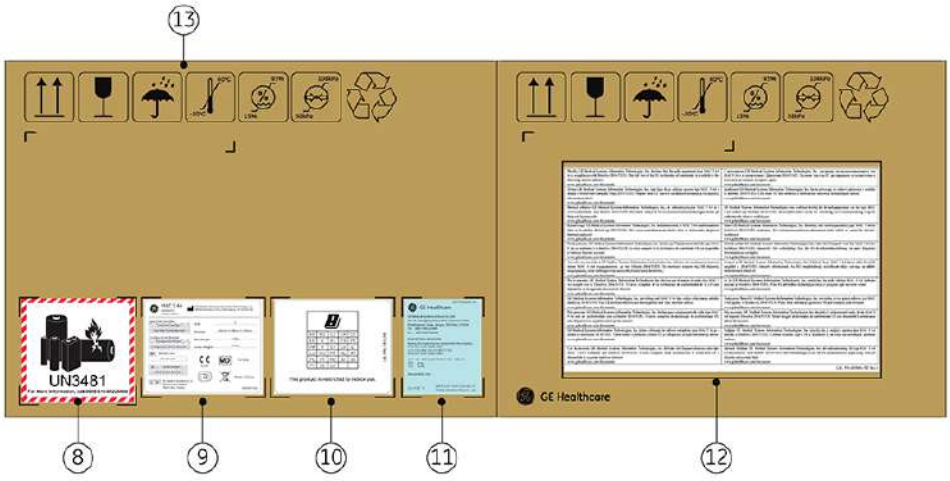
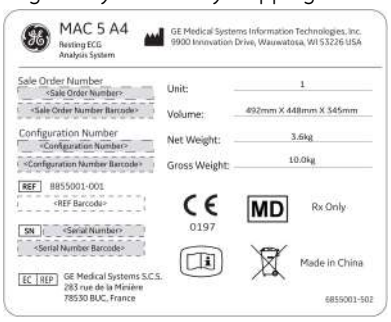
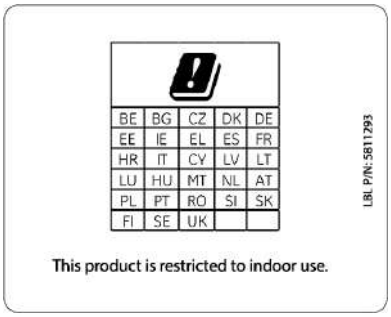


Table 136: Label Descriptions on the Shipping Package of the Device

Item	*Label*	*Description*
8	Battery Shipping Label	Lithium Ion battery damaged caution label. 
9	Shipping Label	Regulatory and safety shipping information. 
10	Radio Equipment Directive (RED) Label	The Radio Equipment Directive registration information. 

Item	Label	Description
11	Battery Transportation Label	The battery transportation information.  LBL P/N:2062005-501 GE Healthcare GE Medical Systems (China) Co., Ltd. No.19, Changjiang Road, WuXi National Hi-Tech Development Zone, Jiangsu, P.R.China 214028 Tel：(86510)85225888 Fax：(86510)85226688 DESCRIPTION OF GOODS: Resting ECG Analysis System packed with Lithium battery FLEX-3S2P 10.8V 3.80Ah 41Wh 心电分析仪 MAC 5 A4 内含锂离子电池 FLEX-3S2P 10.8V 3.80Ah 41Wh 生产厂商：通用电气医疗系统（中国）有限公司 净重： 3.6 kg 毛重： 10.0 kg (Remark: MAC 5 A4) 出口/代理厂商 通用电气医疗系统(中国)有限公司 GE Medical Systems (China) Co., Ltd.
12	Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance	The Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance. 
13	Environmental Symbols	Safety indicators required for shipping. For a full description of symbols, see *Symbol Descriptions on page 366*.

MAC 5 A5 Hardware Label Locations

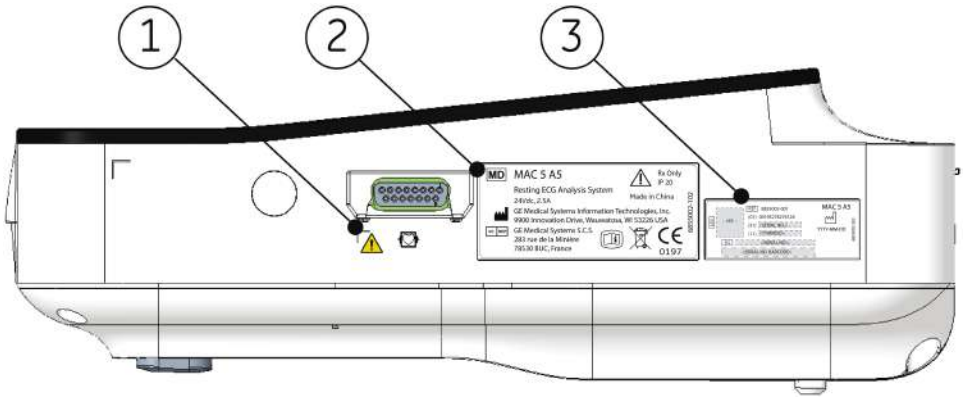


Table 137: Label Descriptions on the Right Side of the Device

Item	Label	Description
1	General Warning Symbol	See *Symbol Descriptions on page 366* for an explanation of the label.

Item	Label	Description
2	Product and Rating Label	Regulatory and cautionary information. See *Device Address Label and Rating Plate on page 365* for an explanation of the label.
3	Serial Number Label	Device identification. See *Serial Number Label on page 364* for a description of the label contents.

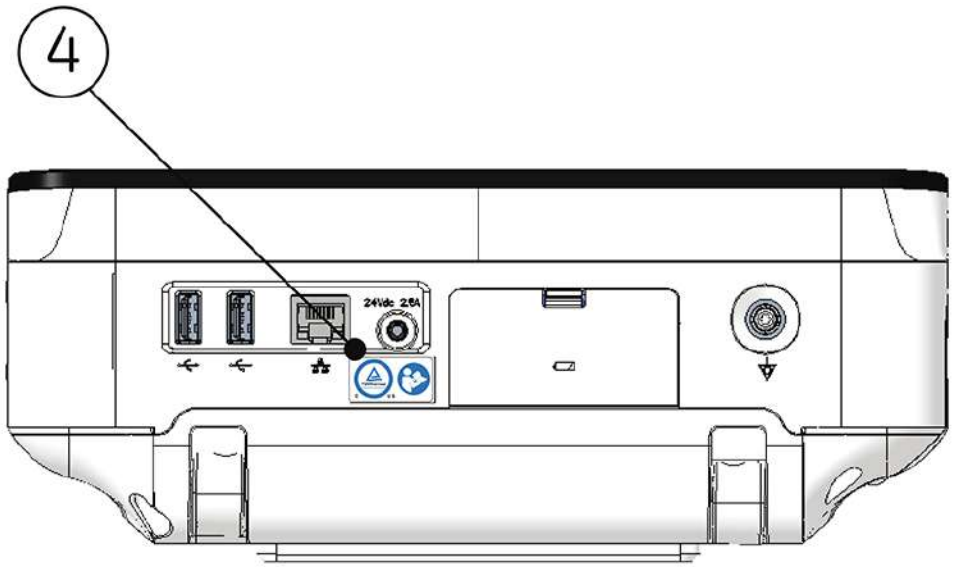


Table 138: Label Descriptions on the Back Side of the Device

Item	Label	Description
4	TUV and IFU Symbol Label	See *Certification Information on page 345* and *Symbol Descriptions on page 366* for a description of the label contents.

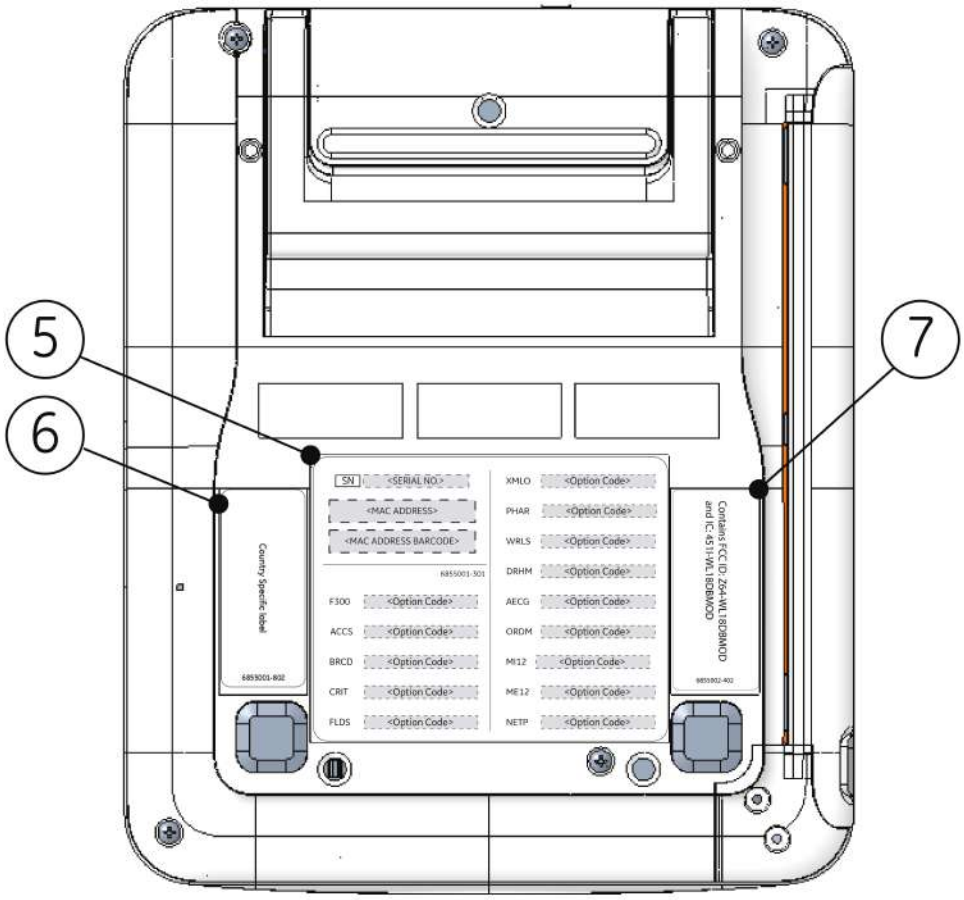
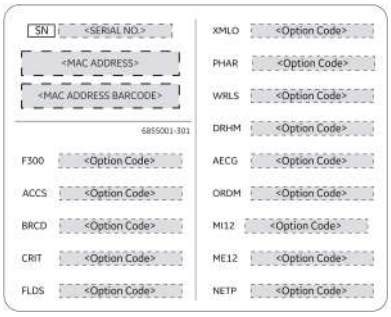


Table 139: Label Descriptions on the Bottom of the Device

Item	*Label*	*Description*
5	Option Code and MAC Address Label	The MAC device address of the device. Use the option codes to set up the purchased options in your system. 
6	Country Specific Label	Country registration information.

Item	Label	Description
7	Wireless Label	The wireless registration information. Contains FCC ID: Z64-WL18DBMOD and IC: 451I-WL18DBMOD 6855002-402

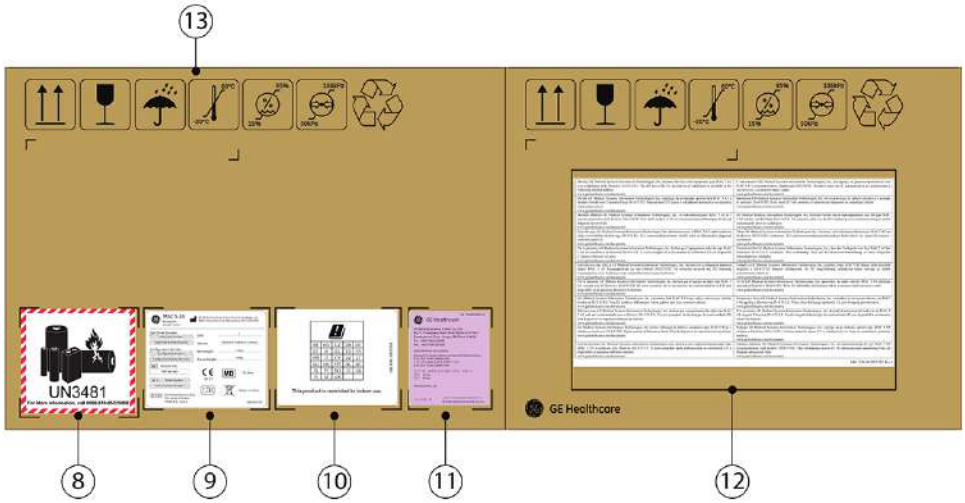
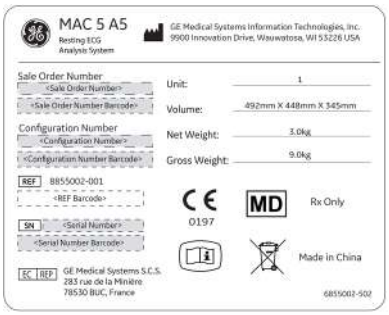
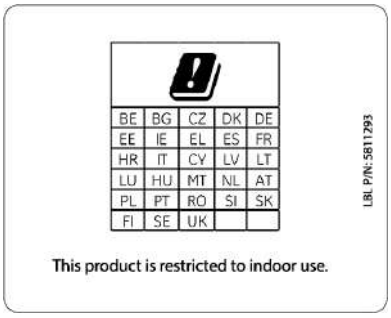


Table 140: Label Descriptions on the Shipping Package of the Device

Item	Label	Description
8	Battery Shipping Label	FRAGILE—Lithium Ion batteries can cause fire if damaged. UN3481 For More information, call 0086-510-85225888

Item	*Label*	*Description*
9	Shipping Label	Regulatory and safety shipping information. 
10	Radio Equipment Directive (RED) Label	The Radio Equipment Directive registration information. 
11	Battery Transportation Label	The battery transportation information. 
12	Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance	Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance. 

Item	Label	Description
13	Environmental Symbols	Safety indicators required for shipping. For a full description of symbols, see *Symbol Descriptions on page 366*.

MAC 5 Lite Hardware Label Locations

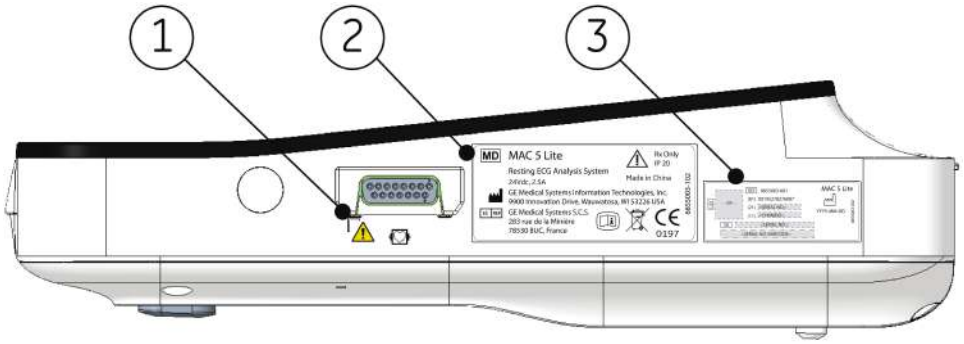


Table 141: Label Descriptions on the Right Side of the Device

Item	Label	Description
1	General Warning Symbol	See *Symbol Descriptions on page 366* for an explanation of the label.
2	Product and Rating Label	Regulatory and cautionary information. See *Device Address Label and Rating Plate on page 365* for an explanation of the label.
3	Serial Number Label	Device identification. See *Serial Number Label on page 364* for a description of the label contents.

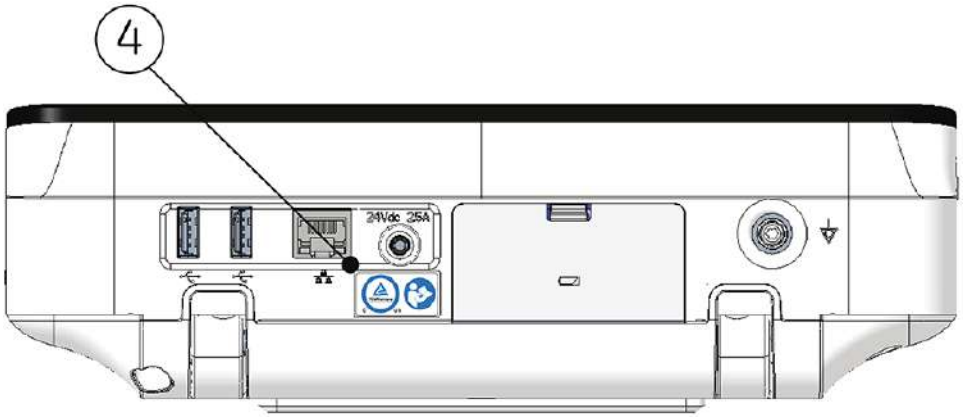


Table 142: Label Descriptions on the Back Side of the Device

Item	Label	Description
4	TUV and IFU Symbol Label	See *Certification Information on page 345* and *Symbol Descriptions on page 366* for a description of the label contents.

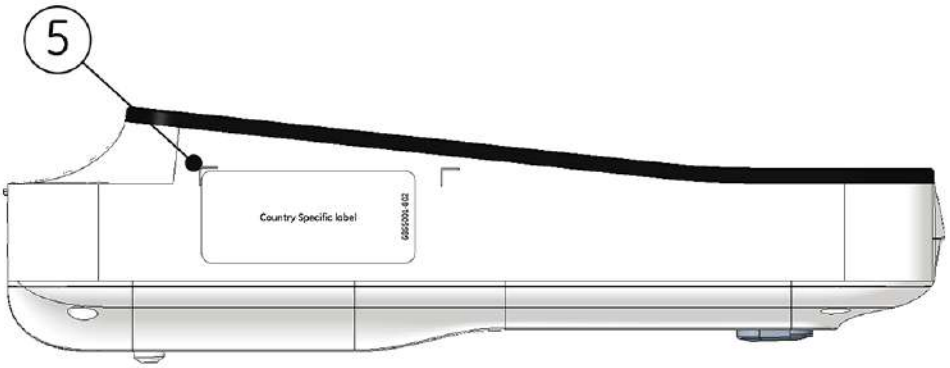


Table 143: Label Descriptions on the Left Side of the Device

Item	*Label*	*Description*
5	Country Specific Label	Country registration information.

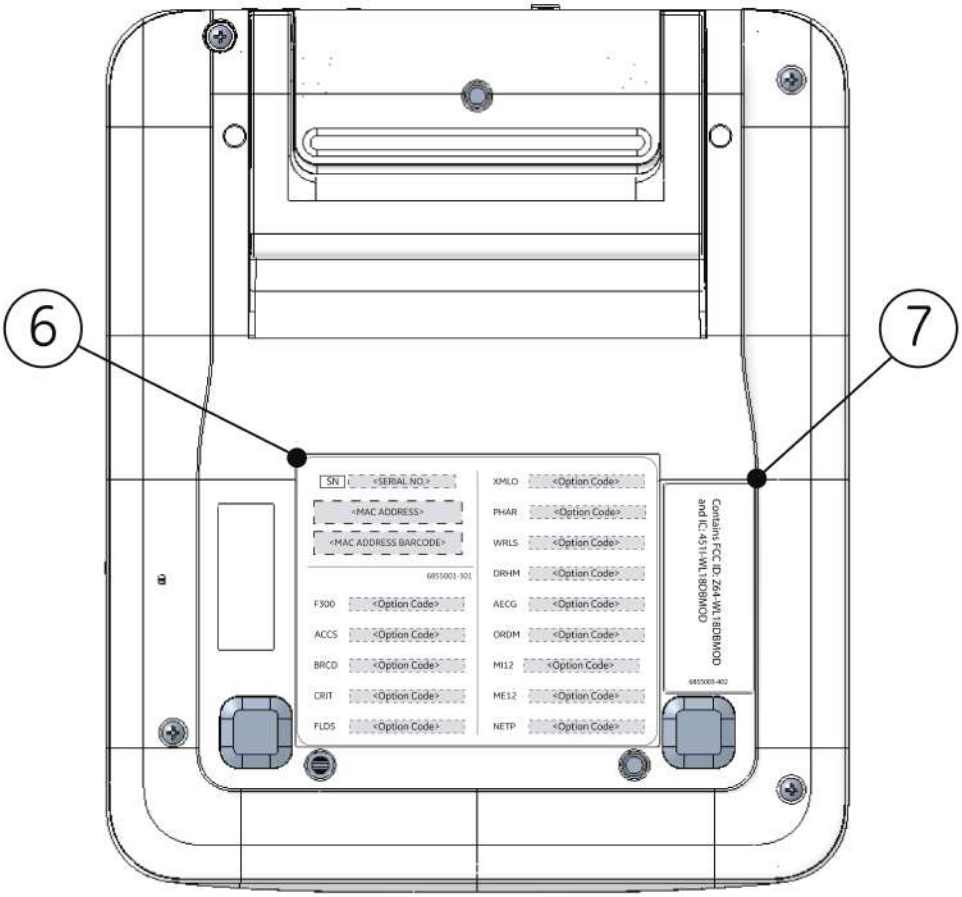
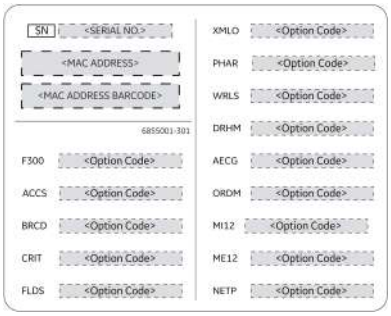


Table 144: Label Descriptions on the Bottom of the Device

Item	*Label*	*Description*
6	Option Code and MAC Address Label	The MAC device address of the device. Use the option codes to set up the purchased options in your system. 
7	Wireless Label	The wireless registration information. 

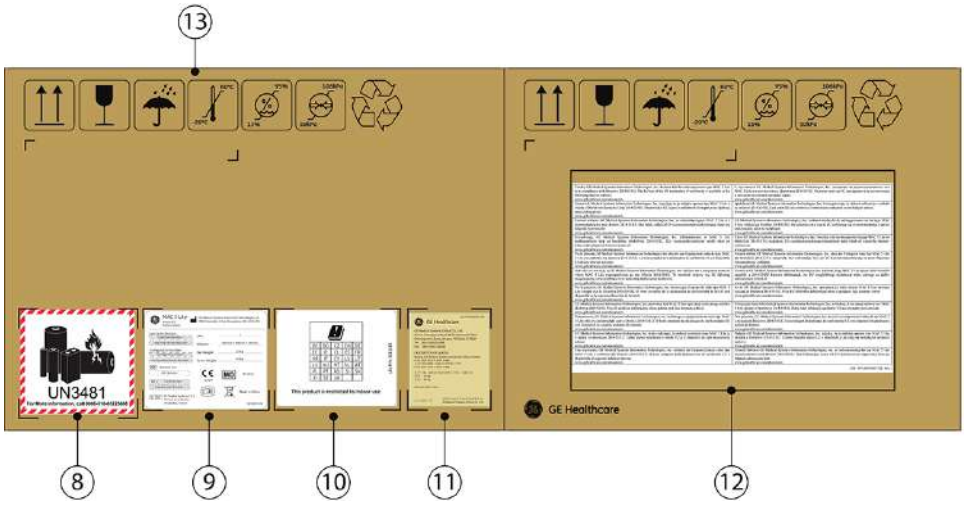
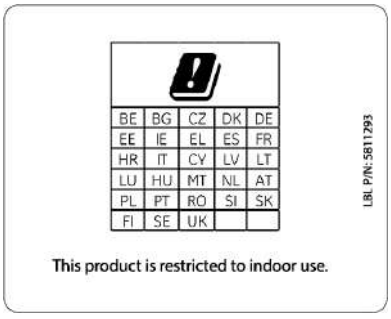


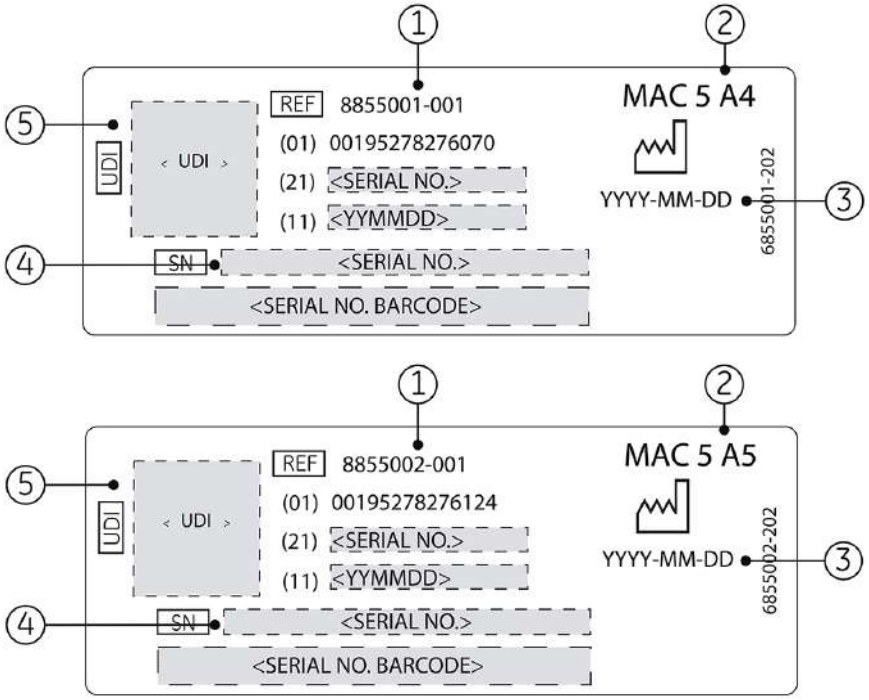
Table 145: Label Descriptions on the Shipping Package of the Device

Item	*Label*	*Description*
8	Battery Shipping Label	FRAGILE—Lithium Ion batteries can cause fire if damaged. 
9	Shipping Label	Regulatory and safety shipping information.
10	Radio Equipment Directive (RED) Label	The Radio Equipment Directive registration information. 
11	Battery Transportation Label	The battery transportation information. 

Item	Label	Description
12	Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance	Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance. 
13	Environmental Symbols	Safety indicators required for shipping. For a full description of symbols, see *Symbol Descriptions on page 366*.

Serial Number Label

The serial number labels are in the format as follows:



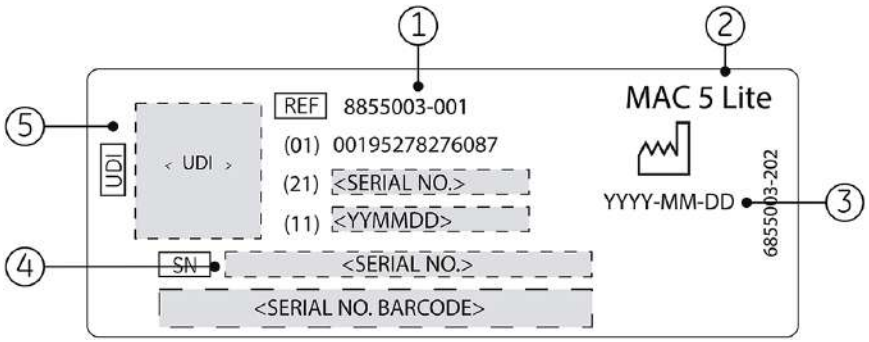
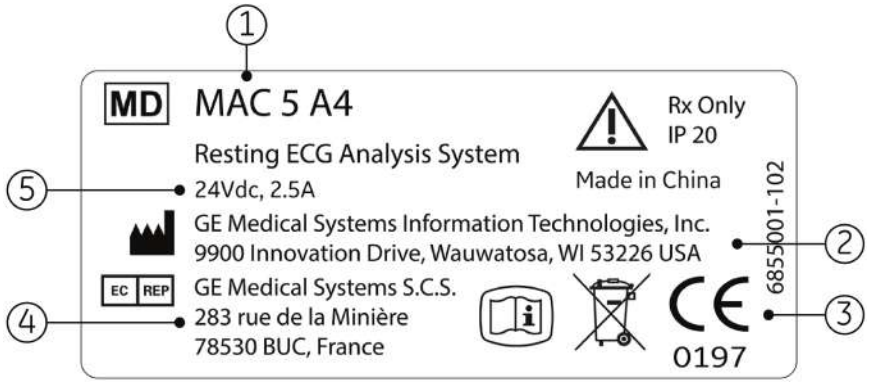


Table 146: Serial Number Label Format

Item	*Description*
1	Product Part Number
2	Product Mode
3	Date of Manufacture in YYYY-MM-DD Format
4	Device Serial Number
5	UDI Barcode

Device Address Label and Rating Plate

The device address label and rating plate is in the format as follows:



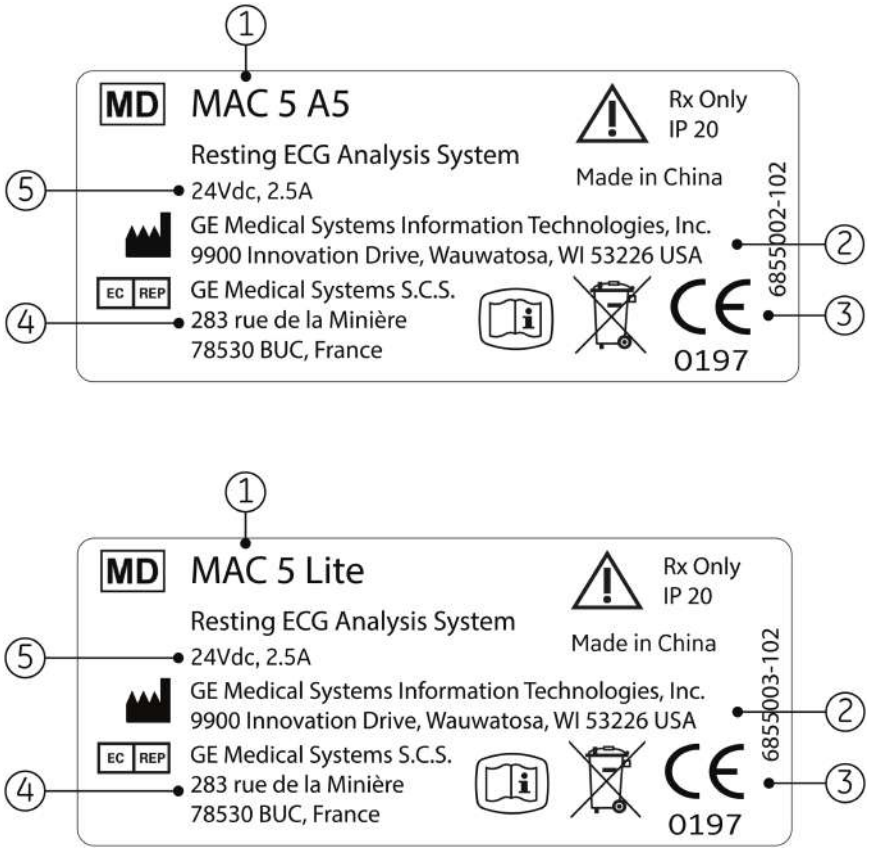


Table 147: Device Address Label and Rating Plate Format

Item	*Description*
1	Product Mode
2	Manufacturer Name and Address
3	Symbols See *Symbol Descriptions on page 366* for a description of the symbols used on this label.
4	Authorized European Representative Information
5	Electrical Rating of the Device

Symbol Descriptions

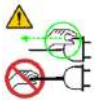
For equipment symbols not shown, refer to the original equipment manufacturer (OEM) manuals.

Table 148: Symbols, Icons, and Descriptions on the device or packaging

Symbol	*Description*
REF	**Catalog or Orderable Part Number** The manufacturer's catalog or part number.
SN	**Serial Number** The manufacturer's serial number.
LOT	**Batch Code or Lot Number** The manufacturer's batch code or lot number.
MD	**Medical Device** The device is used for medical purpose.
	**Date of Manufacture** The original manufacture date for this device.
	**Manufacturer** The name and address for the manufacturer of this device. It may also include the date it was manufactured.
EC REP	**Authorized Representative in the European Community** The name and address of the authorized representative in the European Community for this device.
Rx Only	**Rx Only** US Federal law restricts this device to sale by or on the order of a physician.
12SL MARQUETTE	**12SL** The device uses the Marquette™ 12SL ECG Analysis Program to analyze and interpret ECG readings.
IPxx	**IP Code (Ingress Protection Rating)** Classifies and rates the degree of protection provided against the intrusion of solid objects (such as body parts, dust, accidental contact), and liquids. The first numeral (x) represents the degree of protection against the ingress of solid objects. The second numeral (x) represents the degree of protection against the ingress of liquids. For products with an IPxx rating, see the Classification of Medical Device in this chapter for a description of that rating. Not all products have an IPxx rating.
CE	**CE Mark** The device or product conforms with applicable EU (European Union) directives.

Symbol	*Description*
	**Regulatory Compliance Mark (RCM)** Compliance with electrical safety, EMC, EME, and telecommunications requirements, as applicable, to the product. Required for Australia and New Zealand.
	**Wireless Communication** The equipment can be connected through wireless communication.
	**Waste Electrical and Electronic Equipment (WEEE)** Indicates this equipment contains electrical or electronic components that must not be disposed of as unsorted municipal waste, but collected separately. Contact an authorized representative of the manufacturer for information for the decommissioning of your equipment.
	**Consult Instructions for Use** Consult the operating instructions.
	**Electronic Instructions for Use (eIFU)** Consult the electronic instructions for use.
	**Follow Instructions For Use** Read and understand the operator's manual before using the device or product. *As a mandatory action sign, this symbol is identified by a blue background and white symbol.*
	**CAUTION**: CONSULT ACCOMPANYING DOCUMENTS - There may be specific warnings or precautions associated with the device that are not otherwise found on the label. Consult the accompanying documentation for more information about safely using this device.
	**General Warning Sign** Protection of the ME EQUIPMENT against the effects of the discharge of a cardiac defibrillator is dependent upon the use of GE recommended ECG cables.
	**This Way Up** The correct upright position of the package.
	**Keep Dry** You need to keep the container away from rain and other sources of moisture.

Symbol	*Description*
	**Can Be Recycled** You may recycle this material or device. Recycle or dispose of in accordance with local, state, or country laws.
	The upper and lower temperature limits for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
	The upper and lower humidity limits for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
	The upper and lower barometric pressure limitations for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.
	**Defibrillation-proof Type CF Applied Part** Identifies a defibrillation-proof type CF applied part on medical equipment that complies with IEC 60601–1. This device meets the requirements for protection against electric shock for an earth-free (floating) applied part (one intended for contact with patients) for cardiac application.
	**No User– or Field-serviceable Parts** Do not open or disassemble the device for any reason.
	**Protective Earth** (ground) Identifies the terminal of a protective earth (ground) electrode or any terminal that is intended for connection to an external conductor for protection against electric shock in case of a fault.
	**Do Not Stack** You should not stack the container or place a load on the container.
	**WARNING**: ELECTRIC SHOCK - Indicates the presence of hazardous energy circuits or electric shock hazards. To reduce the risk of electric shock hazards, do not open this enclosure. Refer servicing to qualified personnel.
	Equipotentiality Connect non-grounded peripheral devices to ensure equipotential.

Symbol	*Description*
	**Environmental Friendly Use Period (EFUP)** Per Chinese standard SJ/T11364–2014, the number of years from the date of manufacture during which you can use the product before any restricted substances are likely to leak, causing a possible environmental or health hazard. **NOTE**: • If the device contains less than the maximum concentration of restricted substances, the symbol contains a lowercase ***e*** • This is also referred to as China RoHS.
	**Fragile** The contents are fragile. Handle with care.
	**CAUTION**: SAFETY GROUND PRECAUTION - Pulling on the cable can cause the cord to deteriorate resulting in electrical problems. Remove the power cord from the mains source by grasping the plug. DO NOT pull on the cable.
	**Contains <heavy metal chemical symbol>** This equipment contains heavy metal and must not be disposed of as unsorted municipal waste but collected separately. The example shows Lithium Ion.
	**Pushing Prohibited**
	**Unique Device Identification** Indicates a unique marking for identification of the medical device.

Serial Number Format

Each device has a serial number that uniquely identifies the device and provides important information about the device. The serial number format is shown in the illustration below:

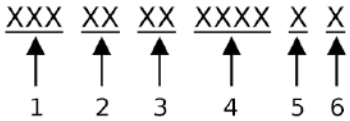


Table 149: Serial Number Format

Item	*Name*	*Description*
1	Product Code	A three-character code that uniquely identifies the product line.
2	Year Manufactured	A two-digit code identifying the year the device was manufactured. Values range from 00 to 99. For example: 00 = 2000, 04 = 2004, 17 = 2017 (and so on).
3	Fiscal Week Manufactured	A two-digit code identifying the week the device was manufactured. Values range from 01 to 52. GE Healthcare's fiscal weeks correspond to the calendar week. For example, 01 = the first week in January.
4	Product Sequence	A four-digit number identifying the order in which this device was manufactured. Values range from 0001 to 9999.
5	Manufacturing Site	A one-letter code identifying the site where the device was manufactured. For example, F = Milwaukee, N = Freiburg, P = Bangalore, W = Wuxi, H = Helsinki, S = Mexico
6	Miscellaneous Characteristic	A one-letter code identifying manufacturing status. For example, P = the device is a prototype, R = the device was refurbished, U = the device was upgraded to meet the specifications of another product code, A = device is in production.

Unique Device Identifier

Medical devices require a unique marking for identification—the Unique Device Identifier (UDI). In the event that you need the UDI for this product, check the product label on the back of the device.

Wireless Regulations

The wireless and wired LAN functionality of the MAC 5 A4/MAC 5 A5/MAC 5 Lite is used to retrieve ECG orders and send ECG reports to an ECG Management System. In addition, the wireless and wired LAN functionality can be used to interface to other hospital information systems to provide additional data to the care giver operating the electrocardiograph. These tasks are an adjunct to the device's intended use of acquiring, analyzing, displaying and printing an electrocardiogram. Because the wireless and wired LAN functionality is not required for the device to fulfill its intended use, network performance is not critical to the performance of the device. Furthermore, the MAC 5 A4/MAC 5 A5/MAC 5 Lite does not transmit any real-time data or alarm information over the network. Network Quality of Service (QoS) parameters such as reliability of data transmission, latency, transfer rate, error rate, and priority levels are not critical to the MAC 5 A4/MAC 5 A5/MAC 5 Lite functionality and are not specified.

FCC Compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the two conditions below: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION:

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the measures below:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Limited by local law regulations, version for North America does not have region selection option.

To satisfy FCC RF exposure requirements, a separation distance of 20 cm or more should be maintained between the antenna of this device and persons during device operation.

To ensure compliance, operations at closer than this distance is not recommended.

IC Compliance

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada’s licence-exempt RSS(s). Operation is subject to the two conditions below:

1. This device may not cause interference.
2. This device must accept any interference, including interference that may cause undesired operation of the device.

This equipment complies with radio frequency exposure limits set forth by the Innovation, Science and Economic Development Canada for an uncontrolled environment.

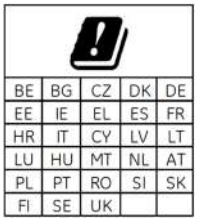
This equipment should be installed and operated with a minimum distance of 20 cm between the device and the user or bystanders.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.

The device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;

RED Information

The MAC 5 embedded wireless module complies with CE RED 2014/53/EU.



This product is restricted to indoor use.

Frequency Range	2.4 GHz frequency bands: 2.4-2.483 GHz 5 GHz frequency bands: 5.15-5.35 GHz, 5.47-5.725 GHz
Modulation Type	CCK/DSSS/OFDM
Maximum Effective Radiated Power (ERP)	20 dBm

Declaration of Conformity

Glossary

ACS Acute Coronary Syndrome

ADT Admission, Discharge, Transfer

Filter A filter sets the upper frequency limit for the ECG waveform displayed on the Acquisition screen and the printout. Selecting a filter eliminates signals that exceed that frequency. The smaller the filter selected, the more signal is filtered out. For example, a filter of 40 Hz displays only signals less than 40 Hz; signals greater than 40 Hz are ignored.

Gain Gain indicates how many mm represent 1 mV of waveform data on the screen and printout. You can change the gain to modify the display or printout of the waveform to your preference. Changing the gain changes the amplitude of the waveforms. A higher gain makes the amplitude of the waveform appear higher; a lower gain makes the amplitude of the waveform appear lower.

The 10/5 mm/mV setting is used to display the limb leads (I, II, III, aVr, aVl, and aVf) at 10mm/mV and chest leads (V1 to V6) at 5 mm/mV. This is done to reduce or prevent waveform overlap in the chest leads, while avoiding tiny waveforms in the limb leads.

HIS Hospital Information System

LAN Local Area Network

Speed Speed indicates the speed the ECG waveform displays on the screen and rhythm printout. You can change the speed to render the waveform slower or faster to aid in viewing or analysis of the waveform. A faster speed makes the waveform display more stretched out; a slower speed makes the waveform display closer together.

WLAN Wireless Local Area Network

GE Medical Systems
Information Technologies, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226 USA

EC REP

GE Medical Systems S.C.S.
283 rue de la Minière
78530 BUC, France

GE Medical Systems *Information Technologies, Inc.*, a General Electric Company, going to market as GE Healthcare.

www.gehealthcare.com

CE 0197

GE Healthcare

Marquette™ 12SL™ ECG Analysis Program

Physician Guide

2056246-007 1

Publication Information

The information in this manual only applies to 12SL version 24. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

The document part number and revision are on each page of the document. The revision identifies the document's update level. The revision history of this document is summarized in the following table.

Revision	***Date***	***Comment***
1	14 June 2021	Customer release.

To access other GE Healthcare Diagnostic Cardiology documents, go to the Common Documentation Portal (CDP), located at http://www.gehealthcare.com/documents. To access Original Equipment Manufacturer (OEM) documents, go to the device manufacturer's website.

Intended Audience

This manual is intended for qualified health care professionals using the 12SL ECG Analysis Program. It may also be useful for those who are not responsible for interpreting 12-lead ECGs but want to learn more about the capabilities and limitations of this medical device. See Contents for more details.

Manual Purpose: Ancillary Documentation, Product Labeling

GE's Marquette 12SL ECG Analysis Program is a prescriptive class II medical device, cleared by the Food and Drug Administration (FDA). The 12SL program does not directly acquire the ECG signal. It is used as a component in devices such as electrocardiographs, which digitize the analog ECG, and in computer systems, which receive digital 12-lead ECGs from other sources so that an initial ECG interpretation can be generated by 12SL for review and correction by a physician.

The International Electrotechnical Commission (IEC) requires manufacturers to disclose the performance of ECG analysis programs used in diagnostic electrocardiographs. "The intent is that this performance information be readily available to customers who want to know the information. The intent is not to require expansion of OPERATOR documentation to include this performance information. This information may be disclosed in one of the documents that are created and made generally available by the manufacturer of an ELECTROCARDIOGRAPH. Examples of these documents are physician's guides and technical notes, in addition to the OPERATOR's guide."[1]

This *12SL Physician's Guide* is not an operator manual. It is ancillary to the operator's manual and is considered product labeling. What the FDA terms "product labeling" extends beyond what is printed on the medical device or in an operator manual. It is brochures or any material regarding the product. If a manufacturer discloses the accuracy of the program in its Physician's Guide, it needs evidence to support it.

Intended Use of Computerized ECG

Computerized electrocardiography has been in existence since the late 1950's.[2, 3] Despite its widespread use,[4] there is little written that directly addresses the intent of computerized electrocardiography.

The pioneers of this technology had motivations which ranged from the esoteric - like demonstrating that a computer could mimic human intelligence - to the basic need of recording artifact free tracings.[5] Some of the favorable developments which resulted from the evolution of this technology were hardly imagined at its inception. For example, computerized ECG has been shown to reduce the cost of managing ECG services, especially as the volume of ECGs that need to be interpreted increases.[6] A major reason for this is that it reduces "analysis time by up to 24% to 28% for experienced readers."[7]

It should be made clear that a computerized analysis of the ECG is not a substitute for human interpretation. Statements of accuracy need to be viewed from a statistical perspective. Although accuracy levels may be high, outliers can and will exist. A computer does not have the ability to include the entire clinical picture of the patient. A person with organic heart disease can exhibit an ECG within normal limits. In a study of 391,208

patients with acute myocardial infarction, the initial ECG obtained in the emergency department was normal in 30,759.[8] Conversely, a normal individual can have an abnormal appearing ECG.[9, 10] The ECG must always be reviewed by a physician in the context of the patient and acted upon with sound clinical judgement.

Intended Use of 12SL Program as Registered with FDA (510k# K141963)

The 12SL ECG Analysis Program assists the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. The interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The analysis program is intended for use in the general population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The analysis program is intended for use in hospitals, outpatient clinics, emergency departments, and out-of-hospital sites such as ambulances and patients' homes.

The ACS Tool option is intended for adult patient populations who are suspected clinically to have acute coronary syndrome.

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Introduction

The Marquette™ 12SL™ Program: A Brief History

The Marquette™ 12SL™ program has been in existence since 1980. It was the first commercially available program to analyze all 12 leads simultaneously recorded for the entire 10-seconds of the diagnostic resting ECG. In 1982, the 12SL program was embedded into a computerized electrocardiograph known as the MAC-II. It was the first of its kind, generating a 12 lead interpretation at the bedside in less than 10 seconds.[11]

Since then, GE Healthcare has continued to evolve the Marquette™ 12SL™ program. The Marquette™ 12SL™ program has been validated on a variety of platforms beyond the diagnostic electrocardiograph, including bedside monitors, stress-testing systems, pre-hospital defibrillators, Holter recorders, and PC-based systems.

ECG Analysis/12SL Timeline

1980 – 12SL™ program introduced on MUSE™ system[11]

1982 – Incorporated into a computerized electrocardiograph: MAC-II™[11, 12]

1984 – 12SL™ Serial Comparison program[13]

1986 – Automated testing of 12SL using non-ECG, gold-standard databases[14]

1987 – Pediatric analysis, based on Davignon tables, incorporated into 12SL[15]

1988 – Analysis of extra leads, generating vector loops at an electrocardiograph[16]

1989 – Recognition of ST-elevated acute myocardial infarction (MI) in pre-hospital setting[17]

1991 – 12SL™ in a pre-hospital defibrillator equipped with 12-lead ECG[18]

1992 – 500 samples per second analysis, compression and storage[19]

1993 – 12SL™ in a bedside monitor, equipped with 12-lead ECG[20]

1995 – ACI-TIPI integrated into 12SL for prediction of acute cardiac ischemia[21]

1997 – Automated QT dispersion and T-wave principal component analysis[22]

1998 – ECG Research Workstations for systematic assessment of ECG measurements[23-25]

1999 – MacRhythm: 12SL™ incorporates asynchronous P wave detector based on QRS subtraction[26]

2000 – Gender specific acute MI criteria[27]

2001 – Improved pacemaker detection using ECG acquired at 4,000 samples per second (SPS)[28]

2002 – 12SL™ in a Holter recorder, equipped with 12 lead ECG[29-31]

2003 – New 12SL™ QT algorithm,[25] validated by core lab on more than 40,000 ECGs[32]

2004 – Pattern recognition of noise via Hook-up Advisor™ tied to interpretation performance[33]

2005 – 12SL™ cleared for measurement and trending of 12-lead ambulatory recordings[34]

2006 – Recognition of acute right ventricular infarction via analysis of V4R[35]

2010 – Detection of biventricular and low energy artificial pacing on data acquired at 75K SPS[36]

2011 – Acute coronary syndrome tool based on the use of a neural network[37]

2012 – T-wave morphology measures related to hERG channel block[38-46]

2014 – Detection of left ventricular hypertrophy (LVH) in accordance with ACC recommendation[47]

2015 – Detection of Brugada Type 1 pattern in accordance with ESC guideline[48]

2017 – Combined LVH criteria improves prediction of stroke, myocardial infarction, etc.[49]

2020 – Lead swap detection for torso as well as chest electrodes

Hazard Information

The terms Danger, Warning, and Caution are used throughout this manual to point out hazards, and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance.

Hazard is defined as a source of potential injury to a person.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

NOTE provides application tips or other useful information to assure that you get the most from your equipment.

Additional safety messages that provide appropriate safe operation information may be found throughout this manual.

WARNING:
INTERPRETATION HAZARD
12SL analyses should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and or invasive tests.
12SL analyses must be reviewed by a qualified physician.

Prescription Device

CAUTION:
United States federal law restricts this device to sale by, or on the order of, a physician.

An Overview of 12SL in Two Parts

To show an overview of the Marquette 12SL ECG Analysis Program, we can follow the same steps the software uses to analyze an ECG. Start with acquisition, followed by detection, measurement, and so on. Often, a physician wants to know the clinical evidence regarding the performance of the program, not the steps it took to analyze the ECG. Consequently, this manual is divided into two parts:

- Part I: Criteria and Methodology
- Part II: Statement of Validation and Accuracy

A side-effect of approaching this from both perspectives is that portions of the document will appear redundant. Whenever Part-II happens to cover the same topic as Part-I, the emphasis will not be on the “how”, but rather, “how well” the program performed the task. Given there are over a hundred peer-reviewed scientific articles about 12SL, there are well over a hundred pages of performance metrics that must be presented in a series of tables using a format defined by the IEC. The approach of dividing the *12SL Physician Guide* into two parts allows the guide to be used as a reference manual. Instead of having to read the *12SL Physician Guide* from cover-to-cover, find the information you need using the table of contents and the hyperlinks provided throughout the document.

Part I: Criteria and Methodology

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Digitization of the Analog ECG

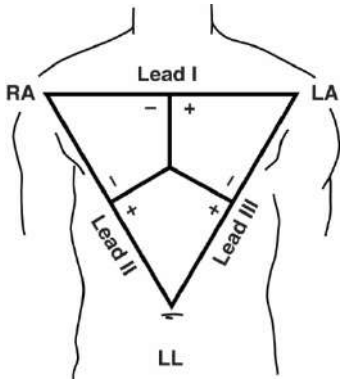
Simultaneous 12-Lead Acquisition

In 1979, GE Healthcare introduced simultaneous recording of 12 leads so that the computer could use all signals from all 12 leads to properly detect and classify each QRS complex.[11, 12] The Common Standards for Electrocardiography independently verified the advantage of this technique:

> *"Conclusion: The simultaneous recording and analysis of all 12 standard leads...is certainly an improvement over the conventional recording of three leads at a time. Similarly...multi-lead programs proved to be more stable than those obtained by conventional programs analyzing three leads at a time..."*[50]

Although the 12SL program can be used in a variety of ECG devices, the 12SL program only analyzes data simultaneous recorded for 10 seconds from at least 12 leads. Eight of the leads are acquired directly (I, II, and V1 through V6). The remaining four are derived via Einthoven's law (III) and Goldberger's equations (aVR, aVL, and aVF):

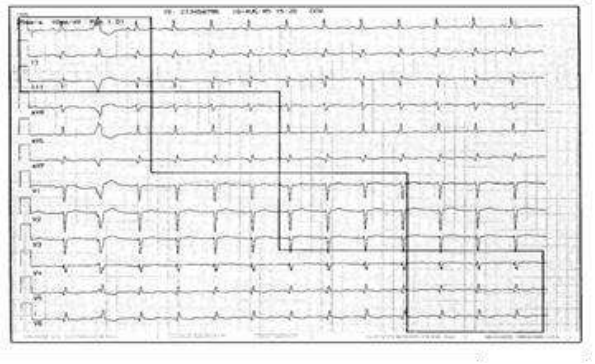
- III = II - I
- aVR = -(I + II)/2
- aVL = I - II/2
- aVF = II - I/2



Because of the inherent relationship of the standard limb leads to each other, Einthoven stated that at any given instant during the cardiac cycle, the sum of the potentials of leads I and III equals the potential of lead II. Similarly, Goldberger said that the sum of the three augmented leads at any instant in time equals zero (aVR + aVL + aVF = 0).

Most formats show only a portion of the 12-lead, 10-second data. An example of this is the standard 12-lead presentation which displays only 2.5 seconds from each of the 4 lead groups. Regardless of the data that you see, the complete data is always acquired. This is used by the 12SL analysis program for precise waveform measurement. It also allows you to choose from a multiple set of formats for accurate rhythm and contour diagnosis.

This ability to acquire all leads simultaneously complies with the American Heart Association recommendations.[51]



Sampling Rate

All resting electrocardiographs currently sold by GE Healthcare analyze the waveform at a minimum of 500 samples per second (SPS). In some GE Healthcare resting electrocardiographs, the ECG is sampled at a much higher rate, such as 4,000 SPS. This is referred to as over-sampling and it used by the device to generate an average, cleaner signal at 500 SPS. Specifications for electrocardiographs, across the industry, often cite the raw sample rate (e.g. 4K SPS or higher) without clarifying that the ECG analysis and measurement software executes on data with a lower sample rate. Current guidelines for resting ECG analysis cite 500 SPS,[52] which is the minimum sample rate executed by 12SL. In some GE Healthcare electrocardiographs, the 12SL program can be configured to analyze the ECG at 1,000 SPS.

Before the physiological data is sampled, analog filtering is applied. These filters attenuate high-frequency electrical noise that is not part of the physiological signal. If these analog filters were not present in the device, high-frequency signals could be digitized by the device and appear as low frequency noise, inter-mixed with the physiological cardiac signal. To eliminate this possible source of contamination, GE Healthcare applies an analog filter, known as an anti-aliasing filter.

To detect high-frequency artifacts generated by electronic cardiac implants, GE Healthcare developed a patented[53, 54] high-bandwidth acquisition system that runs in parallel with the acquisition system for the physiological signal.[55-57] In some systems available from GE Healthcare there are two parallel digital data streams for analysis: one at 2K SPS (for the physiological signal from 0.04 to 250Hz), the other at 75K SPS (for pacemaker detection from 22 to 11KHz). The pacemaker channel is analyzed at 75K SPS.

Hookup Advisor™ and Electrode Placement

Operator manuals exist for all GE Healthcare devices that acquire ECGs. These manuals specify proper electrode positions and patient preparation for obtaining a quality ECG. The following serves as a reminder to physicians and administrators of the importance of quality control. This is especially because ECG services are often dispersed throughout the hospital, diminishing the role of the "Heart Station" in setting acceptable standards.

GE Healthcare's Hookup Advisor™ scores the 12-lead ECG for signal quality and encapsulates this information with the ECG before it is sent to the MUSE system. From there, analytical tools available on the MUSE system can be used to determine the origin of poor-quality ECGs so that corrective action can be taken.

Hookup Advisor provides real-time feedback to the person acquiring the ECG. Hookup Advisor statements display on the screen during ECG acquisition on cardiographs that have the Hookup Advisor enabled. These statements never appear in an original interpretation.

In the cardiograph, Hookup Advisor provides an on-screen green / yellow / red assessment of the quality of the ECG. When the lead quality is anything other than green, a message describing the noise and affected leads is displays. Depending on the specific cardiograph model, the green / yellow / red quality level of the individual electrodes may be displayed on-screen (for example, on a torso figure) and/or on the acquisition module.

The lead quality is defined as follows:

- ***Green***: Generally good technical quality ECG free from noise such as muscle artifact, baseline wander, electrode noise, and powerline interference.
- ***Yellow***: Moderate degree of noise in one or more ECG leads from sources such as muscle artifact, baseline wander, electrode noise, or powerline interference. Electrode reversals will also result in yellow quality.
- ***Red***: Extreme baseline offsets or wander in one or more ECG leads or any disconnected electrodes (lead fail). This is generally unacceptable quality. A red quality ECG will trigger the 12SL "*Poor data quality*" interpretation statement.

Methodology Based on Pattern Recognition, Not Skin Impedance

As opposed to measuring skin impedance, which has been found to be poorly correlated with signal quality,[58] Hookup Advisor uses pattern recognition on ECGs manually scored by cardiologists for acceptable quality. After such training, automated quality scores generated by Hookup Advisor have been found to be predictive of the accuracy of automated interval measurements as well as rhythm interpretations.[33, 59] See graphs of reported performance metrics for Hookup Advisor in Part II.

Proper Electrode Placement for Diagnostic Resting ECG

In addition to artifacts, incorrect placement of electrodes can have a negative impact on the diagnostic value of the ECG. Although a limb-lead reversal has the most pronounced effect, a study of 150 subjects found that moving limb electrodes onto the torso shifted the P/QRS/T axis rightward and eliminated approximately 50% of significant Q-waves in cases of an old inferior infarction.[60]

Although less obvious than a limb lead reversal, swapping chest electrodes is a common cause of poor R-wave progression and false positive interpretations of anterior-septal infarction.[61] In a study of 60 patients with known cardiac disease, ECG morphology changes became evident when chest electrodes were moved beyond 2 cm from their proper location, with V2 being the most sensitive to displacement errors.[62]

Electrode Placement: Continuous Monitoring versus Diagnostic 12-lead ECG

In some monitoring environments, all 6 chest leads are applied with the result being that continuous 12-lead ECGs can be acquired by the monitor. Under this circumstance, the limb leads are usually put on the torso using the Mason-Likar or Lund positions.[63] This results in QRS axis changes and, in some case, the elimination of significant Q-waves in inferior leads. This practice is done to reduce noise and the tangling of lead wires on the monitored patient, and has been shown to be beneficial for capturing transient ST/T wave changes due to acute ischemia,[64, 65] T-wave alternans,[66] complex drug-induced T-wave changes[67, 68], or transient arrhythmias that need to be effectively localized for ablation.[69]

To reduce the confusion resulting from leaving the limb-leads on the torso, some institutions use the following techniques:

- Identify 12-leads coming from bedside monitors using a torso configuration for the limb-leads.
- Do not continuously send 12-leads to the MUSE system, and instead, sequester the 12-leads in the monitoring environment that come from continuous acquisition.
- Send only 12-leads from the monitor that reflect an important change, or only send those when the frontal plane configuration of the electrodes has been returned to the limbs.

Consistency of Serial ECGs

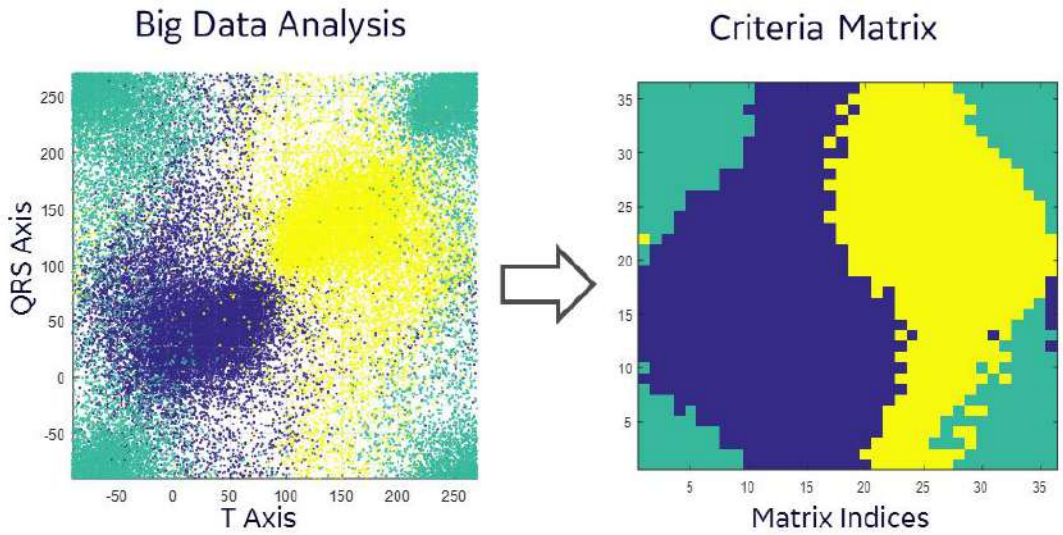
Even when the skin is marked as to where to place chest electrodes for repeat ECGs for serial analysis, normal day-to-day variation is considerable, especially with respect to QRS voltage measurement in the precordial leads.[70-72] An undisciplined approach to recording ECGs increases the variability of ECG measurements and interpretive findings by both the computer and physician.[73, 74] This is unfortunate, given the growing evidence that serial ECG measurements can be predictive of heart failure or other serious clinical conditions.[75-78]

In conclusion, studies have shown a significant incidence of limb lead reversal and wide variability in chest electrode placement, even among experienced ECG technicians.[79, 80] Training in proper lead positioning has demonstrated a reduction in these errors.[81] Periodic retraining should be routine for all personnel who are responsible for the recording of ECGs as recommended in clinical guidelines.[82]

LEAD SWAP DETECTION IN HOOKUP ADVISOR AND 12SL PROGRAM

Reversal of limb or chest electrodes can have negative consequences on accurate interpretation of acquired ECGs. In some cases, the reversed electrodes generate ECG patterns that are easily noticeable by a trained physician and do not severely affect interpretation. In other cases, electrode reversal can mimic alarming situations such as infarction, or even cause loss of information necessary for accurate interpretation.

Both the 12SL program and Hookup Advisor help manage electrode reversal detection. A total of 19 pairs of electrode reversals are identified and specified when detected. In the event of multiple-pair reversals or 3-way interchanges, Hookup Advisor will provide notification of possible reversal but will not specify electrodes involved due to non-uniqueness of complicated lead misplacements. Refer to the Electrode Reversal in the 12SL criteria section for more details.



Summarizing big data analysis into computational criteria matrix. A large data analysis of axis based on hundreds of thousands of ECGs are simplified into a matrix of criteria. The blue data points and grids represent a correctly positioned ECG, while yellow and green represents lead reversed axis, respectively. In the blue samples, the axis is not always within "normal" range. By using this technique, we can summarize criteria based for various abnormal conditions in a computationally efficient manner.

Detection of an electrode reversal in a single ECG without comparison against a prior ECG can be challenging. Many factors must be taken into consideration such as axis, P-QRS-T consistency, progression of QRS and T waves, and certain possible abnormal patterns resembling reversed electrodes as confounders (such as posterior infarction). Unlike detection of a well-known pattern of clinical interest, the total number of patterns of lead reversal is multiplied by the possible alteration in contour or arrhythmic features and becomes relatively difficult to depict in conventional ECG criteria.

To meet this challenge, the sheer weight of Big Data is leveraged to our advantage. Most key criteria in the lead reversal detection are summarized using a large number of clinically diverse ECGs to cover the ground beyond normal ECGs. These data-driven analysis results are concretized and simplified into computationally efficient matrices of criteria and stored in the algorithm to ensure that the clinical performance of the big data analysis do not overburden the system.

Pacemaker Detection and Annotation

Over the last decade, there has been a significant increase in permanent pacemaker implantation as well as advancements in pacemaker technology.

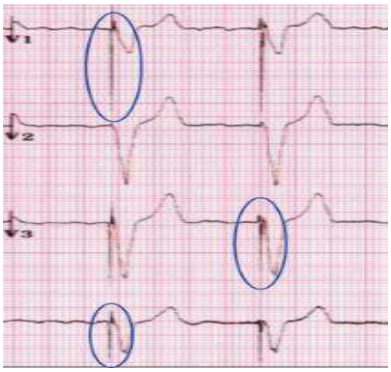
A worldwide survey found that virtually all countries showed increases in the number of pacemaker implants.[83] More specifically, the United States "had the largest number of cardiac pacemaker implants (225,567) and Germany the highest new implants per million population (927)."[83]

With regards to technological advancements of artificial pacing, consider the following:

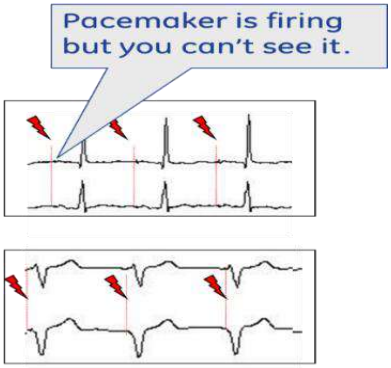
- Artificial stimulation used to be confined to a single location: the apex of the right ventricle. Fast forward to the advent of cardiac resynchronization therapy (CRT) and artificial stimulations occurring in the right atrium as well as the right and left ventricle. Now optimum resynchronization therapy is being explored via multipoint pacing of the left ventricle.[84]
- Lead wires used to only support unipolar pacing. Now even bipolar pacing is being replaced by leadless pacing.[85]
- Pacemaker pulses observed at the body surface were so large, standards had to be developed to make monitoring manufacturers avoid falsely detecting them as QRS complexes.[86] Now, they "are often too small to be recognized on the standard ECG."[51]
- The minimum timing intervals between artificial stimuli was relatively fixed and certainly greater than 100ms. Now these are configurable and the interval so small, multiple pulses can appear as single artifact on the surface ECG.[87]

Examples of Artificial Pacing, Then and Now

Older Pacing Technology



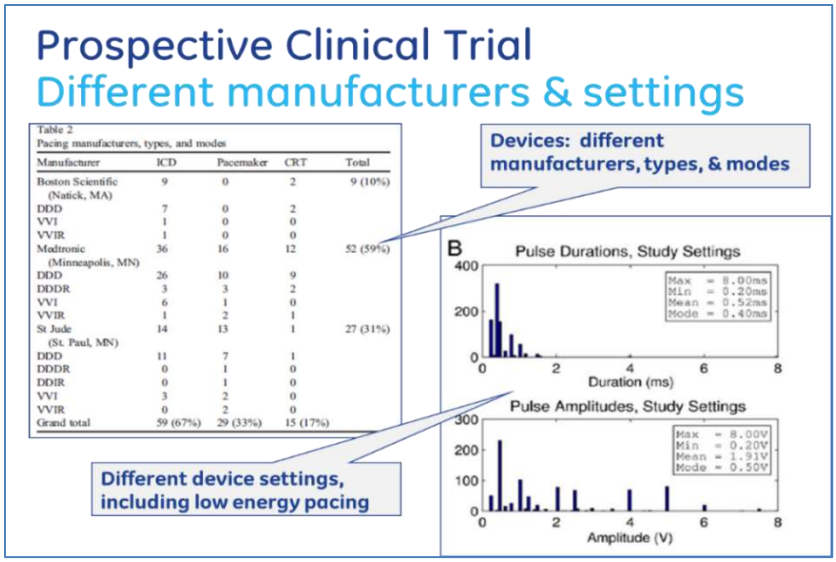
Contemporary Artificial Pacing



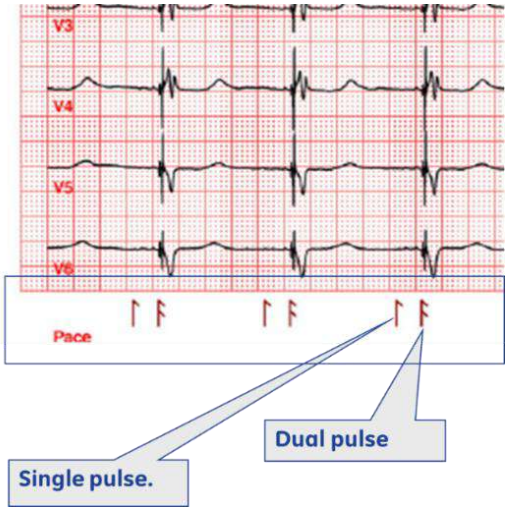
All of this makes the interpretation of the paced ECG difficult and given it has been reported that roughly 10% of in-hospital ECGs are paced,[88] it has become a significant challenge for both the computer[89] and human reader.[85, 90] To combat this, GE Healthcare (Milwaukee, WI) developed a new high-bandwidth acquisition system to detect artificial stimuli that runs in parallel with the acquisition system for the physiological signal. There are two parallel digital data streams for analysis: one at 2K SPS (the physiological signal from 0.04 to 250Hz), the other at 75K SPS (the pacemaker detector channel from 22 to 11KHz).

The pacemaker channel is analyzed at 75K SPS. By sampling the high-frequency spectrum, the challenge is to discriminate the electrical stimuli generated by the artificial pacemaker versus other high-frequency noise unrelated to pacing the heart, such as a left ventricular assist device (LVAD), pacemaker programmer or electro-static discharge.

In 2010, this system was prospectively evaluated on patients with implanted pacemakers (different vendors at different settings) and challenged with differing levels of noise.



The sensitivity for the detection of artificial pacing exceeded 99% while the positive predictive value remained at 100% regardless of the level of noise.[36] This system can detect pulses as small as .5mV and 0.2ms, which is several times more sensitive than the AAMI standard of 2mV and 0.5ms, and provides pacemaker annotations, including indications of biventricular pacing. In accordance with AHA/ACC/HRS recommendations, these annotations are supplied separately from the waveform in a "single row of the standard output tracing."[51]



Signal Conditioning and Removal of Noise

In the presence of noise, both physicians and computers make frequent mistakes.[91] If there is a way to remove noise from the signal without reducing the clinical value of the ECG, it should be pursued. This is known as signal conditioning, done by removing signals that exhibit characteristics which could not possibly be generated by the heart.

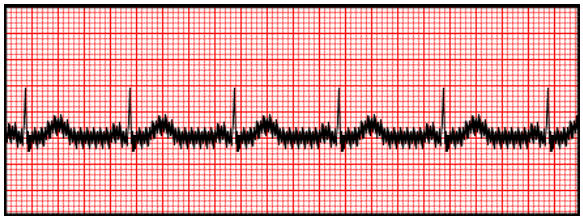
Fortunately, the characteristics of the P-QRS-T have been well studied and there is plenty of documentation as to the limitation of which frequencies can be generated by the heart.[1, 52, 86, 92, 93] Frequencies below 0.67Hz cannot be generated by the heart. If the recorded signal exhibits a waveform below 0.67Hz, it is not of cardiac origin.[94] Frequencies above 20Hz only occur during a QRS complex and only for a brief period of time (<20ms), such as during the onset, peak or notch of a QRS.[95] The duration of a QRS complex resulting from an intact conduction system can be no more than 140ms long.[96] As a result, a complex that is longer than 200ms which contains frequent, high-frequency components (>20Hz) cannot come from the heart; it is more likely due to electrode motion artifact.

The signal conditioning and removal of noise performed in conjunction with 12SL, includes the following topics:

- Removal of AC interference
- Removal of baseline wander
- Removal of high frequency artifact
- Upper cut-off frequency

Removal of AC Interference

A good example of a signal that has a characteristic which could not be generated by the heart is the signal that results from the radiated or conducted energy of wires or devices powered by alternating current (AC). As opposed to the QRS complex, AC interference is continuous and sinusoidal.



GE Healthcare electrocardiographs have a configurable setting for the removal of AC interference. The setting, either 50 or 60 cycles per second (Hz), should match the line/mains frequency of the power grid where the electrocardiograph is operating. This allows the system to select a filter that specifically targets that frequency.

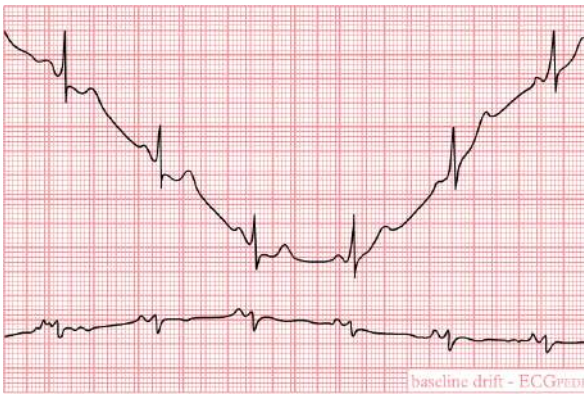
A filter that attempts to eliminate a single frequency from the spectrum of frequencies is often referred to as a “notch filter”. The “notch filter” used in GE Healthcare’s electrocardiographs does more than simply attenuate either 50 or 60 Hz. It locks onto the artifact and measures its amplitude as well as shape. Instead of eliminating either 50 or 60 Hz, the system forms a model of the noise and then subtracts it from the raw waveform.[97]

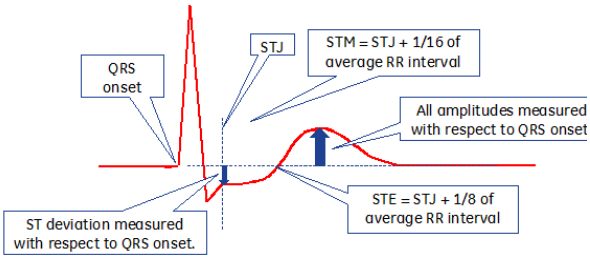
There are a couple of advantages to an adaptive AC interference notch filter. First, the filter attenuates the signal at just the right amount, no more, no less. Second, because the filter is synched up with the AC interference, it does not attenuate the naturally occurring transient 50/60 Hz frequencies that reside within the QRS complex. This is because the model of the artifact adapts only to a continuous 50/60Hz signal, not a transient signal.

REMOVAL OF BASELINE WANDER

Baseline wander can be due to respiration, perspiration, body movements, loose electrodes, dry electrodes or the lack of using Ag/AgCl electrodes versus other electrode designs.[98] Measuring the ECG can be challenging in the presence of such artifact. In fact, if the baseline is wandering so much the signal does not remain on the page or saturates an amplifier, measurement of the ECG is not possible.

Even in mild cases of baseline wander, the assessment of the ST-segment deviation from the raw ECG will be compromised since its amplitude should be measured in relation to QRS onset. A representative complex generated from this data is not immune to the problem. It will incorporate the amplitude variation occurring across each QRS complex. This will be particularly noticeable in the ST- segment of the representative complex. The slope of the ST segment will be a composite of the wandering baseline immediately following each QRS.





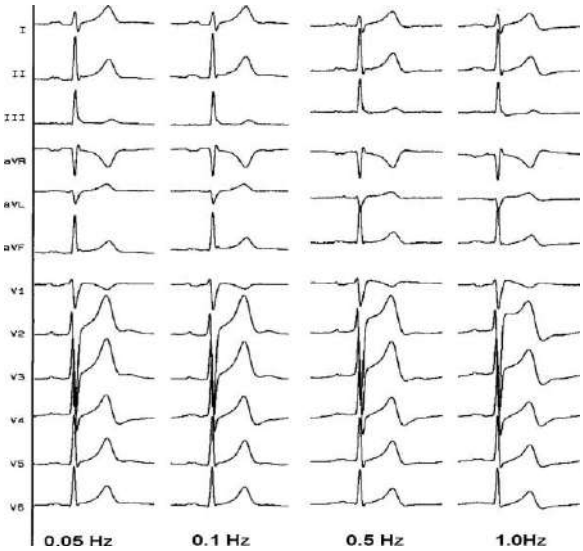
Baseline wander is a low frequency signal. Filters that remove low frequencies are referred to as high-pass filters since they pass along higher frequencies yet leave behind lower frequencies.

To deploy a high-pass filter, it is important to know the lowest possible frequency generated by the heart so that it will remain untouched by the filter. This can be determined via the heart rate. If the heart rate is 60 beats per minute (bpm), the lowest possible frequency is 1 cycle per second or 1Hz. “Heart rates below 40 bpm (0.67 Hz) are uncommon in practice.”[51] The 2007 ACC/AHA recommendations for standardization of the ECG stipulate that frequencies below 0.67Hz can safely be removed from the ECG.[51]

Not all high pass filters are alike. Some not only attenuate low frequencies but shift them in time versus the high frequency components of the signal. This is known as phase distortion.

The below example is of the use of a high pass filter that exhibits phase distortion.[99] As the filter setting progressively goes beyond 0.05Hz, the ST segment becomes so distorted it appears to be an ST-elevated acute myocardial infarction (STEMI). While using a high pass filter with phase distortion, the only way to preserve the ST segment is to use a less aggressive filter setting (≤.05Hz.). This comes at the expense of not correcting the baseline.

Example of ST-Segment Distortion Due to High-Pass Filter from the Literature.[99]



With the advent of digital sampling and storage of the ECG, high-pass filters can be designed so that they have zero phase distortion (ZPD). The use of a ZPD high-pass filter at a setting of 0.67 Hz can "correct baseline drift while preserving the fidelity of the ST-segment."[51]

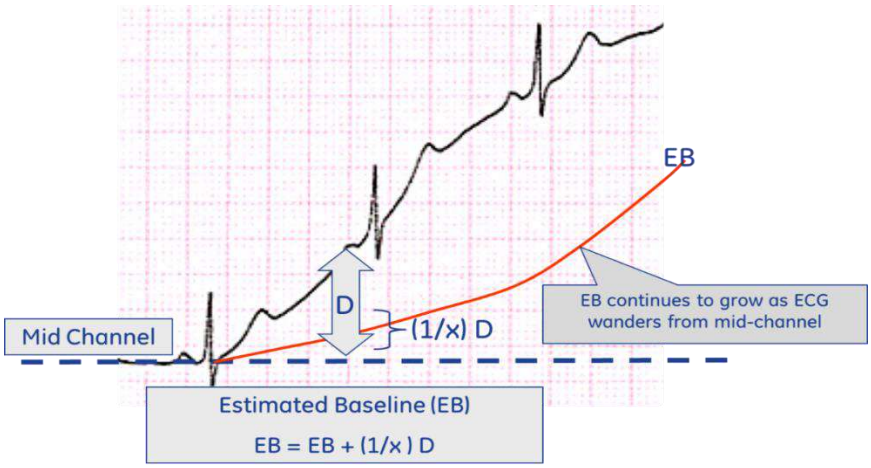
Since the introduction of the 12SL program, a ZPD high pass-filter (≤0.32 Hz) has been used to remove baseline sway. Baseline wander is aggressively removed from the 12-lead report without ST-segment distortion. The representative complex generated by 12SL reveals a ST-segment not contaminated by baseline wander. Until recently, real-time rhythm strips were another matter.

Not until the advent of the MAC VU360 or MAC 2000 has it been possible to use a ZPD high pass filter when acquiring and printing continuous rhythm strips. Via these newer products, the ST segment on a continuous rhythm strip will be the same as the ST-segment on the 12-lead report, even at the most aggressive filter setting, which on the MAC VU360 is 0.56 Hz. This means anyone printing a rhythm strip does not have to be trained to properly contend with the tradeoff of selecting the appropriate filter setting to either preserve the ST-segment with a lower setting (≤0.05 Hz), or remove the baseline sway via a higher setting (>0.05 Hz). With these newer products, the high-pass filter setting can be set once and behave the same way for both the rhythm and 12-lead report without ST-segment distortion.

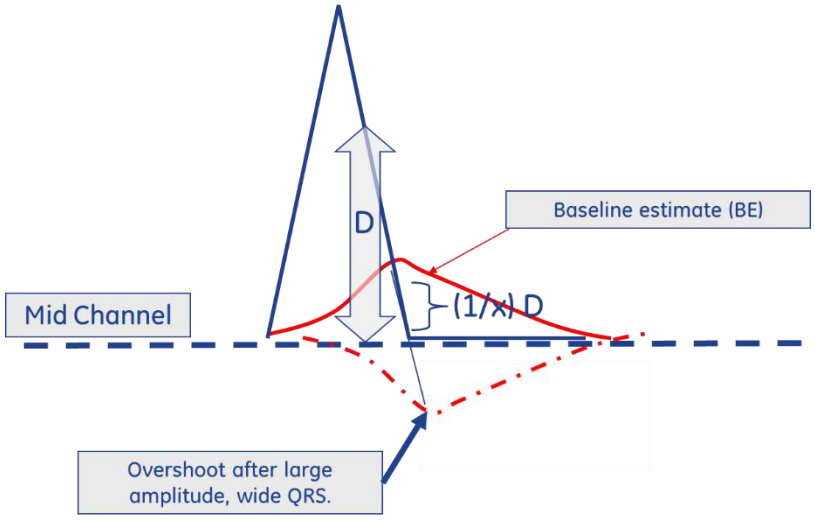
ZPD is an important advancement now available when printing a rhythm strip. Consider that a study conducted in an emergency department found, that as opposed to the 12-lead ECG reports, 93% of rhythm tracings had clinically significant alterations that could be construed as an acute coronary syndrome (ACS) due to the use of a baseline roll filter without ZPD at a setting of 0.5 Hz.[100] ZPD on both the rhythm and 12-lead report eliminates this confusion.

The following four diagrams are useful for describing what changed in GE Healthcare's high-pass filter design. The first diagram portrays a high-pass filter that continuously corrects the baseline in real-time as the signal is acquired. The second diagram shows the ST-segment distortion that results when such a filter encounters a QRS complex that is either tall or long. The third diagram shows how 12SL can do the same operation without ST-segment distortion, because the system can correct the entire recording in both directions. The final diagram shows a high pass filter that utilizes digital rhythm. It digitizes the rhythm for a couple of seconds before correcting the waveform. In the latter case, the system can use the samples before and after the point where it corrects the baseline.

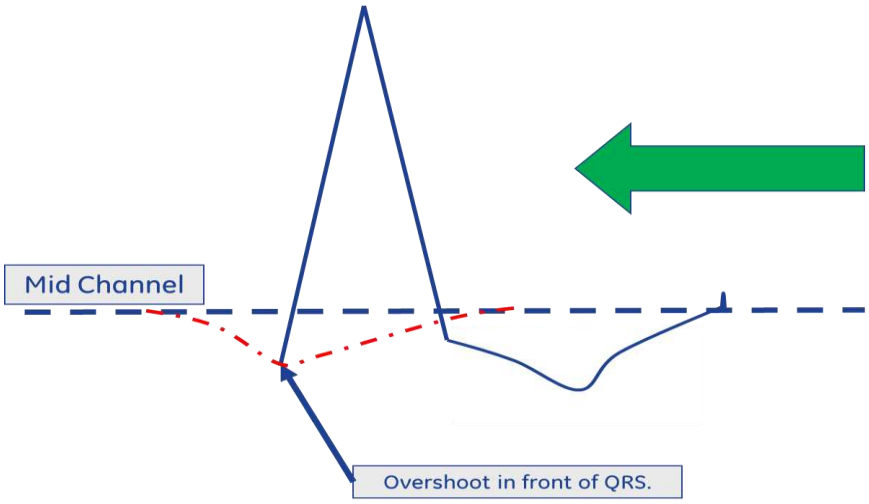
More precisely, the first diagram shows the computer estimating the baseline sway and then subtracting it from the incoming signal. In real-time, the amplitude of each sample is measured relative to the middle of the channel. The estimate of the baseline sway is determined by having a running tally of a fraction of these amplitudes. That fraction becomes larger as the high-pass filter setting increases.



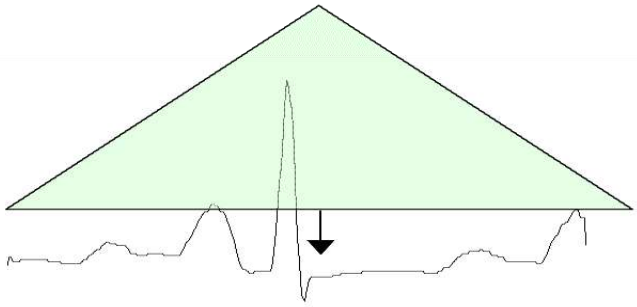
Unfortunately, this filter cannot discriminate between a large or wide QRS complex versus baseline sway. See figure below. The filter can be unduly influenced by the QRS, resulting in an overshoot immediately after the QRS. This effect is apparent in the ECG presented above. Those leads with the largest QRS complex (such as V2) have the greatest distortion, while those leads exhibiting a smaller QRS complex (such as aVL) have almost no ST-segment distortion. When using a filter of this type, the distortion from the ST segment can only be eliminated using a filter setting of 0.05Hz, but the baseline wander will not be removed.



The 12SL program has always been able to remove low frequencies (for example, < 0.32 Hz) without ST-segment distortion. It does this by running this same filter, forwards and backwards, over the entire 10 seconds. In this way, both sides of the QRS are similarly impacted and the ST is no longer depressed in relation to QRS onset.



The MAC VU360, MAC 2000 and subsequent electrocardiographs have obsoleted this approach. Instead, the correction of each sample point is based on a weighted average of the samples before and after it.



To accomplish this on a scrolling rhythm strip, the signal must be digitized and buffered for a couple seconds before it is displayed. This 2 second delay enables the filter to aggressively correct the baseline without ST-segment distortion.

To keep abreast of the ACC/AHA recommendations, which relaxed the high-pass filter setting from 0.05 Hz to 0.67 Hz for filters capable of ZPD, IEC/AAMI issued new performance standards for the low frequency response of diagnostic electrocardiographs.[92] This includes a simple test which can be performed by a biomedical engineer to evaluate the low-frequency response of any electrocardiograph and determine whether it uses a high-pass filter with ZPD. A 3 mV, 100 ms square wave fed into an electrocardiograph should not result in an artifact that exceeds 100 µV; otherwise the user must select a lower filter setting (0.05 Hz) to preserve the ST segment.

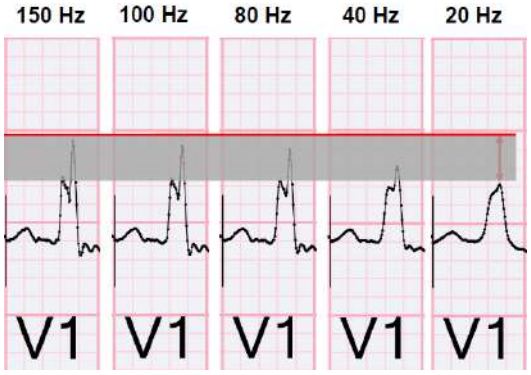
Removal of High-frequency Artifact

Electrocardiographs have various low-pass filter settings, including 40 Hz, 100 Hz, or 150 Hz. The lower the filter setting, the more aggressively the filter removes high frequency signals, which includes noise due to muscle tremor, electrode-motion artifact, etc. These low-pass filters also operate on the entire ECG signal and attenuate all high-frequency elements of the ECG signal, such as the QRS complex and pacemaker artifacts. To consistently measure the resting ECG and capture the proper QRS amplitude, the 12SL program always analyzes the ECG at the AHA / AAMI recommended full bandwidth of 150Hz,[52, 93] regardless of the low-pass filter setting. These settings are sometimes referred to as “writer settings” since they do not affect the ECG interpretation.

It should be noted that all filter settings travel with the ECG. That is, the MUSE system can be configured to either portray the ECG signal as it was acquired at the electrocardiograph or at another specified filter setting. Over-reliance on aggressive, low-pass filtering implies that the 12SL program is subjected to more high-frequency noise than the physician sees in a filtered ECG tracing.

Using an aggressive low-pass filter has significant consequences especially when comparing ECGs. The following is an example of an ECG waveform that is low pass filtered at different settings, all the way down to 20Hz.

Lead V1 in Presence of RBBB at Different Low-Pass Filter Settings



Notice that the most peaked aspects of the QRS complex are more attenuated by filtering. This is because the peaked components of the waveform contain the highest frequencies. Regardless of the filter setting, the shape and duration of the QRS complex indicates right bundle branch block (RBBB). Comparing any of these complexes could lead to the erroneous conclusion that a clinically significant change has taken place when, in fact, the "change" is due to filtering.

Upper Cut-off Frequency

The ACC/AHA/HRS recommendations for standardization of the ECG states that "to measure routine durations and amplitudes accurately in adults, adolescents, and children, an upper frequency cutoff of at least 150 Hz is required."[51] The ACC/AHA/HRS recommendation discusses a 250 Hz cutoff for infants in relation to research performed in 2001 which reported higher QRS amplitudes at a bandwidth of 330 Hz in children.[101] Yet, in 2008, this same researcher found no clinical benefit in measuring the QRS amplitude at a cutoff frequency of 250 versus 150 Hz.[102]

Extending the cutoff frequency from the required 150 Hz to 250 Hz, will generate more noise and increase the amplitude of the QRS.* It does not impact the amplitudes of the P or T-wave. The only value of measuring QRS amplitude is for the diagnosis of ventricular hypertrophy. When evaluating these higher QRS amplitudes versus ultrasound, Rijnbeek discovered for the detection of hypertrophy the "sensitivity decreased slightly (from 20% to 17%) while the specificity improved (from 88%–92% to 94%–100%)."[102] Even when applying customized criteria for hypertrophy, extending the cutoff frequency from the required 150 Hz to 250 Hz generated no clinical benefit.

It is important to consider that along with a higher cutoff frequency comes noise.[51] Despite the significant reduction in QRS amplitude, many users opt for applying a cut-off frequency at 40 Hz to obtain the cleanest signal possible and yet still be able to identify rhythm as well as other contour-based diagnostic findings besides hypertrophy.[103]

In spite of these tradeoffs, there are those who demand evaluating a pediatric ECG at the highest possible bandwidth. GE Healthcare offers the ability to view and print an ECG at a high-frequency limit of 300 Hz on its latest version of its electrocardiographs (such as the MAC VU360).

* A higher cut-off frequency will also increase the amplitude of a pacemaker spike. In accordance with AHA/ACC/HRS recommendations, pacemaker annotations are supplied separately from the waveform in a "single row of the standard output tracing."

Detection and Measurement

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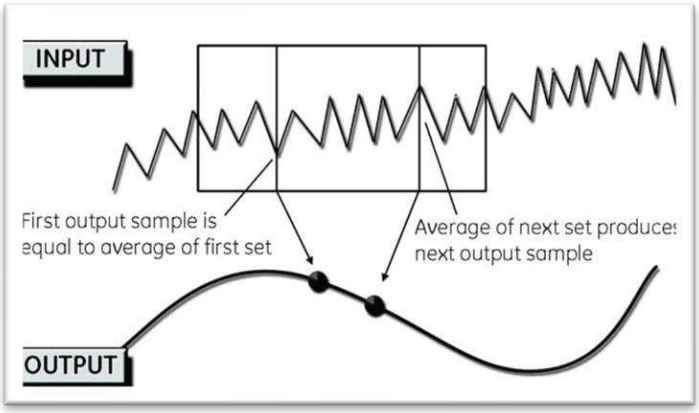
QRS DETECTION

The first step in computerized ECG analysis is the identification of each QRS complex. This step is vital. If it is done incorrectly, all subsequent steps in the analysis will be in error. Since all 12 leads are available to the 12SL program, correct identification is maximized. Even when individual leads have low voltage complexes, the program can use all signals from all leads to properly identify each QRS.

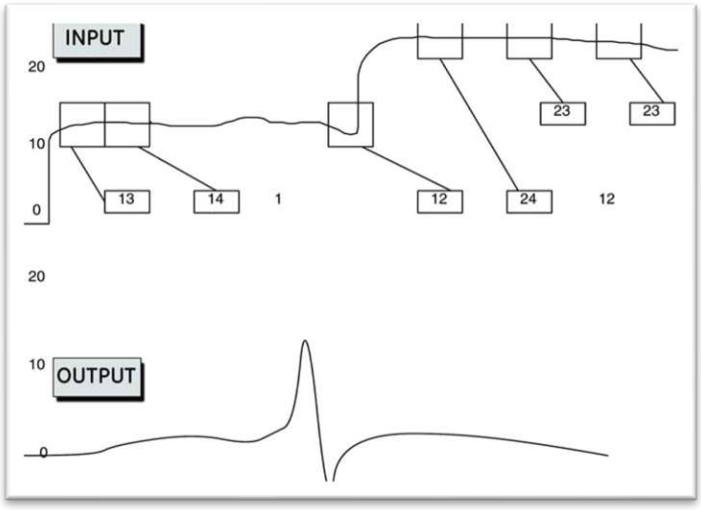
Before the QRS detector can scan the signal data for something that resembles a QRS, it must first remove any pacemaker artifact. This is because pacemaker signals can be large in amplitude and they could fool the detector. The program identifies pacemaker artifact through two independent methods. Separately, the 12SL analysis program identifies pacemaker artifact in the ECG data by finding large amplitude spikes (greater than 1000 µV) or lower amplitude spikes (greater than 250 µV) that pass further scrutiny, so as not to be deceived by muscle artifact. Regardless of how the spikes are detected, the 12SL program remembers their height and position and then removes them. When the program is finished, it replaces these spikes.

After the pacemaker spikes are removed, the QRS detector filters the data. It attenuates both low frequency and high frequency waves, leaving untouched the mid-band frequencies that are usually evident in the QRS. This may sound complicated, but it is ultimately reduced to the adding and subtracting of samples. High frequencies are attenuated by adding samples together while low frequencies are attenuated by subtracting samples. See the following examples.

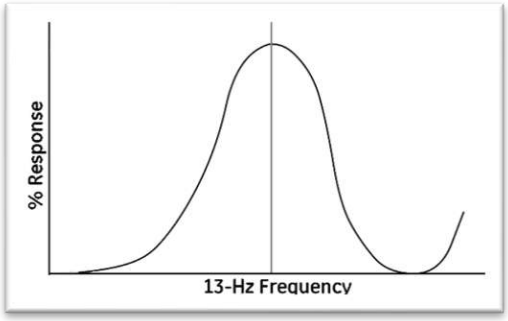
Reduce High Frequencies by Adding



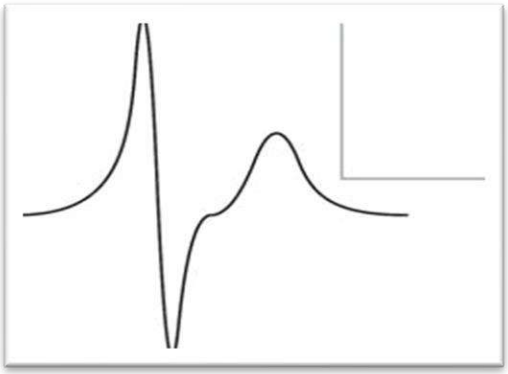
Eliminate Low Frequencies by Subtracting



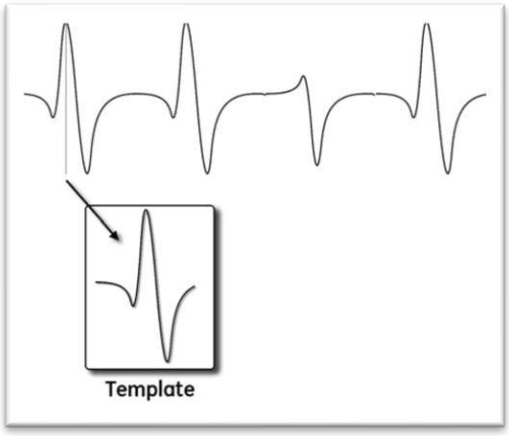
This filter makes the QRS detector more resilient in the presence of noise. It also decreases the probability of a false detection due to T waves. Following is a diagram of the frequency response of the QRS detector.



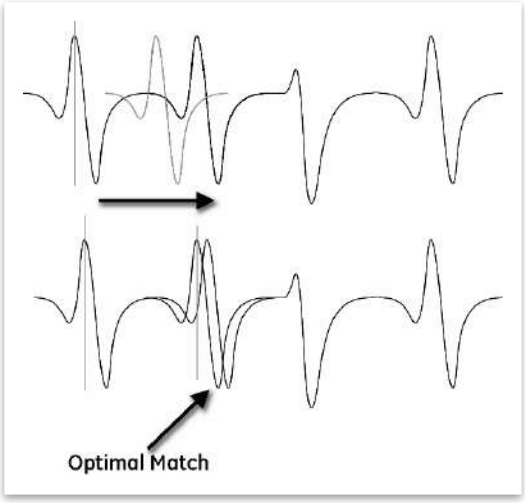
The output of this filter is summed across all 12 leads. Once the summed output crosses a specific threshold, a QRS is detected. To avoid the following T wave, the threshold is increased for a short period of time (200 ms).



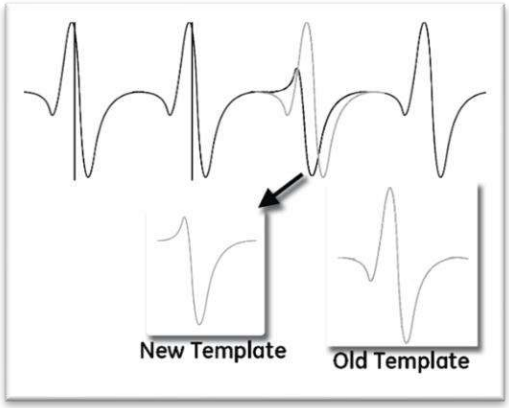
Once a QRS is detected, the 12SL analysis program makes a template of it for each lead.



From this point on, the QRS detector looks for the same shape. If it finds a match, the program classifies it as another QRS detection and slides the waveforms past one another looking for the optimal match. This sample time will be used later when we form a composite cycle.



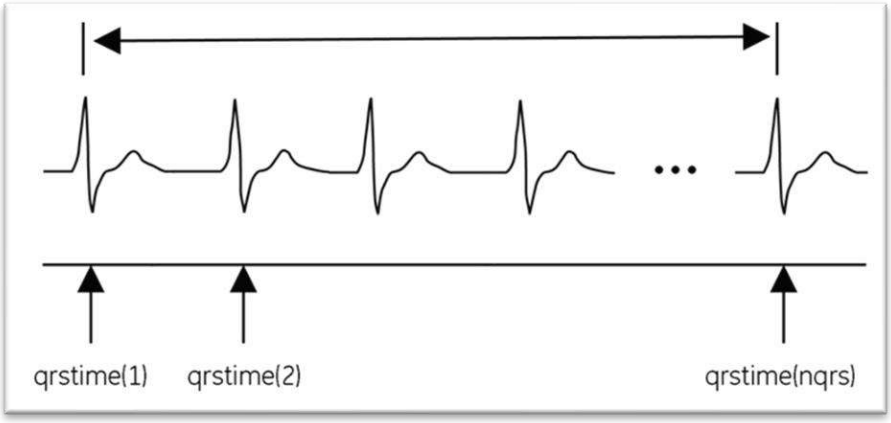
If the filter output exceeds thresholds, but there is no match, it is assumed that a different beat type has been detected and an additional set of lead templates is made for further matching tests.



In summary, the QRS detector uses filter and template matching techniques to both detect and group, by shape, the QRS complexes which occur in the ECG record. The QRS detector also defines the points in the ECG record that can be used to align in time, with maximum correlation, the respective beats of a beat type.

Ventricular Rate Calculation – Average RR

After the QRS complexes have been detected, the ventricular rate is computed by counting the number of beats detected and dividing by the time difference between the first and last beats.



$$rate = \frac{(\text{number of QRSs} - 1)\ beats}{(\text{time difference between first and last QRS})\ msec} * 60000\ msec/min$$

The number of R-R intervals (number of QRS complexes minus one) is divided by the time difference between the first and last beats, and the result is converted to units of beats per minute. Note that the first half of the above equation is equal to the inverse of the average RR interval.

$$rate = \frac{60000\ msec/min}{(\text{average RR})\ msec/beat}$$

NOTE: The interpretations of *Sinus bradycardia*, *Sinus rhythm*, and *Sinus tachycardia* are based on the *atrial* rate, not the ventricular rate. The atrial rate is determined from the P wave detections. The atrial rate will equal the ventricular rate for most ECGs. In cases of 2nd and 3rd degree AV blocks, for example, the atrial rate will legitimately differ from the ventricular rate.

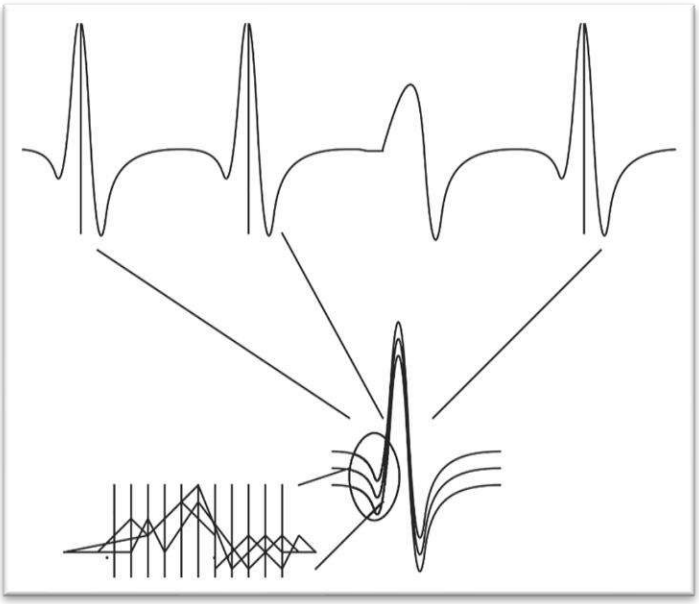
MEDIAN FORMATION

Before any further signal processing takes place, the 12SL program must determine which beat type will be used for the morphology measurements. The 12SL program uses the RR intervals and the location of any pacer spikes to decide which beat type has the highest level of origin in the conduction system. This selection is not dependent upon the number of beats per beat type. The beat type which is most informative for analysis is the one sought after and any beat type with three or more complexes can qualify.

The beat type considered to be most informative of normal conduction is often referred to as the "primary beat type" or "dominant beat." Later in this guide you will see the rhythm criteria refer to "a normally shaped beat." This is a QRS complex with the same shape as the primary beat.

After a primary beat type has been chosen, each of its associated beats is used in generating a *representative (median) complex* for each lead. This is done using the sample times that were generated by the QRS detector. These times not only indicate the occurrence of a QRS, but they also indicate when the QRSs for a specific beat

type are optimally matched. The representative complex is then generated with the median voltages from this aligned group of beats; that is, it is formed by taking, at each sample time, the middle voltage of the superimposed beats.



This process has several advantages. As opposed to other analysis programs, the alignment is done in all channels simultaneously. The problem of reconciling data from different lead groups is eliminated. This technique is excellent for diminishing noise. A median is better than an average. It disregards the contributions that could be made by outliers. The net result is the most artifact-free picture of the electromotive forces generated by the heart cycle.

Consider, for example, the following set of five voltages, which may be the voltages at the same point in the cardiac cycle of five beats of the primary beat type. The median is defined as the value at which half of the samples are above this value and half of the samples are below this value. For this example, the median is 10 (two samples are greater than 10 and two samples are less than 10). The average is 26. The average was greatly biased by the outlier value of 100, whereas the outlier did not unduly bias the median.

Median

0	5	10	15	100	Median is 10

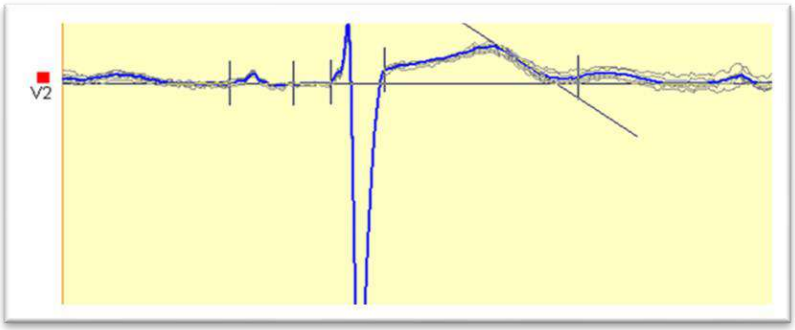
Average

0	5	10	15	100	Average is 26

Starting with 12SL version 22, ECG data acquired at 1,000 samples per second (SPS) can be analyzed at 1,000 SPS. Under this circumstance, 12SL generates an additional copy of the signal data at 500 SPS. QRS detection times are determined with the data at 500 SPS. 12SL then generates two sets of medians. One at 1,000 SPS; the other at 500 SPS. The medians at 1,000 SPS are formed first using the same principles as defined above. The medians at 500 SPS are formed by decimating (that is, averaging) the 1,000 SPS data down to 500 SPS.

GLOBAL ONSETS/OFFSETS AND INTERVALS

At this point, the median for the primary cycle has been established for each of the 12 leads. Since all leads were sampled and time aligned synchronously, the median complexes are also synchronous. Since noise has been eliminated, the accuracy of the identification of wave onset/ offset has been increased and the process simplified.



The onsets and offsets of the P, QRS, and T are found in a specific order. QRS onset is detected first because it is the easiest to find; the slope change is usually very rapid and in great contrast to the other slopes in the median. This is followed by QRS offset and T offset. Next, the representative complex is searched for a P wave. P waves will be found in the representative complex only if P waves are present and are synchronous with the QRS complexes. For example, junctional rhythms may not have a P wave and the P waves of Mobitz I (Wenckebach) second degree AV block will not have a constant PR interval and are asynchronous with QRS complexes. Finally, if a P wave is found, the onset and offset of the P wave are delineated.

When data has been acquired at 1,000 SPS, all onsets/offsets are still calculated at 500 SPS. This is done by using the additional set of medians that were formed at 500 SPS.

The onsets and offsets are determined by an analysis of the simultaneous slopes in all 12 leads. Onsets are defined as the earliest deflection in any lead, and offsets are defined as the latest deflection in any lead. The *QRS duration* is measured from the earliest onset in any lead to the latest deflection in any lead. Similarly, the QT interval is measured from the earliest detection of depolarization in any lead to the latest detection of repolarization in any lead. The PR interval is measured from the earliest detection of atrial depolarization in any lead to the earliest detection of ventricular depolarization in any lead (the QRS onset). A PR interval is reported only if synchronous P waves are detected (for example, P waves are detected and have a constant PR interval for each beat).

QT Correction Formulas

The QT interval is corrected for heart rate (QTc). The correction of QT based on heart rate is a large area of study. Not everyone agrees that Bazett should be used exclusively for calculating the corrected QT. At higher heart rates (HR > 100), Bazett has been criticized for being too sensitive. For these reasons, the 12SL program now supports the Bazett, Fridericia, and Framingham correction formulas.

$$\text{QTc (Bazett)} = \frac{QT}{\sqrt{RR}}$$

$$\text{QTc (Fridericia)} = \frac{QT}{\sqrt[3]{RR}}$$

$$\text{QTc (Framingham)} = \text{QT} + 0.154\ (1 - \text{RR})$$

In all three formulas, RR is the average RR interval across the 10 second ECG, in seconds. QTc will be in the same units as QT; for example, if QT is in milliseconds, QTc will also be in milliseconds. Likewise, if QT is in seconds, QTc will also be in seconds.

Regardless of the correction formula used, the purpose of correcting the QT interval for heart rate is to normalize the QT interval to what it would be if the patient's heart rate was 60 bpm. The QTc will always equal the QT interval for a heart rate of 60 bpm (RR = 1 second).

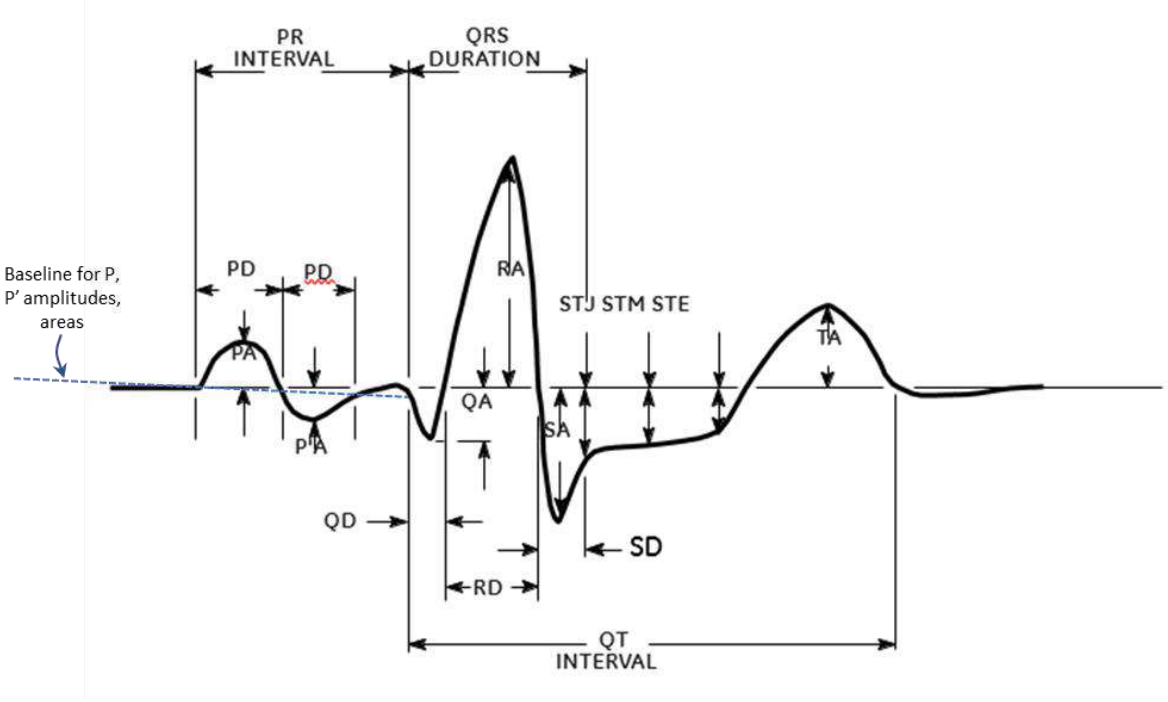
NOTE:

- Not all products will display Fridericia or Framingham QTc.
- Unless otherwise denoted on the ECG report, the reported QTc is the Bazett-corrected value.

WAVEMEASUREMENT – BASIS FOR MEASUREMENT MATRIX

After the P, QRS, and T complexes have been demarcated in the median complex, the waves for each complex are identified. This is done separately for each lead. The program finds the points at which the signal crosses the baseline within each complex. If the crossing points define a wave that has an area greater than or equal 160µV-ms, the wave is considered significant. If the area is less than this value, the program considers the wave to be insignificant, and it will not label it as a separate wave.

The measurement matrix contains the amplitudes, areas, and durations of all individual waves for each lead (i.e., P, P', Q, R, S, R', S', T, T').



The median complex is shifted so that the voltage at the QRS onset is 0 by definition. Amplitudes of waves within the QRS and within the T wave, as well as the ST levels are measured with respect to the voltage at the QRS onset. Amplitudes of significant waves within the P wave (P, P') are measured with respect to a baseline level that is a line interpolated from P onset to P offset. All wave amplitudes and ST levels are voltages in µV.

The P, P', T, and T' amplitudes and the STJ, STM, and STE voltages may be positive or negative values, depending on whether the values are greater than or less than 0. Because the Q, S, and S' waves are always defined as negative deflections, their amplitudes are represented as positive values with the implicit understanding that they are negative deflections.

Areas of the waves are the integral with respect to the interpolated P baseline for P and P', or with respect to the 0 µV baseline for all other waves. The measurements are provided as the sum of samples in waveform data units (4.88 µV per data unit), normalized to 250 samples per second. To put this in perspective, consider the area of one small grid box at standard gain and scale (10 mm/mV, 25 mm/s). In this case, the small grid box equals 100 µV * 40 ms, or 4000 µV*ms (4 µV*s). In data units and sample counts the small grid box equals 20.5 data units * 10 samples, or a value of 205. Thus, to convert an area from data units*samples to µV*s, the following conversion formula is used:

$$area\ value\ [\mu V * s] = \frac{4}{205} * area\ value\ [data\ units * samples]$$

Refer to Definition and Measurement of Waves in Part II for additional details on wave definitions and measurements.

In addition to the individual wave durations and amplitudes defined above, the following measurements are also defined for each lead:

STJ — The ST level (with respect to QRS onset) at the QRS offset (commonly referred to as the "J point")

STM — ST level at the QRS offset plus 1/16 of the average RR interval

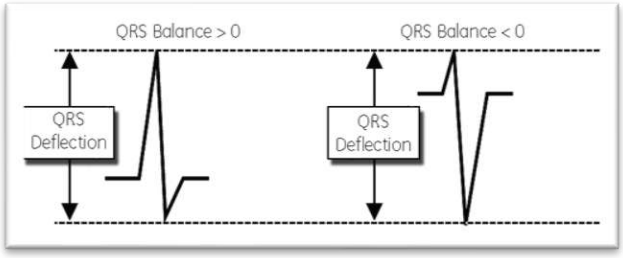
STE — ST level at the QRS offset plus 1/8 of the average RR interval

Maximum R amplitude — Maximum of the R or R'. This is the maximum positive deflection.

Maximum S amplitude — Maximum of the Q, S, or S'. This is the maximum negative deflection. (a positive value)

QRS balance, QRS amplitude — Maximum R amplitude minus maximum S amplitude. Will be positive if the QRS is predominantly positive. Will be negative if the QRS is predominantly negative. The terms QRS balance and QRS amplitude are used interchangeably in this document.

QRS deflection — Maximum R amplitude plus maximum S amplitude. The maximum peak-to-peak deflection.



Maximum ST amplitude — Maximum of STJ, STM, and STE

Minimum ST amplitude — Minimum of STJ or STM

Special T amplitude — This value reflects the T amplitude without ST segment effects.

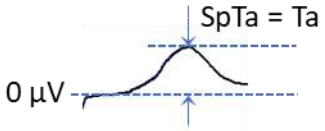
The value of the special T amplitude depends on the pattern of the overall T wave. For example, monophasic vs biphasic and the polarity. There are four cases.

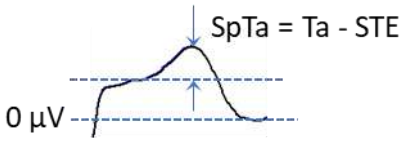
Case 1. This is the default definition of special T amplitude and includes:

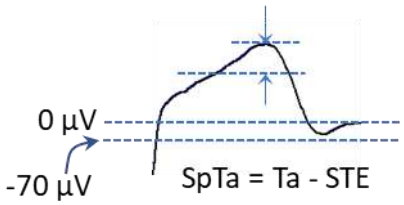
- Monophasic positive T waves (T amplitude ≥ 0 and T' amplitude = 0)
- Biphasic T waves with a positive T and negative T' where T' amplitude > -70 µV and the T amplitude > 4 times the absolute value of the T' amplitude
- Any other patterns that do not expressly match cases 2 – 4

In this case, the special T amplitude is the minimum of either the T amplitude or T amplitude minus STE. This will be the definition of special T amplitude in the vast majority of instances.

SpTa = min(Ta, Ta - STE)

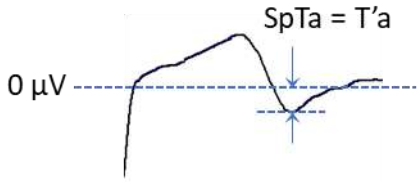






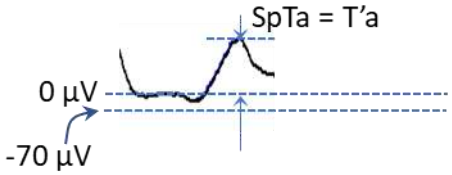
Case 2: Biphasic T wave with positive T and small negative T', where the T' is larger than the small negative T' of case 1.

In this case, the special T amplitude is equal to the T' amplitude.



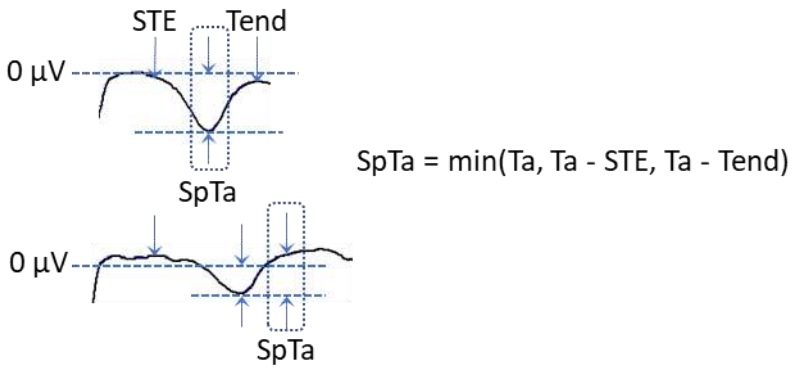
Case 3: Biphasic T wave with small negative T and positive T', where the T amplitude is > -70 µV and the T' amplitude > 4 times the absolute value of the absolute value of the T amplitude.

In this case, the special T amplitude is equal to the T' amplitude.



Case 4: Monophasic negative T wave (T amplitude < 0 and T' amplitude = 0).

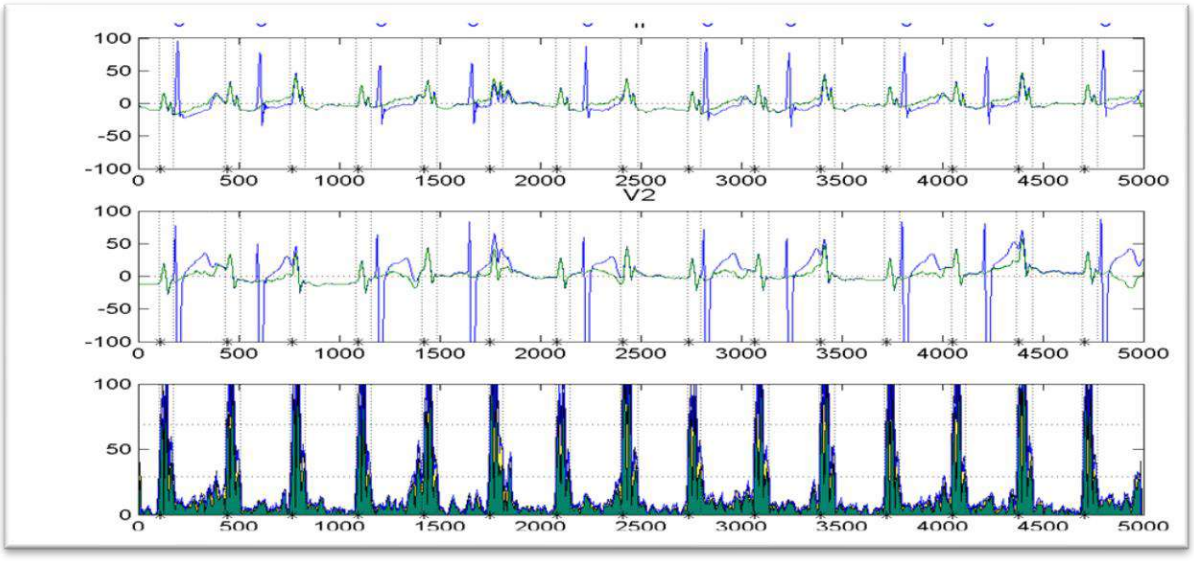
In this case, the special T amplitude is the minimum of T amplitude, T amplitude minus STE, or T amplitude minus amplitude at T offset (T_{end}). Note that in this case, a negative STE *and* T_{end} makes the SpTa equal to the T amplitude, while a positive STE *or* T_{end} makes the SpTa more negative than the T amplitude.



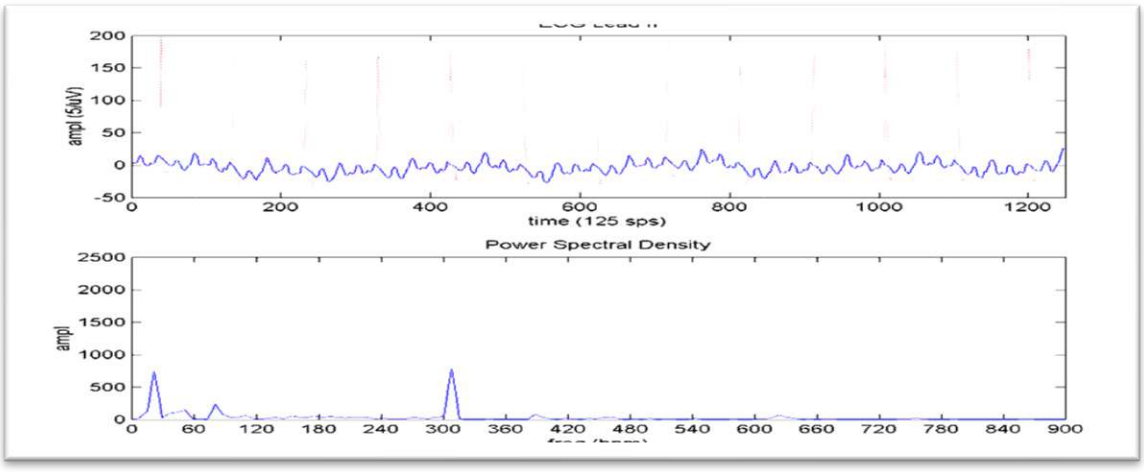
P WAVE DETECTION

In addition to P wave detection in the median complex, the raw rhythm data is also analyzed for atrial activity following the QRS detection and median formation. All leads are first examined for the greatest probability of proper P wave detection. One of leads I and II is selected and one precordial lead (V1 - V6) is selected. The QRST portion of the median complexes of the two selected leads are subtracted from the corresponding QRST locations in the rhythm data as previously described in the literature.[26, 104-106] The remaining signals for the two leads are referred to as "residual" signals. Next, atrial waves (P, fibrillatory, or flutter waves) are detected from a composite signal of the two residual signals using a threshold based on the maximum values in the regions between the QRS complexes.

Onsets and offsets of the detected atrial waves are delineated using a second threshold based on the baseline activity. Each detected atrial wave is assigned a confidence score based on how closely its measurements resemble those of most of the detected waves. A contextual analysis is then applied to the measurements of the detected atrial waves, their confidence scores, and their temporal relations to each other and to QRS complexes. This is intended to exclude erroneously detected P waves and to perform a second search, using lower thresholds, for P waves that are suspected to be missing.



MacRhythm, the rhythm analysis component of 12SL, uses a QRST subtraction method to precisely locate P waves within the T waves for accurate rhythm interpretation. In addition to traditional time-domain criteria, a power spectral density provides improved sensitivity for detection of atrial flutter.



Criteria – Rules for Interpretation

The intent of this section is to provide the criteria, that is the rules, which the 12SL program uses to interpret the ECG. A pediatric or an adult interpretation is available with the 12SL program. If an age of less than 16 years is entered, the program employs pediatric as opposed to adult criteria. Age can also adjust thresholds within these two main bodies of criteria, as in the characterization of left ventricular hypertrophy. If age is not entered, the program enters a default adult age.

Age is used by the rhythm criteria but in very limited ways. For example, age is used to define normal sinus rates for pediatric ages. The rhythm criteria for both pediatric and adult analysis is presented as a single unit.

Morphology analysis cannot be presented as a single unit since a pediatric interpretation is not possible through simple adjustments of adult thresholds. A whole other approach is required. The morphology criteria for pediatrics and adults are presented separately, with the adult criteria presented first.

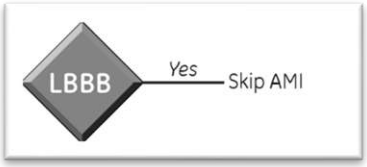
Rules for interpreting the ECG can be quite complex. This manual presents an overview of each unit before delving into the details. The hyperlinks below will allow you to skip to the section you are interested in finding.

Rhythm Criteria 33
Adult Contour Criteria.....48
Pediatric Contour Criteria 77

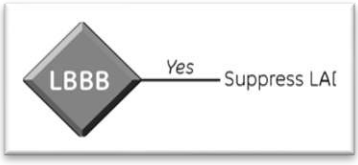
The following figures and flow-chart symbols are intended to facilitate the use of this guide:

- The flow of the program can be comprehended by viewing the drawings from top to bottom.
- The logic symbols are used to indicate tests that cause the program to proceed forward or to suppress statements that the program has already made. For example:

Proceed forward:

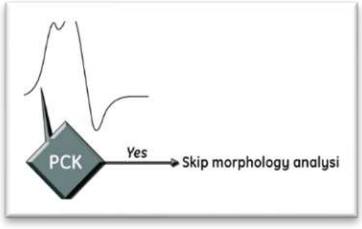


Suppress statement:



Most of the acronyms are obvious, but if they are not, consult the statement library acronyms in Appendix A: Statement Library Arranged by Statement Category.

Rhythm criteria are presented first. This sequence is required because information regarding the rhythm is needed before a proper morphology interpretation can take place. For example, an electronically paced ventricular rhythm is not analyzed for myocardial infarction, and so on.



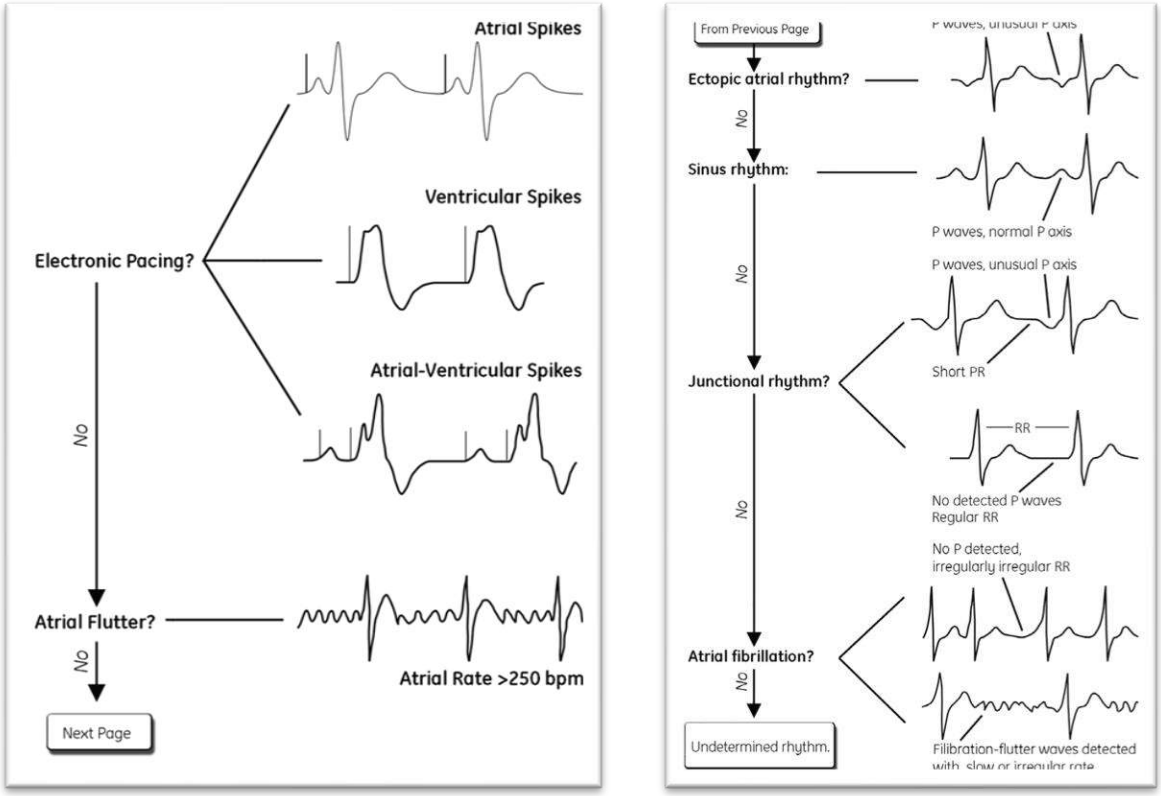
RHYTHM CRITERIA

Unless otherwise indicated in the following criteria, the rhythm analysis is the same for pediatric and adult patients.

The rhythm criteria first determine the origin of the predominant rhythm in the 10 seconds of analyzed data. The program chooses from the following major categories:

- Electronic artificial pacing
- Atrial flutter
- Ectopic atrial rhythm
- Sinus rhythm
- Junctional rhythm
- Atrial fibrillation

A set of statements exists for each of these categories; for example, sinus rhythm includes sinus tachycardia, normal sinus rhythm, sinus bradycardia, and marked sinus bradycardia. See details under Criteria for Predominant Rhythms.



If the program is not able to choose a rhythm that is described by one of the above categories, it defaults to the undetermined rhythm category. This category includes such statements as wide QRS tachycardia and supra-ventricular tachycardia; these describe the overall rhythm but refrain from defining the mechanism. If the rhythm cannot be labeled by these descriptive statements, the program states “Undetermined Rhythm.”

After the program states the predominant rhythm, several rhythm modifier statements can be appended for abnormalities of conduction and/or ectopy. Some of the modifier statements are only used for specific rhythms. For example, the statement "with rapid ventricular response" is used only in conjunction with atrial fibrillation.

The following figure portrays in simplified graphical form the criteria for the predominant rhythms. Notice that if the program does not find a match in the first six categories, it defaults to the undetermined rhythm category. Since the use of the rhythm modifiers are dependent upon the stated predominate rhythm, the document will first describe the criteria that is used for determining the predominant rhythm. See Criteria for Rhythm Modifiers.

Criteria for Predominant Rhythms

There are seven categories of predominant rhythm statements:

- Electronic Artificial Pacing
- Atrial Flutter
- Ectopic Atrial Rhythm
- Sinus Rhythm
- Junctional Rhythm
- Atrial Fibrillation
- Undetermined Rhythm

Each of these categories is presented with its associated statements. Each statement is shown in its actual wording, followed by the statement acronym, and any specific criteria associated with that statement. For statements that further define the rhythm, see Criteria for Rhythm Modifiers.

ELECTRONIC ARTIFICIAL PACING

This category requires that the predominant rhythm (i.e., the dominant beats) be artificially paced. The following statements are included in this category; they delineate the origin of the artificial pacing.

Rhythm Statement	***Acronym***	***Description***
Atrial-paced rhythm	APR	Pace spikes in front of P waves, where P waves are synchronous with QRS complexes.
Ventricular-paced rhythm	VPR	Pace spikes in front of QRS complexes and either no organized atrial activity or atrial activity asynchronous to the QRS complex.
Atrial-sensed ventricular-paced rhythm	ASVPR	Pace spikes in front of QRS complexes which follow non-paced, organized atrial activity (for example, sinus or ectopic atrial rhythm)
AV dual-paced rhythm	AVDPR	Pace spikes in front of the P waves and the QRS complexes.

Although not "rhythm" statements per se, the following statements may be made regarding detected pace spikes. The generation of both of the following statements will depend on the specific product and version used in the acquisition of the ECG. Not all products or versions will make these statements.

Rhythm Statement	***Acronym***	***Description***
****** Suspect unspecified pacemaker failure***	PMFAIL	Requires that less than half of the detected pace spikes are associated with P waves or QRS

		complexes. This was only implemented in 12SL v22. This test has since been retired.
Bi-ventricular pacemaker detected	BIVPCK	Requires at least 50% more ventricular spikes detected than ventricular- paced beats.

ATRIAL FLUTTER

Rhythm Statement	***Acronym***	***Description***
Atrial Flutter	FLUT	The program must detect an atrial rate from 200 to 350 bpm for adults, and 300 to 350 bpm for pediatrics.

ECTOPIC ATRIAL RHYTHM

This category is chosen if a P wave, with an abnormal axis, is found before the primary beats. Specifically, this category requires:

- Rigidly coupled P wave detected for primary beat, and
- No flutter or second-degree AV block
- P axis less than -30 or greater than 120. (For pediatrics, P axis less than -20 or greater than 100.)

For adults the ectopic atrial rhythm statements are rate dependent.

Rhythm Statement	***Acronym***	***Description***
Unusual P axis, possible ectopic atrial bradycardia	EABRAD	Requires atrial rate less than 60 bpm.
Unusual P axis, possible ectopic atrial rhythm	EAR	Requires atrial rate from 60 to 100 bpm
Unusual P axis, possible ectopic atrial tachycardia	EATACH	Requires atrial rate greater than 100 bpm. For pediatrics, the ectopic atrial rhythm statements are dependent on both rate and origin of impulse. If low right atrial rhythm is stated, the P axis is greater than 100 degrees. A left atrial rhythm is stated if the P axis is less than -20. Rate thresholds are age dependent. • Low Right Atrial Bradycardia — RABRAD • Low Right Atrial Tachycardia — RATACH • Left Atrial Bradycardia — LABRAD • Left Atrial Tachycardia — LATACH • Low Right Atrial Rhythm — RAR • Left Atrial Rhythm — LAR

SINUS RHYTHM

This category requires the program to detect P waves with a normal axis. Specifically, it requires.

- Rigidly coupled P wave detected for primary beat
- Normal P axis
- P waves detected at a regular rate and not associated with primary beat.

Sinus rhythm statements are rate and age dependent. *Marked Sinus Bradycardia* is stated for both adults and pediatrics at a rate below 45 bpm.

The determination of sinus bradycardia, sinus rhythm, or sinus tachycardia is based on the atrial rate, not the ventricular rate. This is because it is the atrial rate that reflects the rate of the sinus node. While these two rates will be identical for the majority of sinus rhythms, they may differ in cases such as 2nd or 3rd degree AV block. For example, an ECG with complete heart block and an atrial (sinus) rate of 115 bpm and a ventricular rate of 55 beats per minute would be interpreted as Sinus tachycardia with complete heart block even though the ventricular response might normally be thought of as bradycardia.

Rhythm Statement	***Acronym***	***Description***
Sinus bradycardia	SBRAD	Requires atrial rate from 45 to 59 bpm.
Normal sinus rhythm	NSR	Requires atrial rate from 60 to 100 bpm and no rhythm modifiers appended or only with sinus arrhythmia appended.
Sinus rhythm	SRTH	Requires atrial rate from 60 to 100 bpm and any rhythm modifiers appended beyond with sinus arrhythmia.
Sinus tachycardia	STACH	Requires atrial rate over 100 bpm.
Marked sinus bradycardia	MSBRAD	Requires atrial rate less than 45 bpm.

JUNCTIONAL RHYTHM

Two sets of criteria are used for this category. One set of criteria is applicable to those junctional rhythms that have a P wave which precedes the QRS. The other criteria are for when the P wave is submerged in the QRS or T. If the P wave precedes the QRS, it must be ectopic in shape with a short PR interval. Pediatric patients exhibit shorter time intervals before the onset of ventricular activation. As a result, they rarely exhibit AV nodal rhythms with a short PR interval. Pediatric analysis leaves this rhythm categorized as ectopic atrial rhythm.

Specifically, if P waves are visible before the QRS then the criteria require:

- Rigidly coupled P wave detected for primary beats
- No flutter or second-degree AV block
- PR interval less than 140 ms
- P wave axis outside of -60 to 240 degrees
- An adult age

The statements for these criteria are rate dependent.

Rhythm Statement	***Acronym***	***Description***
Unusual P axis and short PR, probable junctional bradycardia	JBRAD	Requires ventricular rate less than 50 bpm.
Unusual P axis and short PR, probable junctional rhythm	JR	Requires ventricular rate from 50 to 75 bpm.
Unusual P axis and short PR, probable junctional tachycardia	JTACH	Requires ventricular rate greater than 75 bpm. If P waves are not visible, then the program requires a very regular, narrow QRS rhythm. Specifically: No P waves found A regular RR interval (a range of RR intervals that is less than 10% of the average RR interval)

Rhythm Statement	Acronym	Description
		A narrow primary beat (<120 ms for QRS duration for adults, for pediatrics refer to Appendix C: Pediatric Tables. A ventricular rate less than 90 bpm Junctional rhythm statements are rate dependent. The rate thresholds are the same for both pediatric and adult analyses.
Junctional bradycardia	JUNBRAD	Requires rate less than 45 bpm.
Junctional rhythm	JUNCT-R	Requires rate from 45 to 65 bpm.
Accelerated	ACCEL	This statement precedes Junctional Rhythm when the rate is greater than 65 bpm.

Atrial Fibrillation

If none of the other aforementioned categories has been chosen, the program tests for atrial fibrillation. The program looks for an irregular rhythm or fibrillatory waves in the presence of a slow heart rate. Specifically, it requires test 1 or test 2 to be true.

Test 1 requires:

- An irregularly irregular rhythm (range of RR intervals more than 15% of the average RR interval and RR intervals not organized)
- No regular atrial rhythm detected.

Test 2 requires an atrial rate >400.

Only one statement is generated for this category. The rhythm can be further defined by rhythm modifier statements.

Rhythm Statement	Acronym	Description
Atrial Fibrillation	AFIB	Atrial fibrillation occurs so rarely in pediatric individuals that the program requires an adult age for this diagnosis.

Undetermined Rhythm

This category is chosen if none of the other previously mentioned categories fits the description of the measurements extracted from the ECG. Some descriptive statements can be issued from this category without specifying the mechanism.

Rhythm Statement	Acronym	Description
Idioventricular Rhythm	IVR	Requires: • A slow ventricular rate (≤ 40 bpm for adult and pediatric ages). • A wide QRS (QRS duration > 120 ms; refer to Appendix C: Pediatric Tables for pediatric ages). A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).
Wide QRS Rhythm	WQR	Requires:

Rhythm Statement	*Acronym*	*Description*
		• Ventricular rate between 40 and 120 bpm; refer to Appendix C: Pediatric Tables for pediatric upper rate limit. • A wide QRS (QRS duration > 120 ms; refer to Appendix C: Pediatric Tables for pediatric ages). • A regular heart rate (the range of RR intervals is less than 20% of the average RR interval).
Wide QRS Tachycardia	WQTACH	Requires: • A fast ventricular rate (>120 bpm; refer to Appendix C: Pediatric Tables for pediatric ages). • A wide QRS (QRS duration > 120 ms; refer to Appendix C: Pediatric Tables for pediatric ages). • A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).
Supraventricular Tachycardia	SVT	Requires: • A fast ventricular rate (>140 bpm; >220 bpm for pediatric). • A narrow QRS (QRS duration <120 ms; refer to Appendix C: Pediatric Tables for pediatric ages). • A regular heart rate (that is, the range of RR intervals is less than 20% of the average RR interval).
Narrow QRS Tachycardia	NQTACH	Requires: • Pediatric age. • Same criteria as described for supraventricular tachycardia but allows rates below 220 bpm that are still above the fast heart rate for age.
Undetermined Rhythm	UR	If the criteria cannot be met for these descriptive statements, then the program will state *Undetermined rhythm*.

Criteria for Rhythm Modifiers

Rhythm modifiers may be added to the predominant rhythm statement. Rhythm modifiers are grouped into the following categories:

- Sinus arrhythmia (e.g., with marked sinus arrhythmia)
- Irregular rhythm (e.g., with undetermined rhythm irregularity)
- PR interval (e.g., with 1st degree AV block)
- AV block (e.g., with complete heart block)
- Ectopy (e.g., with premature ventricular complexes)
- Paced complexes (e.g., with occasional ventricular-paced complexes)

The rhythm modifiers that may be added to the rhythm statement are dependent on the predominant rhythm. Following is a list of the predominant rhythms and the applicable rhythm modifier categories, as well as a more complete description of each rhythm modifier category, including the specific statements that may be made.

Rhythm Modifier Categories for Each Predominant Rhythm

The following table lists the rhythm modifier categories for each predominant rhythm.

Predominant Rhythm	*Modifier Categories*
Sinus Rhythm	• Sinus arrhythmia • PR interval • AV block • Ectopy • Paced complexes
Ectopic Atrial Rhythm including Junctional Rhythm with P waves preceding QRS	• Irregular rhythm • AV block • Ectopy • Paced complexes
Atrial Fibrillation, Atrial Flutter	• AV block (tailored for fibrillation/flutter) • Ectopy (tailored for fibrillation/flutter) • Paced complexes
Junctional and other rhythms with no distinct P waves preceding QRS (e.g., WQRS, IVR)	• Ectopy • Paced complexes
Electronic Artificially Paced Rhythm	• PR interval • AV block (tailored for paced rhythms) • Ectopy • Paced complexes

Rhythm Modifiers by Modifier Category

Some rhythm modifier categories are tailored for specific predominant rhythms to make them more appropriate for that rhythm. For example, ectopy can occur with atrial fibrillation or flutter, but the origin of it is harder to define. That is why atrial fibrillation and atrial flutter have a tailored set of ectopy statements. This section covers the details for the following rhythm modifiers:

- Sinus Arrhythmia
- Irregular Rhythm
- PR Interval
- AV Block
- Ectopy
- Paced Complexes

Sinus Arrhythmia

Predominant rhythm: *Sinus*

Requires a rigidly coupled P wave detected for the primary beat and no premature supraventricular beats (normal shape but without P wave) or premature ectopic beats (shape other than primary beat).

Sinus arrhythmia is stated if the range of RR intervals exceeds a particular limit. The limits are much higher for the pediatric population, which has much more sinus arrhythmia. Specifically:

Statement	***Acronym***	***Description***
with sinus arrhythmia	SAR	Requires range of RR intervals 20 to 39% (greater than 40% for pediatrics) of average RR interval.
with marked sinus arrhythmia	MSAR	Requires range of RR intervals 40% or greater of average RR interval (not used for pediatric ages).

Irregular Rhythm

Predominant rhythm: *Ectopic atrial*, *junctional (with P waves)*

This category is analogous to the sinus arrhythmia category for sinus rhythms. If the program did not detect any ectopy and if the rhythm is irregular, the program will describe the condition with the following statements.

Statement	***Acronym***	***Description***
with undetermined rhythm irregularity	IRREG	Requires adult age and range of RR intervals greater than 20% of average RR interval. This statement will not appear if screening criteria is turned on. See for more information.
Irregular	IRR	Requires pediatric age and range of RR intervals greater than 20% of average RR interval. In this case, this statement is prefixed to the existing rhythm statement, for example, “Irregular right atrial rhythm”.

PR Interval

Predominant rhythm: *Sinus, paced*

The modifiers that can be added for sinus rhythms are different than those for paced rhythms as indicated below.

Statement	***Acronym***	***Description***
with short PR	SPR	Requires sinus rhythm and PR interval 110 ms or less (for pediatrics, it must be less than the 2nd percentile for age. Refer to Appendix C: Pediatric Tables for pediatric threshold). Is not made if WPW is detected.
with 1st degree AV block	FAV	Requires sinus rhythm and PR interval of 210 ms or longer (for pediatrics, it is the 98th percentile plus 20 ms; refer to Appendix C: Pediatric Tables for pediatric threshold).

with prolonged AV conduction	PROAV	Requires any paced rhythm and PR interval of 210 ms or longer (for pediatrics, it is the 98th percentile plus 20 ms; refer to Appendix C: Pediatric Tables for pediatric threshold).

AV Block

Predominant rhythm: *Sinus*, *ectopic atrial*, *junctional* (with P waves)

This section lists the statements that express 2nd and 3rd degree AV block.

* Statements with an asterisk (*) will not appear if Screening Criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for more information.

Statement	***Acronym***	***Description***
with 2nd degree AV block (Mobitz I)	MBZI	Requires: • At least one beat that follows an RR interval which is longer than 1.4 times the longer of the previous RR or the median RR. • No rigidly coupled P wave for this beat. • Two P waves preceding that beat. • PR interval for this beat is shorter than average. • This beat follows a normally shaped beat.
with 2nd degree AV block (Mobitz II)	MBZII	Requires: • Two or more P waves preceding a beat. • This beat follows a normally shaped beat • that beat follows an RR interval which is longer than one of the following: • 2.2 times the longer of the previous RR or the median RR • 1.8 times the longer of the previous RR or the median RR and there is a rigidly coupled P wave for this beat.
with 2:1 AV conduction *	W2TI	For MBZI and MBZII Requires: • Synchronous blocked P wave identified in the median complex in addition to synchronous conducted P wave. • Pattern of blocked P, conducted P, blocked P, conducted P detected somewhere in the rhythm analysis
with 2nd degree AV block	SAV	Requires: • Rigidly coupled P wave detected for primary beats. • Atrial rate less than 200 bpm. • The atrial rate is less than 10 bpm different than twice the ventricular rate.
with 2:1 AV conduction	W2T1	For **SAV** Requires:

Statement	*Acronym*	*Description*
		• Synchronous blocked P wave identified in the median complex in addition to synchronous conducted P wave. • Pattern of blocked P, conducted P, blocked P, conducted P detected somewhere in the rhythm analysis. • Atrial rate is within 5 bpm of 2 times the ventricular rate.
with 3:1 AV conduction	W3T1	For SAV Require atrial rate is within 10 bpm of 3 times the ventricular rate.
with 4:1 AV conduction	W4T1	For SAV Requires atrial rate is within 15 bpm of 4 times the ventricular rate.
with complete heart block	CHB	Requires: • No AV Block (Mobitz I or II). • Regular atrial rhythm detected. • No rigidly coupled P wave detected for primary beats. • Atrial rate more than 6 bpm faster than ventricular rate • One of the following: • PR variance greater than 200 ms. • Atrial rate more than 25 bpm faster than ventricular rate. See note regarding ventricular activity in next row.
with AV dissociation	AVDIS	Requires: • No AV Block (Mobitz I or II). • No flutter. • Regular atrial rhythm detected. • No rigidly coupled P wave detected for primary beats. • One of the following: • Atrial rate more than 25 bpm faster than ventricular rate. • PR variance greater than 200 ms. **NOTE:** If *complete heart block* or *with AV dissociation* is stated, then additional statements regarding the ventricular activity will follow. The presence of an atrioventricular dyssynchrony requires that both the atrial and the ventricular activity be specified. The ventricular activity will be stated as one of the otherwise predominant rhythm statements of: *Junctional rhythm*, *Junctional bradycardia*, *Idioventricular rhythm*, *Wide QRS rhythm*, or *Wide QRS tachycardia*.

AV Block (Tailored for Atrial Fibrillation)

Predominant rhythm: Atrial fibrillation

* Statements with an asterisk (*) will not appear if Screening Criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for more information.

Statement	Acronym	Description
with rapid ventricular response *	RVR	Requires ventricular rate higher than 100 bpm.
with slow ventricular response *	SVR	Requires ventricular rate lower than 60 bpm.

with a competing junctional pacemaker *	CJP	Requires:
		• No electronic pacer spikes detected.
		• One of the following:
		  ○ Range of RR intervals less than 5% of average RR.
		  ○ the 3 longest RR intervals are longer than 800 ms and within 40 ms of each other.

AV Block (Tailored for Atrial Flutter)

Predominant rhythm: *Atrial flutter*

* Statements with an asterisk (*) will not appear if Screening Criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for more information.

Statement	Acronym	Description
with variable AV block	VAVB	Requires range of RR intervals is 10% or more of the average RR interval.
with 2:1 AV conduction *	W2T1	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 2 times the ventricular rate.
with 3:1 AV conduction *	W3T1	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 3 times the ventricular rate.
with 4:1 AV conduction *	W4T1	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 4 times the ventricular rate.
with 5:1 AV conduction *	W5T1	Requires: • Range of RR intervals less than 10% of average RR interval. • Atrial rate is within 10 bpm of 5 times the ventricular rate.

AV Block (Tailored for Paced Rhythms)

Predominant rhythm: *Paced*

If the predominant rhythm is ventricular-paced and not atrial-sensed or - paced, the program continues to look for P waves. If P waves are asynchronous with ventricular pacing and with a regular P-P interval, then the program will prefix the *Ventricular-paced rhythm* statement with *Sinus rhythm with complete heart block*.

Ectopy

Predominant rhythm: *Sinus*, *ectopic atrial*, *junctional* (with or without P waves), *paced*

The ectopy group contains statements that pertain to premature beats, fusion beats, or escape beats.

Modifiers that are associated with premature beats are always preceded by a phrase that indicates how often the beats occur. Specifically:

Statement	***Acronym***	***Description***
with occasional	OCC	Requires 1 or 2 beats.
with frequent	FREQ	Requires greater than 2 beats. If ectopic shaped beats appear as at least one consecutive pair, then not only is the frequency of the beats commented on, but the consecutive nature of the beats is also indicated.

and consecutive	CSEC	Requires:
		• At least one pair or beats.
		• These beats are either
		  ○ Separated by less than 600 ms for rates lower than 85 bpm.
		  ○ At least 100 ms premature for rates over 85 bpm.

Following are the various premature beat modifier statements that follow the previous prefixes.

Statement	***Acronym***	***Description***
premature supraventricular complexes	PSVC	Requires: • No AV block, Mobitz I or II. • No AV dissociation. • At least one QRS that is premature, normally shaped. • No P wave found before this QRS.
premature atrial complexes	PAC	Requires: • No AV block, Mobitz I or II. • No AV dissociation. • At least one QRS that is premature, normally shaped. • A P wave found preceding this QRS
premature ventricular complexes	PVC	Requires: • At least one QRS that is premature, ectopic shaped

Statement	Acronym	Description
		• Has a QRS duration greater than 120 ms (for pediatrics, wide for age; refer to Appendix C: Pediatric Tables. • No fusion beats detected.
in a pattern of bigeminy	BIGEM	Requires: • A strict 10-second pattern of alternating premature and not premature beats. • One of the following: ○ At least one QRS that is premature, ectopic shaped. ○ At least one premature atrial or supraventricular beat.

Statements that specifically deal with fusion beats or escape beats are not conjugated with the phrase *With Occasional* etc. These statements are as follows.

* Statements with an asterisk (*) will not appear if Screening Criteria is turned on. See Screening Criteria: Suppressed Statements, Increased Specificity for more information.

Statement	Acronym	Description
fusion complexes	$SFUS	Requires QRS complex that is different from dominant beat type and is not premature and not late.
with junctional escape complexes	JESC	Requires: • No AV block, Mobitz I or II. • No AV dissociation. • At least one QRS that is premature, normally shaped. • A P wave found preceding this QRS
premature ventricular complexes	PVC	Requires: • No AV block, Mobitz I or II. • At least one beat that follows an RR interval which is longer than 1.4 times the longer of the previous RR or the median RR. • No P wave preceding that beat. • Follows a normally shaped beat
with ventricular escape complexes	VESC	Requires: • At least one beat that is ectopic shaped. • Has a QRS duration greater than 120 ms, (for pediatrics, wide for age; refer to Appendix C: Pediatric Tables). • Follows an RR interval of more than 1200 ms. • Follows a normally shaped beat.

Statement	Acronym	Description
with fusion or intermittent ventricular pre-excitation (WPW)	ALTWPW	Requires: • Fusion beats. • No premature ectopic shaped beats. • Delta waves in three or more leads of the fusion beat. A fusion beat requires: • A QRS that is not premature but ectopic shaped. • Not the first QRS of the 10 second strip • Within 100 ms of the expected RR interval
with retrograde conduction *	RETC	Requires: • Junctional bradycardia, junctional rhythm, or accelerated junctional rhythm stated. • No AV dissociation or complete heart block. • Regular atrial rhythm detected. • Number of P waves detected < number of QRSs plus 5 • Short RP interval.

Ectopy (Tailored for Atrial Fibrillation / Atrial Flutter)

Predominant rhythm: Atrial fibrillation, atrial flutter

In the presence of atrial fibrillation or atrial flutter, it is difficult to define the origin of ectopic shaped beats. The following statement is used in most instances of ectopy.

Statement	Acronym	Description
with premature ventricular or aberrantly conducted complexes	ABER	Requires any complexes that are of a different morphology than the dominant beat shape unless they are otherwise classified as ventricular escape or paced.
with ventricular escape complexes	VESC	Requires: • At least one beat that is ectopic shaped. • Has a QRS duration greater than 120 ms, (for pediatrics, wide for age; refer to Appendix C: Pediatric Tables) • Follows an RR interval of more than 1200 ms. • Follows a normally shaped beat.

Paced Complexes

Predominant rhythm: *any*

With the exception of *intrinsic complexes*, all of the statements in this category will be preceded by "*with occasional*" or "*with frequent*".

Statement	Acronym	Description
atrial-paced complexes	APCX	Requires atrial-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not Atrial-paced rhythm.

Statement	*Acronym*	*Description*
ventricular-paced complexes	VPCX	Requires ventricular-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not Ventricular- paced rhythm.
AV dual-paced complexes	AVPCX	Requires AV dual-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not AV dual- paced rhythm.
atrial-sensed ventricular-paced complexes	ASVPCX	Requires atrial-sensed ventricular-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not Atrial-sensed ventricular-paced rhythm. **NOTE:** No more than one of the previous four statements will be made. If there are multiple paced beat types, only the most frequently occurring will be commented on.
sinus complexes	SCX	Requires predominant rhythm of paced and QRS complexes of a normal morphology with normal P waves.
supraventricular complexes	SVCX	Requires: predominant rhythm of paced and QRS complexes of a normal morphology but with abnormal or no P waves. **NOTE:** No more than one of the previous two statements will be made. If there are both sinus and supraventricular complexes, only the most frequently occurring will be commented on.
with intrinsic complexes	WITH + INTRIN	Requires predominant rhythm of paced, non-paced QRS complexes of morphology different from the dominant beat type, and no other statements from either this section or regarding ectopy are made.

ADULT CONTOUR CRITERIA

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The morphology interpretation consists of two separate bodies of criteria: one for adults, the other for pediatrics. If an adult age is entered (16 years or older) or if no age is entered, an adult analysis is performed.

The 12SL analysis program has adult age and gender-specific contour criteria. These criteria are invoked if an adult age is entered and if the patient's sex is entered. If age and sex are not entered, 12SL returns to conventional criteria.

The categories of abnormalities that the program always examines for are listed in the table below. This outline is expanded upon in succeeding figures which describe, in very simplistic terms, the basic flow and logic of the program. That the order of the steps is important since information obtained from tests, performed earlier in the sequence, are applied to subsequent tests.

Adult Contour Criteria Summary

Major Category	***Subcategory***	***Acronyms/Statements***
Electrode Reversals		SREV: Suspect electrode reversal
Wolff-Parkinson-White		WPW: Wolff-Parkinson-White WPWA: WPW type A WPWB: WPW type B
Atrial Enlargement		RAE: Right atrial enlargement LAE: Left atrial enlargement BAE: biatrial enlargement
QRS Abnormalities	QRS Axis	RWA: Rightward axis RAD: Right axis deviation RSAD: Right superior axis deviation LAD: Left axis deviation
	Low Voltage QRS Pulmonary Disease Pattern	LOWV PULD
	Brugada	BRUG1: Brugada pattern, type 1
	Conduction Abnormalities	RBBB: Right bundle branch block LBBB: Left bundle branch block

Major Category	*Subcategory*	*Acronyms/Statements*
		IRBBB: Incomplete right bundle branch block ILBBB: Incomplete left bundle branch block RSR: RSR' pattern in V1 IVCB: Intraventricular conduction block IVCD: Intraventricular conduction delay LAFB: Left anterior fascicular block LPFB: Left posterior fascicular block
	Ventricular Hypertrophy	RVH: Right ventricular hypertrophy LVH: Left ventricular hypertrophy BIVH: Biventricular hypertrophy RVE+: plus, right ventricular hypertrophy QRSW: with QRS widening
	Myocardial Infarction	MI: Myocardial infarction AMI: Anterior MI SMI: Septal MI LMI: Lateral MI IMI: Inferior MI PXT: with posterior extension (IMI)
	Poor R-wave Progression	PRWP: Poor R-wave progression
ST Abnormalities—QRS Related	ST + T abnormality with Ventricular Hypertrophy (refer to sections on RVH and LVH)	2ST: with repolarization abnormality
	Dating Infarcts (refer to Infarctions)	AC: possibly acute AU: age undetermined
ST Elevation Abnormalities	Epicardial Injury	INJ: Injury AINJ: Anterior LINJ: Lateral IINJ: Inferior
	Pericarditis	PCARD: Acute pericarditis
	Early Repolarization	REPOL: Early repolarization
	Undefined ST Elevation	STEL: ST elevation, consider early repolarization, injury, or acute pericarditis
	Nonspecific	NST: Nonspecific ST abnormality
ST Depression Abnormalities	Subendocardial Injury	SBINJ: Subendocardial injury SSBINJ: Septal ASBINJ: Anterior LSBINJ: Lateral ISBINJ: Inferior

Major Category	*Subcategory*	*Acronyms/Statements*
		STDEP: ST depression, consider subendocardial injury
	Nonspecific	NST: Nonspecific ST abnormality
	Junctional ST Depression	JST: Junctional ST depression, probably abnormal JSTN: Junctional ST depression, probably normal
T Wave Abnormalities	Ischemia	T: Ischemia AT: Anterior ischemia IT: Inferior ischemia LT: Lateral ischemia MT: Marked Ischemia MAT: Marked anterior ischemia MIT: Marked inferior ischemia MLT: Marked lateral ischemia
	Nonspecific QRS-T Angle	NT: Nonspecific T wave abnormality AQRST: Abnormal QRS-T angle, consider primary T wave abnormality
QT Interval		LNGQT: Prolonged QT QTcB/QTcFrid/QTcFram ≥ 480 msec
ST Elevated MI		STEMI: ** ** ACUTE MI / STEMI ** **

Electrode Reversals

Acronyms: SREV, NOREV

Skip electrode reversal checks if any atrial or ventricular pacing or if any ST elevation injury is detected.

More so than most any other part of the 12SL program, the electrode reversal criteria were tuned to sacrifice sensitivity in order to maximize specificity and positive predictive accuracy. Some reversals may be missed, but if a reversal is stated, there is a high degree of confidence that it will be correct.

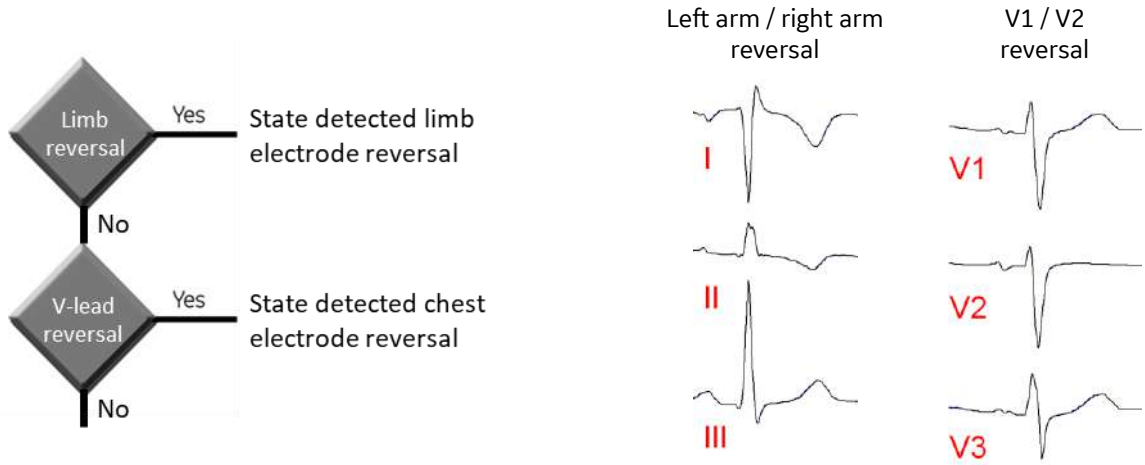
The following four limb electrode reversals and twelve precordial electrode reversals are detected:

- LA/RA, LA/RL, RA/LL, RA/RL
- V1/V2, V1/V3, V1/V4, V1/V5, V1/V6
- V2/V3, V2/V4, V2/V5, V2/V6
- V3/V4, V3/V5, V3/V6

Reversals among the trio of left precordial electrodes V4, V5, and V6 are not detected. This is due to a lower positive predictive accuracy as well as slightly reduced clinical impact of reversals amongst this set of electrodes.

Reversal of only a single electrode pair can be detected. In cases of a limb/chest electrode reversal or a multi-electrode interchange, the results are undefined.

The program inspects first for the four limb-lead reversals. Inspection for V-lead reversals is done only if no limb-lead reversals are detected.



If a reversal is detected, state ****** Suspect electrode reversal: xx yy; interpretation assumes no reversal***, where xx and yy are the names of the two interchanged electrodes. The remaining 12SL interpretation proceeds with the ECG as-is, assuming that no reversal was present.

ELECTRODE REVERSALS: 12SL VERSUS HOOKUP ADVISOR

The same analysis for electrode reversal is done for both 12SL and Hookup Advisor. However, Hookup Advisor extends the set of reversals detected to include reversals of the V4, V5, and V6 electrodes. That is, for Hookup Advisor, the list of reversals given above can be extended to include:

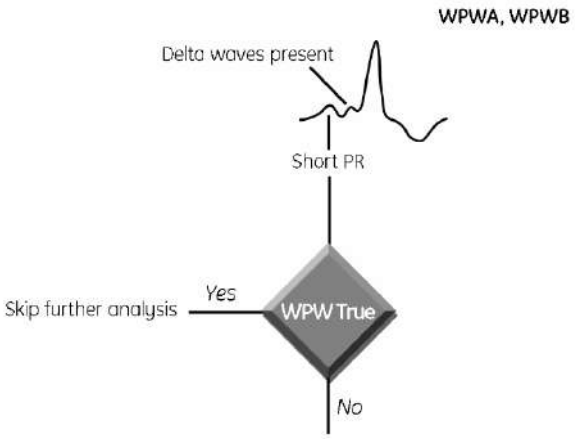
- V4/V5, V4/V6
- V5/V6

When an electrode reversal is detected by Hookup Advisor, the message ***Possible reversal: xx yy*** will be displayed, where xx and yy are the names of the two interchanged electrodes.

In addition to these three reversals, a non-specific reversal statement may also be generated by Hookup Advisor. If the analysis of the chest leads determines an abnormal progression that does not fit into one of the 15 prescribed chest lead reversals, Hookup Advisor will state ***Possible reversal: precordial leads***.

Wolff-Parkinson-White

Acronyms: WPW, WPWA, WPWB



Test is skipped if rhythm is atrial fibrillation, atrial flutter, or no P wave is present.

Wolff-Parkinson-White requires delta waves in three or more of 12 leads and P axis between -30 and 120 degrees.

Ventricular pre-excitation, WPW pattern type A requires WPW test and predominantly positive QRS in V1 or V2.

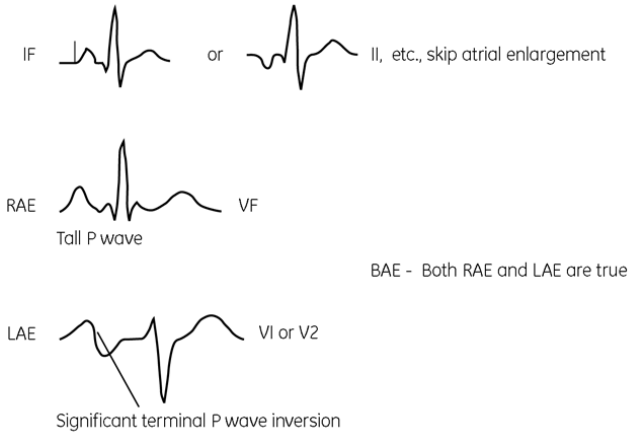
Ventricular pre-excitation, WPW pattern type B requires WPW test and predominantly negative QRS in V1 or V2.

If any *WPW* is stated, all further tests except QT interval abnormalities are skipped.

Atrial Enlargement

Acronyms: RAE, LAE, BAE

Tests are skipped if WPW, rhythm is not sinus, or abnormal P axis.



Right atrial enlargement requires P wave amplitude > 250 µV in any of leads II, III, aVF, V1, or V2.

Left atrial enlargement considers the terminal P amplitude, duration, and area in leads V1 and V2. This statement may be prepended with the qualifier ***Possible*** if the terminal negative P wave in V1 or V2 is not as large.

If tests pass for both RAE and LAE, then ***Biatrial enlargement*** is instead stated.

QRS Axis

Acronyms: RAD, RAD4, RAD5, LAD3, INDAX

Tests are skipped if WPW is stated.

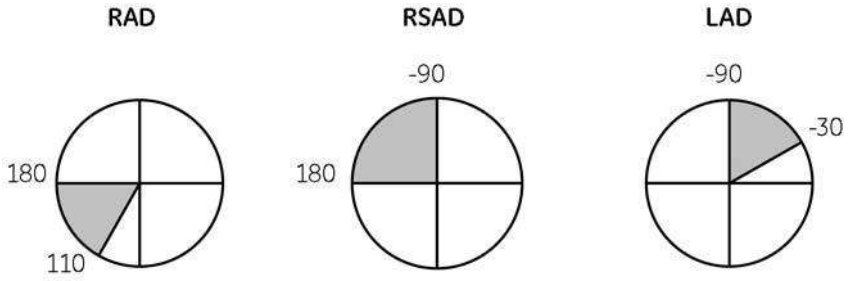
Rightward axis requires QRS axis QRS axis between 90 and 109 degrees.

Right axis deviation requires QRS axis between 110 and 180 degrees.

Right superior axis deviation requires QRS axis between 181 and 270 degrees.

Left axis deviation requires QRS axis between -30 and -89 degrees.

Indeterminate axis requires absolute value of R amplitude minus S amplitude is <50 µV or <10% of the total QRS deflection in leads I, II, and III (i.e., the QRS complexes of leads I, II, and III are all essentially equiphasic)

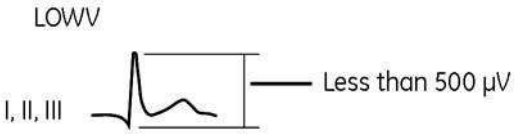


Low Voltage QRS

Acronym: LOWV

Test is skipped if WPW is stated or QRS duration > 120 ms.

Low voltage QRS requires QRS deflection of all limb leads < 500 µV or QRS deflection < 1000 µV in all 12 leads.

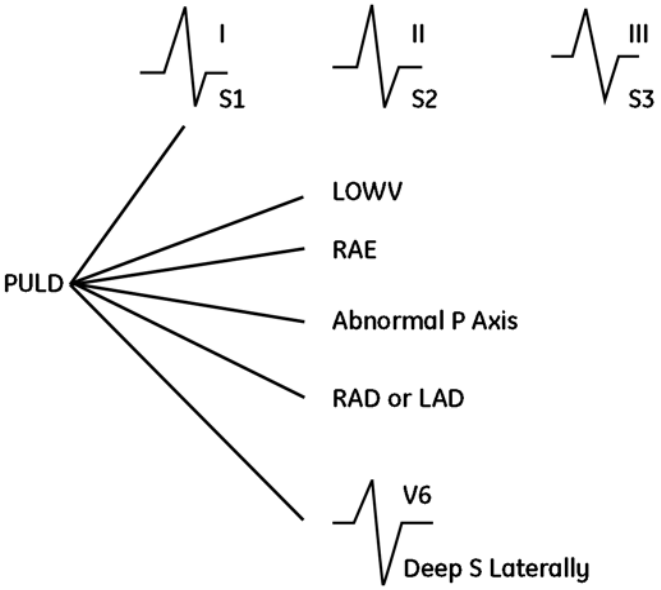


Pulmonary Disease Pattern

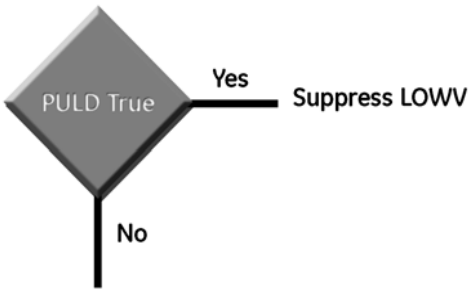
Acronym: PULD

Test is skipped if WPW is stated or QRS duration > 120 ms.

Tests for pulmonary disease pattern check for several attributes, including S1-S2-S3 pattern, low voltage, right atrial enlargement, abnormal P axis, right or left QRS axis deviation or indeterminate axis, and deep S wave in V5 or V6. If at least 4 of these are present, ***Pulmonary disease pattern*** is stated.



If *pulmonary disease pattern* is stated, do not redundantly state *low voltage QRS*.



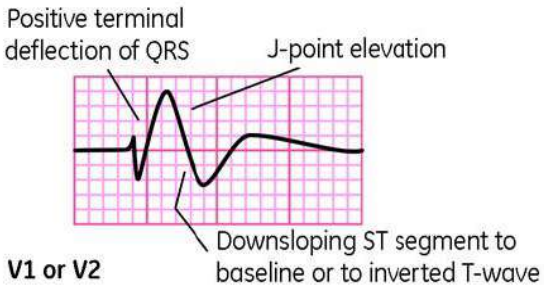
Brugada

Acronym: BRUG1

Test is skipped if WPW is stated, QRS duration > 150 ms, or ventricular rate > 150 bpm.

The Brugada type 1 pattern is characterized by a prominent coved ST-segment elevation displaying J-point amplitude or ST-segment elevation ≥ 200 µV at its peak followed by a negative T-wave, with little or no isoelectric separation.

If the Brugada type 1 pattern is found in V1 or V2, and right bundle branch block and anterior injury are ruled out, state ***Brugada pattern, type 1***.



Conduction Abnormalities

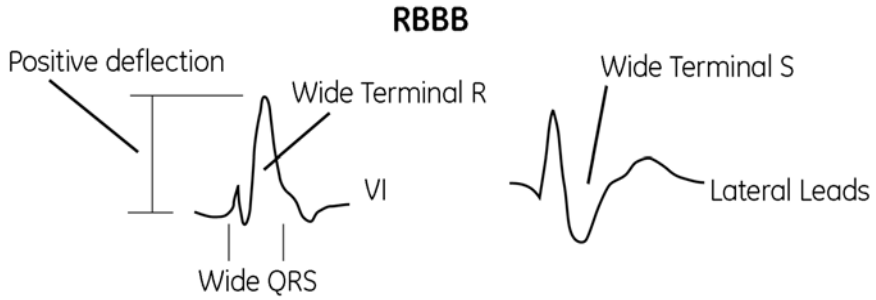
All tests for conduction abnormalities are skipped if WPW is stated.

All tests for *right* ventricular conduction abnormalities (RBBB, and so on) are skipped if Brugada is stated.

MAJOR BLOCKS

Right Bundle Branch Block

Acronyms: RBBB, RVE+

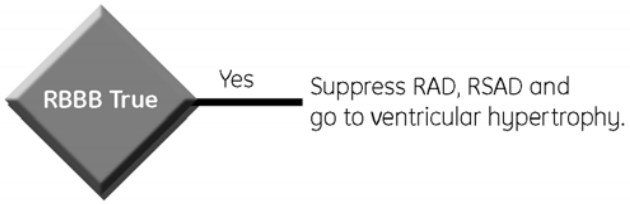


Tests for ***Right bundle branch block*** examine for a wide QRS, predominantly upright QRS with terminal R or R' in leads V1 or V2, and wide terminal S waves in the lateral leads.

If RBBB is true and R or R' amplitude > 1500 µV in lead V1 and QRS axis > 110 degrees, then state ***Right bundle branch block, plus right ventricular hypertrophy***.

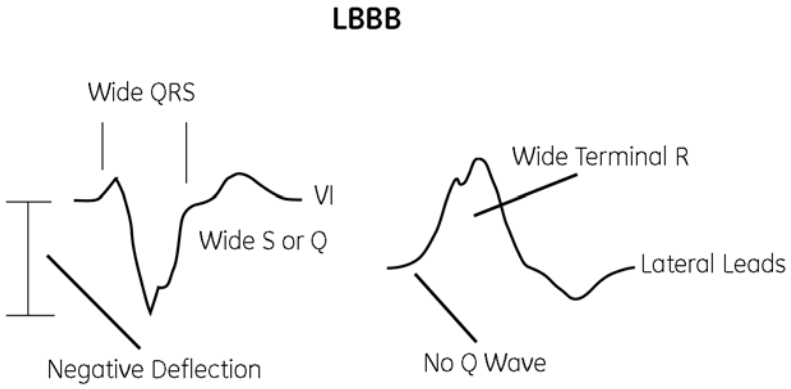
If RBBB is true, suppress *right axis deviation* and *right superior axis deviation*.

If RBBB is true, skip further conduction tests and go to ventricular hypertrophy tests.



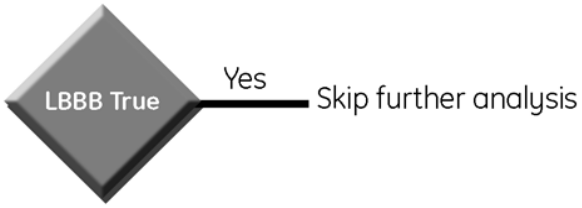
Left Bundle Branch Block

Acronym: LBBB



Tests for ***Left bundle branch block*** examine for a wide QRS, predominantly upright QRS with wide R and/or R' in lateral leads (I and V6), and predominantly negative QRS in leads V1 and V2 with wide Q or S waves.

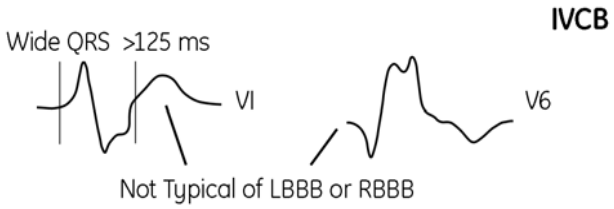
If LBBB is true, skip all further analysis.



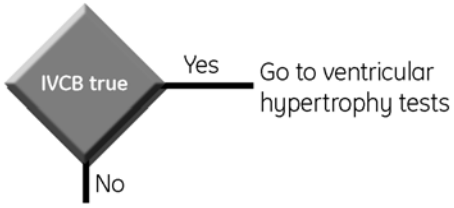
Nonspecific Block

Acronym: IVCB

If the QRS duration is > 125 ms and neither RBBB nor LBBB are stated, then ***Nonspecific intraventricular conduction block*** is stated.



If IVCB is true, go to ventricular hypertrophy tests. If not true, test for incomplete blocks.



INCOMPLETE BLOCKS

Acronyms: IRBBB, RSR, ILBBB

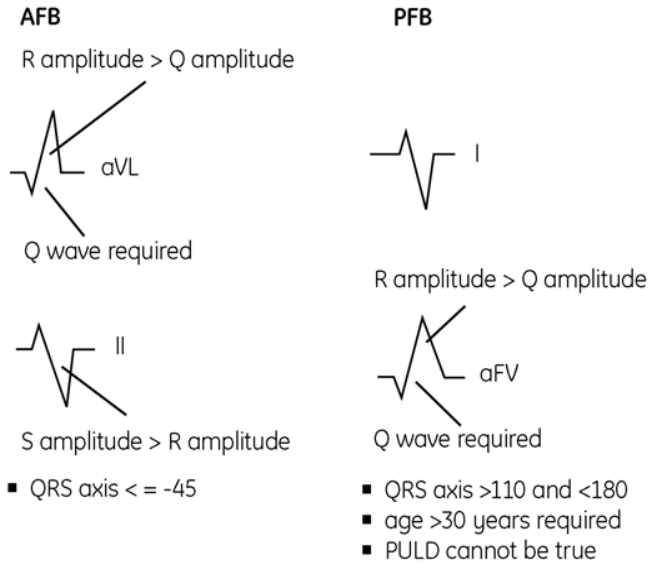
Incomplete right bundle branch block criteria are similar to RBBB, but less stringent. QRS duration is greater than 90 ms and less than 120 ms.

RSR' or QR pattern in V1 suggests right ventricular conduction delay statement requires an RSR' or QR pattern without meeting the criteria for RBBB or IRBBB.

Incomplete left bundle branch block criteria are similar to LBBB, but less stringent. QRS duration is greater than 105 ms and less than 120 ms.

HEMIBLOCKS

Acronyms: AFB, PBF



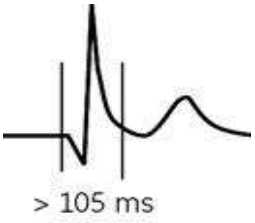
Left anterior fascicular block requires QRS axis ≤ -45 degrees, R amplitude > Q amplitude in leads I and aVL, any Q wave in lead I, and maximum of S and S' is greater than R and R' in lead II.

If LAFB is true, suppress ILBBB and LAD.

Left posterior fascicular block requires age > 30 years, no S1-S2-S3 pattern, no pulmonary disease statement, QRS axis between 110 and 180 degrees, and Q wave present and R amplitude greater than R amplitude in leads III and aVF.

If LPFB is true, suppress RAD.

If either LAFB or LPFB is true and RBBB is also true, then also state ***bifascicular block***.



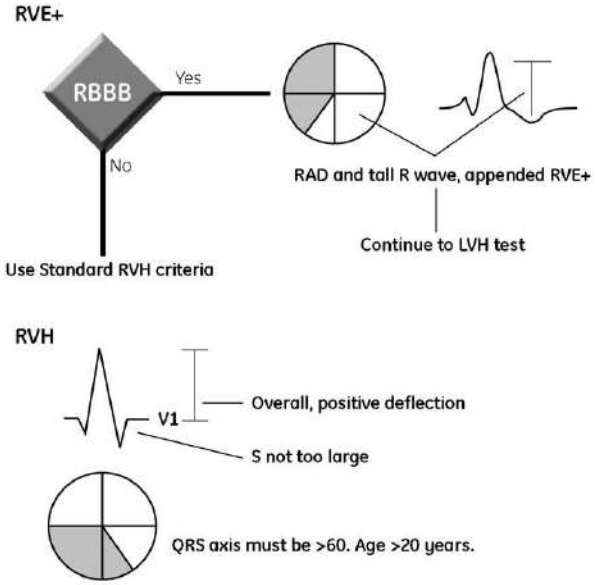
If no conduction abnormality is stated and QRS duration is greater than 105 ms, then state ***Nonspecific intraventricular conduction delay***.

Ventricular Hypertrophies

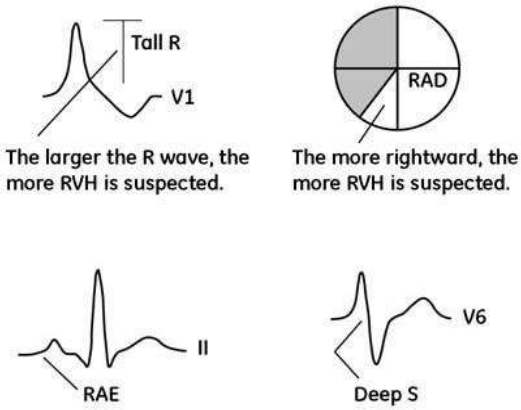
All tests for ventricular hypertrophy are skipped if WPW is stated.

RIGHT VENTRICULAR HYPERTROPHY

Acronyms: RVH, RVE+, 2ST



If RBBB is true and R or R' amplitude > 1500 µV in lead V1 and QRS axis > 110 degrees, then state ***Right bundle branch block, plus right ventricular hypertrophy***.

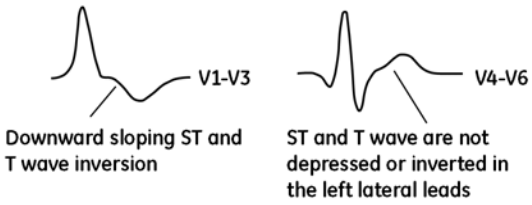


In the absence of RBBB, more standard criteria are used for RVH. In this case, the test is skipped of WPW or Brugada are detected, the QRS amplitude is negative or the S amplitude > 100 µV in V1, or the QRS axis is < 60 degrees.

The RVH tests consider the R or R' amplitude of V1, the S amplitude in V5 or V6, a rightward QRS axis, the presence of right atrial enlargement, patient age, and the presence of the S1-S2-S3 pattern. Depending on the level to which these characteristics exist, the statements ***Possible right ventricular hypertrophy*** or ***Right ventricular hypertrophy*** may be made.

If RVH is true, suppress *rightward axis*, LPFB, LOWV, RSR, and IVCD.

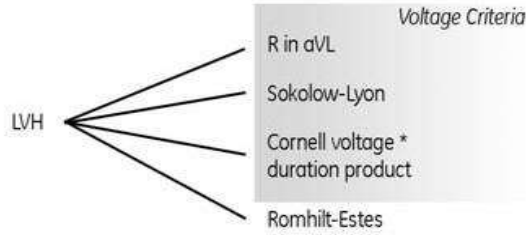
If the program finds a repolarization abnormality that is also indicative of RVH, it will upgrade any RVH call to ***Right ventricular hypertrophy with repolarization abnormality***.



LEFT VENTRICULAR HYPERTROPHY

Acronyms: QRSV, LVH3, LVH, LVH2, 2ST, QRSW, RAVL, SOKLYON, CORNPROD, ROMESTES

The 12SL program incorporates four commonly used LVH criteria from the literature.



In brief, the *R in aVL* test requires the maximum R amplitude of aVL > 1100 > µV.

The *Sokolow-Lyon* voltage is the maximum S amplitude in V1 plus the maximum R amplitude of V5 or V6, whichever is greater. This test requires the Sokolow-Lyon voltage > 3500 µV and age ≥ 30 years.

The *Cornell* product is the product of the Cornell voltage times the QRS duration, where the Cornell voltage is the maximum S amplitude in V3 + the maximum R amplitude in aVL. For women, 600 µV is added to the Cornell voltage. This test requires a Cornell product > 244 µV*sec, age ≥ 30 years, and no RBBB.

The *Romhilt-Estes* test is a well-established point-scoring test for LVH on the ECG that considers maximum R amplitudes in lateral leads, maximum S amplitudes in rightward leads, intrinsicoid deflections and repolarization pattern consistent with LVH in lateral leads (i.e., LV "strain" pattern), left atrial enlargement, QRS axis, QRS duration.

The 12SL program generates four statements related to LVH. In increasing order of severity, these statements are:

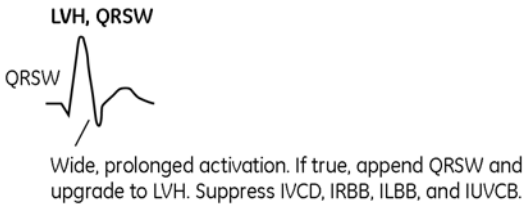
- ***Minimal voltage criteria for LVH, may be normal variant*** (QRSV)
- ***Moderate voltage criteria for LVH, may be normal variant*** (LVH3)
- ***Voltage criteria for left ventricular hypertrophy*** (LVH)
- ***Left ventricular hypertrophy*** (LVH2)

If one or more of the voltage criteria tests are positive, one of the three LVH voltage criteria statements is made. The specific voltage criteria statement depends on the number of positive voltage criteria tests and the patient age.

The program makes the stronger statement ***Left ventricular hypertrophy*** without the phrase *voltage criteria* if the Romhilt-Estes test is positive or if any of the voltage criteria tests are true and the program finds additional indications of hypertrophy, namely left ventricular "strain" pattern, widened QRS, or left atrial enlargement.

For any of the four LVH statements, the names of the any positive tests will be displayed in parentheses at the end of the statement.

If any LVH statement is made, suppress LOWV.



If left ventricular "strain" pattern is observed, then append ***with repolarization abnormality***.

If the QRS duration > 115 ms and not RBBB, then append ***with QRS widening***.

If both of the above conditions are true, then append ***with QRS widening and repolarization abnormality***.

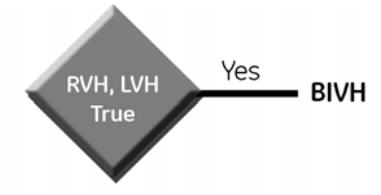
If *with QRS widening* is stated, suppress IRBBB, IVCD, IVDB, and ILBBB.

BIVENTRICULAR HYPERTROPHY

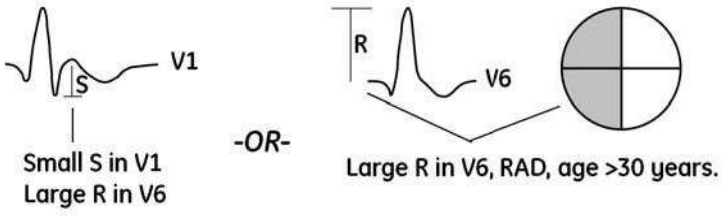
Acronyms: BIVH, 2ST, QRSW

All tests for biventricular hypertrophy are skipped if RBBB is stated.

If both *RVH* and *LVH* are true, then state ***Biventricular hypertrophy***.



It is also possible to call *BIVH* based upon other tests.



If *BIVH* is stated, the program will not make separate statements about *LVH* or *RVH*, they will be suppressed.

If LVH QRS widening is true, then append ***with QRS widening***.

If repolarization abnormality is true for either RVH or LVH, then append ***with repolarization abnormality***.

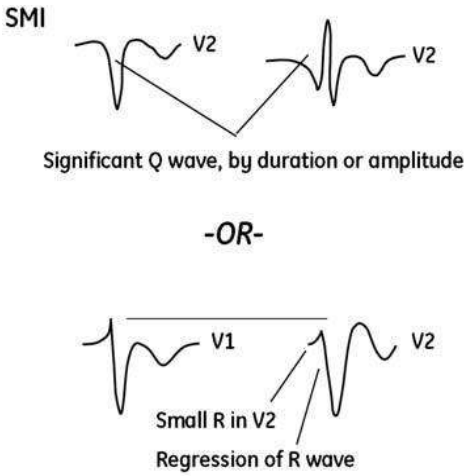
If both of the above conditions are true, then append ***with QRS widening and repolarization abnormality***.

Infarction / Poor R-wave progression

All tests for infarction are skipped if WPW or LBBB is stated.

SEPTAL MYOCARDIAL INFARCTION

Acronym: SMI

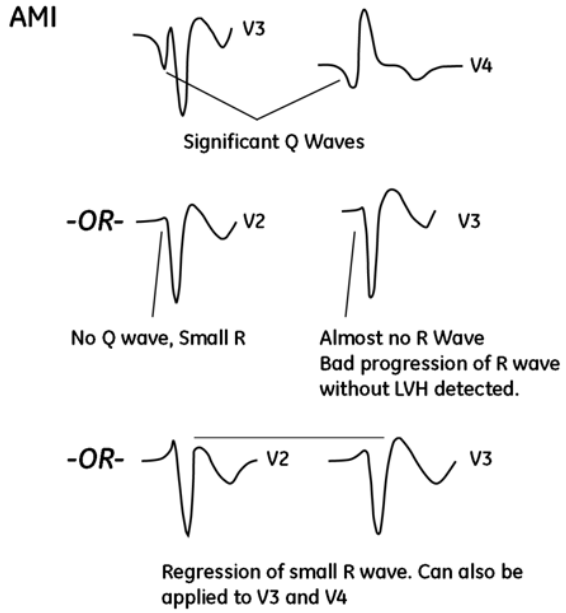


Degree of confidence is based on repolarization. If the ST is elevated, with terminal or complete T wave in version, ***Septal infarct*** is stated without qualification, otherwise it is preceded by ***Cannot rule out***.

If *anterior* injury is present, then append: ***, possibly acute***, otherwise, append: ***, age undetermined***.

ANTERIOR MYOCARDIAL INFARCTION

Acronym: AMI



Depending on the degree of Q wave width or R-wave regression, the program may state one of the following, in increasing order of severity:

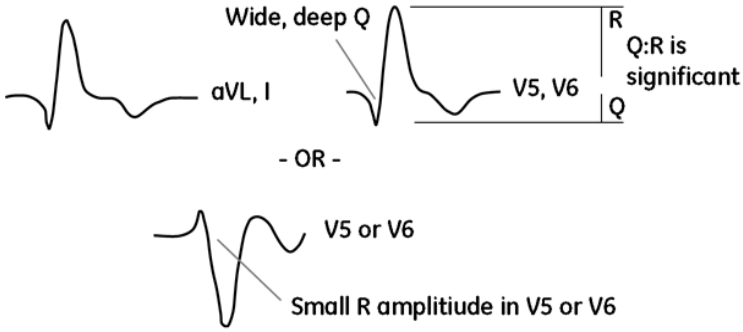
- ***Cannot rule out anterior infarct***
- ***Possible anterior infarct***
- ***Anterior infarct***

If anterior injury is present, then append: ***, possibly acute***, otherwise, append: ***, age undetermined***.

LATERAL MYOCARDIAL INFARCTION

Acronym: LMI

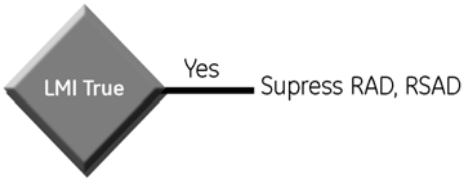
The program looks for R wave regression or poor R wave progression in V5 and V6 and also considers if at least two of the four lateral leads have wide and deep Q waves that have significant Q:R ratios.



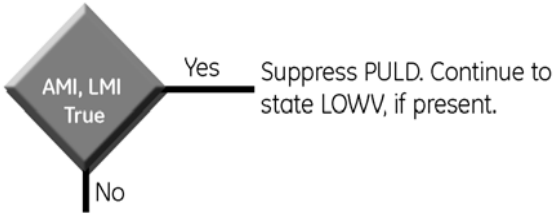
If the criteria detected significant Q waves, it states an unqualified ***Lateral infarct***; otherwise it will prepend ***Possible***.

If inferior injury is present, then append: ***, possibly acute***, otherwise, append: ***, age undetermined***.

If *LMI* is true, suppress all statements concerning right axis deviation.



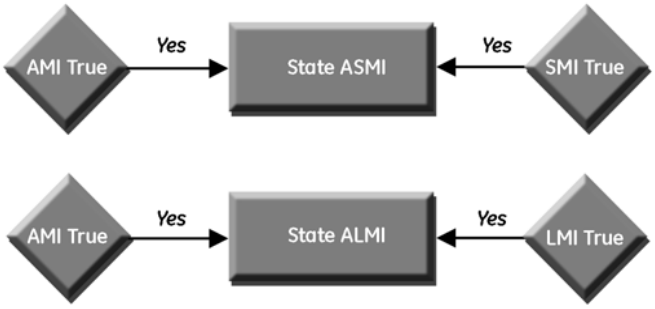
If *AMI* or *LMI* is true, suppress *PULD*.



INFARCTIONS SPANNING CONTIGUOUS PRECORDIAL REGIONS

Acronyms: ASMI, ALMI

At this point the program will issue conjunctions of the different MIs it detected in the horizontal plane, namely, ***Anteroseptal infarct*** or ***Anterolateral infarct***.



INFERIOR MYOCARDIAL INFARCTION

Acronym: IMI

Depending on the significance of Q waves in leads II and aVF, the program may state one of the following, in increasing order of severity:

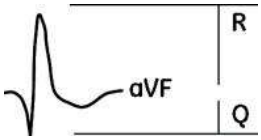
- ***Cannot rule out inferior infarct (masked by fascicular block?)***
- ***Cannot rule out inferior infarct***
- ***Possible inferior infarct***
- ***Inferior infarct***

If extra lead V4r is present and has ST elevation, then append ***with right ventricular involvement***.

If inferior injury is present or extra lead V4r has ST elevation, then append: ***, possibly acute***, otherwise, append: ***, age undetermined***.

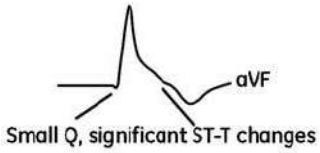
The first statement above requires the detection of *left anterior fascicular block* but will be overridden if criteria for one of the stronger statements is met.

Significant Q:R ratio is the main component of the IMI tests.

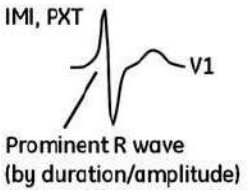


The significance of the Q:R ratio is evaluated in conjunction with other parameters, namely: Q amplitude, Q duration, QRS axis, and presence of Q in lead II.

The qualification of the infarct is based upon the QRS and repolarization. Small Q waves in aVF will be qualified as ***cannot rule out*** or ***possible*** unless there are ST-T changes commensurate with infarction.



If *IMI* is true, then inspect for posterior involvement.



If posterior involvement is found, then instead state ***Inferior-posterior infarct***.

POSTERIOR MYOCARDIAL INFARCTION

Acronym: POSTMI

Tests for true posterior infarct are skipped if any of the following are true: WPW, inferior-posterior, septal, or anterior infarct, anterior injury, RBBB, IRBBB, RVH, age ≤ 30 years, or QRS duration ≥ 120 ms.

This test looks for changes in leads V1 - V3 that could be considered reciprocal changes to the posterior wall. For example, a posterior Q wave becomes a larger than expected R wave and/or posterior ST elevation exhibits as ST depression in the reciprocal leads.

This test requires positive QRS balance in leads V1 and V2, or V2 and V3, along with ST depression and upright T waves in V1 and/or V2.

If PMI is true, then state ***Posterior infarct***.

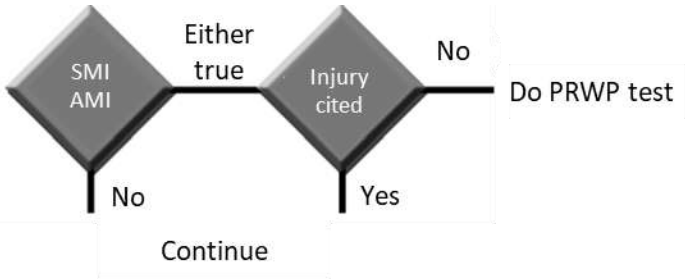
If the max ST elevation in V2 < -150 µV, then append: "***, possibly acute***, otherwise, append: ***, age undetermined***".

If the strict criteria for PMI are not met but the R wave of V1 is larger than expected with no evidence of reciprocal ST depression in the septal leads, then state ***Increased R/S ratio in V1, consider early transition or posterior infarct***.

POOR R-WAVE PROGRESSION

Acronym: PRWP

This test is skipped if neither AMI nor SMI are stated, or if anterior injury is present.



If *possible* or *cannot rule out anterior* and/or *septal infarct* is detected with no corresponding injury pattern (i.e., ST elevation), the program takes a second look at some of the discrete tests within the septal and anterior infarct criteria. It specifically looks for patterns of poor R-wave progression that are more likely to be due to precordial electrode misplacement than an age-undetermined infarct.

If detected, state ***Poor R wave progression*** instead of the anterior and/or septal infarct statement.

Depending on which of the septal and/or anterior infarct tests were positive, append one of:

- **; consider septal infarct, lead placement, or normal variant**

- **; consider anterior infarct, lead placement, or normal variant**
- **; consider anteroseptal infarct, lead placement, or normal variant**

ST Elevation Abnormalities

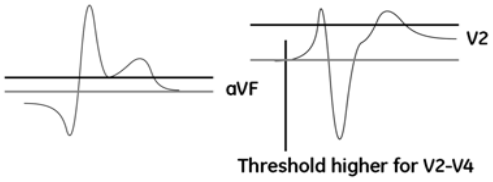
Skip all tests for ST elevation abnormalities if WPW, LBBB, or ventricular rate > 120 bpm and RBBB.

EPICARDIAL INJURY

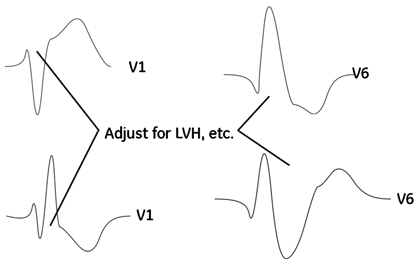
Acronyms: AC, INJ, AINJ, LINJ, IINJ, ALINJ, ILINJ, AIOHAI, LIOHAI, IIOHAI, ALIHAI, ILIHAI

Three items are used for stating injury: *degree of ST elevation*, *ST:T ratio*, and *reciprocal changes*.

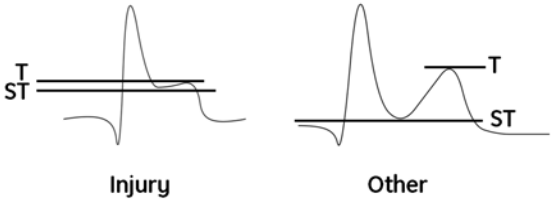
All leads are inspected for *ST elevation*. Anteroseptal leads are tested with a higher threshold than the other leads.



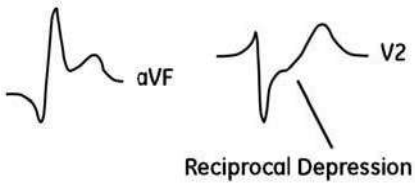
The thresholds are also adjusted for repolarization abnormalities that can occur with *LVH* and/or conduction abnormalities.



If any lead is over threshold, the program then applies several additional tests. As the *ST:T ratio* gets larger, the program considers the character of the *STT* to be more like injury.

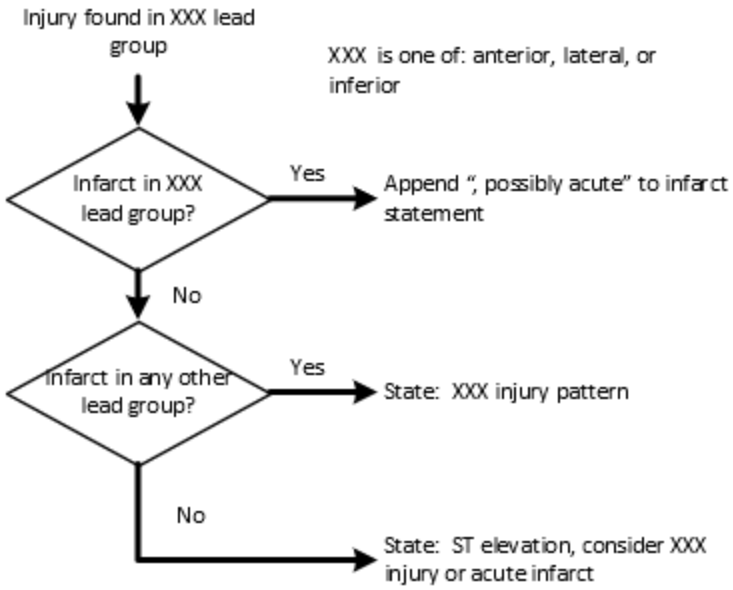


All leads on the opposite side of the ST vector are analyzed for *reciprocal depression*. If present, the ST elevation is considered more like injury.



Injury is stated for those lead groups where it is most pronounced (anterior, lateral, inferior).

As shown in the diagram below, the specific way the injury is stated depends on the presence of an infarct in the same lead group, an infarct in a different lead group, or no infarct present.



If an infarct has already been cited for that lead group, then the program does not state injury separately. Instead, it qualifies the MI as acute. For example, it appends "***, possibly acute***" to the infarct statement instead of the "***, age undetermined***" that would otherwise be appended to the infarct statement.

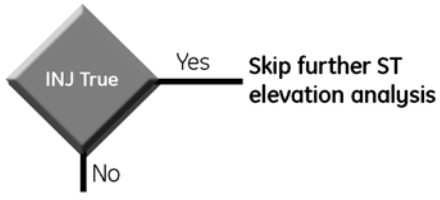
If an infarct has been cited for a different lead group (with or without injury) but not for the lead group with the injury pattern, the program will state ***XXX injury pattern***, where XXX is anterior, lateral, or inferior.

If no infarcts have been cited, the program will state ***ST elevation, consider XXX injury or acute infarct***, where XXX is anterior, lateral, or inferior.

Similar to what is done for describing infarctions, the "XXX" will be combined for anatomically contiguous lead groups with injury, i.e., anterior injury + lateral injury = anterolateral injury and inferior injury + lateral injury = inferolateral injury.

15-lead ECG only: If inferior injury is cited and extra lead V4r is present and has ST elevation, the statement ***with right ventricular involvement*** will be appended to the applicable inferior injury statement.

If injury has been stated, do no further analysis of ST elevation abnormalities.



The program has three choices
(1) pericarditis,
(2) early repolarization, or
(3) unknown origin.

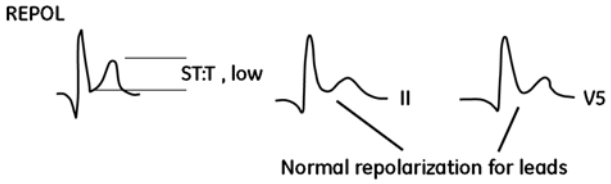
EARLY REPOLARIZATION

Acronyms: SERYR2, REPOL

Early repolarization is stated if the ST:T ratio is low and the repolarization characteristics appears normal (that is, T waves are upright in appropriate leads, the ST concordant with the T wave and no reciprocal ST depression).

One of two statements may be made for early repolarization, depending on the amount of ST elevation, the number of leads with ST elevation and the number of leads with taller T waves:

- ***ST elevation, probably due to early repolarization***
- ***Early repolarization***



ACUTE PERICARDITIS

Acronym: PCARD

This test is skipped if any infarctions are cited or the QRS duration > 120 ms.

Pericarditis has similar criteria to early repolarization except more ST elevation is required. One of two statements may be made:

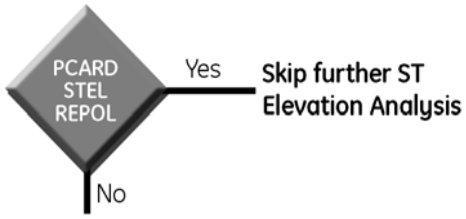
- ***Possible acute pericarditis***
- ***Acute Pericarditis***

ST ELEVATION, MECHANISM UNKNOWN

Acronym: SERYR1

If pericarditis or early repolarization cannot be stated, the program identifies the ST elevation and suggests the three aforementioned mechanisms: ***ST elevation, consider early repolarization, pericarditis, or injury***.

If *PCARD*, *REPOL*, or *STEL* is stated, skip further ST elevation analysis.



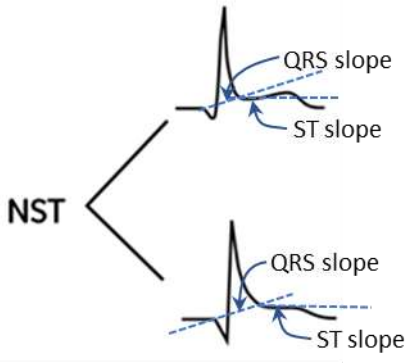
NONSPECIFIC ST (ELEVATION) ABNORMALITY

Acronym: NST

This test is skipped if RBBB, Brugada, or any MI stated, or the QRS duration > 120 ms.

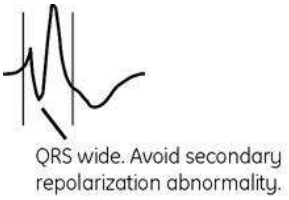
Nonspecific ST elevation abnormality requires that no other ST elevation abnormalities stated and ST elevation > 50 µV, slope from QRS onset to J-point greater than slope of ST segment, and T wave not tall in any 2 of leads I, II, III, aVF, and V3 through V6.

If true, state ***Nonspecific ST abnormality***.

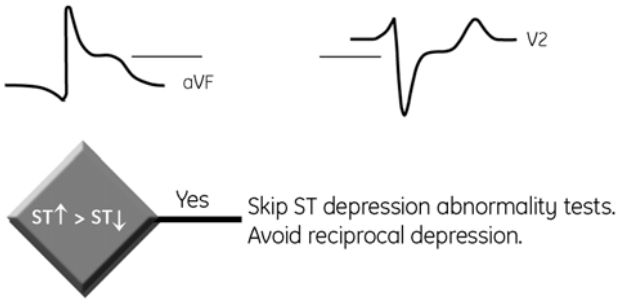


ST Depression Abnormalities

Skip all tests for ST depression abnormalities if WPW, LBBB, or ventricular rate > 120 bpm and RBBB



Skip all tests for ST depression abnormalities if injury has been called and the ST elevation is larger than the depression.

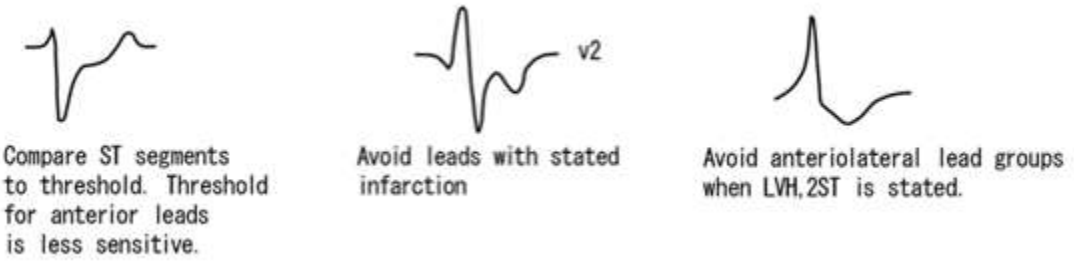


SUBENDOCARDIAL INJURY

Do not test for subendocardial injury if pericardial injury (i.e., ST elevation injury) already stated.

Subendocardial injury is characterized by marked ST depression that is not attributable to other causes of ST depression such as reciprocal depression of ST elevated MI or repolarization abnormality due to ventricular hypertrophy.

Thresholds for subendocardial injury are -100 µV for frontal plane leads and -200 µV for precordial leads.

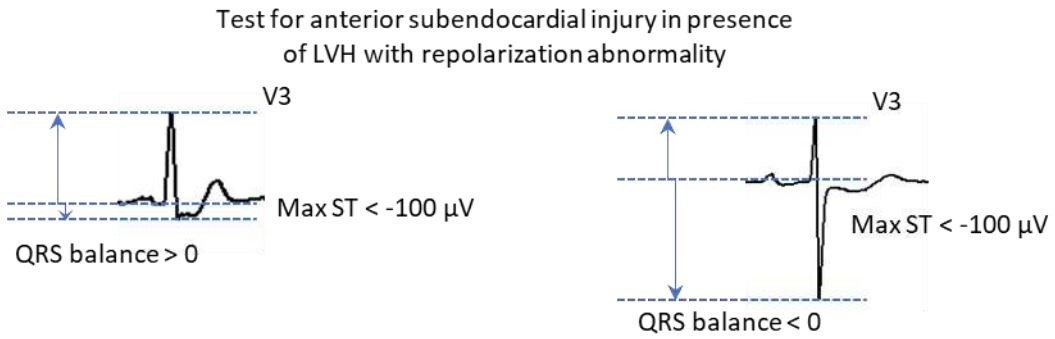


Septal subendocardial injury requires no septal MI, no posterior MI, and the maximum ST of either V1 or V2 below the threshold.

Anterior subendocardial injury requires no anterior MI, no posterior MI, no LVH with repolarization abnormality, and the maximum ST of either V3 or V4 below the threshold.

Further, a second test is done for anterior subendocardial injury that allows for the presence of *LVH with repolarization abnormality*. This test is not performed if any of the following are true: any subendocardial injury, pericardial injury, acute infarction, posterior MI, RBBB, LBBB, and QRS duration ≥ 150 ms.

If the QRS balance is negative, the test requires that in at least two of leads V2, V3, and V4, the maximum ST level < -100 µV. If the QRS balance is positive, the test also requires a positive T wave amplitude.



Lateral subendocardial injury requires no lateral MI, no LVH with repolarization abnormality, and the maximum ST of at least one of V5, V6, I, or aVL below their respective thresholds.

Inferior subendocardial injury requires no inferior MI, no LVH with repolarization abnormality, and the maximum ST of either II or aVF below the threshold.

If multiple anatomically contiguous lead groups are true for subendocardial injury, combine as applicable:

- Septal subendocardial injury + anterior subendocardial injury = anteroseptal subendocardial injury
- Anterior subendocardial injury + lateral subendocardial injury = anterolateral subendocardial injury
- Inferior subendocardial injury + lateral subendocardial injury = inferolateral subendocardial injury

State ***Marked ST abnormality, possible XXX subendocardial injury*** for the applicable lead group or groups, where ***XXX*** may be: ***septal, anterior, lateral, inferior, anteroseptal, anterolateral,*** or ***inferolateral***.

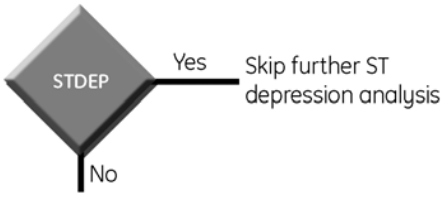
If subendocardial injury is true, skip all further tests for ST depression abnormalities.

If any repolarization abnormality has been stated in association with ventricular hypertrophy, skip all further tests for ST depression abnormalities.

Next, a more generalized and more sensitive test is performed for subendocardial injury. This test does not localize the injury and ignores leads aVR, III, and V1-V3. If RBBB is true, leads V2-V4 are also skipped. Of the remaining leads, the test result is true if at least two of the non-skipped leads have a maximum ST depression < 100 µV.

If true, state ***ST depression, consider subendocardial injury*** *(STDEP)*.

If STDEP is true, skip all further tests for ST depression abnormalities.

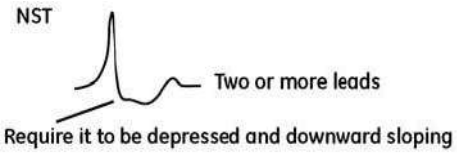


If RBBB or Brugada are true, or nonspecific ST elevation abnormality has already been found from the ST elevation tests, skip all further tests for ST depression abnormalities.

NONSPECIFIC ST (DEPRESSION) ABNORMALITY

Acronym: NST

Analyze the ST segment with even more sensitivity.



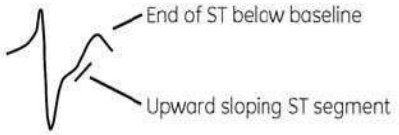
If this occurs in at least two leads, state ***Nonspecific ST abnormality***.

JUNCTIONAL ST DEPRESSION

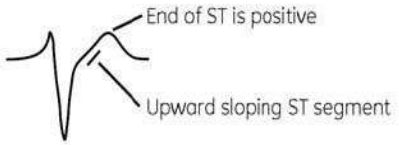
Acronyms: JST, JSTN

Skip tests for junctional ST depression if any infarct is cited.

Junctional ST depression requires the ST level at the J-point (STJ) < -100 µV and an upsloping ST segment in 2 or more leads, excluding leads aVR, V1, V2, and V3.



If true, with negative STE, state: ***Junctional ST depression, probably abnormal***.



If true, with positive STE, state: ***Junctional ST depression, probably normal***.

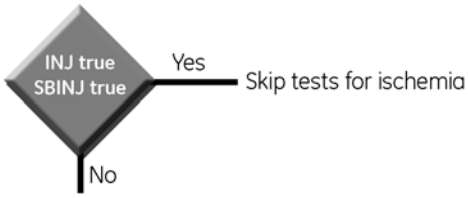
T Wave Abnormalities

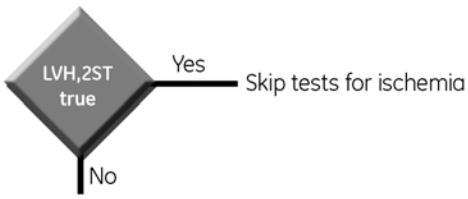
ISCHEMIA

Acronyms: AT, LT, IT, ALT, ILT, MAT, MLT, MIT, MALT, MILT

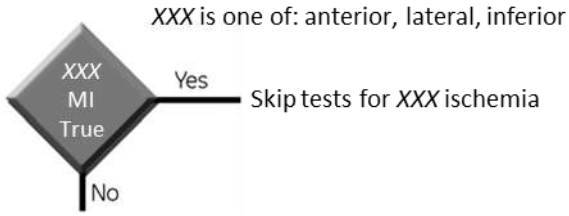
Tests for ischemia look at inverted T waves, after ruling out other causes or confounders.

If any injury statement has been made (i.e., epicardial injury or subendocardial injury), do not test for ischemia. Likewise, if *LVH with repolarization abnormality* is stated, do not test for ischemia.

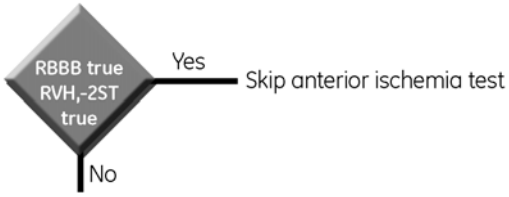




T wave abnormalities are also not tested in lead groups where infarction is stated.



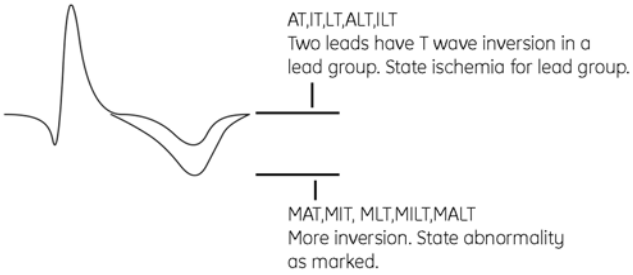
Additional restrictions are applied to anterior leads in order to avoid calling anterior ischemia in the presence of posterior infarct (PMI), Brugada, *RBBB* or right ventricular hypertrophy with repolarization abnormality (*RVH,-2ST*).



For each lead group, the program may state one of the following, in increasing order of severity, where *XXX* is one of anterior, lateral, inferior:

- ***T wave abnormality, consider XXX ischemia***
- ***Marked T wave abnormality, consider XXX ischemia***

For each lead group, tests require two or more leads with special T amplitude < -100 µV for the less severe statement, or two or more leads with special T amplitude < -500 µV for the more severe (*Marked*) statement



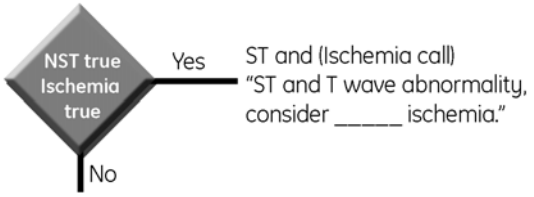
If anatomically contiguous lead groups are true for ischemia, combine as applicable:

- Anterior ischemia + lateral ischemia = ***anterolateral ischemia***
- Inferior ischemia + lateral ischemia = ***inferolateral ischemia***

If one or both lead groups are the more severe "*marked*" level, then the combined statement will say "*marked*".

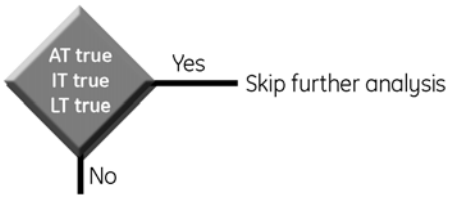
If ischemia is stated and a nonspecific ST abnormality was previously detected, make one statement as opposed to two:

ST & (Marked) T wave abnormality, consider XXX ischemia

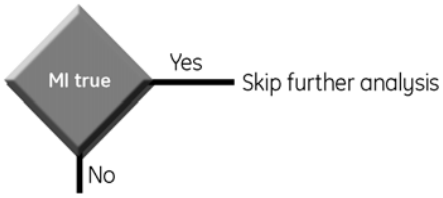


If any ischemia is stated, suppress *Early Repolarization* and *ST elevation, probably due to early repolarization*.

If ischemia is called, skip further analysis of T waves.



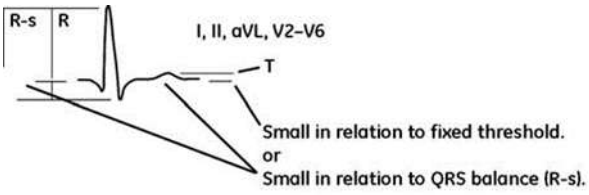
If any infarction is present, skip further analysis of T waves.



NONSPECIFIC T WAVE ABNORMALITY

Acronym: NT

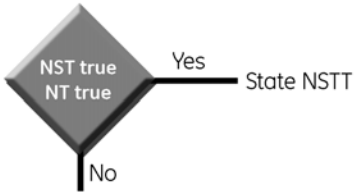
Small T waves or shallow T wave inversion are found in at least two leads.



If the test passes, state ***Nonspecific T wave abnormality***.

If a nonspecific ST abnormality is found in conjunction with NT, then make one statement as opposed to two:

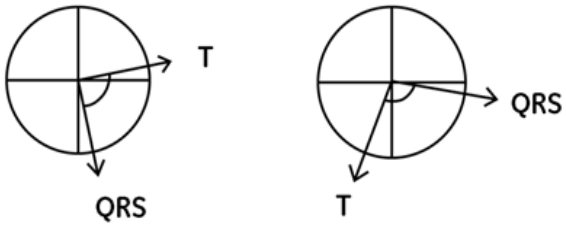
Nonspecific ST and T wave abnormality



ABNORMAL QRS-T ANGLE

Acronym: AQRST

Do not test for abnormal QRS-T angle if any other T wave abnormality has already been stated. This test looks for an abnormal T axis with discordant QRS and T axes.



Abnormal T axis
and
Abnormally large QRS-T angle

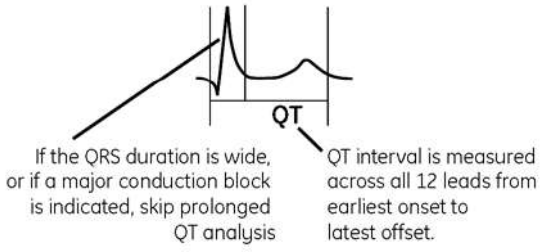
The test requires a difference between the QRS and T axes ≥ 60 degrees and T axis less than 0 degrees or more than 90 degrees.

If test passes, state ***Abnormal QRS-T angle, consider primary T wave abnormality***.

Prolonged QT

Acronyms: LNGQT, LQT480, LQT480FRID, LQT480FRAM

QT interval is corrected for heart rate using the Bazett, Fridericia, or Framingham formula, depending on how 12SL is configured on the acquiring cardiograph. On products where the correction formula is not configurable, the default Bazett correction is used. (See QT Correction Formulas for more information about formulas for QT correction.) As the ventricular rate increases, the corrected QT increases for a given QT interval.



Tests for prolonged QT are skipped if any of the following are true: WPW, IVCB, RBBB, LBBB, QRS duration ≥ 120 ms, or ventricular rate > 120 bpm.

If QTc ≥ 500 ms, then say ***Prolonged QT***.

If the QTc ≥ 480 ms but less than 500 ms, then say ***QTcX >= 480 msec***, where *QTcX* is one of ***QTcB***, ***QTcFrid***, or ***QTcFram***, depending the correction formula used, as described above.

Acute MI / STEMI

Acronyms: STEMI, CRVI

Unless 12SL is running in ACS mode (see ACS Tool Methodology: Neural Network), the statement of acute myocardial infarction will be at the end of the 12SL interpretation, followed only by the classification statement (unless disabled) and the Serial Comparison analysis.

Acute MI will be stated if any of the following are true (where *XXX* is an anatomic lead group):

- Any "***, possibly acute***" infarct statement is made
- Any ***ST elevation, consider XXX injury or acute infarct*** statement is made
- Any ***XXX injury pattern*** statement is made *and* either any "***, age undetermined***" infarct statement is made (or would have been made but was suppressed by Screening Mode) or ***Increased R/S ratio in V1, consider early transition or posterior infarct*** statement is made

If true, state ***** ***** ACUTE MI / STEMI ***** *****.

For standard 12-lead ECGs, if STEMI stated, inferior injury detected, and either ST elevation in lead III is greater than ST elevation in lead II or 2nd or 3rd degree AV block present, then also say ***Consider right ventricular involvement in acute inferior infarct***.

If the ACS Tool is enabled, then instead say ***Inferior injury pattern suggests right ventricular involvement, recommend adding leads V3r and V4r to confirm***.

The above two statements regarding RVI will not be made in the case of a 15-lead ECG that includes extra lead V4r. In that case, the statement with right ventricular involvement will be appended to the applicable inferior injury statement, as noted in the section on epicardial injury.

PEDIATRIC CONTOUR CRITERIA

Wolff-Parkinson-White 78
Dextrocardia 79
Atrial Enlargement 79
QRS Axis 80
Low Voltage QRS 81
Pulmonary Disease Pattern 81
Brugada 81
Conduction Abnormalities 82
Ventricular Hypertrophies 84
Infarction 89
ST Elevation Abnormalities 90
ST Depression Abnormalities 92
T Wave Abnormalities 95
Prolonged QT 98

If an age of 15 years or less is entered, a pediatric analysis is performed, and the program will state ***** ***Pediatric ECG analysis***** at the beginning of the interpretation.

Pediatric analysis employs a set of tables which contain the normal values for 12 different age groups. QRS duration limits are important in the diagnosis of conduction blocks. Amplitude limits are used in the diagnosis of ventricular hypertrophy. See Appendix C: Pediatric Tables.

Listed below are the categories of abnormalities that the pediatric analysis program always checks for. This outline is expanded upon in succeeding figures which describe, in very simplistic terms, the basic flow and logic of the pediatric criteria. Note that the order of the steps is important since information obtained from tests performed earlier in the sequence are applied to subsequent tests.

Pediatric Contour Criteria Summary

Major Category	***Subcategory***	***Acronyms/Statements***
Wolff-Parkinson-White		WPW
Dextrocardia		DEXTRO
Atrial Enlargement		RAE: Right atrial enlargement LAE: Left atrial enlargement BAE: Biatrial enlargement
QRS Abnormalities	QRS Axis	RAD: Right axis deviation LAD: Left axis deviation NWA: Northwest axis INDAX: Indeterminate axis
	Low Voltage QRS	LOWV
	Brugada	BRUG1: Brugada pattern, type 1
	Conduction Abnormalities	RBBB: Right bundle branch block RBBRVH: Right bundle branch block or right ventricular hypertrophy RVE+: plus, right ventricular hypertrophy IRBBB: Incomplete right bundle branch block LBBB: Left bundle branch block ILBBB: Incomplete left bundle branch block

Major Category	*Subcategory*	*Acronyms/Statements*
		IVCB: Intraventricular conduction block IVCD: Intraventricular conduction delay
	Ventricular Hypertrophy	LVH: Left ventricular hypertrophy RVH: Right ventricular hypertrophy BIVH: Biventricular hypertrophy QRSW: with QRS widening
	Myocardial Infarction	LMI, Lateral MI IMI, Inferior MI
ST Abnormalities—QRS Related	ST + T abnormality with Ventricular Hypertrophy (refer to sections on LVH and RVH)	2ST: with repolarization abnormality WSTR: with strain pattern
ST Elevation Abnormalities	Marked ST Elevation	STELIN: ST elevation in ... ANT: anterior leads LAT: lateral leads INF: inferior leads
	Early Repolarization	REPOL: Early repolarization
	Pericarditis	PCARD: Acute pericarditis
	Undefined ST Elevation	STEL: ST elevation, probably due to repolarization, injury, or acute pericarditis
ST Depression Abnormalities	Marked ST Depression	STDEPIN: ST depression in ... SEP: septal leads ANT: anterior leads LAT: lateral leads INF: inferior leads
	Undefined ST Depression	STDEP: ST depression, consider subendocardial injury
	Nonspecific ST Depression	NST: Nonspecific ST abnormality
	Junctional ST Depression	JSTN: Junctional ST depression, probably normal JST: Junctional ST depression, probably abnormal
T Wave Abnormalities	T Wave Inversion	TINVIN: T Wave inversion in ... LAT: lateral leads INF: inferior leads
	Nonspecific	NT: Nonspecific T wave abnormality NSTT: Nonspecific ST and T wave abnormality
	QRS-T Angle	AQRST: Abnormal QRS-T angle
QT Interval		LNGQT: Prolonged QT

Wolff-Parkinson-White

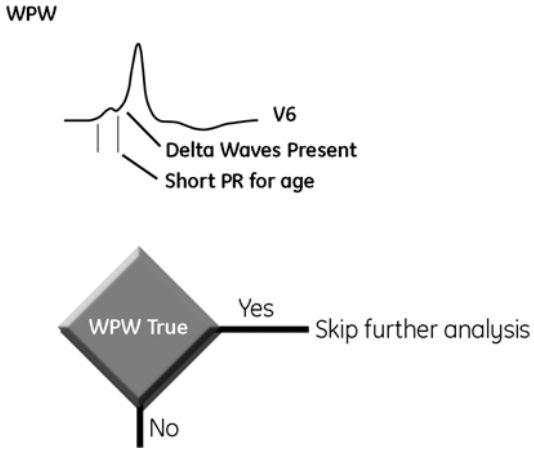
Acronym: WPW

Test is skipped if rhythm is atrial fibrillation, atrial flutter, or no P wave is present.

Wolff-Parkinson-White requires delta waves in three or more of 12 leads, P axis between -30 and 120 degrees, and short PR for age.

WPW type A or type B differentiation is not done for pediatric analysis.

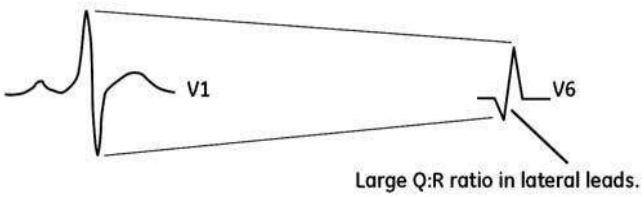
If WPW is stated, all further tests except QT interval abnormalities are skipped.



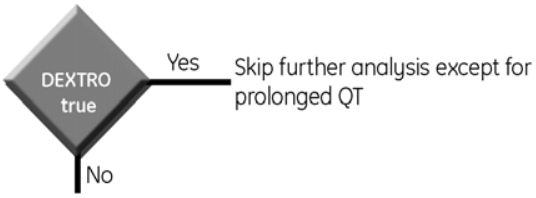
Dextrocardia

Acronym: DEXTRO

The test for ***Dextrocardia*** looks for a QRS deflection much greater in right precordial leads as opposed to left lateral leads.



If *dextrocardia* is stated, do no further analysis except for prolonged QT.



Dextrocardia is not detected for adult ECG analysis (age 16 and older).

Atrial Enlargement

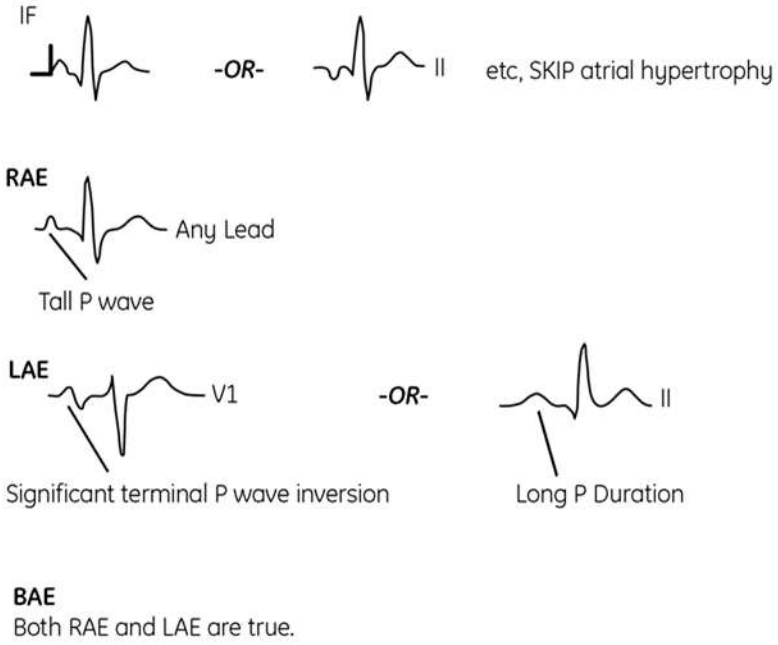
Acronyms: RAE, LAE, BAE

Tests are skipped if WPW, DEXTRO, rhythm is not sinus, or abnormal P axis.

Right atrial enlargement requires P wave amplitude > 250 µV in any of the standard 12 leads.

Left atrial enlargement requires a large positive P wave in lead II or a biphasic P wave in V1 with a large negative P'. This statement may be prepended with the qualifier ***Possible*** if the P in lead II or the P' in V1 is not as large.

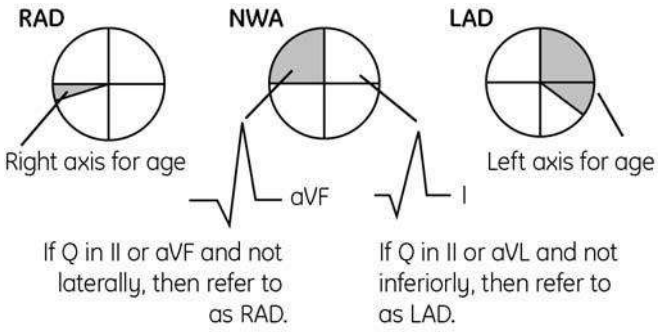
If tests pass for both RAE and LAE, then ***Biatrial enlargement*** is instead stated.



QRS Axis

Acronyms: RAD, NWA, LAD, INDAX

Tests are skipped if WPW or DEXTRO are stated.



To differentiate between *Northwest axis* and *Left axis deviation* when the QRS axis is in the northwest quadrant, Q waves are examined in the frontal leads to avoid stating *Northwest axis* if Q waves provide a hint about differentiating between *Left anterior fascicular block* and *Left posterior fascicular block*. If there is a Q wave in a frontal lateral lead (I, aVL) and in an inferior lead (II, III, aVF), or there are no Q waves in any of those 5 leads, then *Northwest axis* will be stated.

Right axis deviation requires QRS axis ≥ right axis limit for age.

Northwest axis requires age ≥ 1 month, QRS axis between 181 and 270 degrees, and either a Q wave in a lateral lead and in an inferior lead or no Q waves in any of those 5 leads.

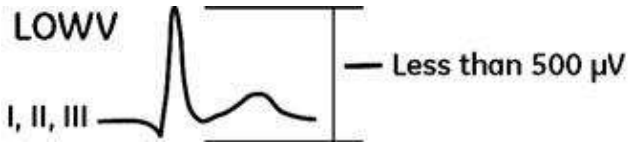
Left axis deviation requires (a) QRS axis between left axis limit for age and -89 degrees, or (b) QRS axis in northwest quadrant, age ≥ 1 month, and at least one Q wave is present in either a lateral lead or an inferior lead, but not in both lead groups.

Indeterminate axis requires absolute value of R amplitude minus S amplitude is <50 µV or <10% of the total QRS deflection in leads I, II, and III (i.e., the QRS complexes of leads I, II, and III are all essentially equiphasic)

Low Voltage QRS

Acronym: LOWV

Tests are skipped if WPW or DEXTRO are stated or if QRS duration > 120 ms.



Low voltage QRS requires (a) QRS deflection of all limb leads < 500 µV or (b) QRS deflection < 1000 µV in all limb leads and < 1500 µV in all precordial leads.

Pulmonary Disease Pattern

Not diagnosed by pediatric program.

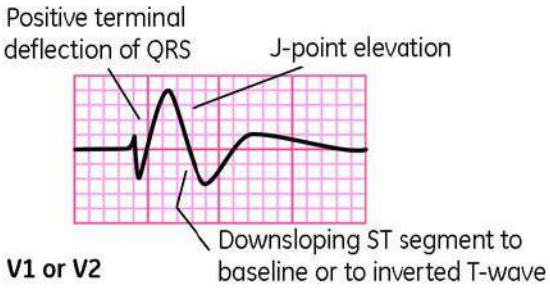
Brugada

Acronym: BRUG1

Test is skipped if WPW or DEXTRO are stated, QRS duration > 150 ms, ventricular rate > 150 bpm, or if age is less than 5 years.

The Brugada type 1 pattern is characterized by a prominent coved ST-segment elevation displaying J-point amplitude or ST-segment elevation ≥ 200 µV at its peak followed by a negative T-wave, with little or no isoelectric separation.

If the Brugada type 1 pattern is found in V1 or V2, and right bundle branch block and anterior injury are ruled out, state ***Brugada pattern, type 1***.



Conduction Abnormalities

The pediatric analysis includes detection of complete and incomplete right and left bundle branch block and nonspecific intraventricular conduction blocks and delays. Hemiblocks (left anterior fascicular block and left posterior fascicular block) are not stated for the pediatric analysis.

All conduction abnormality tests are skipped if WPW or DEXTRO are stated.

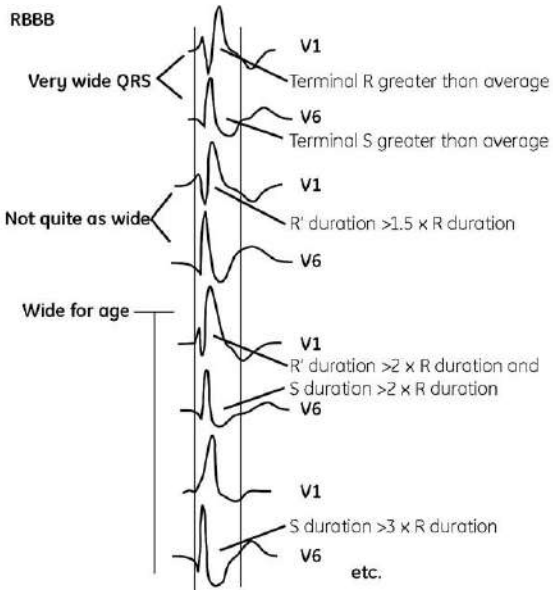
RIGHT BUNDLE BRANCH BLOCK

Acronyms: RBBB, RBBRVH, IRBBB, RVE+

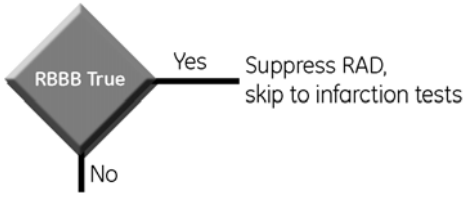
Test is skipped if BRUG is stated.

It is sometimes difficult to discriminate among *RBBB*, *RVH*, or normal variants. The pediatric criteria for *RBBB* is the most complicated of the conduction abnormalities.

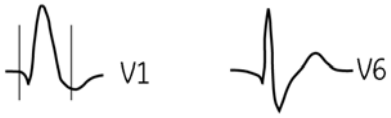
If the QRS is very wide, the program tests for terminal slowing on the right. As the QRS gets narrower, the tests for terminal slowing on the right become increasingly more difficult to pass.



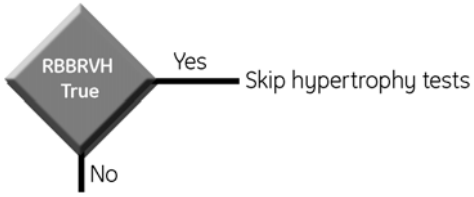
If *RBBB* is true, state ***Right bundle branch block*** and suppress all statements concerning right axis deviation and do not test for hypertrophy.



If the QRS is wide for age and the terminal force is towards the right, but there is no evidence of terminal conduction delay, this could be due to RVH or RBBB. In this case, the program will state ***Right bundle branch block -or- Right ventricular hypertrophy***.

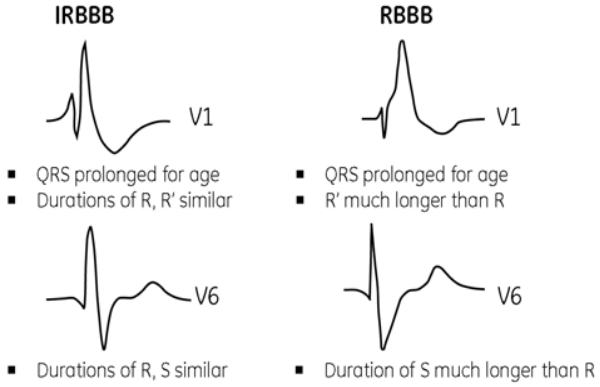


If RBBRVH is called, bypass hypertrophy tests.



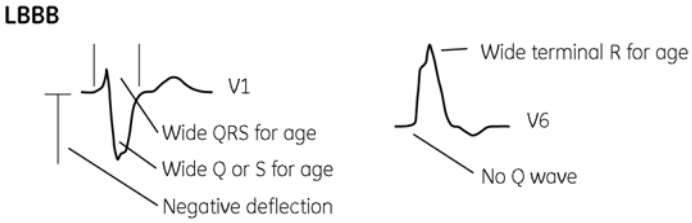
If the QRS has some of the attributes of RBBB, but the rightward terminal slowing is not evident enough for the criteria to state a complete block, the program will state ***Incomplete right bundle branch block***.

If IRBBB is true and the maximum R amplitude is large in V1, the statement "***, plus right ventricular hypertrophy***" will be appended to the IRBBB statement.



LEFT BUNDLE BRANCH BLOCK

Acronyms: LBBB, ILBBB



Tests for ***Left bundle branch block*** examine for a wide QRS for age, predominantly upright QRS with wide R and/or R' in lateral leads (I and V6), and predominantly negative QRS in leads V1 and V2 with wide Q or S waves.

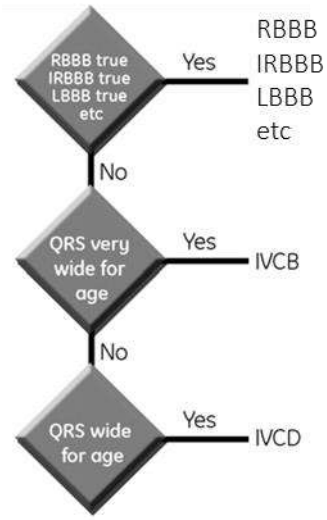
If LBBB is true, skip all further analysis.

The criteria for ***Incomplete left bundle branch block*** are similar to LBBB, but less stringent. The QRS duration is slightly prolonged for age and not as wide as complete LBBB.

NONSPECIFIC BLOCK

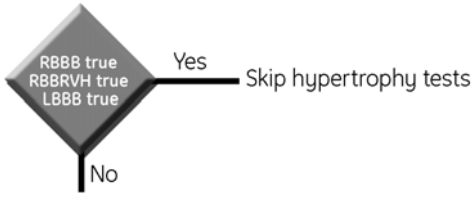
Acronyms: IVCD, IVCB

If a conduction abnormality has not been cited, and the QRS is wide for age, ***Nonspecific intraventricular conduction delay*** or ***Nonspecific intraventricular conduction block*** will be cited.



Ventricular Hypertrophies

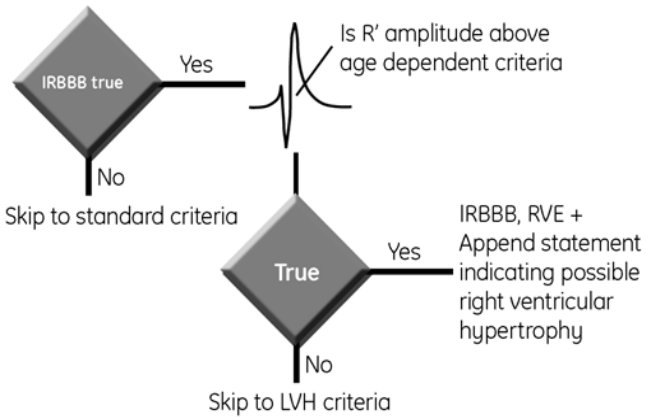
If WPW, DEXTRO, or any complete block has been stated, do not test for ventricular hypertrophy, and continue to test for infarction.



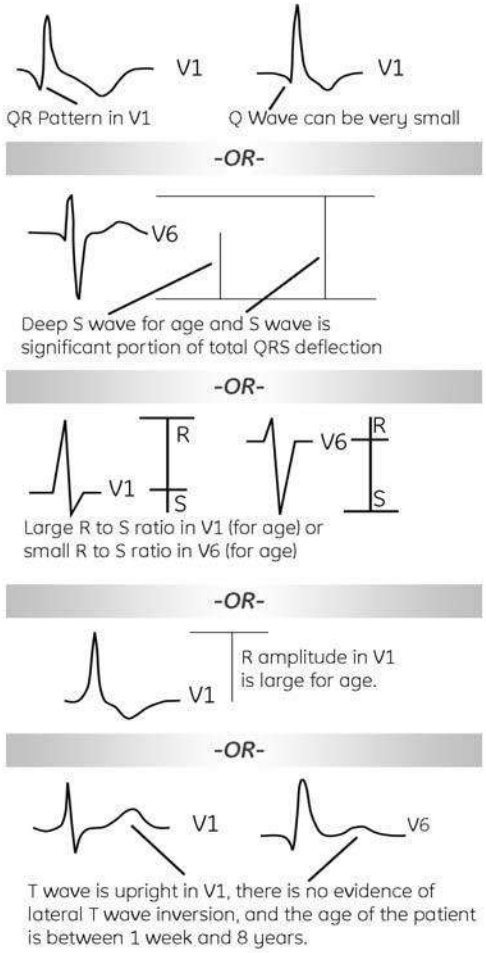
RIGHT VENTRICULAR HYPERTROPHY

Acronyms: RVH, RVE+

If *IRBBB* has been stated, use the special criteria for *RVH* described in the IRBBB section above instead of the standard RVH criteria.

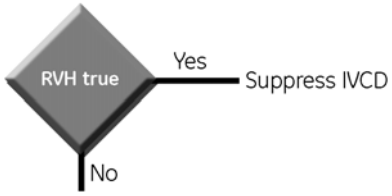


There are several ways in which *RVH* can be diagnosed via the standard criteria. ***Possible right ventricular hypertrophy*** is stated if any of these tests are true.

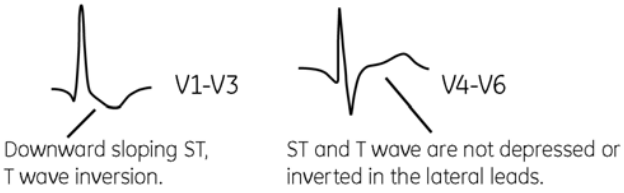


If the R amplitude in V1 is large for age, or there is a QR pattern in V1, the program states ***Right ventricular hypertrophy*** without the prefix *possible*.

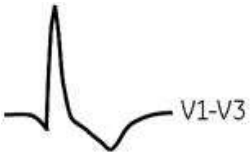
If *RVH* is stated (with or without the prefix *possible*), *IVCD* and *LOWV* are suppressed.



When *RVH* is stated (not *possible RVH*), the repolarization of the right precordial leads is inspected.



If the ST is downward sloping with an inverted T wave in V1-V3 and the ST is not depressed and the T not inverted in V4-V6, and is not typical of *RVH* with strain, the program will append ***with repolarization abnormality***.

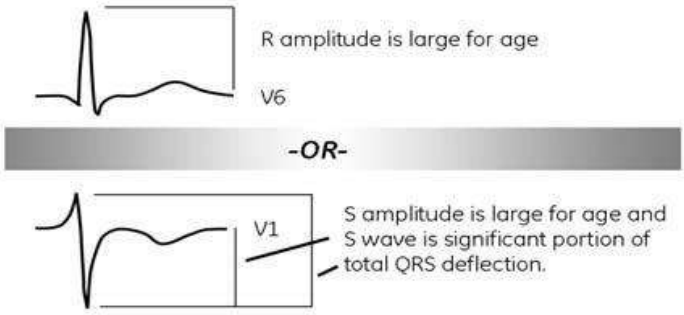


If the ST-T meets the criteria for *RVH* with repolarization abnormality and also meets more rigid criteria for strictly downward sloping (STM > STE > T amplitude and T amplitude < -200 µV in at least two of V1-V3), the program will append ***with strain pattern***.

LEFT VENTRICULAR HYPERTROPHY

Acronym: LVH

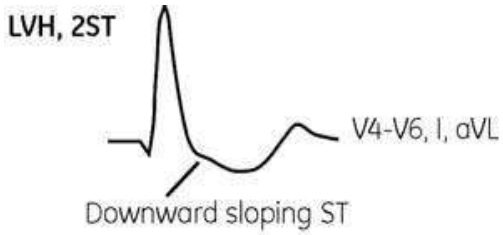
The criteria first examine the voltage in leads V1 and V6.



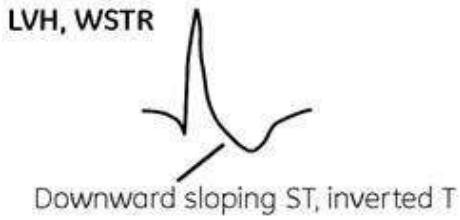
If either of these criteria are true, the program will state ***Possible left ventricular hypertrophy***. If the voltage significantly exceeds these criteria, the program will state ***Left ventricular hypertrophy*** without any qualifier.

Repolarization in the lateral leads is the next item tested.

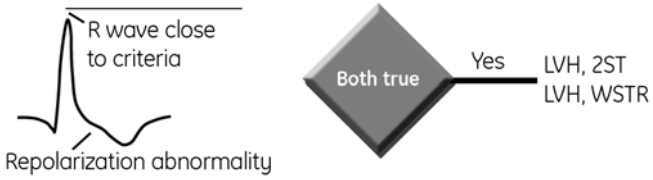
If this repolarization abnormality is found in conjunction with voltage criteria for *LVH*, the program will state: ***Left ventricular hypertrophy with repolarization abnormality***.



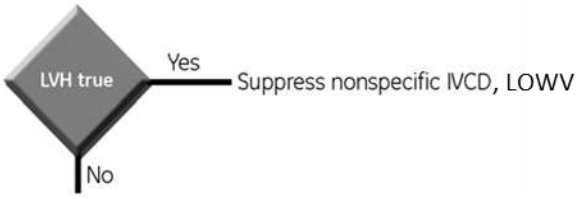
If the ST-T meets the criteria for *LVH with repolarization abnormality* and also meets more rigid criteria for strictly downward sloping (STM > STE > T amplitude and T amplitude < -200 µV in at least two of V4-V6, I, or aVL), the program will state ***Left ventricular hypertrophy with strain pattern***.



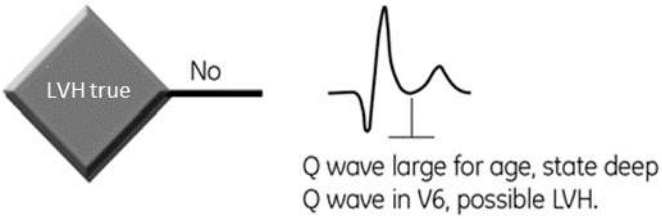
T wave inversion in the lateral leads is abnormal for all ages. If a repolarization abnormality is detected in the lateral leads and the ECG exhibited voltage that was close to the aforementioned criteria, the program would upgrade the diagnosis to *LVH*.



If any *LVH* is cited, suppress the statements *Nonspecific interventricular conduction delay* and *Low voltage*.



If LVH was not cited but the Q wave in V6 is large for age, state ***Deep Q wave in lead V6, possible left ventricular hypertrophy***. This is not considered as LVH in further criteria that includes checks for LVH.

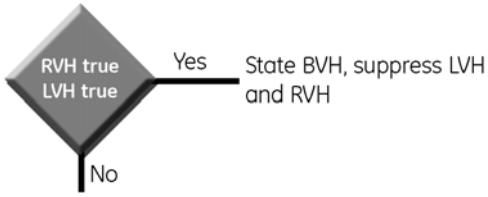


BIVENTRICULAR HYPERTROPHY

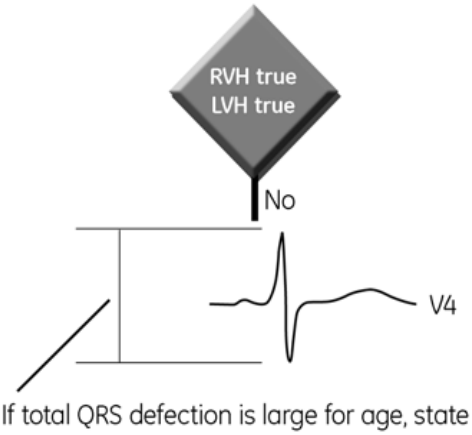
Acronyms: BVH, PMDPV

The way in which the program detects *BVH* is dependent upon what hypertrophy has already been detected by the program.

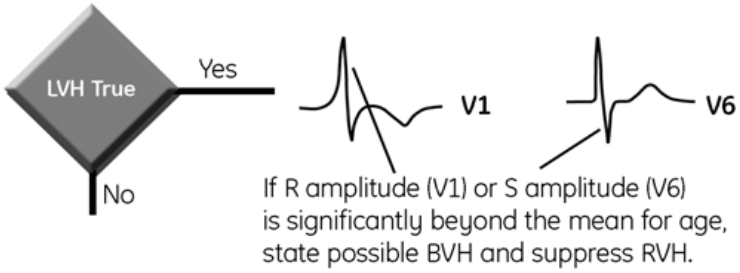
If both *RVH* and *LVH* have already been detected by the program, the program will state ***Biventricular hypertrophy***.



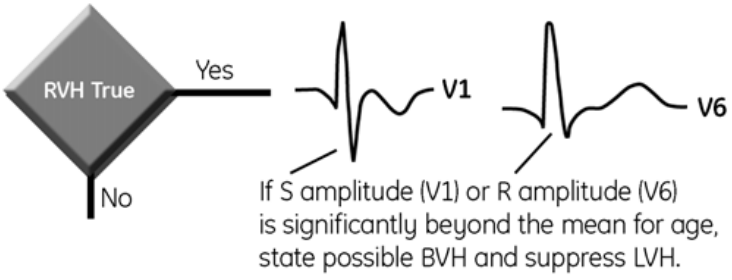
If neither *LVH* nor *LVH* have been detected, then inspect mid-precordial leads. If the total QRS deflection in V4 is large for age and the QRS is balanced (neither predominantly positive nor negative), then state ***Prominent mid-precordial voltage, possible biventricular hypertrophy***.



If definite *LVH* has been detected, then see if there are some indications of *RVH*.



If definite *RVH* has been detected, then see if there are some indications of *LVH*.



In either of the above two cases, ***Possible biventricular hypertrophy*** will be stated.

If any *BVH* statement is made and either *RVH* or *LVH* was stated and included *with repolarization abnormality*, but not *with strain pattern*, then instead state ***Biventricular hypertrophy with repolarization abnormality***.

If any *BVH* statement is made and either *RVH* or *LVH* was stated and included *with strain pattern*, then instead state ***Biventricular hypertrophy with strain pattern***.

Infarction

Note that unlike the adult analysis, dating of infarction is not performed by the pediatric program. That is, unlike the adult analysis, which will always append either , *possibly acute* or , *age undetermined* to any infarction statement, no such modifiers are appended to infarction statements for pediatric analysis.

SEPTAL MYOCARDIAL INFARCT

Not diagnosed by pediatric program.

ANTERIOR MYOCARDIAL INFARCT

Not diagnosed by pediatric program.

LATERAL MYOCARDIAL INFARCT

Acronym: LMI

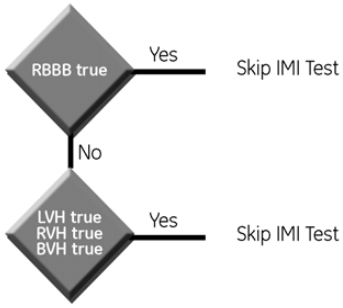
Criteria for lateral MI is very specific. Deep, wide Q waves with a large Q:R ratio in at least three of leads I, aVL, V4, V5, and V6 are required for diagnosis. These criteria are used to avoid the deep Q waves that occur normally in the pediatric ages.

If the criteria are met, state ***Possible lateral infarct*** and suppress *Deep Q wave in lead V6, possible left ventricular hypertrophy*.

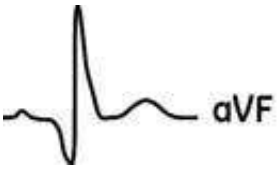
INFERIOR MYOCARDIAL INFARCT

Acronym: IMI

Do not test if RBBB or any hypertrophy is detected.



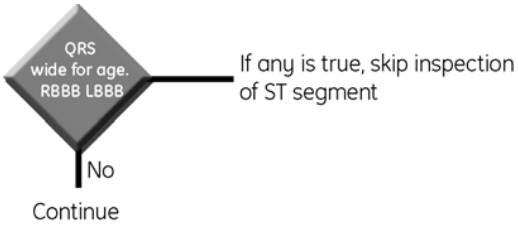
Criteria for inferior MI is very specific. A deep, wide Q wave with a large Q:R ratio in lead aVF is required for diagnosis. These criteria are used in order to avoid the large Q waves that occur normally in the pediatric ages.



If the criteria are met, state ***Possible inferior infarct*** and suppress *Deep Q wave in lead V6, possible left ventricular hypertrophy*.

ST Elevation Abnormalities

If WPW, DEXTRO, LBBB, or RBBB has been stated or the QRS duration exceeds 120 msec, do not test for any ST elevation abnormalities.

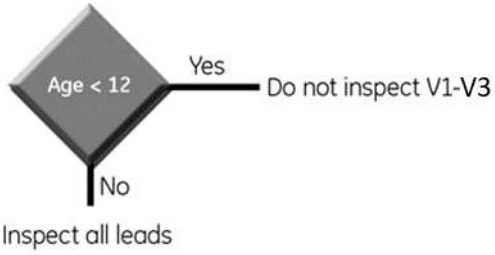


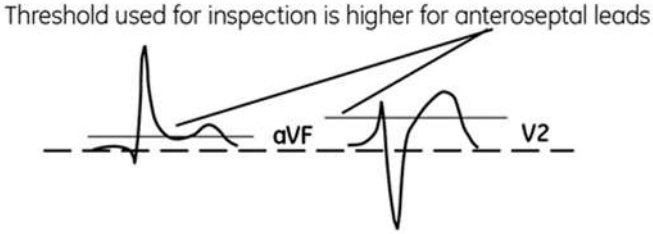
MARKED ST ELEVATION

Acronym: STELIN

The program examines lead groups for ST elevation characteristic of an injury pattern. However, the program will merely state these descriptively rather than mentioning injury, e.g., *ST elevation in anterior leads*.

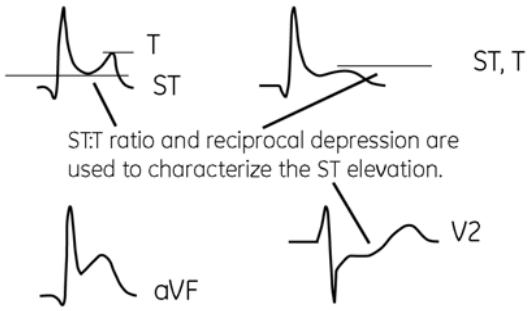
The number of leads inspected for ST elevation is dependent on age.





If any ST segment is over threshold, then several other tests are applied.

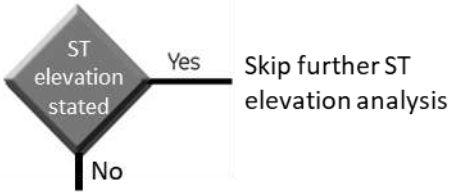
An injury pattern is suspected the larger the ST elevation and ST:T ratio. Reciprocal depression is also considered to be an indicator of injury.



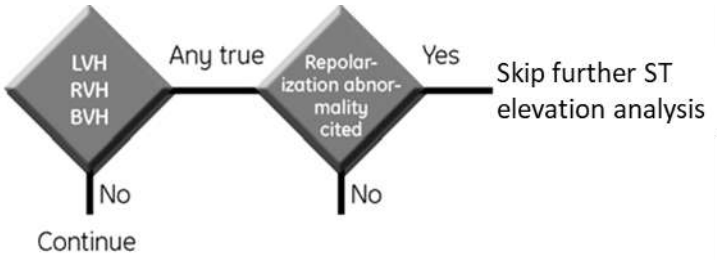
ST elevation that has these injury-like characteristics is stated descriptively by lead group. The following may be stated:

- ***ST elevation in anterior leads***
- ***ST elevation in lateral leads***
- ***ST elevation in inferior leads***
- ***ST elevation in anterolateral leads***
- ***ST elevation in inferolateral leads***

If any of these statements are made, no further ST elevation analysis is done.



If repolarization abnormality has been stated with *RVH*, *LVH*, or *BVH*, do no further analysis for ST elevation abnormalities.



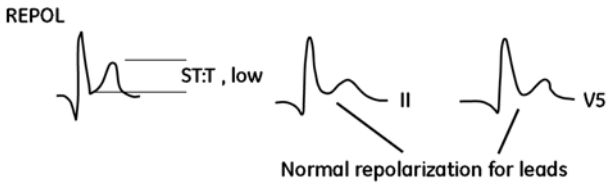
EARLY REPOLARIZATION

Acronyms: SERYR2, REPOL

Early repolarization is stated if the ST:T ratio is low and the repolarization characteristics appears normal (that is, T waves are upright in appropriate leads, the ST concordant with the T wave and no reciprocal ST depression).

One of two statements may be made for early repolarization, depending on the amount of ST elevation, the number of leads with ST elevation and the number of leads with taller T waves:

- ***ST elevation, probably due to early repolarization***
- ***Early repolarization***



ACUTE PERICARDITIS

Acronym: PCARD

This test is skipped if any infarctions are cited or the QRS duration > 120 ms.

Pericarditis has similar criteria to early repolarization except more ST elevation is required. If the criteria are met, ***Possible acute pericarditis*** is stated.

ST ELEVATION, MECHANISM UNKNOWN

Acronym: SERYR1

If pericarditis or early repolarization cannot be stated, the program identifies the ST elevation and suggests the three aforementioned mechanisms: ***ST elevation, consider early repolarization, pericarditis, or injury***.

NONSPECIFIC ST (ELEVATION) ABNORMALITY

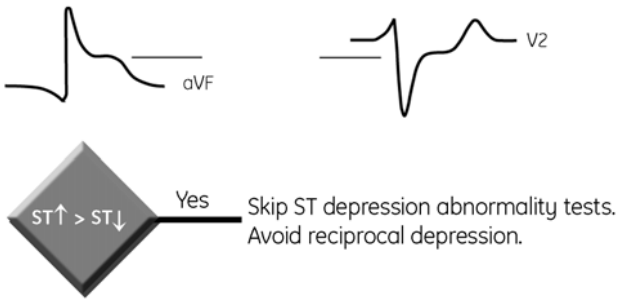
This test, with its associated statement *Nonspecific ST abnormality*, is not done in the pediatric analysis. Note, however, that this same statement may still be made for nonspecific ST depression abnormalities.

ST Depression Abnormalities

Tests for ST depression abnormalities are skipped if any of the following are true:

- WPW or DEXTRO has been stated
- Complete LBBB or RBBB has been stated
- Any ventricular hypertrophy with repolarization abnormality or strain pattern has been stated
- The QRS duration exceeds 100 msec

If ST elevation injury has been called and the ST elevation is larger than the depression, do not test for any ST depression abnormality.



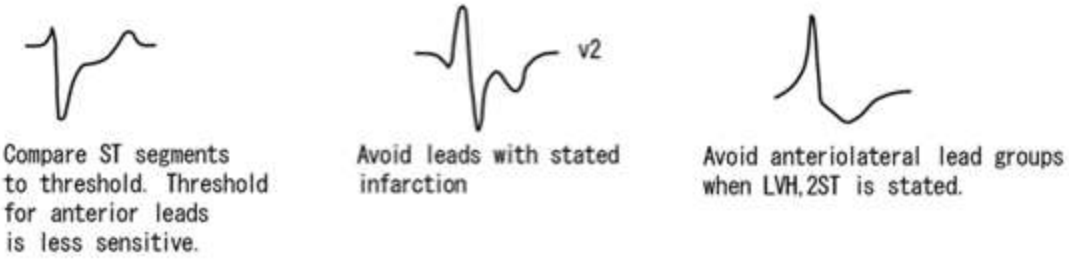
MARKED ST DEPRESSION

Acronym: STDPIN

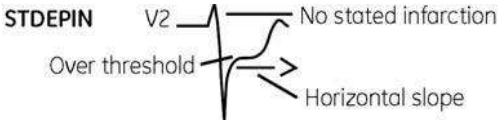
Do not test for significant ST depression if ST elevation injury already stated.

Significant ST depression is characterized by marked ST depression that is not attributable to other causes of ST depression such as reciprocal depression of ST elevated MI or repolarization abnormality due to ventricular hypertrophy.

Thresholds for significant ST depression injury are -100 µV for frontal plane leads and -200 µV for precordial leads.



If all of these conditions are true, state ST elevation in the specific lead group.



ST depression in septal leads requires no septal MI, no posterior MI, and the maximum ST of either V1 or V2 below the threshold.

ST depression in anterior leads requires no anterior MI, no posterior MI, no LVH with repolarization abnormality, and the maximum ST of either V3 or V4 below the threshold.

ST depression in lateral leads requires no lateral MI, no LVH with repolarization abnormality, and the maximum ST of at least one of V5, V6, I, or aVL below their respective thresholds.

ST depression in inferior leads requires no inferior MI, no LVH with repolarization abnormality, and the maximum ST of either II or aVF below the threshold.

If anatomically contiguous lead groups have ST depression, combine as applicable:

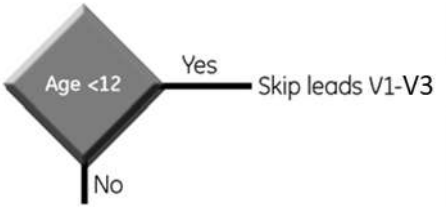
- ST depression in septal leads + ST depression in anterior leads = ST depression in anteroseptal leads
- ST depression in anterior leads + ST depression in lateral leads = ST depression in anterolateral leads

- ST depression in inferior leads + ST depression in lateral leads = ST depression in inferolateral leads

If any significant localized ST depression statements are made, skip all further tests for ST depression abnormalities.

If any repolarization abnormality has been stated in association with ventricular hypertrophy, skip all further tests for ST depression abnormalities.

For remaining ST depression tests, the anteroseptal leads are not inspected if the age is less than 12 years.



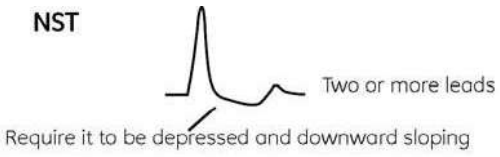
Now look for ST depression as before but with more sensitivity. If true, state ***ST depression, consider subendocardial injury*** and skip further ST depression analysis.

NONSPECIFIC ST ABNORMALITY

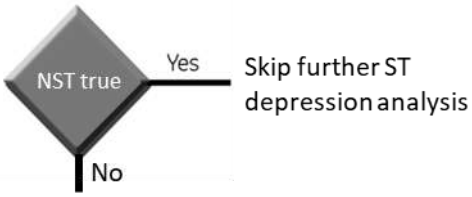
Acronym: NST

Skip this test if any ventricular hypertrophy with repolarization abnormality, RBBB, or BRUG.

Analyze the ST segment with even more sensitivity.



If this occurs in at least two leads, state ***Nonspecific ST abnormality*** and skip further ST depression analysis



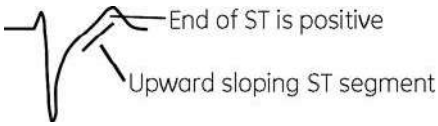
JUNCTIONAL ST DEPRESSION

Acronyms: JSTN, JST

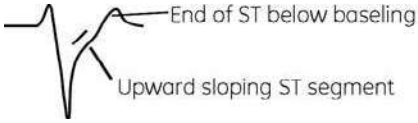
Skip this test if any ventricular hypertrophy with repolarization abnormality, RBBB, BRUG, or any infarct.

Examine leads for upsloping ST segment, where ST at the J-point is less than -100 µV. Skip lead aVR. For age less than 12 years, also skip V1-V3.

If, in at least two leads, the STJ is less than -100 µV and STE is positive, state: ***Junctional ST depression, probably normal***.

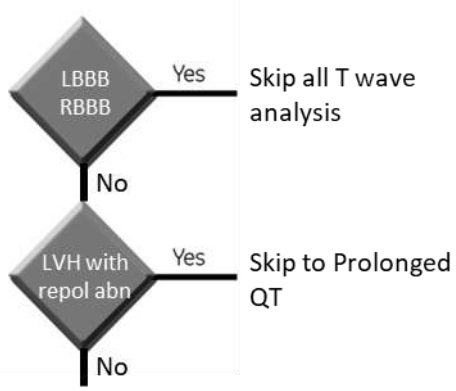


If, in at least two leads, the STJ is less than -100 µV and STE is greater than one half of STJ, state: ***Junctional ST depression, probably abnormal***.



T Wave Abnormalities

Do not test for any T wave abnormalities if LBBB or, RBBB. If LVH with repolarization abnormality or strain pattern, skip to Prolonged QT.



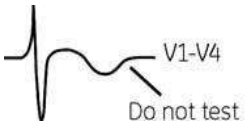
T WAVE INVERSION

Acronym: TINVIN

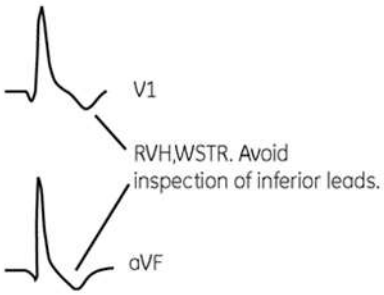
Examine leads for inverted T waves. If T waves are inverted, then state descriptively as opposed to stating ischemia.

If an infarct has been cited, skip T wave inspection of leads in the respective lead group(s).

Anteroseptal leads V1–V4 are not inspected as T wave inversion in this lead group is normal for pediatric ages.

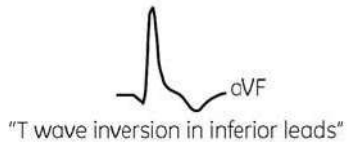


If *RVH with strain pattern* was noted, do not inspect inferior leads.



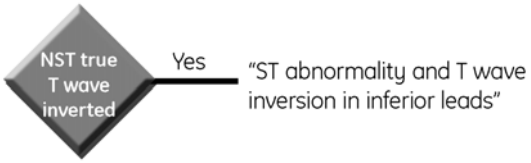
If two or more lateral leads (V5, V6, I, aVL) have inverted T waves, state ***T wave inversion in lateral leads***.

If T is inverted in lead II or lead aVF is predominantly upright with an inverted T wave, state ***T wave inversion in inferior leads***.



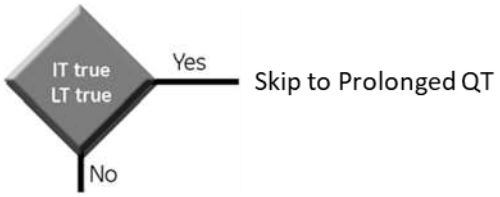
If T wave inversion noted in both lateral and inferior lead groups, instead state ***T wave inversion in inferolateral leads***.

If a nonspecific ST abnormality was previously detected, make one statement as opposed to two by pre-pending the statement ***ST abnormality and*** to the *T wave inversion* statement.

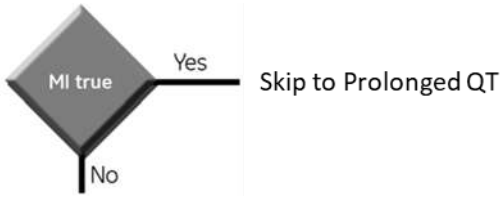


If any T wave inversion is stated, suppress *Early Repolarization* and *ST elevation, probably due to early repolarization*.

If *T wave inversion* is stated, skip to Prolonged QT.



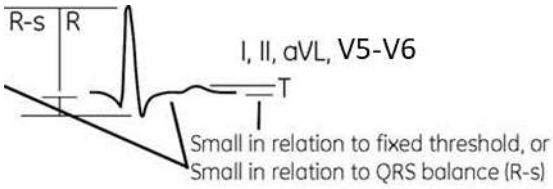
If *infarction* is present, skip to Prolonged QT.



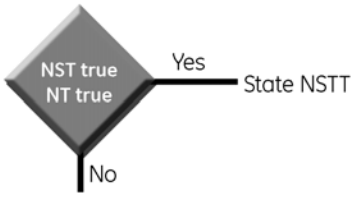
NONSPECIFIC T WAVE ABNORMALITY

Acronyms: NT, NSTT

If small T waves or shallow T wave inversion are found in at least two leads, state ***Nonspecific T wave abnormality***.



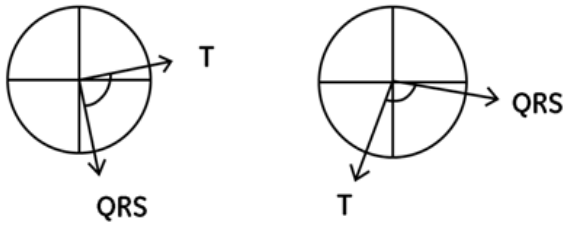
If a nonspecific ST abnormality is found in conjunction with NT, then make one statement as opposed to two and instead state ***Nonspecific ST and T wave abnormality***.



ABNORMAL QRS-T ANGLE

Acronym: AQRST

Do not test for abnormal QRS-T angle if any other T wave abnormality has already been stated. This test looks for an abnormal T axis with discordant QRS and T axes.



Abnormal T axis
and
Abnormally large QRS-T angle

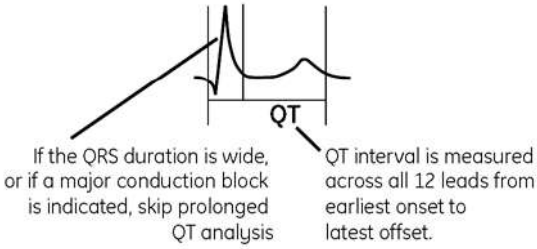
The test requires a difference between the QRS and T axes ≥ 60 degrees and T axis less than 0 degrees or more than 90 degrees.

If test passes, state ***Abnormal QRS-T angle, consider primary T wave abnormality***.

Prolonged QT

Acronyms: LNGQT, SNDQA, BO

QT interval is corrected for heart rate using the Bazett, Fridericia, or Framingham formula, depending on how 12SL is configured on the acquiring cardiograph. On products where the correction formula is not configurable, the default Bazett correction is used. (See QT Correction Formulas for more information about formulas for QT correction.) As the ventricular rate increases, the corrected QT increases for a given QT interval.



Tests for prolonged QT are skipped if any of the following are true: WPW, IVCB, RBBB, LBBB, QRS duration ≥ 120 ms.

Prolonged QT will also be skipped if the ventricular rate exceeds the maximum of 180 bpm and 120% of the age-dependent tachycardia limit (refer to Pediatric Tables in the Appendix). This ventricular rate cut-off will be 180 bpm for patients from 3 through 15 years old. The cut-off will be higher than 180 bpm for pediatric patients less than 3 years old.

If QTc ≥ 460 ms and < 480 ms, then say ***Borderline Prolonged QT***.

If QTc ≥ 480 ms, then say ***Prolonged QT***.

If any hypertrophy, incomplete block, or nonspecific conduction abnormality is cited, then append ***, may be secondary to QRS abnormality***.

Screening Criteria: Suppressed Statements, Increased Specificity

With *Screening Criteria* turned on at the electrocardiograph (also referred to as Hi-Spec, or High Specificity mode) certain lower-acuity 12SL statements are suppressed from appearing on the report. By suppressing these statements when *Screening Criteria* is turned on, 12SL is placed in a higher specificity mode; that is, fewer interpretive statements will be generated. Most statements that are suppressed are either of lower clinical acuity, such as "incomplete right bundle branch block", or represent lower confidence levels of abnormalities, such as those prefixed with "cannot rule out" or "possible".

Note that not all platforms offer the screening mode as a user-configurable choice. Screening mode is turned off by default (i.e., statements are not suppressed).

NOTE Running 12SL with the ***Screening Criteria*** turned on can affect the ECG classification. For example, an ECG with the diagnosis ***Normal sinus rhythm; Right axis deviation***, will be classified as an ***Abnormal ECG*** when ***Screening Criteria*** is off. If ***Screening Criteria*** is turned on, ***right axis deviation*** will not be stated, and the ECG will be classified as a ***Normal ECG***.

Statements Suppressed when Screening Criteria Turned On

Statement Text	***Acronym***
Rhythm Statements	
... with undetermined rhythm irregularity	IRREG
... with rapid ventricular response	RVR
... with slow ventricular response	SVR
... with a competing junctional pacemaker	CJP
... with x:1 AV conduction (x=2,3,4,5)	W2T1, W3T1, W4T1, W5T1
... with retrograde conduction	RETC
... [and/with] possible premature atrial complexes with aberrant conduction	[AND/WITH] + PO + PAC + WITH + ABCOND
Axis / Voltage	
Rightward axis	RAD
Right axis deviation	RAD4
Northwest axis *	NWA
Right superior axis deviation	RAD5
Pulmonary disease pattern	PULD
Ventricular conduction	
RSR' or QR pattern in V1 suggests right ventricular conduction delay	RSR
Incomplete right bundle branch block	IRBBB
Nonspecific intraventricular conduction delay	IVCD
Hypertrophy	

Statement Text	***Acronym***
Minimal voltage criteria for LVH, may be normal variant	QRSV
Moderate voltage criteria for LVH, may be normal variant	LVH3
Possible right ventricular hypertrophy	PO + RVH
... plus right ventricular hypertrophy	RVE+
Possible left atrial enlargement	PO + LAE
Possible left ventricular hypertrophy *	PO + LVH
Deep Q wave in lead V6, possible left ventricular hypertrophy *	QV6 + PO + LVH
Possible biventricular hypertrophy *	PO + BIVH
Prominent mid-precordial voltage, possible biventricular hypertrophy *	PMDPV + PO + BIVH
Myocardial Infarction	
Cannot rule out septal infarct	CRO + SMI
Cannot rule out anteroseptal infarct	CRO + ASMI
Cannot rule out anterior infarct	CRO + AMI
Cannot rule out inferior infarct	CRO + IMI
Cannot rule out inferior infarct (masked by fascicular block?)	CRO + IMI + MAFB
Possible anteroseptal infarct	PO + ASMI
Possible anterior infarct	PO + AMI
Possible anterolateral infarct	PO + ALMI
Possible lateral infarct	PO + LMI
Possible inferior infarct	PO + IMI
ST-T	
ST elevation, consider early repolarization, pericarditis, or injury	SERYR1
ST elevation, probably due to early repolarization	SERYR2
Early repolarization	REPOL
Possible acute pericarditis	PO + PCARD
Junctional ST depression, probably normal	JSTN
Junctional ST depression, probably abnormal	JST
Abnormal QRS-T angle, consider primary T wave abnormality	QRST

* Statements marked with asterisk are statements that are only made when doing pediatric ECG analysis (age < 16 years).

ECG Classification

Unless generation of ECG Classification is suppressed in a platform's setup, each ECG is assigned one of the following classifications by the 12SL analysis program (listed in order of increasing severity):

- Normal ECG (N)
- Otherwise normal ECG (O)
- Borderline ECG (B)
- Abnormal ECG (A)

Most statements generated by 12SL have a classification associated with them. Some statements are informative only and do not have an associated classification. These are typically statements that are appended or prepended to a primary statement. The classification of each 12SL statement is given in Appendix B: Statement Library Arranged by Statement Number. The overall ECG classification is made based on the most severe single statement in the 12SL diagnosis.

As a very simple example, say an ECG contained the single 12SL statement: "Normal Sinus Rhythm". The classification for this statement is "N". The overall classification for this ECG would be "Normal ECG".

As another example, say 12SL generated the following statements for an ECG (the classification of each single statement is shown in parentheses):

- Sinus bradycardia (O)
- with frequent (none)
- premature ventricular complexes (O)
- in a pattern of bigeminy (O)
- Left ventricular hypertrophy (A).

In this case, the most severe single statement is "Left ventricular hypertrophy", with a classification of "A", which would result in an ECG classification of "Abnormal ECG".

Decision Support for Acute Coronary Syndromes (ACS)

CONTENTS FOR THIS SECTION

Definition of ACS 102
Requires Diagnosis by a Physician 102
First Step: Get an ECG within 10 minutes 102
Introduction: GE Healthcare's Decision Support for ACS 103
The Challenges Associated with Diagnosing ACS 103
GE Healthcare's Toolset for ACS 107
ACI-TIPI and GE ACS Tool: Probability of ACS 113
Automated Serial Comparison Detects Changes Commensurate with ACS 120
High Sensitivity Troponin and Role of ECG 122

DEFINITION OF ACS

"The term acute coronary syndrome (ACS) refers to any group of clinical symptoms compatible with acute myocardial ischemia and includes unstable angina (UA), non-ST-segment elevation myocardial infarction (NSTEMI), and ST-segment elevation myocardial infarction (STEMI)."[107]

REQUIRES DIAGNOSIS BY A PHYSICIAN

ACS is ultimately a clinical diagnosis made by a physician. Although electrocardiography (ECG) is an essential tool for this purpose, the diagnosis of ACS should not rely solely on ECG findings. In fact, in a study of 391,208 acute myocardial infarctions (AMI), 7.9% (30,759) had a normal initial ECG.[8] In short, a normal ECG does not rule out ACS.[108] Please refer to current ACC/AHA guidelines for the latest information on the diagnosis and management of patients suspected of having an acute coronary syndrome.

> **WARNING** - INTERPRETATION HAZARD: 12SL analyses, including results from either ACI-TIPI or the ACS Tool, should be used only as an adjunct to clinical history, symptoms, and the results of other non-invasive and or invasive tests.
> All reports must be reviewed by a qualified physician.
>
> **WARNING** – INTERPRETATION HAZARD: ACI-TIPI or the ACS Tool, is only intended for adults with symptoms suggestive of ACS. Applying it to all patients without symptoms will result in false-positive interpretations of the ECG as having ECG abnormalities commensurate with ACS.

FIRST STEP: GET AN ECG WITHIN 10 MINUTES

"The standard 12-lead ECG remains the single most important diagnostic tool in the evaluation of ACS and should be performed within 10 minutes of the first contact with medical personnel."[109] A STEMI pattern is the most specific finding for ACS, especially if different from a prior ECG.[110, 111] Clinical guidelines, from across the globe, recommend time-to-treatment benchmarks for STEMI via thrombolytic (30 minutes) or emergency cardiac catheterization (90 minutes).[112, 113]

Prehospital ECG (PHECG) has been found to significantly reduce time-to-ECG and time-to-treatment. The 2015 American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care states "prehospital 12-lead ECG should be acquired early for patients with possible ACS".[114] Likewise, outside the U.S., PHECG is recommended by the European Society of Cardiology (ESC),[115] backed by evidence gathered by UK's national MI registry which shows a survival advantage in STEMI and non-STEMI patients when PHECG is used.[116]

A timely ECG in the emergency department (ED) remains elusive "despite decades of quality-improvement efforts."[117] As opposed to a paramedic attending to a patient as soon as they arrive by ambulance, "the first

10 minutes of an ED visit typically consists of intake processes (registration and triage) that usually occurs well before a physician encounter."[117] In a study published in 2017 which monitored several ED's across the U.S., there was a significant percentage of STEMI cases that did not have an ECG taken within 15 minutes of ED arrival. In fact, on average, 12.8% of all STEMI's missed the 15 minute benchmark, with the best ED at 3.4%, the worst at 32.6% and a case of one STEMI taking over 80 minutes to obtain an ECG.[117] This variation appears to be due to the screening criteria (symptoms etc.) for who should get an ECG; a broader, more inclusive set of criteria seems warranted and is under evaluation.[118]

In any case, time-to-first-ECG is so vital it is a quality and performance metric monitored by several regulatory bodies.[119-122]

INTRODUCTION: GE HEALTHCARE'S DECISION SUPPORT FOR ACS

Since the advent of prehospital ECG for selecting candidates for thrombolytic therapy,[21, 123] GE Healthcare has been developing solutions to assist the physician in the diagnosis of ACS.

GE Healthcare's toolset for ACS includes ECG connectivity from prehospital to hospital as well as the following algorithms which are further described under the following headings:

- Automated STEMI Recognition in Prehospital or Hospital Setting via 12SL™
- ACI-TIPI/ACS Tool for Indicating Probability of ACS in the Symptomatic Patient
- Automated Serial Comparison for Detection of ECG Changes Commensurate with ACS

Before delving into this tool set, it is best to understand the challenges the healthcare system faces in assessing patients suspected of ACS. See The Challenges Associated with Diagnosing ACS.

Given the magnitude of the problem, research and development continues to be done to find new ways to deal with the challenge of ACS. This includes the use of biomarkers for accurate detection of ACS, such as use of high-sensitivity Troponin. See "ECG and the Advent of High-sensitivity Troponin."

Although the adoption of high-sensitivity Troponin is quite widespread, the knowledge regarding how to use them properly for the diagnosis and management of ACS is still unsettled and sometimes fundamentally questioned via results from recent randomized controlled trials.[124, 125] Risk stratification scores or diagnostic algorithms that include these values "has led to a constantly evolving and unquestionably chaotic scenario."[126] Regardless, it appears the ECG has a steadfast role at the extremes of the ECG patterns seen with ACS: that is, identifying patients with a STEMI in need of immediate intervention versus low-risk patients with a normal ECG that may safely benefit from an accelerated rule out protocol.[127] It is in between these extremes where further discovery will certainly take place. GE Healthcare is interested in partnerships which will tease out which computerized ECG metrics provide added value to high-sensitivity Troponin values for the diagnosis and management of ACS.

THE CHALLENGES ASSOCIATED WITH DIAGNOSING ACS

Challenges of diagnosing ACS include:

Limited Resources and Overwhelming Number of Patients Suspected of ACS ... 103
Low Prevalence of ACS (≈15%) in Symptomatic Population ... 104
Inability to Differentiate Based on Symptoms ... 105
Rate of False Negative / False Positive in ED and Consequence of Each ... 105
Higher False Negative (FN) Rate in Office ... 105
Top Reasons for Misdiagnosis ... 106

Limited Resources and Overwhelming Number of Patients Suspected of ACS

According to national health statistics for 2015, over 7 million visited the emergency department (ED) in the United States (U.S.) with the primary complaint of chest pain or related symptoms of ACS.[128] On top of that,

overall ED visits are increasing at a rate of about 2.9 million visits per year (or 3.2 percent) while the number of EDs "has decreased from 4,019 to 3,833."[129] Similar trends are occurring outside the U.S., where ED visits are increasing at reported range of 3% to 7%, annually.[130-134]

Low Prevalence of ACS (≈15%) in Symptomatic Population

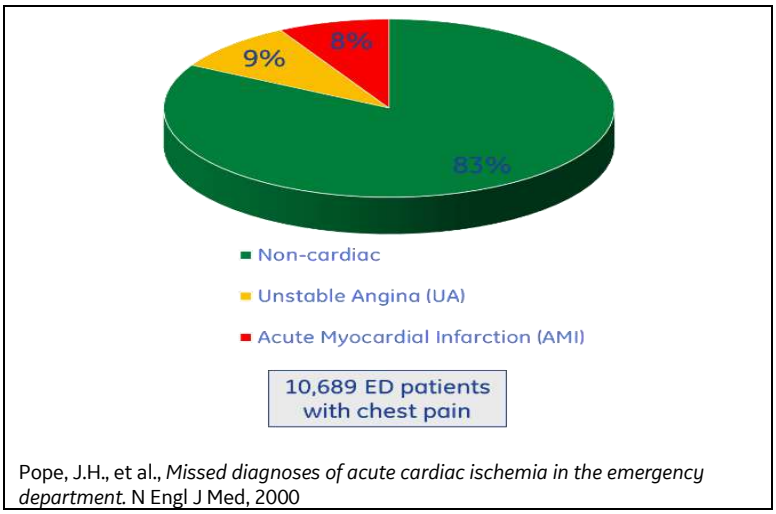
Even in the presence of chest pain, the prevalence of ACS has been found to be roughly 15%.

The reported prevalence can vary substantially based on the following factors: a.) the person performing the evaluation, b.) the location of the evaluation (e.g. office, ambulance or emergency department) and c.) whether a true-positive instance of ACS is primarily based on a blood sample versus clinical outcomes.

For example, one study reported a prevalence of 2%, another 60%, yet both stated they used similar inclusion criteria for selecting a population suspected of ACS: namely, all patients complaining of chest pain, shortness of breath, etc. It is the details of how these criteria were applied that likely accounts for the marked difference in reported prevalence.

In the case of the extremely low prevalence of 2%, 18,759 ED patients were selected based on whether their "non-processed chief complaint" matched one from a list of five preselected from data mining methods as being most predictive of acute MI.[135] At the other end of the spectrum, the prevalence of 60% was reported from a study of 511 patients who called for an ambulance due to symptoms associated with ACS, as confirmed by ambulance personnel.[136] Regardless, neither of these studies included follow-up data. There is no way to know whether either method resulted in a higher percentage of missed cases of ACS.

Unfortunately, since follow-up is time consuming and expensive, few studies have evaluated the prevalence of ACS in the admitted as well as discharged populations. One of the largest included 7 EDs that followed 10,689 ED chest-pain patient for 30 days. [137] In this case, the true-positive prevalence of ACS was found to be 17% (acute myocardial infarction 8%, unstable angina 9%) while the rate of missed cases of myocardial infarction was 2.1% (19 out of 899).



Pope, J.H., et al., *Missed diagnoses of acute cardiac ischemia in the emergency department.* N Engl J Med, 2000

In another large study published in 2018, over 48,000 ED patients suspected of ACS were followed for 1 year. Conventional serial Troponin measurements were used as a gold-standard for ACS. In this case, the prevalence of myocardial infarction or death from cardiovascular causes was 5% and unplanned hospital admission within 30 days, 18%.[124]

In any case, most studies report an incidence of ACS between 6 and 18% in chest-pain patients evaluated in the ED. [137-140] If patients in the ED were evaluated solely based on symptoms, the false positive rate would be ≈80%.

Inability to Differentiate Based on Symptoms

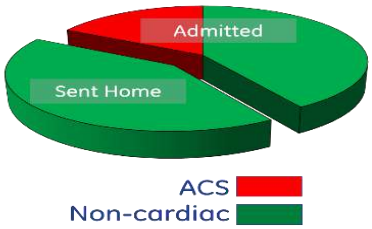
Signs and symptoms of ACS usually begin abruptly and include any of the following: chest pain (often described as aching, pressure, tightness or burning) which may radiate to the shoulders or arms; pain in the upper abdomen, back, neck or jaw; shortness of breath; nausea or vomiting; etc.[107] These symptoms do not effectively differentiate ACS. Indeed, in a meta-analysis of 16 studies, "it was not possible to define an important role for signs and symptoms in the diagnosis of acute myocardial infarction or acute coronary syndrome."[141] In fact, only chest-wall tenderness on palpation was found useful in ruling out ACS.[141] In conclusion, "it is well established that clinicians cannot use clinical judgment alone to determine whether an individual patient who presents to the emergency department has an acute coronary syndrome."[142] Indeed, "half of all ST segment elevation myocardial infarction patients do not experience a typical episode of acute severe chest pain – the so-called 'Hollywood heart attack' – but have atypical symptoms."[133]

It is also important to know the inability to use symptoms to differentiate ACS is linked to the low prevalence of acute cardiac disease in the symptomatic population. For instance, in the aforementioned study that included 10,689 ED chest-pain patients, the percentage who identified chest pain as their chief complaint was statistically lower in those who were not found to have ACS (62%) versus those that did (88%); due to the sheer number of patients who were not found to have ACS (8,150 out 10,689) the predictive value of chest pain as a primary complaint was diminished to the point where it made little difference in the accurate diagnosis of ACS.

Rate of False Negative / False Positive in ED and Consequence of Each

If the initial ECG is not indicative of a STEMI, further workup is required to accurately diagnose ACS.[115, 143] After repeated testing and serial trending of ECG and/or cardiac biomarkers over several hours, more than half of patients with chest pain or other symptoms associated with ACS are diagnosed with a non-cardiac cause for their symptoms.[144] The costs for this are large and primarily due to the substantial over-admission of patients for non-cardiac conditions.[145] In rural settings, costs are compounded due to transfers to tertiary centers,[140] where approximately 20% of the transfers are reported to be a false-positive or not necessary.[146]

This diagram shows the relative proportion of noncardiac patients admitted versus sent home from the study of 10,689 chest pain patients identified in the prior figure. Notice that ACS only makes up about a third of all admitted patients.



Selker, H.P., et al., *Use of the acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI) to assist with triage of patients with chest pain or other symptoms suggestive of acute cardiac ischemia. A multicenter, controlled clinical trial.* Ann Intern Med, 1998.

There are severe consequence for a missed case of ACS, which occurs at a reported rate of 2% in the urban ED[137] and 3-5% in the rural ED.[140] A patient inadvertently sent home with an acute myocardial infarction (AMI) has a mortality rate of 16%.[147] In the U.S., complications or death due to missed cases of ACS "accounts for the highest dollar losses in emergency department malpractice cases."[148]

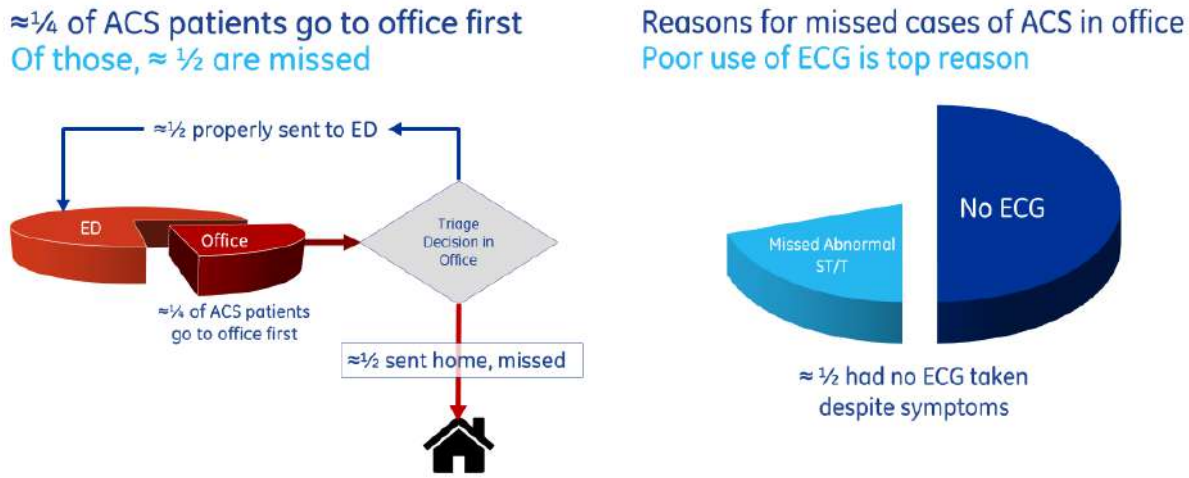
Higher False Negative (FN) Rate in Office

"Each year, approximately 1.5% of the population consults a primary care physician for symptoms of chest pain."[149] From an article published in 2018 on *Managing chest pain patients in general practice: an interview-based study* it is stated that "most guidelines clearly state that general practitioners (GPs) should refer every patient suspected of ACS to secondary care facilities as soon as possible" or, for that matter, "be bypassed to prevent loss of time and myocardial cell necrosis. For every chest pain patient with a life-threatening disease

as ACS, GPs encounter 11 patients with chest pain of non-severe cause. Clinical judgement and triage by GPs remains inevitable to prevent unnecessary referrals ..."[150] Despite this stance, GP evaluation of new-onset chest pain is occurring in the office without follow-up to ensure the FN rate approximates that seen in the ED. Given the expense and the daunting task of a follow-up study which includes hundreds of GPs and their patients, an alternative approach is to simply ask what happened before a patient showed up in the ED with an acute myocardial infarction (AMI). When this is done, the FN rate for the office appears alarmingly high.

For example, consider a study conducted in the U.S. which found that a quarter of all AMI patients went to the office first before showing up later in the ED with an AMI. In more detail, it was found for a covered population of 250,000 over a four year period, 27% of the 966 hospital admissions for AMI had primary care visits in the preceding month for symptoms suggestive of coronary disease, and 41% (106/261) of these patients were not referred for hospital care.[151] Instead of a FN rate of 2%, it is possible the FN rate for the office could be as high as 40%. Even though these patients were symptomatic when they went to the office, "half of the patients did not have an ECG performed during the office visit, and among those who did, the ECG was not always interpreted before the patient left the office."[151]

Using a similar approach, a study conducted in Germany found "421 AMI patients, 327 (77.7%) were directly admitted to hospital after examination by the [GP] physician, whereas 94 (22.3%) were not admitted." The conclusion of the study was that missed AMI in the office setting "is a common problem."[152]



Sequist, T.D., et al., *Missed opportunities in the primary care management of early acute ischemic heart disease.* Arch Intern Med, 2006

This is a significant concern since the norm in some healthcare systems is for chest-pain patients to see their physician before calling emergency services.[134] This practice has been shown to result in significant delays in care.[133]

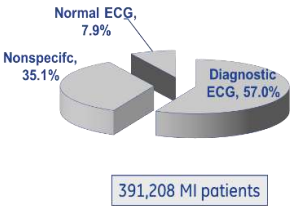
Top Reasons for Misdiagnosis

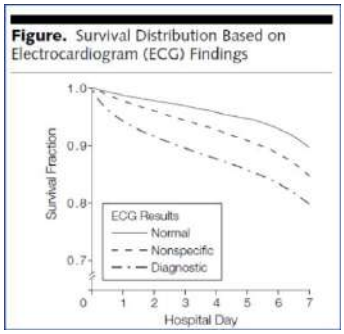
In the paper, "Missed opportunities in the primary care management of early acute ischemic heart disease",[151] half of missed cases of ACS had no ECG taken despite complaining of chest pain or other symptoms indicative of ACS.[151] See figure above.

This error of omission has not been reported in any study conducted in the ED. Instead, an incorrect ECG interpretation has been cited as a top contributor to a missed case of ACS in the ED. For example, in a study that included over 10,000 ED patients suspected of ACS, investigators "found a small but important incidence of failure by the emergency department clinician to detect ST-segment elevations of 1 to 2 mm in the electrocardiograms of patients with myocardial infarction (11%). This incidence represents an important and potentially preventable contribution to the failure to admit such patients."[137]

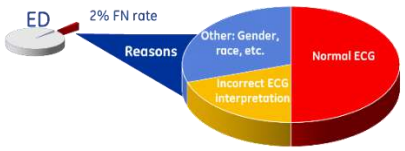
ED physicians failed to identify "significant ST-segment depressions, ST-segment elevations, or T-wave inversions on the presenting ECG."[153] in 12% of AMI's, and these errors significantly increased the in-hospital mortality of these patients, from 4.9% to 7.9% (P=0.1).[153]

In a study of missed cases of ACS in the ED, 53% had a normal or non-diagnostic ECG.[137] Although a normal initial ECG is prognostic of a good outcome when admitted to the hospital,[8] it should not be used to exclude a diagnosis of ACS. It should be appreciated among ACS patients with normal or nonspecific initial ECGs, evidence shows that 20.1% became STEMIs.[8]





Welch, R.D., et al., *Prognostic value of a normal or nonspecific initial electrocardiogram in acute myocardial infarction.* Jama, 2001.



Pope, J.H., et al., *Missed diagnoses of acute cardiac ischemia in the emergency department.* N Engl J Med, 2000

Gender and race have also been reported to be significant factors.[137] Even if correctly diagnosed with ACS, women suffer from higher mortality rates,[154-156] which appear related to less-aggressive treatment.[157-161] Although a complex issue integral to biological differences between men and women, increased mortality in women may be due "to bias or under use of aggressive therapy".[162]

GE Healthcare's Toolset for ACS

GE Healthcare's tool set for ACS includes the following:

- Access to a prior ECG
- Prehospital ECG connectivity
- Automated STEMI recognition in prehospital or hospital setting
- ACI-TIPI/ACS Tool: Probability of ACS
- Automated serial comparison

Access to a Prior ECG via the MUSE System

Access to prior ECG has been shown to significantly reduce unnecessary admissions. Evidence for that comes from a large multi-center prospective cohort study of 5,673 patients who went to the ED complaining of symptoms commensurate with ACS. [163] Those without a cardiac condition with a prior ECG available for review were more likely to avoid CCU admission than those without prior ECGs.

This improvement was most marked in the 2,024 patients (out of 5,673) whose current ED ECG had baseline changes consistent with ACS. In this case, those not suffering from a cardiac condition were "more than twice as likely to be discharged (26% vs. 12%) and about 1.5 times as likely to avoid CCU admission (39% vs. 27% p < 0.0001)."[163] This reduction in unnecessary admissions was attained without a significant drop in proper admission to the hospital or to the coronary care unit (CCU) for those actually suffering from a heart attack.

Likewise, it has been found that a significant portion of false positive activations of the Cath Lab could have been avoided if the current ECG was compared with the prior ECG on file at the hospital. For example, in a study where 1,345 patients who underwent emergency cardiac catheterization, 187 (14%) were not suffering from a heart attack and did not have a blocked coronary artery.[111] Of these, most had a prior ECG that

exhibited an abnormality that mimicked a heart attack. This study makes the appeal that there should be time for a obtaining a prior "ECG for comparison or the time to observe evolutionary ST-segment changes."[111]

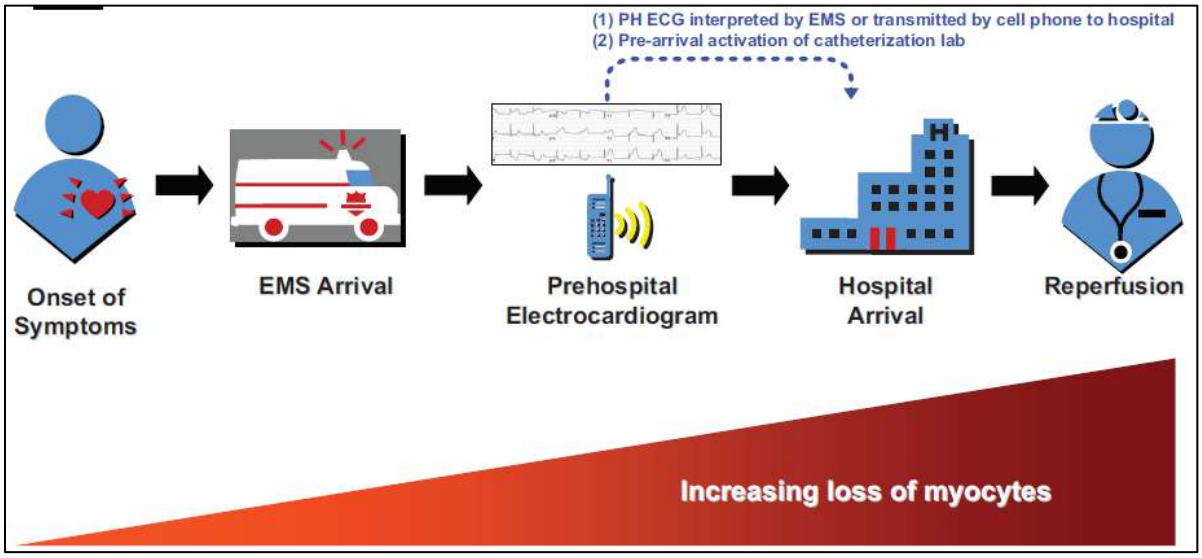
When the current ECG is negative, a significant change from a prior is predictive of poor outcome and a 2.1 times greater likelihood of intervention. This result was obtained via a year-long study at a single hospital, where 258 out of the 498 patients admitted for a heart attack had a prior ECG on file.[164] As can be expected, the prognostic value of a serial change was also present when the initial ECG in the ED was positive; in this case, the effect of the serial change was even more prognostic, resulting in more "interventions (2.0 times), complications (2.6 times), life-threatening complications (4.2 times), and acute myocardial infarctions (6.6 times)."[164]

Prehospital ECG Connectivity with the MUSE System

GE Healthcare was first to provide prehospital 12-lead ECG analysis with digital transmission to the hospital.[165, 166] Although GE Healthcare no longer manufacturers prehospital defibrillators, GE's Marquette 12SL™ program is available on prehospital defibrillators from other manufacturers. The MUSE system can acquire prehospital ECGs from any vendor using such standards as DICOM or XML.

According to an AHA scientific statement, "multiple studies have demonstrated the benefits of prehospital ECGs for decreasing door-to-drug time and door-to-balloon time in patients with STEMI. The direction and magnitude of the time savings are clinically relevant, resulting in an approximately 10-minute decrease in door-to-drug time and 15- to 20-minute decrease in door-to-balloon time. These time savings may not reflect the full potential of prehospital ECGs to decrease delays in reperfusion therapy. In fact, studies have shown further reductions in door-to-balloon time when prehospital ECGs are used to activate the catheterization laboratory while the patient is enroute to the hospital."[167]

Based on evidence published in 2018, time-to-treatment is especially important in STEMI patients experiencing cardiogenic shock. In fact, if these patients have not yet experienced a cardiac arrest, it has been found that every 10-min treatment delay results in 3.31 additional deaths for every 100 patients successfully treated in via emergency cardiac catheterization.[168] Solutions that streamline this decision process and accelerate the path to reperfusion are very important.



The figure shows a clinical workflow for a prehospital ECG from: Ting, H.H., et al., Implementation and integration of prehospital ECGs into systems of care for acute coronary syndrome: a scientific statement from the American Heart Association Interdisciplinary Council on Quality of Care and Outcomes Research, Emergency Cardiovascular Care Committee, Council on Cardiovascular Nursing, and Council on Clinical Cardiology. Circulation, 2008.

Despite the value of ambulance transport and prehospital ECG, roughly half of patients suspected of ACS delay seeking care and go to the ED on their own. This is an age-related behavior. In fact, 72% of those from ages 45 to 64 walk in to the ED.[169] This is despite public education of the value of ambulance care for chest pain.[170]

Regardless of how chest pain patients seek emergency care, it is important to consider the MUSE™ system provides connectivity with ECGs acquired in the ambulance, ED, or cardiac care unit. Instead of one system for linking the ambulance to Cath Lab and another for walk-in patients, the MUSE system manages ECGs from both paths which can then be compared to any prior ECG for that patient.

Automated STEMI Recognition in Prehospital or Hospital Setting via 12SL™

GE's Marquette 12SL™ program has undergone considerable validation in both the prehospital and hospital setting. Although not as sensitive as an expert electrocardiographer for the recognition of STEMI, it is highly specific. In fact, several studies have reported that 12SL identifies STEMI with a higher predictive value than expert electrocardiographers.[123, 171, 172] In addition, it has been found useful in classifying normal versus abnormal ECGs for triage in patients with chest pain.[173]

See further details regarding these performance metrics via this hyperlink. The remainder of this section addresses how 12SL recognizes STEMI and the challenges of accurately identifying STEMI across all types of ECGs including those with left ventricular hypertrophy (LVH).

Identification of a STEMI obviously depends on the presence of significant ST elevation (STE) in the 12-lead ECG. Yet, the "definition of significant ST segment elevation varies considerably with respect to both the required minimum height (mm) of ST elevation, and the numbers of leads with ST elevation."[174]

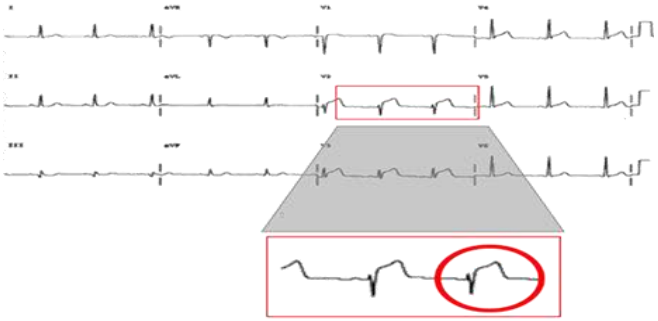
Expert electrocardiographers can identify STEMI with a high level of specificity whether they use the "conventional ST elevation criteria of 1 mm in any 2 contiguous leads"[175] or the more stringent ACC/ESC criteria which requires a 2 mm (200µV) ST deviation in leads V1-V4.[176] Specificity is unacceptably low when strictly applying these ST elevation (STE) thresholds.

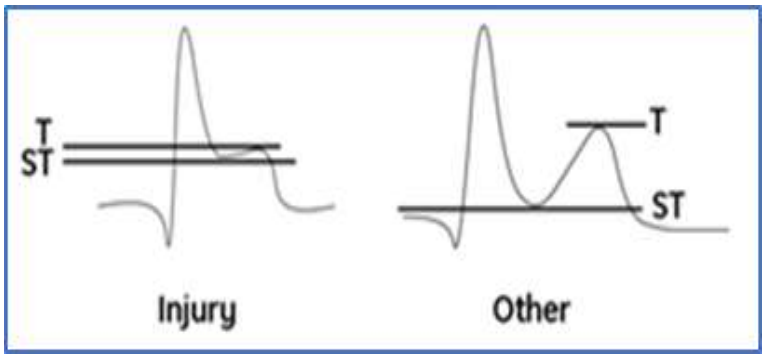
For instance, in an assessment of 6,014 healthy men enrolled in the U.S. Air Force (ages 16 to 58) it was found that "91 percent had ST segment elevation of 1 to 3 mm in one or more precordial leads."[177] In yet another, much larger prospective study, STE >0.1 mV (100µV) in at least 2 inferior or lateral leads was found in roughly half 10,957 enrolled subjects. In short, STE alone is not sufficient to accurately identify a STEMI.[178]

Isolated ST-segment elevation in the presence of AMI is "distinctly unusual".[123] There are typically other abnormalities evident in the ECG. These can occur in leads with ST-segment elevation (STE) or elsewhere in the ECG.

ST-SEGMENT MORPHOLOGY

In a lead with STE, the most common pattern taught to students for discriminating STE due to STEMI is to see if the ST-segment is convex. If the ST-segment is concave or the STE is small in relation to the T-wave, the STE is likely to be normal or due to early repolarization.

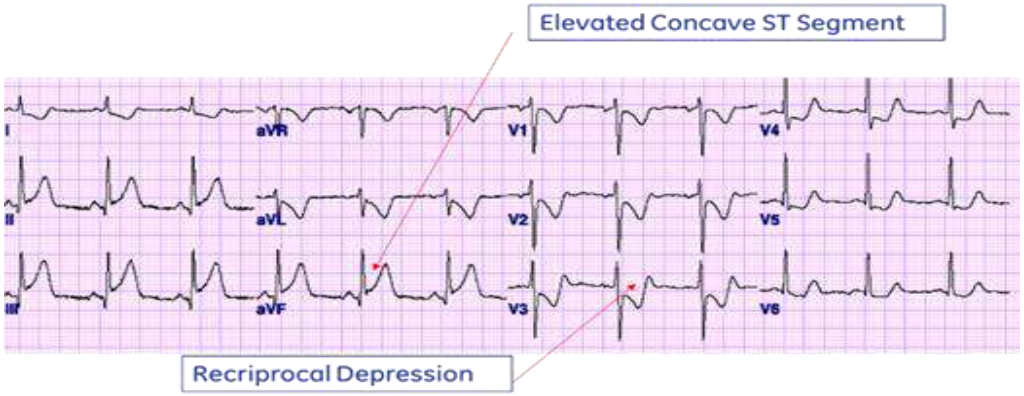




Discrimination of a STEMI based on whether the ST-segment is convex versus concave helps, but not that much. Indeed, in the first of a series of studies where PHECGs were obtained by paramedics and correlated against clinical outcomes, only half of STEMI's had convex ST segments.[17] Subsequent studies have reported similar results. Indeed, use of the "non-concave STE morphology for AMI diagnosis is not particularly helpful ..."[179]

Reciprocal Depression

Below is an example of STE which is concave. It is not early repolarization since the STE is localized to leads II, aVF & III and is accompanied by ST-depression in leads V1-V4. Instead, this is an inferior STEMI commensurate with a pattern known as "reciprocal depression".



Reciprocal depression has been noted as absent in ECGs obtained from normals.[180] Before PHECG and automated STEMI recognition based on cardiac biomarkers / clinical outcome, it was not generally appreciated how useful reciprocal depression would be for discriminating a STEMI.[17] Indeed, comparing lead-specific convex/concave criteria versus the use of reciprocal depression, "resulted in over twice the sensitivity (53%), while continuing to maintain a high rate of specificity (98%)."[17]

This same degree of improvement in performance was confirmed a few years later in several studies.[181-183] For instance, in a study of 428 PHECG chest pain patients, 29% met 1 mm (100μV) or more ST segment elevation criteria. Half of these did not have myocardial infarctions. If the 1 mm or more ST segment elevation occurred with reciprocal changes, "a positive predictive value of 94% was achieved and included 18 of the 21 (86%) myocardial infarction patients who had ST segment elevation and received thrombolytic therapy within five hours after hospital arrival." The conclusion of the study was "ST segment elevation criteria that include reciprocal changes identify patients who stand to benefit most from early interventional strategies."[183]

Reciprocal depression has also been found to be predictive of clinical outcome.[184, 185] "When concomitant ST depression is present in patients with STEMI undergoing primary PCI, less than 50% resolution of ST depression was associated with worse 90-day clinical outcomes even after accounting for the baseline risk profile, infarct location, PCI procedural outcome, and resolution of ST elevation. Although favorable outcomes are generally anticipated in patients with ST elevation resolution 50%, our data indicate that ST depression

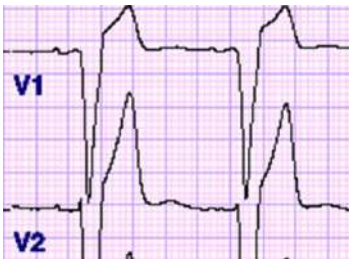
resolution adds additional important prognostic insight and deserves consideration in the management of these patients and future STEMI guidelines."[185]

Appropriate Use of Reciprocal Depression

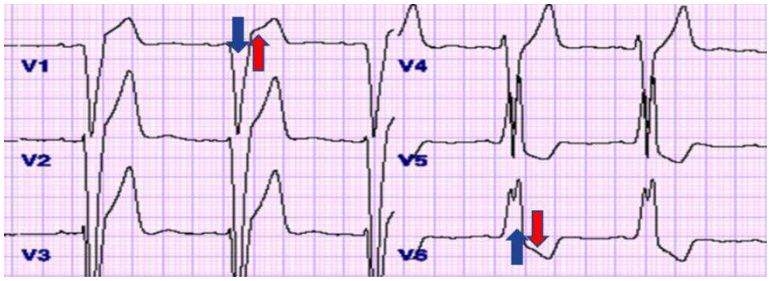
Reciprocal depression is an inherent characteristic of bundle branch blocks (BBB). Below is an example of a left bundle branch block (LBBB). It exhibits STE in V1-V2 and ST depression (STD) in V5-V6. In this case, the reciprocal depression is not the result of a STEMI. The STE and STD are a secondary result of the conduction abnormality.

Secondary repolarization abnormalities due BBB are large and in the opposite direction of the QRS. This is because repolarization begins before the QRS has a chance to end. Consequently, there is a significant ST-segment shift at the end of the QRS. More importantly, the sequence of repolarization is altered. It begins where the conduction system was intact and follows the wave of depolarization as it spreads to the other ventricle. This contrasts with normal repolarization which travels in the opposite direction of depolarization. In normal repolarization, the QRS and T-wave are concordant while in the case of BBB, they are 180° apart.

Although there is marked STE in V1-V2 due LBBB that could erroneously be identified as a STEMI, it is clear the STE is due to a secondary repolarization abnormality. The QRS duration is long. The depolarization (blue arrow) and repolarization (red arrow) are 180 degrees apart. Leads with a predominantly positive QRS complex end up with STD and T-wave inversion and vice versa.

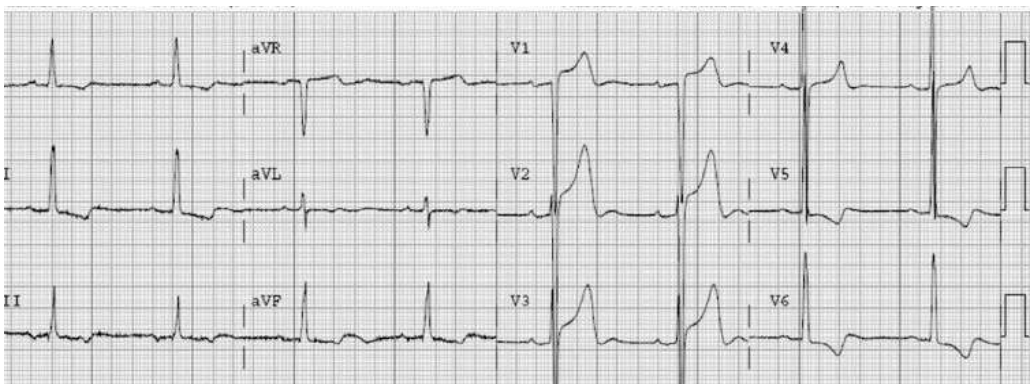


See marked STE in V1-V2



STE caused be secondary repolarization abnormality.

Likewise, in the presence of LVH, there can be significant STE in V1-V3. See example below. Although there is reciprocal depression in V5, V6 & aVL, the wave of repolarization (ST/T-wave) is in the opposite direction of depolarization (QRS). This is typical of LVH and should not be identified as a STEMI.



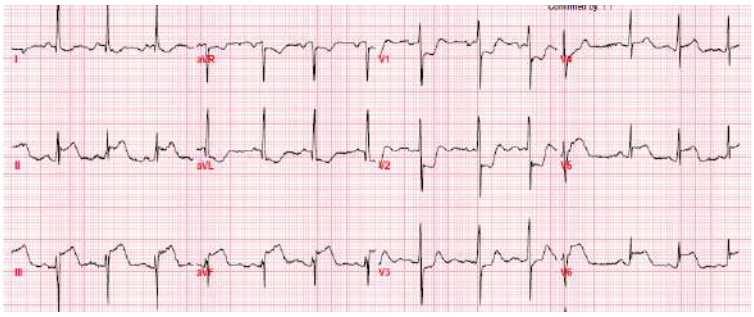
For those skilled in the art of ECG interpretation, it would seem obvious that significant STE in V1-V3 often occurs in the presence of LVH and that this finding needs to be treated with caution before identifying it as due to a STEMI. Two cardiac catheterization laboratory (CCL) registries have reported many cases of anterior STE due to LVH mistakenly identified as STEMI. In fact, it was found to be a significant contributor to a higher reported incidence of inappropriate CCL activations than expected, namely 36%[186] and 45%[187] versus the typically reported level of 15%.[111, 188] Upon closer inspection, it was found that over 30% of the

inappropriate activations were due to LVH-induced anterior STE being identified as a STEMI even when 60% of these had a prior ECG exhibiting no significant change from the current ECG at the time of activation.[187]

To properly apply the clue of reciprocal depression, one must also take into account the changes in repolarization due to a conduction abnormality or hypertrophy.[182, 189] The 12SL program has rules which stipulate when it can use reciprocal depression. Although the details are provided via this hyperlink, the general approach is to evaluate whether the STE is in the opposite direction of the QRS. If it is, the program applies successively higher thresholds for identifying a STEMI based on the duration and amplitude of the QRS.

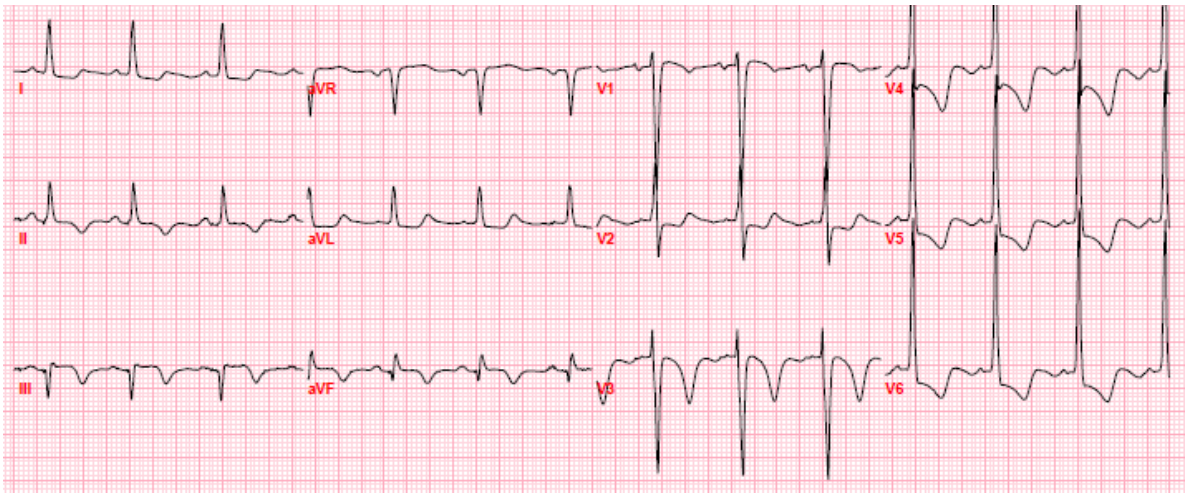
If the STE is not in the opposite direction of the QRS, the 12SL program can apply the rule of reciprocal depression liberally. As opposed to other programs which simply avoid detecting any STEMI in the presence of LVH or a conduction abnormality, these rules allow the 12SL program to go forward and detect legitimate cases of a STEMI in the presence of these QRS abnormalities. See examples below.

Due to the voltage and ST/T pattern in aVL, some programs would identify this as LVH and skip whether the ECG has evidence of a STEMI.

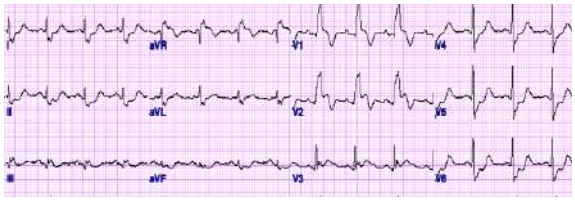


The ST/T vector is not typical of LVH; it is not 180° away from the QRS. This is an inferior-lateral STEMI with reciprocal depression evident in V1-3.

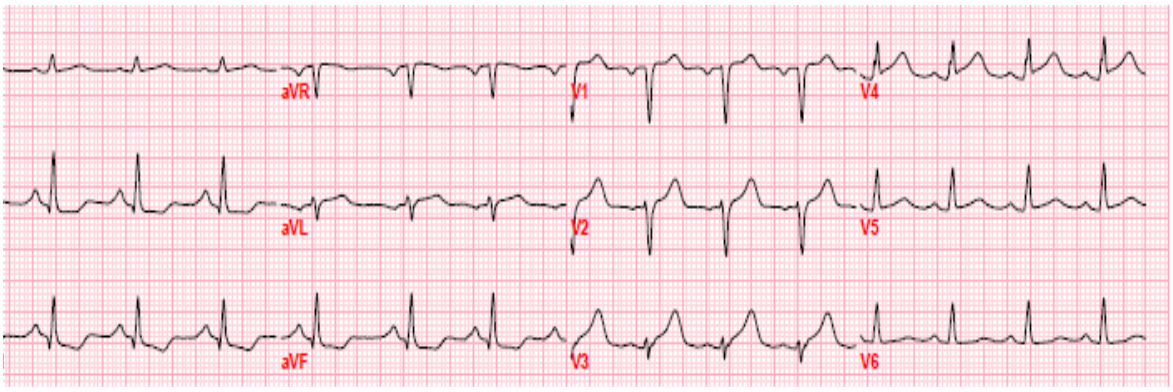
In the ECG below, some programs would not attempt analyzing this for STEMI because it meets voltage criteria for LVH and the ST/T in V5-V6 is typical of LVH. Despite the signs of LVH, this is an inferior STEMI. The STE in aVF and the STD evident in V2 is not typical of LVH. The T-wave in V3 is concordant with the QRS and atypical for LVH.



Although this is a right bundle branch block (RBBB), 12SL can identify this as STEMI because STE (in V1-2) and reciprocal depression (in V5-6) are not typical for RBBB. Likewise, LBBB can be accessed for a STEMI if there is STE in V5-V6.

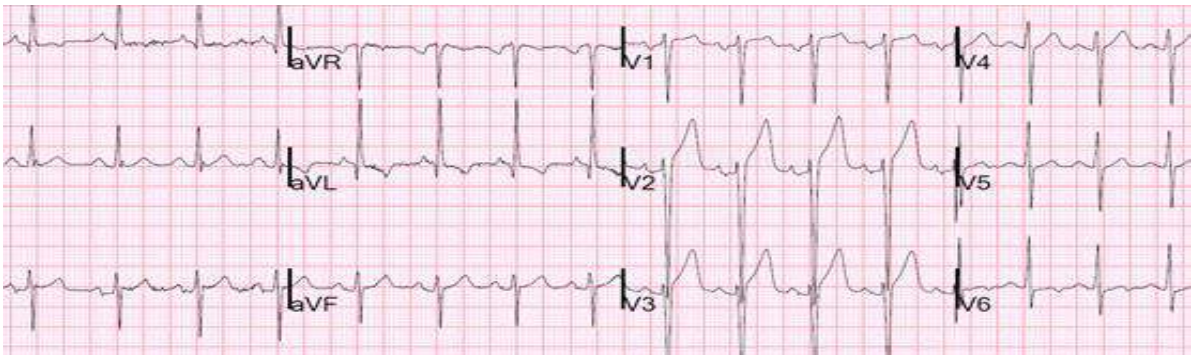


When reciprocal depression is applied correctly, smaller levels of STE can be identified as a STEMI. For instance, see the tracing below. Strictly speaking, only V4 shows STE > 100µV. Yet, given the pattern seen in the inferior leads this can be identified as an anterior STEMI.

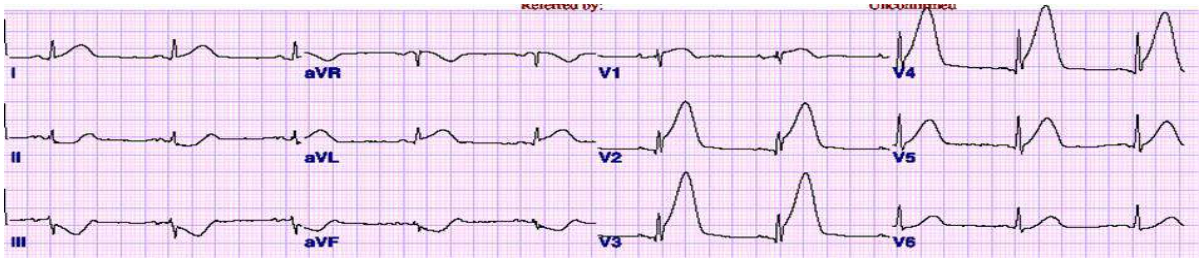


The rule of when to apply reciprocal depression can also be useful for discriminating hyperacute T-waves. See the two tracings below.

The first ECG has STE > 200µV in leads V1-V3 and large T-waves that could be mistaken as hyperacute. But the wave of repolarization is in the opposite direction of the QRS. A higher ST-segment threshold for STEMI is warranted. Any depression seen on the other side (in leads V5/6, I or aVL), should be not be construed as reciprocal depression. The pattern seen in aVL is typical of LVH. This is not a STEMI.



The second tracing has large, broad T-waves. There is significant STE in V2-V4, but it is small in relation to the T-wave amplitude. Given that the STE is in the same direction as the QRS, the ST depression in the inferior leads can be identified as reciprocal depression to an anterior STEMI.



In conclusion, identifying a STEMI is not trivial. Besides the difficulty of defining an appropriate ST-segment threshold for a STEMI, there are several common conditions that mimic, and confound STEMI recognition.[190] Although a convex elevated ST-segment is a highly specific indicator of a STEMI, it is insufficient for identifying most STEMIs. When applied under the appropriate circumstances, reciprocal depression has been shown to be a highly specific indicator of STEMI.[182]

ACI-TIPI AND GE ACS TOOL: PROBABILITY OF ACS

The 12SL program supports two options that may assist the physician in determining the probability of a chest-pain patient having an acute coronary syndrome (ACS). Both ACI-TIPI and the ACS Tool are configurable options. To obtain a result from either tool, they must be “turned-on” when the 12SL analysis is performed. Note that not all GE Healthcare diagnostic electrocardiographs support ACI-TIPI or GE’s ACS Tool.

Both ACI-TIPI and GE Healthcare's ACS Tool were developed using statistical methods applied to large databases of 12-lead ECG measurements correlated with the final clinical determination of ACS from those who entered the emergency medical system (EMS) complaining of symptoms associated with ACS. While ACI-TIPI uses a logistical regression equation, GE Healthcare's ACS Tool uses a neural network for optimum assessment of ECG patterns that have been correlated against the clinical determination of ACS.

ACI-TIPI was developed first, in the 1980's.[191] In 1996, ACI-TIPI was tested on ECGs obtained in an ambulance[21] and implemented in GE Healthcare electrocardiographs. In 1998, results of a prospective evaluation of ACI-TIPI used in GE electrocardiographs was published.[192] Results were obtained from 10 different medical centers on over 10,000 patients suspected of ACS. By turning the ACI-TIPI on, off and on again, its impact on physician decision making could be ascertained. This prospective trial demonstrated that use of ACI-TIPI by the ED physician reduced admissions by 30% without any increase incidence of missed cases of ACS.[192] This reduction was essentially limited to centers with limited resources; if there were plenty of beds available, physicians tended to admit patients regardless of ACI-TIPI values. Since then, further studies have been published using ACI-TIPI. See these articles for more information.[193-195]

GE Healthcare's ACS Tool was developed as an evolution of ACI-TIPI based on customer feedback and preference. The difference between the ACS Tool and ACI-TIPI is more in terms of the user interface and not the statistical performance of the algorithm. These differences are listed below. The use of the ACS Tool has been shown to significantly improve the sensitivity of ED physician recognition of acute coronary syndromes without a loss of specificity.[37]

ACI-TIPI	***GE Healthcare's ACS Tool***
Two-page report. One page for the 12SL interpretation, the other for the ACI-TIPI score and reasons for score.	One-page report. Results of 12SL are fully integrated as part of the tool.
Must delineate whether chest pain is chief or secondary complaint. Report defines symptom as ""chest or left- arm pain" or "other".	No specific symptom is entered. Report simply states patient has symptoms commensurate with ACS.
On each test, ACI-TIPI states "predicted probability of acute cardiac ischemia = x%"	No probability score provided. Instead, report simply states either: ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings "*** ** CONSIDER ACUTE CORONARY SYNDROME (ACS) ** ***
Report identifies positive ECG findings	Report identifies positive ECG findings. The program also makes sure these findings are also identified in the 12SL interpretation.
ECG findings do not necessarily match what is identified by 12SL.	Fully integrated with 12SL. ECG findings match what is identified by 12SL

ACI-TIPI Methodology: Logistic Regression

The ACI-TIPI algorithm uses the following patient information in its logistic regression equation: age, gender, and most importantly, presenting symptom.

With regards to presenting symptom, ACI-TIPI requires that the operator select one of the following conditions regarding chest or left arm pain:

- Chief complaint
- Secondary complaint
- Not present

The pertinent ECG data includes:

- detection of abnormal Q-waves,
- quantification of the amount of ST segment elevation or depression, and
- quantification of the amount of T wave magnitude and polarities.

In addition, ACI-TIPI excludes from analysis the following interpretations as detected by the 12SL program: ventricular paced rhythm, left bundle branch block (LBBB), right bundle branch block (RBBB), or left ventricular hypertrophy (LVH). The equation used by ACI-TIPI to calculate the probability of acute cardiac ischemia uses similar weights for patient demographics and ECG findings. See below:

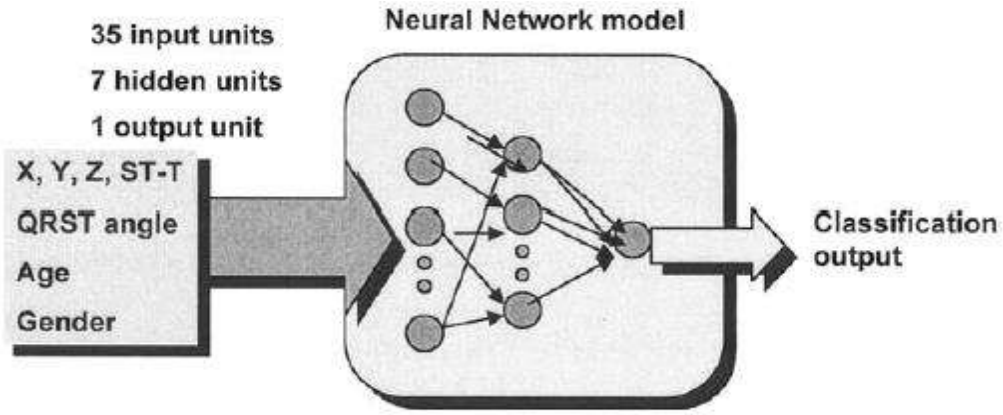
$$probability\% = 100 \times \left[1 - \frac{1}{1 + \exp(b_0 + \Sigma\ b_i x_i)}\right]$$

Variable	Coefficients (b_i)	Description	Value (X_i)
CONSTANT (b_0)	−3.933		
CPAIN	1.231	Chest or left arm pain/pressure present Otherwise	1 0
SX1CPAIN	0.882	Chest or left arm pain chief complaint Otherwise	1 0
MALESEX	0.712	Male Female	1 0
AGE	−1.441	Patient age 40 years or less Otherwise	1 0
AGE50	0.667	Patient age greater than 50 years Otherwise	1 0
SEXAGE50	−0.426	Male patient age greater than 50 years Otherwise	1 0
QWAVE	0.616	ECG Q-waves present Otherwise	1 0
STEL	1.314	ECG ST segment elevated 2 mm or more ECG ST segment elevated 1–2 mm Otherwise	2 1 0
STDEP	0.993	ECG ST segment depressed 2 mm or more ECG ST segment depressed 1–2 mm ECG ST segment depressed 0.5–1.0 mm Otherwise	2 1 0.5 0
TWEL	1.095	ECG T-waves elevated (hyperacute) Otherwise	1 0
TWINV	1.127	ECG T-waves inverted 5 mm or more ECG T-waves inverted 1–5 mm ECG T-waves flat Otherwise	2 1 0.5 0
TW1STDEP	−0.314	Both STDEP and TWINV not 0 Otherwise	1 0

NOTE: Only the largest x_i is used per variable. Electrocardiogram (ECG) findings must be present in *at least* two leads, and ST segment and T-wave changes are "normal" if secondary to right or left complete bundle branch blocks, left ventricular hypertrophy, or a paced QRS. Only one type of abnormality is coded each for ST segment and for T-wave per patient (exclusive of TW1STDEP), with elevation taking priority. Deviations are expressed in mm, using standard ECG scale of 1 mm = 0.1 mV.

ACS Tool Methodology: Neural Network

The ACS Tool uses an artificial neural network. See figure below:



Xue, J., et al., Added value of new acute coronary syndrome computer algorithm for interpretation of prehospital electrocardiograms. J Electrocardiol, 2004

Artificial neural networks are modeled after biological neural networks. A biological neural network consists of a group of neurons that interact with one another. Each neuron can be in one of two states: either firing or quiescent. Between the neurons are synapses. The synapses accumulate at varying weights the number of times they have been stimulated by a single neuron or groups of neurons. At some point, this accumulation exceeds a threshold, resulting in the firing of the next neuron following the synapse. Similarly, the artificial neural network consists of units that are connected to one another. In this case, the configuration as to how the units are connected as well as the weights for accumulating the number of times a unit must be stimulated before it fires the next unit is automatically determined via a computer.

For an artificial neural network to be stable and robust, it must be provided plenty of examples of what it will encounter. This is true both in terms of the patterns it should properly recognize versus those patterns that may deceive it. Given too many inputs for training or too few examples of the patterns it will encounter, the neural network will not be trained properly. Instead, it will be forced to over fit the inputs it is provided to the limited answers in the truth table it was provided. In this case, when the neural network is tested on a different set of data, it will likely fail to recognize the desired pattern or, worse, identify a false positive match when it is simply an artifact.

To reduce the number of inputs that could be used for wiring the artificial neural network, GE Healthcare used derived X, Y, Z from the 12-lead ECG. This transformation was developed and testing using thousands of 12-lead ECGs that also include true Frank X, Y, Z leads.[37]

The inputs include age, gender, ST-segment/T-wave features as the spatial QRS/T angle from the derived X, Y, Z. “The hidden layer includes nonlinear function units to form the nonlinear classification boundaries. The output layer only has one unit to indicate the classification result using a continuous value range from 0 to 1 with 1 as most likely ACS, and 0 as least likely ACS.”

More than 3,000 ECGs were used for training, and another 2,000 ECGs used for testing. The training set included ECG data collected from the Cardiac Care Unit (CCU) at the Mayo Clinic. All ECGs in this set included both standard 12 lead and Frank X, Y, and Z leads. The Milwaukee Chest Pain Database was used as the test set.[196]

The ACS Tool “combines a rule-based model and a data-centered model. The rule-based model used clinical criteria for ACS, while the data-centered model was a supervised artificial neural network (ANN) trained by a clinically confirmed ACS database. The results are then fused together for the final interpretation.”[37]

Performance of ACI-TIPI vs GE Healthcare's ACS Tool: Comparison of ROC Curves

To compare the performance of the ACS Tool in relation to ACI-TIPI, a receiver-operator characteristic (ROC) curve analysis was performed to evaluate and compare the ability of the two methods in the discrimination between ACS and non-ACS ECGs. The Milwaukee Prehospital Chest Pain Database was used for this analysis.[196]

MILWAUKEE CHEST PAIN DATABASE

This Milwaukee Prehospital Chest Pain Database was used only as a test database; it was not used during the development of the ACS Tool. The final patient diagnosis was determined by prehospital, emergency department, and hospital chart review by a team of trained nurse investigators and confirmed by a physician. The final diagnosis included three categories: acute MI, non-MI ACS, and non-ACS.

The final diagnosis of acute MI (STEMI or NSTEMI) was based on clinical features at presentation and throughout the hospital course, ECG findings, and results of cardiac enzyme testing according to World Health Organization criteria. The final diagnosis of non-MI ACS included new-onset angina, as well as unstable and stable angina pectoris, and was based on clinical features at presentation and throughout the patient's course, cardiac testing performed, and the treating physician's diagnosis. Patients without evidence of acute MI or myocardial ischemia (angina pectoris) were classified as non-ACS.

ECG exclusions included ventricular pacemaker, left bundle branch block (LBBB), heart rate > 180 bpm, and QRS duration > 160 msec. After the exclusions, this database included 2,308 ECGs including 550 with a final diagnosis of acute MI, 750 with a final diagnosis of non-MI ACS, and 1008 as non-ACS. Most of the non-ACS ECGs were abnormal ECGs, including prior MI.

ROC CURVE ANALYSIS

ROC curves were generated to assess the sensitivity and specificity at various thresholds for both the ACI-TIPI score and the ACS Tool score. That is, for a given threshold, scores above the threshold were classified as ACS and scores below the threshold were classified as non-ACS. To accomplish this, the ACI-TIPI chest pain level was set to "chief complaint" for the ACI-TIPI analysis.

The area under the ROC curve was 0.78 for the ACI-TIPI score and 0.80 for the ACS Tool score. For an ACI-TIPI threshold of 55, the sensitivity (49%) and specificity (82%). This threshold was selected due to its use as a cut-point for a high-probability of acute cardiac ischemia (ACI) group. See table below from Selker et. al.[197] In comparison, a threshold of 50 applied to the ACS Tool generated a sensitivity of 53% and a specificity of 85%. Since the ACS score is only an internal intermediate result of the ACS Tool, the overall sensitivity and specificity levels were recalculated for the final output with a sensitivity of 47.4% and specificity of 85.9%.

ACI-TIPI Thresholds vs Low, Medium and High Probability

SELKER ET AL. MEDICAL CARE

TABLE 3. Development and Prospective Testing of Performance of TIPI Acute Cardiac Ischemia (ACI) Probability Group

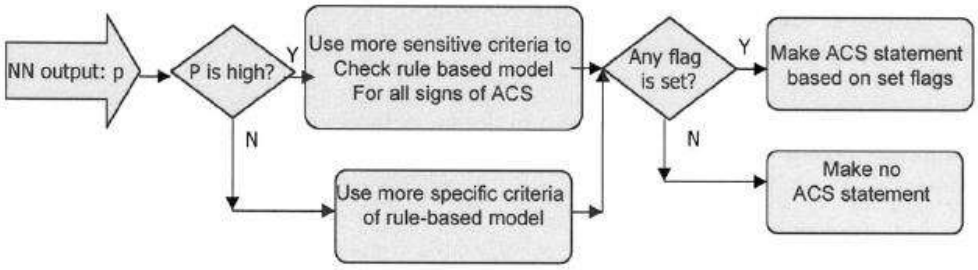
ACI Probability Group		TIPI Scores[a] Range	TIPI Scores[a] Midpoint	Development Phase n	Development Phase % with ACI	Development Phase % with AMI[b]	Test Phase n	Test Phase % with ACI	Test Phase % with AMI
LOW	I	0–10%	5%	734 (21%)	3.8%	1.8%	552 (21%)	1.6%	0.7%
MEDIUM	II	10–25%	17.5%	939 (27%)	17.8%	6.0%	657 (28%)	12.0%	4.4%
	III	25–55%	40.0%	869 (25%)	39.8%	14.7%	627 (27%)	36.7%	12.3%
HIGH	IV	55–100%	77.5%	911 (26%)	77.9%	49.7%	484 (21%)	51.6%	33.3%
				3,453 (100%)			2,320 (100%)		

[a] Patients with group cut-point TIPI scores are assigned to the higher probability group.
[b] Acute Myocardial Infarction.

Statements Generated by the ACS Tool

Based on the neural network output, the ACS tool can apply more sensitive rule-based criteria. For instance, the neural network output provides an indication as to whether a T-wave inversion is due to something like LVH versus a primary repolarization abnormality.

In any case, the ACS Tool interpretation is fully integrated into the 12SL report. For a statement to be issued by the ACS tool, an acute coronary syndrome must be corroborated by rule-based ECG criteria. That is, the ACS tool cannot state "probable acute coronary syndrome" without finding additional evidence via conventional 12-lead rule-based ECG criteria.



Like any 12SL interpretation, the intended use of the tool is to assist the physician in measuring and interpreting resting 12-lead ECGs for rhythm and contour information by providing an initial automated interpretation. Interpretation by the product is then confirmed, edited, or deleted by the physician.

Unlike ACI-TIPI, ECG findings have a higher impact than patient demographics in calculating the probability of ACS. The ACS tool does not require the user to enter whether the patient has "chest or left- arm pain". Instead, when the ACS Tool is selected the ACS Tool presumes and documents that the patient has symptoms commensurate with an acute coronary syndrome (ACS). In addition, the operator is not constrained from entering further details regarding these symptoms. Such symptoms as "chest or left-arm pain" are not used as a weighted variable in the algorithm.

In addition to the statements that are routinely generated by the12SL program, the ACS Tool can state the following at the top of the ECG interpretation:

***** ** ACUTE MI / STEMI ** *****

***** ** CONSIDER ACUTE CORONARY SYNDROME (ACS) ** *****

***** ** CONSIDER ACUTE MI if LBBB is new ** *****

***** ** LBBB with primary ST/T abnormality - CONSIDER ACUTE CORONARY SYNDROME (ACS) ** *****

***** ** LBBB with primary ST elevation abnormality - CONSIDER ACUTE MI ** *****

When the tool detects STEMI or ACS, it states the ECG-based reasons for this interpretation. These reasons are placed at the end of the interpretation, following the phrase "***ECG interpretation of ACS is based on presence of symptoms and***".

Other than ventricular paced beats, the ACS tool will not exclude ECGs from analysis. The ACS Tool evaluates left bundle branch block (LBBB), right bundle branch block (RBBB), and left ventricular hypertrophy (LVH). It does so while considering the possibility of secondary repolarization abnormalities.

When the ACS Tool is "on" and the 12SL program detects LBBB, the LBBB is considered a significant finding. Under these circumstances the program further evaluates the ST/T of the LBBB. [17, 18] This evaluation will result in one of three statements:

***** ** Consider ACUTE MI if LBBB is new ** *****

***** ** LBBB with primary ST/T abnormality - CONSIDER ACUTE CORONARY SYNDROME (ACS) ** *****

***** ** LBBB with primary ST elevation abnormality - CONSIDER ACUTE MI ** *****

Once the ACS Tool determines that there is a high probability of ACS and the 12SL program has not detected a STEMI or LBBB, it goes back to the conventional rule-based ST/T criteria and checks the ECG again with more sensitive thresholds. If the more sensitive thresholds identify ST elevation, then adjacent leads are more closely evaluated for ST elevation while reciprocal leads are more closely evaluated for ST depression.

If the ACS Tool does not find any ST/T findings commensurate with ACS, then no finding will be indicated and no statements regarding ACS or STEMI will be made at the top of the interpretation. The ACS Tool will add the following statement to the 12SL interpretation: "ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings".

When the ACS Tool is on, the bottom of the interpretation will exhibit either of the following statements:

ECG interpretation of ACS is based on presence of symptoms and...

or

ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings

When the statement "ECG interpretation of ACS is based on presence of symptoms and..." is issued, it will be followed by the ST/T findings that resulted in the positive interpretation of ACS noted at the top of the report.

IMPACT OF ACS TOOL: INCREASED ACCURACY OF OVER-READING PHYSICIAN

The use of the ACS Tool interpretation on the ECG report has been shown to significantly improve the sensitivity of physician recognition of acute coronary syndromes without a loss of specificity. The "test portion of the study was conducted in 2 steps: One emergency physician and one cardiologist classified 1,902 clinically correlated out-of-hospital ECGs without seeing the interpretation statement from the algorithm into one of the following categories: acute myocardial infarction, acute ischemia, or non-ischemic. After 9 months, the same 2 physicians classified the same group of ECGs but with the interpretation statement of the algorithm printed on the tracing. The results demonstrated that with the assistance of the new algorithm, the emergency physician and cardiologist improved their sensitivity of interpreting acute myocardial infarction by 50% and 26%, respectively, without a loss of specificity. The new algorithm also improved the emergency physician's

acute ischemia interpretation sensitivity by 53% and still maintained a reasonable specificity (91%). The new ACS algorithm provides added value for improving acute ischemia and infarction detection in the ED."[37] This may be important since, according to ACC/AHA guidelines, "errors in ECG interpretation [by ED physicians] can result in up to 12% of patients being categorized inappropriately, demonstrating a potential benefit of accurate computer-interpreted electrocardiography and transmission to an expert."[198]

AUTOMATED SERIAL COMPARISON DETECTS CHANGES COMMENSURATE WITH ACS

ACC/AHA clinical guidelines state serial ST/T wave changes as the essential part of a serial ECG interpretation. See the following examples:

- "Transient ST-segment changes (≥0.05 mV) that develop during a symptomatic episode at rest and that resolve when the patient becomes asymptomatic strongly suggest acute ischemia."[199]
- "Dynamic ST-segment changes ±1 mm".[199]
- Isolated T-wave changes not known to be previously present.[200]
- New T-wave inversion.[201]

Some automated serial comparison programs only compare statements. Yet these guidelines do not mention changes in interpretive statements as a "significant change".

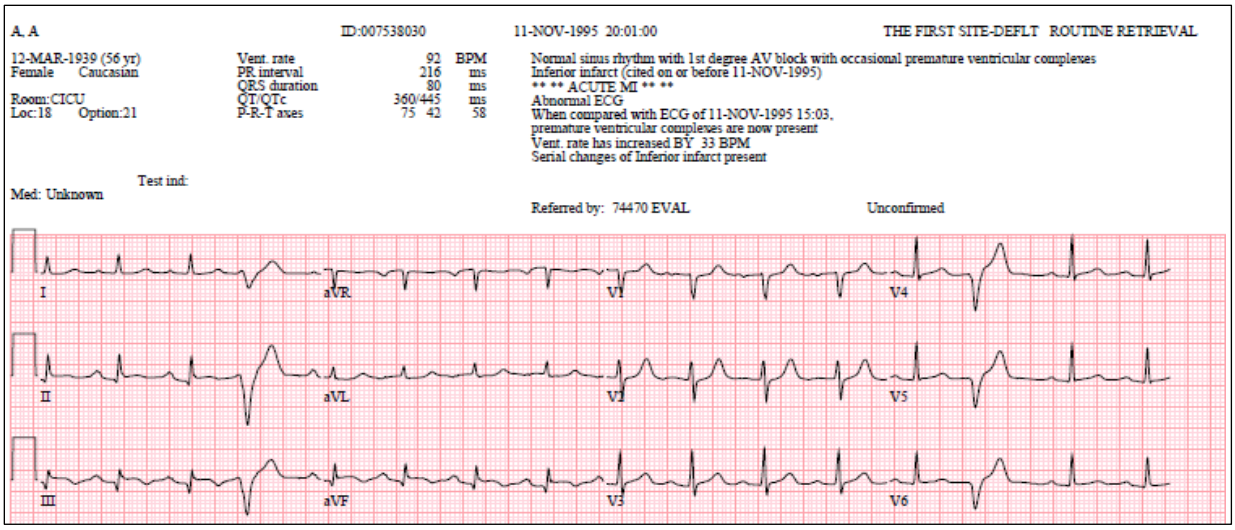
Additional ACC/AHA guidelines focus primarily on the issue of the assessment of serial ECGs in patients suspected of ACS.[200, 202, 203] This is because a significant change across serial ECGs is, in and of itself, the evidence necessary to identify a significant subset of heart attacks (see unstable angina).[202] When the initial ECG acquired in the ED is negative, it has become "common clinical practice",[199] endorsed by published clinical policy, to perform "repeat ECG or automated serial ECGs",[201] for the assessment of new-onset chest pain of unknown origin. Recent guidelines recommend that this comparison include the pre-hospital 12-lead ECG.[167]

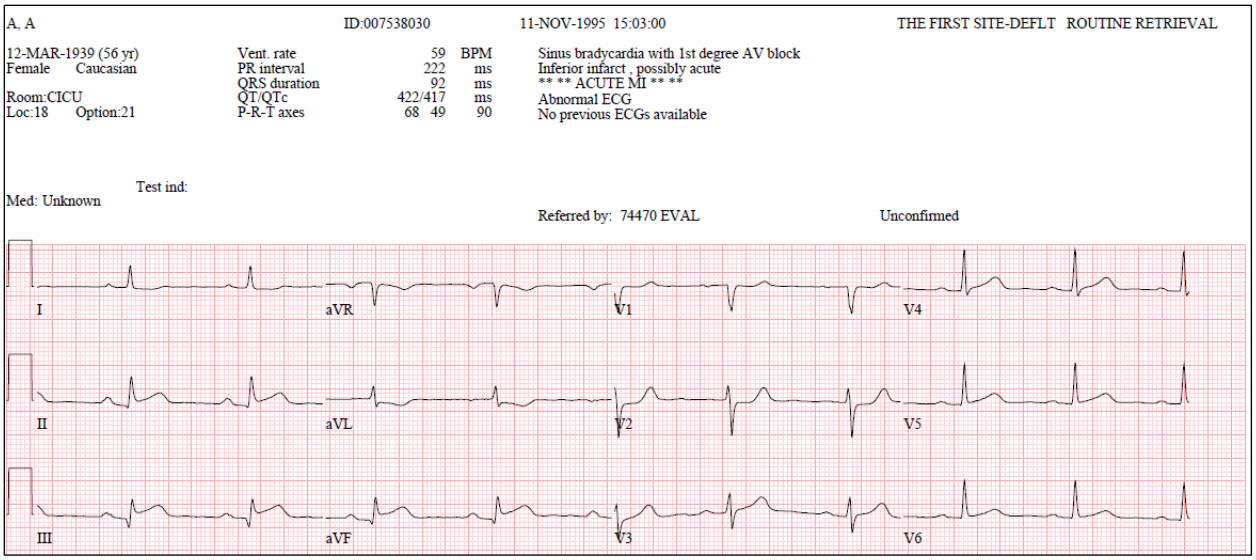
It should also be pointed out that although a significant change across serial ECGs puts a chest pain patient into a high-risk category, the converse is also true. A recent ACC/AHA practice guideline states "that patients with an unchanged ECG have a reduced risk of MI [a heart attack] and a very low risk of in-hospital life-threatening complications even in the presence of confounding ECG patterns."[200]

DEFINITION OF A SIGNIFICANT SERIAL CHANGE

Normal day-to-day variation in the 12-lead ECG is considerable.[70-72, 204] Although moving an electrode by just a few millimeters can affect the reproducibility of ECG measurements, [72, 205] most of the day-to-day variation is due to changes in the position of the heart.[206, 207] That is, as the heart rotates in the chest, the electrical cardiac vector rotates with it. This will result in significant changes per lead, but the overall 12-lead ECG remains essentially the same – at least clinically. In any case, experienced electrocardiographers can discern this type of change versus that due to an acute process.

To determine whether there is a significant change in the ST/T waveform due to an acute process, other factors that can also contribute to these changes must be ruled out. This includes significant changes due to rhythm or conduction. Likewise, since a significant number of heart attacks can occur silently (i.e. without symptoms),[208] the physician must inspect the QRS complex for new Q waves that could result in sustained changes in the ST/T that are different from normal but old, and not due to an acute process. It is only after this process is completed (that is, ruling out ST/T changes due to normal day-to-day variation or other changes due to conduction etc.) can the reader discern whether a ST/T change as outlined in the clinical guidelines is present.





Automated Serial Comparison – Detecting a Significant Change

Detailed documentation included in this guide (see here) states that GE's Marquette 12SL Serial Comparison Program[209] uses statements, measurements, *and* waveforms to compare the current and previous ECGs.

Interpretive statements guide the program as to what to more closely inspect for change. It should be clear that the program can tolerate a change in a statement that is essentially inconsequential to determining a significant change. For example, the current ECG can state incomplete right bundle branch block while the prior ECG states complete right bundle branch block. No significant change will be identified unless it visually obvious. This is important because interpretive statements can change based on a measurement exceeding a specific threshold. As a result, interpretative statements can come and go. The real issue is whether this is a significant change.

"GE Healthcare's Marquette 12SL Serial ECG Comparison Program has been developed to emulate the techniques used by trained electrocardiographers in the comparison of serial electrocardiograms."[209]

When significant changes are detected, they are indicated using descriptive statements. For example, the program will state that the "T wave amplitude in (a specific lead group) has increased or decreased." The same is done for ST segment elevation and depression. If there is T wave inversion, the comparison will indicate the extent of any change in the T-waves by stating "T wave inversion in (specific lead group) is more evident, less

evident, now evident or no longer evident." These changes can be summarized in terms of "an evolving acute myocardial infarction."

The mechanics of how this is accomplished is covered in more detail here. It may be important to know that the program uses the median complexes of both the current and previous ECG. These are superimposed upon one another by the computer and compared.[13] All measurements that are used by the 12SL program for contour analysis are regenerated and compared. Based on whether a specific abnormality was detected by the 12SL program in the current ECG, the comparison program may apply more sensitive criteria for detecting a change. For example, if the current ECG is identified as exhibiting a myocardial infarction, the program becomes more sensitive to changes commensurate to an evolving infarction. To avoid detecting a significant change in the presence of normal day-to-day variation, the program calculates spatial vectors from the 12-lead ECG. If the T-wave and QRS maintain the same spatial angle and are simply rotating in space, the program is less likely to identify a change in repolarization in a single lead.

HIGH SENSITIVITY TROPONIN AND ROLE OF ECG

There is great excitement regarding the use of high-sensitivity Troponin as testified to by the following quote: "After decades of seeking—and failing—to safely rule out myocardial infarction with less than a 1% miss rate, we now have that capability."[210] This excitement stems from the fact that high-sensitivity Troponin can, for a large portion of chest pain patients, significantly reduce the amount of time they need to remain in the ED or hospital for evaluation.

Before the advent of high-sensitivity troponin, it was recommended that patients with chest pain who had normal clinical findings, ECG, and cardiac injury markers in the ED should have repeated testing of ECG and cardiac injury markers (Troponin) for 6 hours.[211] Results from several large studies have shown that use of high-sensitivity cardiac Troponin for this patient group can safely cut this time to less than an hour.

For instance, high-sensitivity cardiac troponin T (hs-cTnT) was used in conjunction with ECG and prospectively evaluated as part of the routine assessment of 14,636 patients suspected of ACS. The conclusion was that "all patients with chest pain who have an initial hs-cTnT level of <5 ng/l and no signs of ischemia on an ECG have a minimal risk of MI or death within 30 days, and can be safely discharged directly from the ED."[212]

In another, even larger study conducted between June 10, 2013, and March 3, 2016, 48,282 consecutive patients suspected of ACS were enrolled. Versus the conventional technique of serial testing of ECG and Troponin, "use of a high-sensitivity assay prompted reclassification of 1771 (17%) of 10,360 patients with myocardial injury or infarction, but was not associated with a lower subsequent incidence of myocardial infarction or cardiovascular death at 1 year."[124] "Although the duration of stay doubled in those reclassified by the high-sensitivity assay, it was reduced by a third across the trial population."[124]

In addition to reducing the amount of time for evaluation for low-risk chest pain patients, it fortunately does appear that use of high-sensitivity Troponin and a "1-h algorithm is associated with reduction in overall AMI diagnostic costs, provided it is carefully implemented in clinical practice."[213] Nevertheless, given that high-sensitivity Troponin will detect ever smaller levels of myocardial necrosis, it is possible that chronic diseases will impact the values obtained via high-sensitivity Troponins[125] which could have a negative impact on increasing unnecessary interventions in a population that would otherwise been left untreated - a topic currently under investigation.[144, 214, 215]

A state-of-the-art review article on the subject of the clinical use of high-sensitivity Troponin states it should not be the only factor in clinical decision making; it should only be used "in conjunction with a full clinical assessment."[127] They "should only be applied after the initial ECG has excluded ST-segment elevation myocardial infarction (STEMI) because these high-risk patients need prompt identification based on the ECG." And finally, "some rule-out strategies require a completely normal ECG to be applied; others allow also for mild and nonspecific ECG abnormalities."

Critical Values

The Critical Values feature in a cardiograph is to provide a means to accelerate the reporting of critical test results. When a critical value or critical test result is present in the ECG, the statement "*** Critical Test Result:" followed by the type of critical values or results present in the ECG, appears as the first line of the 12SL interpretation. Depending on the cardiograph implementation, the user may also be notified by an on- screen prompt or dialog.

The Critical Values module works in conjunction with the 12SL ECG Analysis Program to identify ECGs with critical test results. It uses the outputs of the 12SL program and the user-specified thresholds and options as its input to identify the critical test results. If any critical test results are found, new statements are inserted at the beginning of 12SL interpretation.

The specific critical test results identified are:

High Heart Rate 123
Low Heart Rate 124
Long QTc 124
Arrhythmia 124
AV Block 125
ACS/Ischemia 125
ST-Elevated Myocardial Infarction (STEMI) 125

Each of these notifications can be individually turned on or off. The first three (high and low HR and QTc) are based on user-specified thresholds. In addition, the high and low HR notifications are individually configurable for adults and pediatrics, each with their own user-specified thresholds. For example, high HR notifications can be turned off for pediatric patients and turned on for adults, or they can both be on, with different thresholds for each.

The following are two examples of the critical test result line in a 12SL interpretation:

*** Critical Test Result: Long QTc

*** Critical Test Result: Low HR, Arrhythmia, AV Block

Note that because the notification statements are inserted into the 12SL interpretation, these statements become part of the ECG record.

High Heart Rate

For **adults or patients with unknown age**, the High HR notification will be generated when:

- the Adult High HR notification is enabled, and
- the 12SL ventricular rate is ≥ the Adult High HR threshold

For **pediatric patients** (age < 16), the threshold is the maximum of the user-specified Pediatric High HR threshold and the "upper heart rate" value from the age-specific pediatric table. The notification will be generated when:

- the Pediatric High HR notification is enabled, and
- the 12SL ventricular rate is ≥ the threshold as described above

This strategy was implemented for pediatrics because of the very wide range of normal heart rate between neonatal and adolescent ages. A reasonable upper limit for a 1-day old neonate would miss most 15-year-olds with rates high for their age. Conversely, a reasonable upper limit for a 15-year old would result in notifications for the majority of neonates. The program will use the user-specified threshold unless that threshold would result in a notification when the rate is within the normal limits for that patient age. In other words, the program will avoid saying "High HR" when the rhythm is "Normal sinus rhythm".

Low Heart Rate

For **adults or patients with unknown age**, the Low HR notification will be generated when:

- the High HR notification was not generated, and
- the Adult Low HR notification is enabled, and
- the 12SL ventricular rate is ≤ the Adult Low HR threshold

For **pediatric patients** (age < 16), the threshold is the minimum of the user-specified Pediatric Low HR threshold and the "lower heart rate" value from the age-specific pediatric table. The notification will be generated when:

- the High HR notification was not generated, and
- the Pediatric Low HR notification is enabled, and
- the 12SL ventricular rate is ≤ the threshold as described above

Similar to the High HR notification, the program will use the user- specified threshold unless that threshold would result in a notification when the rate is within the normal limits for that patient age; i.e., we will avoid saying "Low HR" when the rhythm is "Normal sinus rhythm".

Long QTc

The *Long QTc* notification will be generated when all of the following are true:

- the Long QTc notification is enabled
- no LBBB
- no RBBB
- no ventricular pacing
- 12SL QRS duration ≤ 40 msec
- 12SL ventricular rate ≤ 140 bpm
- 12SL QTc is ≥ the Long QTc threshold

The QTc value used for this test will be the Bazett-corrected QT measurement unless a different correction formula for the QT tests has been selected in the device's system setup (most devices do not have this configurability). In any case, the Critical Values test will use the same QTc value as is used by 12SL for the "Prolonged QT" statement, which always defaults to the Bazett correction.

Arrhythmia

The purpose of this notification is to notify on potentially lethal arrhythmias requiring immediate intervention or at least immediate review. The inclusions for this notification include:

- 12SL statement of "Idioventricular rhythm", or
- RR pause > 2500 msec, or
- 3 or more consecutive PVCs (VT > 2), or
- probable ventricular tachycardia

All of these are contingent on the arrhythmia notification being enabled.

AV Block

The AV Block notification is triggered by any of the following statements in the 12SL interpretation, contingent on the AV Block notification being enabled:

- with 2nd degree AV block (Mobitz I)
- with 2nd degree AV block (Mobitz II)
- with 2nd degree AV block
- with complete heart block
- with AV dissociation

ACS/Ischemia

The ACS / Ischemia notification is triggered by the presence of either of the following statements in the 12SL interpretation, contingent on the ACS / Ischemia notification being enabled:

- ** ** LBBB with primary ST-T abnormality - Consider ACUTE CORONARY SYNDROME (ACS) ** **
- ** ** Consider ACUTE CORONARY SYNDROME (ACS) ** **

Note that these two statements are only made when the ACS option is turned on. This means that this notification will never appear unless the ACS option is on. The ACS analysis option is not available on all products.

ST-Elevated Myocardial Infarction (STEMI)

The STEMI notification is triggered by the presence of either of the following statements in the 12SL interpretation, contingent on the STEMI notification being enabled:

- ** ** ACUTE MI / STEMI ** **
- ** ** LBBB with primary ST elevation abnormality - Consider ACUTE MI ** **

Note that the second statement is only made when the ACS option is turned on. The ACS analysis option is not available on all products.

Serial Comparison

GE Healthcare's Marquette 12SL Serial ECG Comparison Program has been developed to emulate the techniques used by trained electrocardiographers in the comparison of serial electrocardiograms and is designed to take advantage of the Marquette 12SL ECG analysis program's interpretation and measurements. The Marquette 12SL ECG serial comparison program was developed to use statements, ECG measurements, and waveform comparison techniques to maximize performance and accuracy in the detection of clinically significant changes in rhythm, P, QRS, ST and T waves. The MUSE system, which stores electrocardiograms with physician edited interpretations to both individual ECGs and serial comparisons, in unison with the serial comparison program, allows for accurate and expedient processing of a patient's ECG data.

Although the 12SL analysis is completed at the cardiograph at the time of the ECG acquisition, the serial comparison analysis is done at the MUSE when the MUSE receives the ECGs. This is transparent to the electrocardiographer who reads the ECGs printed from the MUSE workstation, and because of the integration of the programs, the serial comparison interpretation is appended to the original 12SL interpretation.

Overview of Serial Comparison Analysis

Rhythm Analysis

- Dominant rhythms compared first (sinus, ventricular, atrial fibrillation, etc.) via statements
- Rhythm modifiers compared second only if dominant rhythm does not change

QRS Analysis

- QRS comparison is done via statements, measurements, and waveform analysis
- Aim is to detect changes in conduction and/or infarction
- Changes in axis and voltage (amplitude) are also detected
- Looks for the first occurrence of an infarct and labels it on the ECG
- For infarction (if acute) more sensitive criteria are used
- Time between ECGs is used to adapt criteria sensitivity

ST-T Analysis

- Looks for the presence/absence of acute infarction or ischemia
- Looks for evolution of the ST-T changes in an acute MI
- Uses MI age categories to "adapt sensitivity of detection"
- < 4 days old

NOTE: The serial comparison program looks for significant changes in the waveforms when doing the contour comparisons. It is not unusual to have an ECG that may have narrowly met the criteria for a 12SL statement and have another ECG that just missed the criteria thresholds, yet there are no significant differences in the waveforms themselves. In such a case, the first ECG would have a statement that would be absent from the second and could possibly even have a different overall ECG classification. If the serial comparison program does not discern a significant difference in the actual waveforms, it will simply state that "no significant changes have occurred."

DETAILS OF SERIAL COMPARISON ANALYSIS

Rhythm Comparison

Rhythm comparison is done via statements. (Edited rhythm statements may be used by the program if they are from the original MUSE system library and are not user added statements or free text.) Actual Marquette 12SL program measurements are compared to assist in the detection of significant changes for first degree AV block and short PR interval. If a major rhythm change occurs, it is stated without reference to changes that occur in the rhythm modifier statements. Major rhythm changes are stated without reference to rate. For example, the statement "sinus rhythm has replaced junctional rhythm" is made instead of "sinus tachycardia has replaced unusual P axis and short PR, probable junctional bradycardia." Only when the basic rhythm is the same, does the program mention changes that occur in the rhythm modifier statements (e.g., PVCs, PACs, 1st degree AV Block, etc.).

Clustering of rhythm modifier changes is used. The program "clusters" modifier statements regarding ectopic beats as either premature ventricular or premature supraventricular. Other rhythm modifiers that are also clustered are (complete heart block and AV dissociation), (sinus pause and second-degree SA block Mobitz I and II), (second degree AV block Mobitz I and II). Certain rhythm modifier statements such as second-degree AV block, complete heart block or AV dissociation are given a higher priority than other rhythm modifier statements. For example, if the previous ECG has complete heart block and the current ECG has first degree AV block, then no statement is made about the PR interval for first degree AV block, but complete heart block is stated to be no longer present.

Rate dependent and PR interval calls are checked against the measurements before statements about change are made. Rate change statements are made at a more sensitive level if both ECGs contain electronic ventricular pacemakers. If a rhythm change (i.e. WPW or electronic pacing) results in a QRS change, the QRS-ST-T comparison is suppressed. If either of the ECGs being compared has "undetermined rhythm" then no rhythm comparison is performed.

QRS Comparison

QRS comparison uses statements, measurements, and waveforms. The emphasis is in detecting conduction and infarction changes. Changes concerning axis and/or voltage are also stated but with less sensitive criteria to accommodate "normal variability" in the ECG and changes that may be caused by inaccurate and inconsistent lead placement.

When WPW is stated in either the current or the previous ECG interpretation, then further QRS and repolarization comparisons are inhibited.

For specifying a change in conduction, measurement comparison and waveform correlation are used to determine whether the change is large enough to warrant the program stating it. If a major conduction change occurs, comparison of the repolarization is suppressed (skipped) since these are considered secondary changes.

Comparison concerning infarction is the most complicated and sophisticated analysis scheme in the program. Once a statement concerning infarction occurs in either of the ECGs being compared, then parameters related to infarction along with waveform correlation techniques and measurements are used to detect "clinically significant" change. The program will also search the patient's previous records and inform the user as to when the infarction first appeared in the series of ECGs.

If both ECGs have definite evidence of infarction (or the degree of infarction evidence is unchanged, i.e. the ECG waveform data in the leads exhibiting the infarction "look very similar"), then the program states "no significant change has occurred." If a "clinically significant" waveform change is evident, then the program will state it appropriately as "(specific location) MI now present" or "criteria for (specific location) MI no longer present" or if subtle changes in the Q-waves (initial part of the QRS) have been detected, the program will state "questionable change in initial forces of (specific location)."

This approach is used until repolarization changes or injury (ST-elevation) is evident in either of the ECGs. Upon development of a significant repolarization change in the presence of myocardial infarction evidence (QRS changes), the program becomes much more sensitive to changes in the QRS-ST-T. When there are ST-T wave changes detected by the program, the comparison becomes much more detailed. Sensitivity for detection of "clinically significant changes" changes with respect to the time difference between the two ECGs. Sensitivity and program statements will change depending on the following time differences between the acquisition dates of the ECGs: same day to 3 days, 4 days to 21 days, 22 days to 365 days and more than 365 days (1 year). When the ST-T wave changes occur within the first 3 days, the changes will be labeled as new or acute or as "serial changes of an evolving myocardial infarction." ST-T wave changes occurring between 4 days to 1 year which are becoming less severe (ST-T becoming more normal) will be described as "serial changes of myocardial infarction." If at any time the repolarization (ST-T) become more abnormal, the program will state that there are new changes present.

Repolarization Comparison

The ST segments and T waves are compared via the 12SL measurements. When significant changes are detected, they are indicated using "descriptive statements." For example, the program will state that the "T wave amplitude in (specific lead group) has increased or decreased." The same is done for ST segment elevation and depression. If there is T wave inversion, the comparison will indicate the extent of the T wave inversion by making the statement "T wave inversion in (specific lead group) is more evident, less evident, now evident or no longer evident." When the T wave abnormality is "non-specific," then the program will indicate whether the nonspecific T wave abnormality is worse or improved in (specific lead group).

Miscellaneous Comparisons/Other issues

Pediatric ECGs are not compared but the previous ECGs date and time are indicated by the program.

The Serial Comparison program tracks the length of the total interpretation. This includes the original ECG as well as the serial comparison interpretation. If more than 10 lines of text occurs and the serial comparison interpretation is more than 6 full lines of text, then the serial comparison program will suppress the comparison interpretation and simply state "significant changes have occurred." This is done to prevent the use of an additional page for the printing of the ECG.

If all previous ECGs are on an archive volume that is not "online" then the serial comparison program informs the user with the statement "manual comparison required data is offline and on volume#." If all previous ECGs are analog ECGs, then the program states "manual comparison required, analog tracing."

Part II: Statement of Validation and Accuracy

The following is a comprehensive disclosure of what has been reported in the literature regarding GE's Marquette 12SL™ Program. Regardless of whether the result was negative, positive, or in between, it is provided here and kept current to the date of publication of this document. Topics covered under Part II include the following:

Overall Impact of Computerized ECG 129
Development and Validation Process 135
Program Structure: Measurements Before Interpretation 139
Testing of 12SL™ Measurements via Standardized Database 146
Impact of Hookup Advisor™ on Accuracy of ECG Measurements 149
Independent Evaluation of 12SL™ Measurements 151
Predictive Value/Clinical Correlation of 12SL™ Measurements 161
Accuracy of Interpretive Statements: Reported Results 169
Interpretation of Rhythm: Reported Results 172
Contour Interpretation: Reported Results 182
Overall Classification: Reported Results 205
Serial Comparison 207
Conclusion 208

Overall Impact of Computerized ECG

Approximately 10-15% of computerized ECG interpretations require some form of editing before they are deemed acceptable to a cardiologist.[216-220] There has always been a concern as to whether this technology would be misused and do more harm than good. Below are a variety of categories where the computer has been found beneficial:

Generating Final Report: Speed, Efficiency and Accuracy 129
Initial Interpretation for Physician Before Review by Electrocardiographer 130
Triage, Time-to-Treatment of Chest Pain Patients 131
Identifying Normal versus Abnormal 132
Epidemiological Studies: Automated Measurements and Coding 132
Increased Error Rate in Presence of Non-Sinus Rhythms and/or Artifact 133
Clinical Impact Due to Computer Error or Inappropriate Use 134

This is followed by an assessment of when errors are most prevalent as well as the clinical impact of such errors or inappropriate use of the computerized interpretation. These include the following:

- Increased Error Rate in Presence of Non-Sinus Rhythms and/or Artifact
- Clinical Impact Due to Computer Error or Inappropriate Use

Generating Final Report: Speed, Efficiency and Accuracy

The computer provides a preliminary structured report. Since GE's Marquette12SL™ program tends to overcall, editing is streamlined by deleting or modifying the information provided. In conjunction with the 12SL™ Serial Comparison Program, the date and time of the prior ECG is automatically added to the report as well as statements regarding changes the computer considers to be significant. Even if interpretative statements differ between the current and prior ECG, the program can state, "no significant change" if it detects no significant change in the waveform.

- "The impact of computer assisted interpretation on cardiologists' readings of ECGs is demonstrably beneficial: the main empirical conclusion of this study is that, compared with conventional interpretation, the use of computer assisted interpretation of ECGs cuts physician time by an average of 28% and significantly improves the concordance' of the physician's interpretation with the expert benchmark, without increasing the false-positive rate."[221]
- "In a study of 22 cardiologists, it significantly improved the accuracy of the cardiologist's ECG interpretation (i.e., lowered false-positive and false-negative rates and increased diagnostic concordance with a recognized expert panel). While this may not affect the overall quality of patient care, it is nonetheless encouraging."[221]
- "Combined cardiologist and program results demonstrated the highest accuracy. ... These findings demonstrate that the combination of expert knowledge of computer programs can, similar to panel review and group analysis in clinical practice, enhance diagnostic accuracy."[222]
- "Computer ECG systems provide a valuable function for ECG analysis, storage, retrieval, and serial comparison. The current systems can provide quality control of technician performance, acquisition equipment, and physician over reading. Its overall acceptability and clinical usefulness are documented in a clinical practice setting with a 90.4% computer-physician agreement in more than 20,000 ECGs. Computerized ECG systems have demonstrated their clinical usefulness in patient care."[216]
- "Although computer ECG analysis is still inferior to physician interpretation, it may be a useful adjunct to save physician time."[223]
- "The implementation of a digital ECG system [MUSE and 12SL] in our Children's Hospital increased the total number of ECGs officially interpreted and reported. ... In addition to improving the quantity of ECGs officially interpreted, the overall quality of the ECG for interpretation was improved."[224]

Initial Interpretation for Physician Before Review by Electrocardiographer

All physicians are trained in 12-lead electrocardiography. Expert electrocardiographers excel when the ECG is difficult and the interpretation complex. Physicians at the point-of-care can increase their accuracy of their interpretation by considering the patient's status and other relevant information. In fact, this is true even for a cardiologist. Consider that in a study using 12SL™, "interpretations by cardiologists as primary readers were more accurate than the interpretation provided by overreading cardiologists (94% vs 72%, P < .001)."[225]

- "The quality of computer-assisted ECG interpretation was comparable to that of review provided by a cardiology service. Computerized interpretation may be clinically more useful because it is immediately available."[226]
- On ECGs obtained on pediatric patients and analyzed by 12SL™ in an emergency department (ED) without immediate access to a pediatric cardiologist, "there was a significant discordance in the ECG interpretative accuracy between the ED physicians and the computer-generated report. The computer proved to be more accurate than the ED physicians in interpreting ECGs of less than critical significance. ... But neither could correctly interpret even a simple majority of the most significant abnormalities. We speculate that distributing the computer-generated interpretation to the ED physicians and formal review of all ED ECGs by a skilled interpreter may decrease the number of missed diagnoses."[227]
- "In summary, this study has confirmed that junior doctors have a high error rate in reporting ECGs. Computer generated reports did not significantly improve this, even though the machine achieved a low major error rate compared with the junior doctors. Computer generated reports may have a role in prompting junior doctors to query their own ECG interpretation but should not replace experienced medical support."[228]

TRIAGE, TIME-TO-TREATMENT OF CHEST PAIN PATIENTS

Several prospective clinical trials have demonstrated that prehospital ECGs can effectively be acquired by paramedics,[229] reduce time-to-treatment,[230-232] and "significantly increase the diagnostic accuracy in chest pain patients."[233] GE Healthcare was the first to introduce pre-hospital diagnostic 12 lead ECG as a small, compact unit for the ambulance that could acquire and transmit 12-lead ECGs digitally so that there would be no distortion of the ST/T waveform.[165]

Use of prehospital ECG is considered a standard-of-care. According to the ACC/AHA, prehospital ECG should widely be adopted because "prehospital ECG programs have the potential to improve the way care is delivered to patients with STEMI in the United States."[167] In this case, the paramedic is the first see the preliminary interpretation.

- Current American Heart Association guidelines recommend that paramedics perform and evaluate a prehospital ECG routinely on patients with chest pain suspected of having STEMI (Class IIa, Level of Evidence B)."[167]
- Without a computerized prehospital 12-lead ECG, it is difficult for healthcare systems to meet the time-to-treatment thresholds for STEMI issued by the Joint Commission of American Hospitals (JCAHO) as well as the Center for Medicare and Medicaid Services (CMS).[112, 234-237]
- Results of prehospital activation of the Cath Lab based on STEMI identification by 12SL™ found that prehospital diagnosis as the single most important factor in reducing the door-to-balloon time.[238]
- "A combination of prehospital automated ST-segment elevation myocardial infarction (STEMI) diagnosis [by 12SL™] and 'physician-less' cardiac Cath lab (CCL) activation was safe and effective in ensuring target door-to-balloon times in virtually all patients and resulted in an acceptable rate of inappropriate CCL activation"[172]
- "The present algorithm [12SL™] is clearly adequate for first line screening of patients with chest pain by paramedics or in the emergency department. Its sensitivity is no worse than that of the emergency physician and its specificity is superior to the trained electrocardiographer."[239]
- A total of 855 triage ECGs in the emergency department (ED) were collected over 16 weeks. "Triage ECGs identified by the computer [12SL™] as normal are unlikely to have clinical significance that would change triage care. Eliminating physician review of triage ECGs with a computer interpretation of normal may be a safe way to improve patient care by decreasing physician interruptions."[173]
- "The ED sees more than 73,000 adult patients and treats 120 STEMIs annually. ... Zero control patients were incorrectly labeled 'acute MI suspected.' The specificity [of 12SL™] was 100% (100/100; 95% CI 0.96-1.0) ..."[240]
- "Over a 2-year period, 1,247 ECGs acquired by primary care paramedics for suspected STEMI were collected and interpreted in real time by the GE Marquette 12SL™ ECG analysis program." "For settings with comparable ECG eligibility criteria and similarly low STEMI prevalence, our estimated predictive values appear adequate for the implementation of a strategy to direct patients with a positive computer result to hospitals with angioplasty facilities and patients with a negative interpretation to nonspecialized centers."[171]
- "The emergency physician and cardiologist improved their sensitivity of interpreting acute myocardial infarction by 50% and 26%, respectively, without a loss of specificity. The new algorithm [12SL™, ACS tool] also improved the emergency physician's acute ischemia interpretation sensitivity by 53% and still maintained a reasonable specificity (91%)."[37]
- "Software interpretation [12SL™] of STEMI had good sensitivity and excellent specificity, and theoretically conferred a 17-minute reduction in D2D time."[241]
- This study found that serial ECGs during patient transport increased sensitivity of 12SL™ for STEMI recognition to 100%. More specifically, 325 consecutive prehospital STEMIs were

retrospectively identified. “STEMI was identified on the first prehospital ECG in 275 cases, on the second ECG in 30 cases, and on the third ECG in 20 cases (cumulative percentages of 84.6%, 93.8%, and 100%, respectively). For STEMIs identified on the second or third ECG, 90% were identified within 25 minutes after the first ECG. The median times from identification of STEMI to arrival at the ED were 17.5 minutes, 11.0 minutes, and 0.7 minutes for STEMIs identified on the first, second, and third ECGs, respectively.”[242]

IDENTIFYING NORMAL VERSUS ABNORMAL

Studies have substantiated that 12SL™ has a high negative predictive value in terms of applying a classification of normal versus abnormal. There will be rare instances when 12SL™ will identify an abnormal ECG as normal. Although a normal ECG in the presence of an acute myocardial infarction is predictive of a good outcome, it is not rare; in fact, in a large pooled study of over 390,000 acute MI’s, 8% of initial ECGs were normal.[8]

- The 12SL™ program “is reliable in diagnosing normality: even the disagreements are arguable. … From a practical point of view, the eventual consensus opinion of the cardiologists was that only one tracing reported as normal by the system should have been reported as abnormal to a family doctor, resulting in a negative predictive value of 98.4%. In view of the cardiologists inter-observer variation with regard to what is normal - this may well be higher than an individual cardiologist’s negative predictive value and suggests that the system examined may safely be used to exclude major abnormalities which would affect clinical management”.[243]
- “A total of 39,238 electrocardiograms were reviewed … The 12SL™ program placed the ECG into the following diagnostic classifications: normal 22%, otherwise normal 6%, borderline 5%, and abnormal 66%. The reviewing physician agreed with this classification in 96.3% of all cases … The most striking information shows the agreement of the physicians with the computer diagnosis of an abnormal electrocardiogram in 97.7% of the 25,295 tracings. In only 204 records out of 25,987 tracings (.8%), the physicians edited a computer-called abnormal electrocardiogram and changed it to normal. In only 63 of 8,632 (.7%) tracings of which the computer called normal did the physicians edit this tracing to read abnormal.”[220]
- As tested on 26,734 male and 3,737 female veterans, a classification of a normal ECG by the 12SL™ program “is associated with extremely good survival”.[244]
- “Out of 2072 remaining cases, 776 (37.5%) were read [by 12SL™] as normal … There were no discordances in the ECGs read as normal”[219]
- A study conducted in an emergency department found that using 12SL™ on pediatric patients, “the computer correctly interpreted all normal ECGs.”[227]

EPIDEMIOLOGICAL STUDIES: AUTOMATED MEASUREMENTS AND CODING

Population-based research groups use 12SL™ for generating measurements since it improves their quality control, effectiveness and consistency.[245-263] This has made it possible to identify previously unknown relationships between the resting ECG and predicting such conditions as out-of-hospital cardiac arrest (OHCA), sudden cardiac death, heart failure, atrial fibrillation, poor outcome due to COVID or treatment of COVID with Chloroquine, etc. In additions, large databases of digital ECGs analyzed by 12SL™ have been used for development of machine learning algorithms.[264-267]

- In a large study conducted in Denmark which leveraged the Danish Cardiac Arrest Registry, ECGs obtained on 326,777 individuals in the primary care setting were analyzed by the 12SL™ program to determine the association between common ECG abnormalities and 2,667 (0.8%) OHCA.[254] This study found that several frequently encountered ECG abnormalities in a primary care setting were associated with increased risk of OHCA, especially LBBB, IVCB and ST-depression without concomitant atrial fibrillation.

- In 211,920 patients (aged 18 to 75 years), the prevalence and prognostic significance of early repolarization (ER) as identified by the 12SL program was evaluated at Montefiore Medical Center, the University Hospital for Albert Einstein College of Medicine.[256] "All automated ECG interpretations were reviewed for accuracy by a board-certified cardiologist who confirmed the presence or absence of ER on the basis of the classic definition of ER.." "The primary end point was death during a median follow-up of 8.0 ± 2.6 years," with the conclusion that ER recognized by 12SL "was not associated with an increased risk of death, regardless of race or gender, and should not trigger additional diagnostic testing."[256]
- Using 12SL™ measurements from 6,664 MESA study participants, prediction of heart failure was explored for those with reduced versus preserved ejection fraction (respectively, HFrEF and HFpEF). A multivariable adjusted model included computerized QRS duration, delayed intrinsicoid deflection, left-axis deviation, right-axis deviation, QT interval, ST/T-wave abnormalities, P-wave axis, QRS-T angle, etc. This study concluded "markers of ventricular repolarization and delayed ventricular activation are able to distinguish between the future risk of HFrEF and HFpEF. These findings suggest a role for ECG markers in the personalized risk assessment of heart failure subtypes."[268]
- "The Minnesota Code (MC) and Novacode (Nova) are the most widely used electrocardiographic (ECG) classification systems. ... All electrocardiograms were processed in a central laboratory (Epidemiologic Cardiology Research Center, Wake Forest University, Winston-Salem, North Carolina) and were classified by the Nova and MC using the 2001 version of the GE Marquette 12SL™ program."[269] "In summary, these results show that MC and Nova are valuable classification systems for ECG myocardial infarction or ischemia with no significant gender differences for prediction of CHD events and total mortality."[269]
- By leveraging MUSE™ and the measurements generated by 12SL™, "this longitudinal observational database that contains 979,273 electrocardiograms from 461,178 patients over a 19-year study period ... can provide an opportunity to study electrocardiographic changes caused by medications, disease, or other demographic variables."[270]
- "Processing for the present study utilized the 2001 version of the GE Marquette 12SL program. The repeatability of this program for coding is 100%, unlike repeatability of visual coding by trained electrocardiographers for Minnesota Code (MC) or Novacode (NC), which in turn is superior to that of repeat cardiologist reading for lesser ECG abnormalities. ... The prevalence of ECG abnormalities among blacks in this younger and middle-aged biracial cohort was markedly higher than whites."[271]

Increased Error Rate in Presence of Non-Sinus Rhythms and/or Artifact

Although multiple studies have indicated the 12SL™ program is accurate when it states "normal", it is inadequate for a variety of abnormal conditions. Errors are most frequent in the presence of non-sinus rhythms and/or artifact.

- "Out of 2072 ECGs, 776 (37.5%) were normal, and 1296 (62.5%) were abnormal. ... The errors [by 12SL™] in diagnosis of arrhythmia, [AV] conduction disorders and electronic pacemakers accounted for 178 cases, or 86.4% of all errors."[219]
- While using 12SL™, "sinus rhythm was correctly interpreted in 95.0% of the ECGs (1666/1753), whereas non-sinus rhythms were correctly interpreted with an accuracy of only 53.5% (192/359) (P<0.0001)."[272]
- In a study of "2,298 ECGs identified by 12SL™ as atrial fibrillation, 442 ECGs (19%) were incorrect."[91]
- Most computerized interpretation errors by 12SL™ are for rhythm interpretation, especially those with artificial pacing.[89]
- In a study that reported a sensitivity of 58% for 12SL™ STEMI recognition, "50% of the missed STEMIs were labeled as 'data quality prohibits interpretation'." [240]

- More than half of the ECGs that led to a false positive determination [by 12SL™] of atrial fibrillation exhibited "a rhythm that was irregularly irregular due to premature atrial complexes 137 patients (36%), regular sinus rhythm with marked artifact (28%), or both (11%)."[91]

CLINICAL IMPACT DUE TO COMPUTER ERROR OR INAPPROPRIATE USE

Despite the frequency of errors, there are few studies that have evaluated the clinical impact of computerized ECG interpretation errors.

- A systematic search and ongoing surveillance of MEDLINE, EMBASE and the Cochrane Controlled Register concluded, "Physicians of all specialties and levels of training, as well as computer software for interpreting ECGs, frequently made errors in interpreting ECGs when compared to expert electrocardiographers. There was also substantial disagreement on interpretations among cardiologists. Adverse patient outcomes occurred infrequently when ECGs were incorrectly interpreted."[273]
- "Computer decision support systems can generally improve the interpretive accuracy of internal medicine residents in reading EKGs. Subjects were influenced significantly by incorrect advice, which tempers the overall usefulness of computer-generated advice."[274]
- Based on an initial false-positive interpretation of atrial fibrillation (AFIB) by 12SL™, a study was conducted of the clinical consequences of that interpretation. The study evaluated a total of 2,298 ECGs identified as AFIB. Of these, 442 (19%) were false. This led to unnecessary diagnostic testing in 90 patients (repeat ECGs in 78, cardiac ultrasound in 15, and Holter in 2). Complications due to inappropriate treatment occurred in 2 patients: 1 patient developed hematuria due to the initiation of anticoagulation, and the other patient had symptomatic bradycardia after initiation of atrioventricular nodal blocking agents. "Overreliance on computer-assisted interpretation obviously contributed to unnecessary management steps. When cardiovascular specialists were consulted, the misdiagnosis was corrected in all but 3 cases."[91]
- Door-to-balloon times were negatively impacted due to reliance on 12SL identification of STEMI. Only 12SL STEMI ECGs were immediately over-read by an emergency department physician. In 340 consecutive patients who had ECG changes which met criteria for reperfusion therapy, "92 patients were missed by computer interpretation."[275] 53% of these were identified as "myocardial infarction, age undetermined." When 12SL™ states "age undetermined", it should not imply that it is old. When 12SL identified STEMI, the culprit artery detection rate was 94.4% versus <80% for the other ECGs. Optimum screening processes in the ED for STEMI is still an area of study.[118]
- A chest-pain patient with a single ECG identified as STEMI by 12SL and later corrected by a cardiologist to state "Non-specific ST segment abnormalities" was used to evaluate care management decisions of 110 Internal and Emergency Medicine residents. Among the subgroup of residents who read the ECG as diagnostic (n = 48), residents given the erroneous interpretation were significantly more likely to recommend revascularization (54% vs. 25%, p = 0.048). [276]
- "In 97,046 study ECGs (48.2% from males), a prolonged 12SL-calculated QTc value (ie, ≥470 ms in females >60 years old, and ≥460 ms in other sex/age groups) was displayed in 16,235 (16.7%). Nonetheless, for only 7709 (47.5%) did the automated interpretation include an accompanying 'Prolonged QT' diagnostic statement. ... In evaluating an adult patient whose 12SL-interpreted ECG lacks a prolonged QT diagnostic statement (assuming sinus rhythm <100 beats per minute and QRS duration <120 ms), physicians should examine the actual QTc value displayed on the report before concluding that this parameter is normal. Assessment of the clinical impact of prolonged QT diagnosis suppression by ECG waveform-based criteria is warranted."[277]

Development and Validation Process

GE's Marquette 12SL™ program was introduced in 1980. All improvements to the program have been accomplished via a systematic, logical, controlled methodology. A major aspect of this methodology benefits from the use of stored ECGs.

The items covered for the development and validation process of 12SL include the following:

Reanalysis of Stored ECGs 135
Initiating a Change 135
Measuring the Impact: Evaluation via Library of Databases 135
Selecting an Appropriate Gold-Standard Database 136
Type A Statements: Reliance on Non-ECG Correlates is Not Enough 136
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Porting 12SL to Multiple Platforms: Verification Process 137

Reanalysis of Stored ECGs

All historical ECGs analyzed by the 12SL™ program and stored on the MUSE™ system, can be re-analyzed for the purposes of validating or improving the program.[14] This is because the median QRS complex generated by the program has always been compressed and stored via a lossless Huffman encoding method.[11, 278] The first implementation of this methodology has been described in the literature,[279] was later enhanced by GE Healthcare for ECGs stored at 500 samples per second (SPS),[19] and ultimately served as the basis of a new international standard.[280] This standard includes data fidelity requirements for compressed ECGs; these requirements are surpassed by the data compression/decompression methods currently employed by GE Healthcare. For those who desire additional fidelity, GE Healthcare provides another option (known as Digital View Storage DVS), which uses lossless compression throughout the ECG.

Initiating a Change

Any change to the program requires a great deal of research. This effort can be instigated by a variety of sources:

- The constant pursuit of clinically correlated databases can yield statistics that indicate whether a change should be considered.
- New criteria published in the scientific literature can be evaluated and sometimes incorporated into the program.
- Consultations with cardiologists also stimulate investigations. This is especially true when they have stored ECGs that reveal a measurement or interpretation error.
- GE Healthcare also documents customer complaints. Although complaints can from customer interactions with service, sales or the call center, any GE Healthcare employee who is aware of a complaint must document it. The engineering department tracks these complaints. Any digital ECGs provided by a customer that exemplifies the problem can be reanalyzed to determine the source of the error. If a solution can be found without negatively impacting the rest of the program, the fix will be applied to new versions of 12SL.

Measuring the Impact: Evaluation via Library of Databases

Before a change can be instituted, it must always be evaluated in relation to the current program performance. Stored ECGs are reanalyzed and any difference due to the enhancement is scored and tracked. After this is done, the validation system automatically culls out any ECGs that scored differently between the two versions of the program. This results in an efficient method to automatically determine how a change might affect program performance.[14, 23]

SELECTING AN APPROPRIATE GOLD-STANDARD DATABASE

In the 12SL™ Physician's guide, each 12SL™ interpretive statement has been identified as either Type A, B, or C, a classification methodology approved at the Tenth Bethesda Conference on Optimal Electrocardiography.[281]

Type A statements refer to the diagnosis of anatomic lesion or pathophysiologic state, such as myocardial infarction or hypertrophy. The accuracy of these statements can only be determined in conjunction with non-ECG evidence such as cardiac catheterization (CATH), echocardiography (ECHO), cardiac enzymes, clinical outcome, etc. These statements are evaluated with databases that have been clinically correlated with non-ECG data. The non-ECG data acts as the "gold standard".

Type B statements cover statements referring to the diagnosis of electrophysiological changes and are detected primarily by the ECG itself. This includes arrhythmias and conduction disturbances. Although intracardiac recording can be used to validate the diagnostic conclusions determined via the surface ECG, this is often not practical. As a result, a cardiologist's interpretation is used as the reference.

Type C statements refer to purely descriptive ECG features that usually cannot be documented by any other means. Examples of such statements include "non-specific ST-T abnormality" and "left axis deviation". Again, a database of ECGs with the physician's interpretation is used as the reference.

TYPE A STATEMENTS: RELIANCE ON NON-ECG CORRELATES IS NOT ENOUGH

Databases that have been correlated with non-ECG data are critical for the development and validation of Type A statements. But these databases have their limitations. Reasons include the following:

- The requirement that a non-ECG correlate must be used for validation may force the database to contain a population that is not representative of the disease in the actual clinical setting. For example, an autopsy-proven myocardial infarction (MI) database may not be indicative of what a typical MI looks like, since many patients survive an MI. Another example would be "CATH proven normals". In this case, the patient often receives the CATH because they were symptomatic, or the ECG was "abnormal". As a result, the ECGs from such a database may not be from true "normal" patients.
- Databases from most published clinical investigations have already removed the "confounding influence" of ECGs with conduction defects, artifacts, etc. This does not reflect the real world. The algorithm must operate in the presence of ischemia, conduction defects, drug effects, artifacts, etc.
- A non-ECG value may indicate the presence of an abnormality, but this does not mean that the abnormality is revealed in the surface ECG. For example, an ECG can often appear "normal" even when it is clearly established that it is from a patient with an acute myocardial infarction. It is important to not force the program to identify these ECGs as positive if the abnormality is not revealed in the signal. Otherwise, the program will overcall the abnormality in other environments.
- The database may only contain the extreme cases of normal versus abnormal. Algorithms don't operate in a black and white world.
- And finally, non-ECG data cannot be considered perfect: every test comes with its own inherent level of inaccuracy.

Even when an abnormality can only be positively determined via a non-ECG correlate, a physician's interpretation is critical as an additional check. During development and testing, databases based on a physician's interpretation are used in conjunction with databases that have been correlated with non-ECG data.

As an additional check, GE Healthcare uses large databases that have been gathered as part of routine care. In this case, there may be little quality control of the physician interpretation. These large databases, available

via a MUSE™ system, are useful for determining the rate at which a change in the program will generate a change in an interpretation across an entire institution. Reanalysis on over 100,000 ECGs can be done in a matter of minutes and it confronts the algorithm with multiple kinds of waveforms and varying degrees of abnormality. ECGs that changed their analysis can be further investigated with either confirmation from medical records and/or another expert opinion.

TRAINING VERSUS TEST SETS

Different databases are used for development versus validation. This precludes overtraining an algorithm so that it works beautifully on the training set but cannot be generalized across other sample sets with the same success. This is an important requirement for reliable pattern recognition.[282] In this document, all validation and reported results for interpretation performance are from independent test sets.

PORTING 12SL TO MULTIPLE PLATFORMS: VERIFICATION PROCESS

GE's Marquette 12SL™ Program has been implemented on a variety of platforms, including Holter recorders and prehospital defibrillators. To accomplish this, the program must be completely tested in its target environment. The use of analog ECGs to test every logic path in the target environment is not feasible. Thousands of ECGs would have to be recorded and the results manually compared. A digital solution is required. GE Healthcare invented a program for this purpose, known as EZSIM (i.e. easy simulator).

EZSIM is a program that generates simulated ECGs with the intent of thoroughly exercising the 12SL program. After 12SL processes an ECG made by EZSIM, a checksum is computed across all inputs, the complete analysis output of 12SL, and many intermediate results that never get displayed on a report. Checksum mismatches indicate that 12SL produced a different output than expected on the target platform. A target implementation is only considered successful when over 70,000 ECGS have been analyzed by the target platform without any differences detected in the checksums.

ESZSIM simulates ECGs with a vast variety of shapes and rhythms, covering all categories identified by the program. Each ECG is generated algorithmically and is not restricted to 10 seconds or even 24 hours.

The simulator has two parts: the initialization routine and the running routine. The initialization routine uses about 109 random numbers to create a basic P wave pattern, a basic QRS pattern, a basic PVC pattern, a basic PP interval, an amount of PP variability, a basic PR interval, an amount and frequency of muscle tremor noise and an amount and frequency of baseline sway noise. The running routine uses up to 4 random numbers per sample to determine the noise, 3 random numbers per QRS or unconducted P-wave to determine when the next P-wave, QRS, or PVC will occur. The simulator can overlap one QRS cycle with the next so that the P-waves at higher heart rates can creep into the T-wave of the previous cycle. Types of rhythms generated by EZSIM include the following:

- unconducted P-waves
- modulated coupling intervals, P-P
- random occurrence of ectopy, blocked AV conduction
- dual synthesis of patterns allows overlap, P onto T, or R onto T
- atrial fibrillation – irregular with fibrillatory waves
- atrial flutter – fast, less irregularity, no fibrillatory waves
- ventricular tachycardia
- torsade, ventricular pattern is rotated gradually
- ventricular fibrillation
- muscle tremor noise, electrode motion noise, baseline sway

Although constructed using random numbers, these ECGs are exactly reproducible given a starting point in the random number sequence. That starting point is called the random number seed. That seed is all that is needed to reconstruct that ECG of unlimited length.

Any number can be used as the random number generator seed. All the numbers from 0 to 65535 produce different sequences of random numbers and different ECGs. The simulator algorithm is the equivalent of a database but as opposed to conventional databases that retrieve stored ECGs, this database requires only about 3 kilobytes of code and no storage for the actual ECGs.

Program Structure: Measurements Before Interpretation

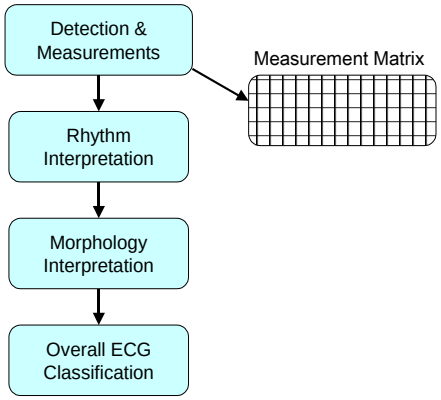
CONTENTS FOR THIS SECTION

The Digital ECG: Data Content and Fidelity 139
Pattern Recognition of Noise/Quantifying Signal Quality 140
Median Beat/Signal Averaging 141
QRS Onset/Offset and Determination of Global Intervals 142
Definition and Measurement of Waves 143

Below is a simple block diagram of GE's Marquette 12SL™ Program. Note that all the interpretative statements are generated following the measurement portion of the program.

All measurements generated by the program are stored in a measurement matrix, which are then later accessed by the interpretive portions of the program. Criteria used by the program are fully described in the 12SL™ Physician Guide: Part I – Criteria and Methodology. Note that these criteria never directly measure the ECG. The criteria use only the values from the measurement matrix. For any given ECG, the measurement matrix can be printed at the interpreting electrocardiograph or MUSE™ ECG storage system.

12SL Block Diagram



Since the interpretive portions of the program are based on measurements, it is critical that the ECG measurements be as robust and as accurate as possible.[283] The following sections address the necessary elements for generating quality measurements, with associated references to substantiate this quality.

THE DIGITAL ECG: DATA CONTENT AND FIDELITY

In addition to resting electrocardiographs, the 12SL program operates in a variety of products, from bedside monitors to prehospital defibrillators. As a result, the 12SL program has been designed to be configurable for different environments.

All 12 leads, simultaneously recorded for 10 seconds, is the minimum data set required by GE's Marquette 12SL™ Program (specifically leads I, II and V1-V6; leads III, aVR, aVL, and aVF are calculated via Einthoven's law). In some applications, the 12SL program analyzes more than 10 seconds or more than 12 leads.

In 1979, GE Healthcare introduced simultaneous recording of 12 leads so that the computer could use all signals from all 12 leads to properly detect and classify each QRS complex. The Common Standards for Electrocardiography independently verified the advantage of this technique:

> *"Conclusion: The simultaneous recording and analysis of all 12 standard leads…is certainly an improvement over the conventional recording of three leads at a time. Similarly…multi-lead programs proved to be more stable than those obtained by conventional programs analyzing three leads at a time…"*[50]

All resting electrocardiographs currently sold by GE Healthcare analyze the waveform at 500 samples per second (SPS). In some GE Healthcare resting electrocardiographs, the ECG is sampled at a much higher rate, such as 4,000 SPS. This is referred to as over-sampling and it used by the device to generate an average, cleaner signal at 500 SPS. Specifications for electrocardiographs, across the industry, often cite the raw sample rate (e.g. 4K SPS or higher) without clarifying that the ECG analysis and measurement software executes on data with a lower sample rate. Current guidelines for resting ECG analysis cite 500 SPS,[52] which is the minimum sample rate executed by 12SL. In some GE Healthcare electrocardiographs, the 12SL program can be configured to analyze the ECG at 1K SPS.

Before the physiological data is sampled, analog filtering is applied. These filters attenuate high-frequency electrical noise that is not part of the physiological signal. If these analog filters were not present in the device, high-frequency signals could be digitized by the device and appear as low frequency noise, inter-mixed with the physiological cardiac signal. To eliminate this possible source of contamination, GE Healthcare applies an analog filter, known as an anti-aliasing filter.

Pattern Recognition of Noise/Quantifying Signal Quality

As opposed to measuring skin impedance, GE Healthcare has adopted an alternative approach for detecting signal quality, which directly analyzes the ECG signal for muscle tremor, AC power interference, electrode motion, or baseline shifts. This software algorithm for detecting these artifacts has previously been described and is referred to as Hook-up Advisor.™[33]

ECG devices often measure the impedance across the skin-electrode interface. When this impedance exceeds 600KΩ, a GE Healthcare resting electrocardiograph informs the user that a lead is off and provides no signal for that lead. The reason the device no longer provides a signal for a "lead-off" condition is because a dangling lead would result in extreme noise, obscuring the rest of the ECG report and making it difficult for both the analysis program and the human to interpret the ECG.

Throughout the ECG industry, impedance across the electrode-skin interface is often used as a surrogate for lead quality. Normal skin impedance can vary dramatically, from 10 to 300KΩ.[284] It has been shown that skin impedance has a poor correlation with the presence of artifacts. [58]

Stating there is poor signal quality below 300KΩ simply results in false-positive calls and great frustration upon the person taking the ECG. A good quality resting ECG can be obtained at an input impedance > 300KΩ.

GE Healthcare continuously analyzes the digital signal for artifacts. For instance, muscle tremor is "detected by counting the number of deflections exceeding a fixed threshold per second."[33] Powerline interference is detected by running a "frequency hunting" filter over each lead of the 10-second ECG.[285] Baseline sway is evaluated by "tracking the minimum and maximum of a low-pass filtered version of the ECG signals."[33] If the difference between these exceeds a threshold, the ECG lead is identified as being contaminated by baseline sway. Electrode noise is "determined by examining QRS complexes for false QRS detections. Individual lead energy content of the QRS, the RR intervals of QRS complexes, and a measure of the correlation of the QRS across all leads is also considered."[33] All of these methods are incorporated into a software algorithm known as Hook-up Advisor™ and its impact evaluated in the following studies.[33, 59, 286]

Hook-up Advisor™ assigns an ECG lead quality level of green, yellow, or red, which is also indicated on the user interface of the electrocardiograph. This was tested on a large database of over 120,000 ECGs. Lead quality distributions and rhythm interpretation discordance rates between the physician and GE's Marquette 12SL™ Program are reported below.

Lead quality and rhythm discordance for combined test set (N = 120,698).[33]

Lead quality	*N*	*Percent of total*	*Discordance rate*
Green	115128	95.39%	3.9%
Yellow	5170	4.28%	7.4%
Red	400	0.33%	12.1%

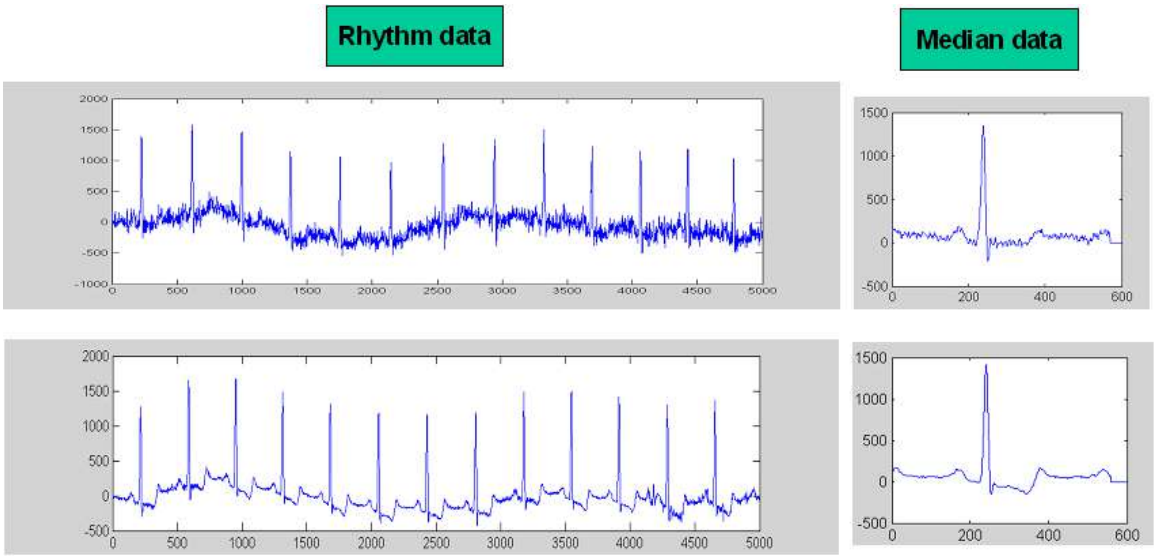
Overall, 95.4% of all ECGs were categorized as green (good) lead quality, 4.3% were assessed as yellow (marginal) lead quality, and 0.3% as red (poor) lead quality. As the primary rhythm from the 12SL reanalysis was compared to the primary rhythm in the confirmed ECG, the discordance of these two interpretations increased sharply, from 3.9% to 7.4% to 12.1% as the lead quality degraded from green to yellow to red.

Lead quality indicators can be stored on MUSE and can be used to monitor the quality of ECG acquisition across an institution.

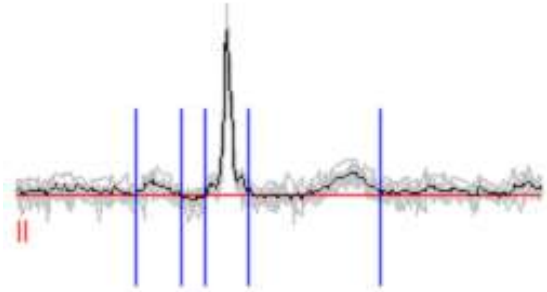
MEDIAN BEAT/SIGNAL AVERAGING

In addition to filtering or signal conditioning, there is another method that is employed to eliminate noise from the cardiac cycle: that is, signal averaging. Instead of analyzing the best raw QRS complex, the GE's Marquette 12SL™ Program generates a median complex. All QRSs of the same shape are aligned in time. Next, the algorithm generates a representative QRS complex from the median voltages that are found at each successive sample time. Although more complicated than creating an average, the method results in a cleaner signal than an average.

Below is an example of the formation of a median from a 12-lead Holter recording.[34]



Presented below is even a closer look at the median. It shows the median complex displayed along with the raw complexes used to form the median complex. Note the noise in the raw signal versus the median complex.



Willems et. al.,[287] independently verified the value of this technique. Without the technique, onsets and offsets were shifted outward in the presence of noise. As quoted from the literature: "Increasing levels of high-frequency noise shifted the onsets and offsets of most programs outward. Programs analyzing an averaged beat showed significantly less variability than programs, which measure every complex or a selected beat. Based on the findings of the present study, a measurement strategy based on selective averaging is recommended for diagnostic ECG computer programs."

Results by Zywietz[288] also showed that programs analyzing an averaged beat exhibited less variability than programs that measure every complex or a selected beat. Zywietz also confirmed that median beats had less noise and generated more accurate measurements than an analysis of raw beats.[289]

Farrell[286] also demonstrated the effectiveness of the median by testing 12SL™ on 90,000 "noisy" ECGs. This test used a repeatable methodology for the creation of "noisy" ECGs, which can be applied for industry-wide assessment of robustness of computerized measurements.

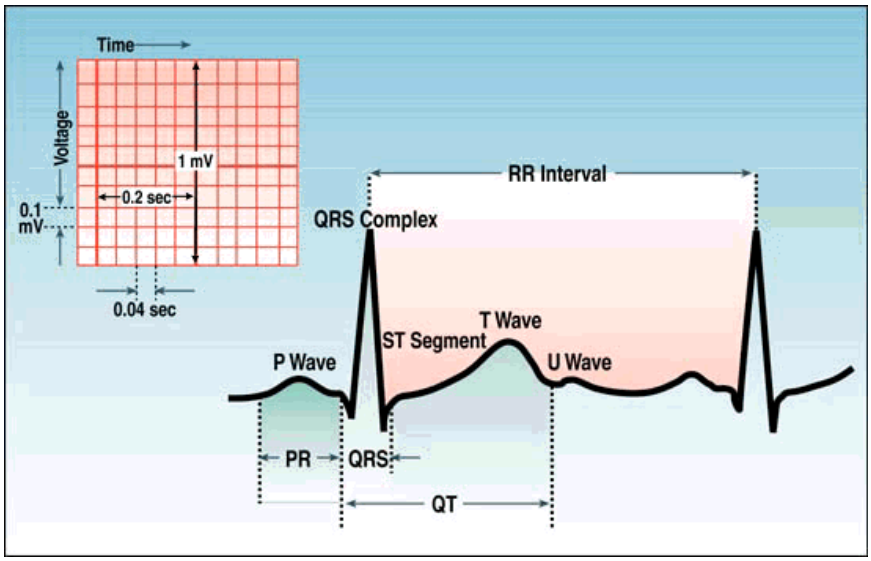
QRS Onset/Offset and Determination of Global Intervals

Good ECG measurements depend upon the proper identification of the fiducial points such as QRS onset and offset. Consistent with the signal-processing portion of the program as well as the physiological definitions for cardiac depolarization and repolarization, these fiducial points are determined by an analysis of the slopes in all 12 simultaneous leads. As a result, each fiducial point refers to the same sample-time where the median complexes are time aligned. Since these fiducial points are applied across all 12 median complexes, they are often referred to as global versus lead-specific.

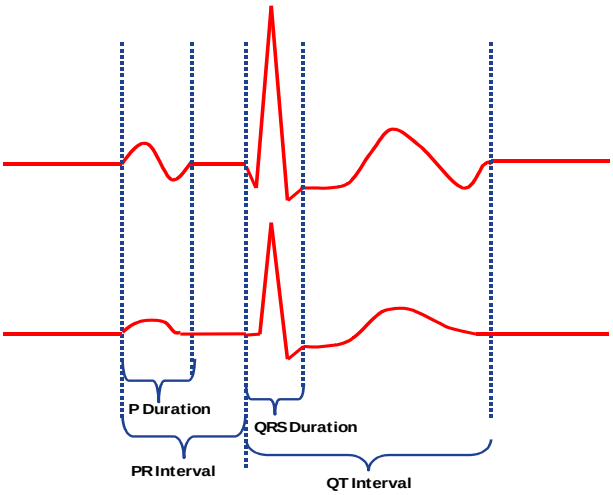
P onset and P offset are also determined via the median complexes unless the computer detects asynchronous P wave activity or an inconsistent PR coupling interval in the rhythm data. In this case, P onset and P offset remain undefined.

As opposed to the human reader, which may only inspect the QRS duration in any single lead of the ECG, the computer measures the QRS duration as a global interval. That is, it measures the QRS duration from the earliest detection of depolarization in any lead (QRS onset) to the latest detection of depolarization in any lead (QRS offset). Similarly, the QT interval is measured as a global interval: that is, from the earliest detection of depolarization in any lead (QRS onset) to the latest detection of repolarization in any lead (T offset). See diagrams below.

Basic ECG Nomenclature



Global Fiducial Points – Across All Median Complexes



DEFINITION AND MEASUREMENT OF WAVES

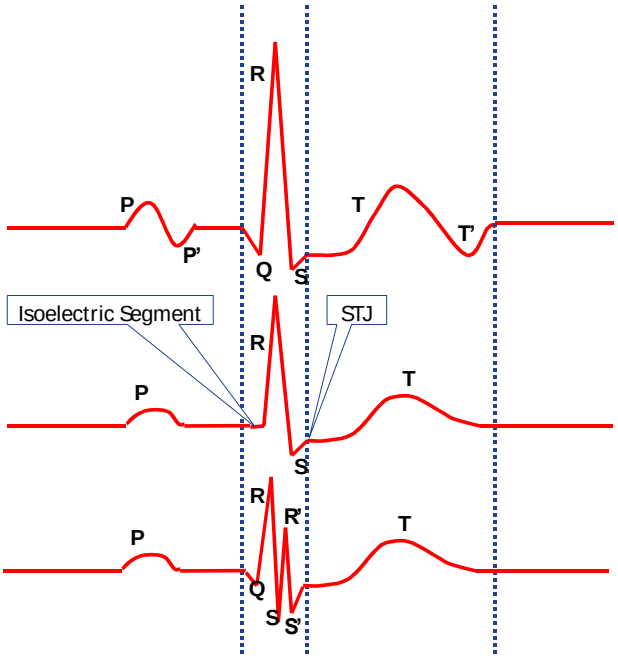
After the global fiducial points (P onset/offset, QRS onset/offset and T offset) have been determined, the waves within each complex are measured according to published standards.[290] This is done separately for each lead. Different ECG analysis programs treat waves within the QRS complex in different ways; as a result, the IEC standard requires that this wave identification process be fully disclosed, as provided below. (See IEC 60601-2-51 clauses 50.101.2-4).[1]

Starting at QRS onset, the program finds the points at which the ECG signal crosses the baseline within each complex. If the crossing points define a wave that has an area greater than or equal to 160 µV-ms, the wave is defined as significant. If the area is less than this value, the program considers the wave to be insignificant, and it will not label it as a separate wave. Sections of the complex that do not exceed the minimum wave criteria of 160 µV-ms are combined with the adjacent significant wave.

Since the wave of depolarization is a spatial entity, the onset of the wave will not be evident in all leads at the same time. Isoelectric sections starting at QRS onset of the complex are treated as part of the subsequent

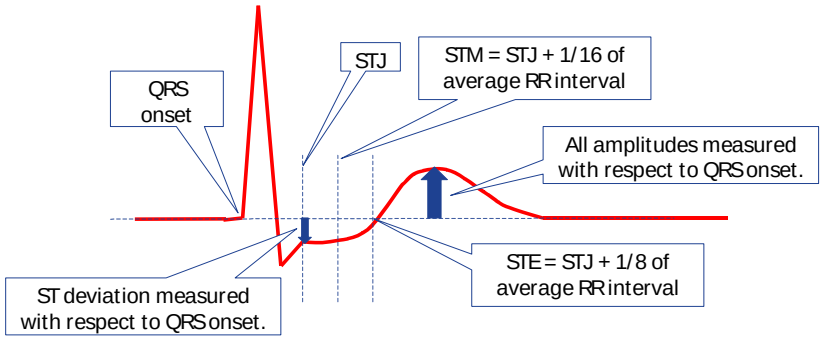
significant wave. Isoelectric sections at the end of the QRS will be incorporated into the preceding significant wave.

Definition of Waves Within Complex



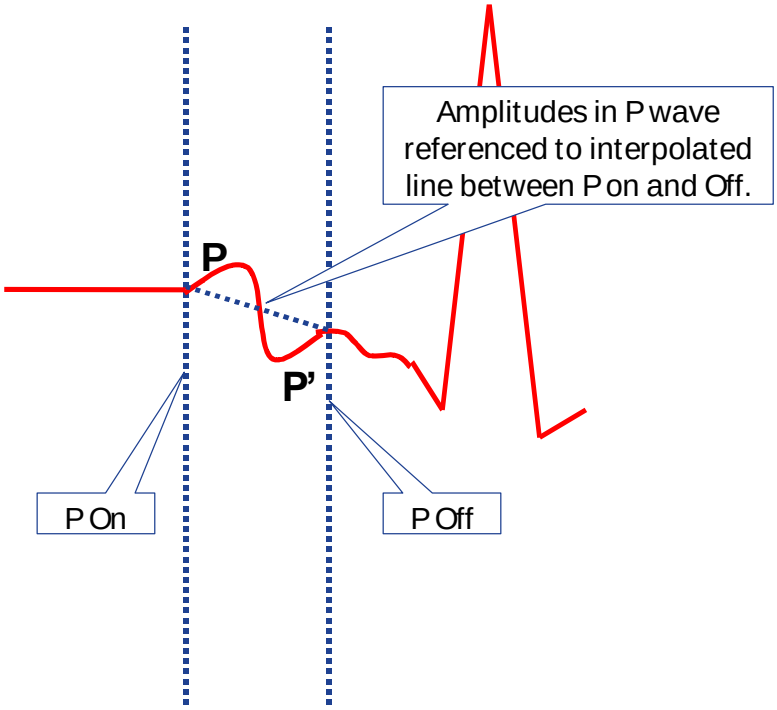
Amplitudes of significant waves within the QRS as well as the T wave are measured with respect QRS onset. Deviation of the ST segment is also measured in relation to QRS onset. STJ is defined as QRS offset. Further definition of the ST segment is defined by STM and STE, which are two additional points along the ST segment that are 1/16 and 1/8 of the average RR-interval from STJ. See diagram below.

Amplitudes of QRS and ST-T Measured in Relation to QRS onset



Amplitudes of significant waves within the P wave are measured with respect to a baseline level that is interpolated from P onset to P offset. This accommodates the phenomena of PR segment depression or cases where the P wave is superimposed on the preceding T wave due to high ventricular rate, long QT, or 1st degree AV block. See diagram below.

P amplitude adjusted for PR-segment depression



These amplitudes and durations result in a measurement matrix containing more than 800 values. Measurements are then passed onto the criteria portion of the program so that it can generate an interpretation.

Testing of 12SL™ Measurements via Standardized Database

COMMON STANDARD FOR ELECTROCARDIOGRAPHY (CSE)

In an effort to standardize and evaluate the performance of ECG computer measurement programs, a 12-lead ECG reference database was developed.[50] Typically referred to as the Common Standards for Electrocardiography (CSE) database,[291] it contains a set of 250 electrocardiograms (ECGs), with selected abnormalities, which were measured by five cardiologists. Attention was focused on the exact determination of the onsets and offsets of P, QRS and T waves. As quoted from the literature:

> *"The cardiologists performed their task on highly amplified, selected complexes from the library in a two-round process. With use of a modified Delphi approach, individual outlying point estimates were eliminated in four successive rounds. In this way final referee estimates were obtained that proved to be highly reproducible and precise."*[292]

All ECG waveforms in the CSE database are available to industry. Only one-half of these ECGs contain the measurements from the CSE referee committee. The other half does not contain these manual measurements. One-half has published measurements; the other half has unpublished referee measurements. As a result, the ECGs that contain the published referee measurements can be used by the industry for the self-assessment and reporting of measurement performance. The other 125 ECGs are unavailable for self-assessment.

GE's Marquette 12SL™ Program was tested using all 250 CSE ECGs (that is, including those without the published CSE measurements). This independent evaluation was done when the program only operated on data sampled at 250 SPS. The data in the CSE database was originally acquired at 500 SPS. To re-analyze this data at 250 SPS, the ECG was down-sampled to generate data at 250 SPS. The results of this independent evaluation are presented below; it includes the mean difference from the manual measurements and the standard deviation of the mean difference.

Complete CSE database evaluation, including unpublished referee annotations.[50]

Interval Measurement	*N*	*Mean difference (ms)*	*Standard Deviation (ms)*
P duration	218	-0.4	9.0
PR interval	218	-0.6	5.8
QRS duration	240	-0.6	5.4
QT interval	238	+0.9	12.2

IEC MINIMUM MEASUREMENT PERFORMANCE REQUIREMENT

The International Electrotechnical Commission (IEC) has issued particular requirements for recording and analyzing electrocardiographs (see 60601-2-51© IEC 2003)[1] For measurement performance assessment and acceptance testing, the standard uses ECGs from the CSE database that contain the published referee measurements. As a result, this is a self-assessment, self-reporting measurement performance test.

In addition to biological ECGs, the CSE database contains analytical and calibration ECGs. These are used to evaluate the accuracy of the global interval measurements and the accuracy of amplitude and wave duration measurements within each complex of each lead. GE's Marquette 12SL program has been evaluated with these analytical and calibration ECGs. With regards to amplitude measurements, no ECGs were excluded due to fiducial point errors; the program passed all amplitude measurement requirements as defined in IEC 60601-2-51 clause 50.101.2. With regards to global interval and wave duration measurements, one ECG was excluded from QRS duration and the S duration measurements due to a QRS offset fiducial point error. All global interval measurements were within acceptable limits. For the per-lead measurements all results are

reported below. No exclusions were made. All per-lead measurements were within the acceptable limits as required in IEC 60601-2-51 clause 50.101.3.1.

Results of Absolute Interval and Wave Duration Measurements for IEC

Measurement	*Mean difference (msec)*	*Standard deviation (msec)*	*Acceptable mean difference (msec)*	*Acceptable standard deviation (msec)*	*Pass / Fail*
P duration	-8.6	1.5	±10	8	**Pass**
PR interval	-6.0	1.6	±10	8	**Pass**
QRS duration	0.0	1.6	±6	5	**Pass**
QT interval	1.4	3.8	±12	10	**Pass**
Q duration	-0.8	2.8	±6	5	**Pass**
R duration	-0.7	2.2	±6	5	**Pass**
S duration	-0.9	2.7	±6	5	**Pass**

In addition to the calibration ECGs, the IEC requires testing on 100 biological ECGs from the 125 ECGs that contain the CSE measurements. In the performance reporting of the 100 ECGs, the IEC standard allows exclusion of up to four measurements with “obvious fiducial point errors”. No obvious fiducial point errors were observed via GE’s Marquette 12SL™ Program. No ECGs were excluded for this reason. The standard then allows exclusion of the “four largest deviations from the mean (outliers) for each measurement”. As a result, the following table contains the global interval results for 96 ECGs, analyzed at 500 SPS. Included in the table are the mean difference from the CSE manual measurements, the standard deviation of the mean difference, and the IEC pass / fail criteria. The global interval measurements are well within accepted limits and pass the test. (See IEC 60601-2-51 clause 50.101.3.2).

Global Measurement Performance for IEC standard on 96 CSE Biological ECGs

Interval Measurement	*Mean difference (ms)*	*Standard Deviation (ms)*	*Acceptable mean difference*	*Acceptable standard deviation*	*Pass / Fail*
P duration	-6.7	9.0	±10	15	**Pass**
PR interval	-1.5	5.5	±10	10	**Pass**
QRS duration	-5.2	5.2	±10	10	**Pass**
QT interval	+1.0	8.9	±25	30	**Pass**

Another test includes only 10 ECGs from the CSE database that contains the published referee measurements. These 10 ECGs were analyzed by the 12SL™ program, first without noise added and then with each of the noise types specified: 25µV RMS high frequency muscle artifact noise, 50 µV peak-to-valley 60 Hz line frequency noise, and 1 mV peak-to-valley 0.3 Hz sinusoidal baseline noise.

For each noise type, the interval measurements were recorded and compared against the measurements of the noise-free ECGs. For each of the interval measurements of each noise type, the mean of the ten differences from the noise-free measurements was calculated. As specified by the IEC standard, two of the largest deviations from the mean were excluded from the final reported mean and standard deviation of the differences. (See IEC 60601-2-51 clause 50.101.4).

50.101.4 –Mean Difference from Recordings without Noise

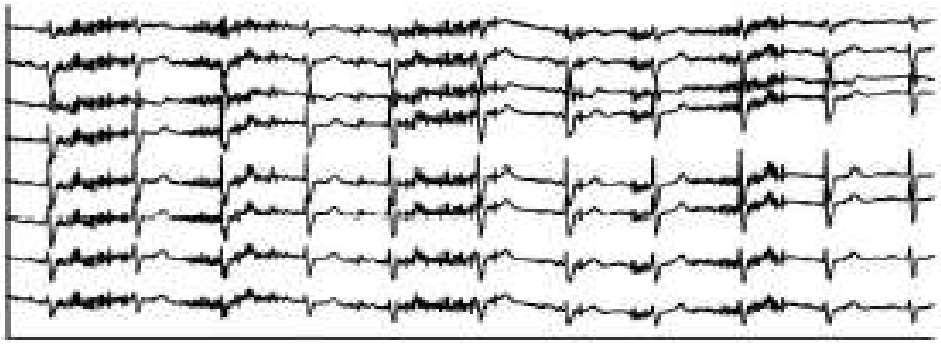
Global Measurement	*Type of added noise*	*Mean Difference (ms)*	*Standard deviation (ms)*
P duration	high frequency	-43.5	9.9
P duration	line frequency	-2.8	6.7
P duration	baseline	1.5	3.7
PR interval	high frequency	-18.5	11.0
PR interval	line frequency	-1.5	2.8
PR interval	baseline	0.3	1.3
QRS duration	high frequency	-7.8	2.7
QRS duration	line frequency	-1.3	4.7
QRS duration	baseline	-0.3	1.7
QT interval	high frequency	-1.3	3.2
QT interval	line frequency	1.5	3.7
QT interval	baseline	-0.3	3.5

Evaluation of 90,000 Noisy ECGs via CSE and MIT-NST Databases

The 125 ECGs of the CSE (containing the published referee measurements) were merged with records from the MIT Noise Stress Test database (MIT-NST).[293] For each CSE ECG, 720 unique noise ECGs were created, for a total of 90,000 noisy ECGs. Computerized measurements from the noisy ECGs were compared to the original ECG measurements. The repeatability of the measurements was assessed as a function of a lead quality score. Noise did not introduce any bias to the measurements, although not surprisingly, the variation of the errors increased as the lead quality degraded.[286]

Below is an example of an ECG generated by the combination of the CSE and MIT-NST databases. The MIT-NST database consists of three 30-minute 2-channel noise records and is specified for the analysis of the robustness of ambulatory ECG analysis by the AAMI standard EC38.[294] The noise recordings were made using physically active volunteers and standard ECG recorders, leads, and electrodes; the electrodes were placed on the limbs in positions in which the subjects' cardiac generated signal was not visible.

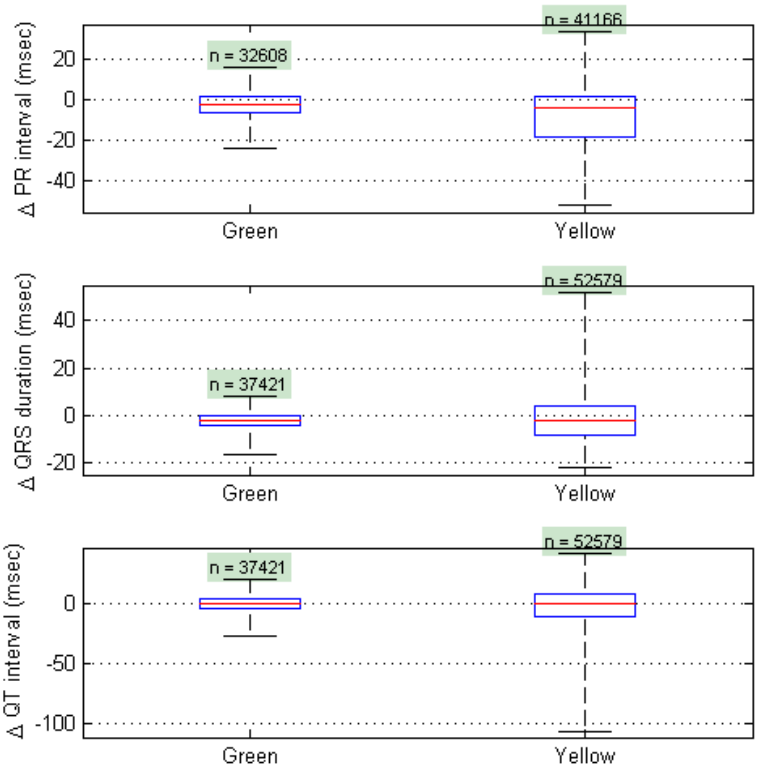
Example of CSE ECG combined with MIT-NST Record



Impact of Hookup Advisor™ on Accuracy of ECG Measurements

For each ECG, interval measurement differences versus the CSE annotations were obtained. These differences were grouped against the Hookup Advisor™ indicators[33] and the ranges of the values reported in the following figure.[286] The reported PR interval tended to shorten as the noise level increased. The mean difference of the QRS duration was relatively unaffected by noise, changing by less than 2ms. The median difference of the QT interval was 0ms for both lead quality levels, while the standard deviation (SD) of the QT differences went from 20.5 to 39ms and the interquartile range went from 8 to 18ms.

PR interval (top), QRS duration (center), and QT interval (bottom) compared to CSE



Boxes in box plots denote 25th and 75th percentiles, with 50th percentile (median) inside the box. Whiskers extend to 2.5th and 97.5th percentiles, spanning 95% of the measurement differences.

Statistics on Performance of Lead Reversal Detection

An internal study involving more than 1 million ECG records was conducted to evaluate the performance of lead reversal detection. Overall, the Positive Predictive Value (PPV) is greater than 95% based on manually examination of a sampled subset (N=100), and the specificity of lead reversal, including all patterns of reversal, is larger than 99.9%. The statistics of specific pairs of reversal are listed in the table below. Our lead reversal detection factors in the necessity of reporting a certain reversal by evaluating whether said reversal may negatively affect the interpretation. If not, the algorithm will restrain from making the statement to avoid necessary disturbance in the procedure and maximize the efficiency in practice.

12SL / Hookup Advisor Sensitivity, Specificity for Chest Electrode Reversals

Sensitivity	V2	V3	V4	V5	V6
V1	0.4914	0.6631	0.6889	0.7341	0.6921
V2		0.4901	0.5643	0.7591	0.7492
V3			0.4135	0.6984	0.643
V4				0.444	0.4526
V5					0.2287

Specificity	V2	V3	V4	V5	V6
V1	0.9997	0.9998	0.9999*	0.9999*	0.9999*
V2		0.9996	0.9998	0.9999*	0.9999*
V3			0.9995	0.9999*	0.9999*
V4				0.9997	0.9998
V5					0.9995

*false positive rate may be smaller than 0.0001

12SL / Hookup Advisor Sensitivity, Specificity for Limb Electrode Reversals

Limb Lead	Sens	Spec
RA / LA	0.6862	0.9999*
RA / LL	0.4988	0.9999*
RA / RL	0.7326	0.9999*
LA / RL	0.7805	0.9999*

*false positive rate may be well smaller than 0.0001.

Independent Evaluation of 12SL™ Measurements

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In addition to the use of standardized databases, there have been several independent assessments of the measurements generated by GE's Marquette 12SL™ Program. These include studies conducted during routine clinical use[243, 295] versus large clinical trials or epidemiology studies.[296]

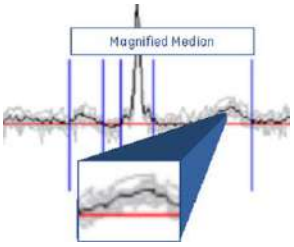
INTERVAL MEASUREMENT COMPARISON ACROSS MANUFACTURERS

A study published in *Europace* (2017),[297] found automated QRS duration (QRSd) measurements significantly differed on 76 patients depending upon which manufacturer's electrocardiograph was used. This difference occurred even when "none of the patients had variability in QRS duration and/or morphology observable at visual inspection of ECG recordings." Due to the variability of QRSd measures by the other vendor, the authors stated that "to achieve the QRSd precision comparable to that of a single GE Healthcare recording, a series of four to five ECGs would have to be recorded and QRSd averaged."[297]

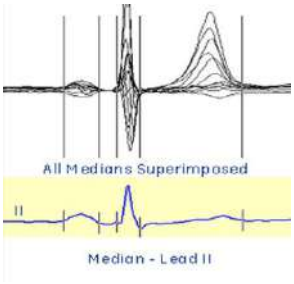
In an interval comparison study published in 2014,[298] the mean PR interval determined via Mortara on LQTS patients had a standard deviation roughly double that of the other ECG vendors.[298] "Since that publication, some algorithms have been adjusted, while other large manufacturers of automated ECGs have asked to participate in an extension of this comparison."[4] As a result, the comparative study was repeated with a different set of ECGs from LQTS patients and published in 2018.[4] In the case of Mortara, the standard deviation of the PR interval markedly improved and came into alignment with the other vendors. Unlike GE Healthcare which provided a PR interval for all the ECGs in the study (n=800), Mortara was unable to provide a PR interval in 15, Schiller 14, and MEANS (Welch Allyn) 11.[4] This study also found that "measurement differences between algorithms for QRS duration and for QT interval are larger in long QT interval subjects than in normal subjects."[4]

Measurement reproducibility is an important aspect of an ECG analysis program.[299] The Common Standards for Electrocardiography (CSE) prescribed the computerized methods used to reduce the influence of noise on measurement reproducibility.[287, 288, 300] These were found to be so critical, the AHA/ACC/HRS promulgated them in their most recent recommendation for standardization of the ECG:[51]

- "Digital electrocardiographs must provide beat alignment that allows selective averaging or formation of a representative complex with fidelity adequate for diagnostic ECG computer programs."



- "Global measurements of intervals should be obtained from time-coherent data in multiple leads to detect the earliest onset and latest offset of waveforms."



"Not all, digital electrocardiographs utilize the time coherence of simultaneously acquired representative complexes to derive "global" measurements of intervals."[51]

P-WAVE DURATION

ECGs from 152,759 primary care patients aged 50 to 90 years were collected from 2001 to 2011 and analyzed by GE's Marquette™ 12SL™ ECG Analysis Program.[301] "Excellent agreement" was found between the 12SL algorithm and manual identification of intra-atrial block (IAB), as defined by the following categories: "normal P-wave duration (<120 ms), partial IAB (P-wave duration ≥120 ms and no biphasic P waves in inferior leads) and 3 groups of IAB (P-wave duration ≥120 ms) associated with biphasic (plus/minus) P-waves in 1, 2, or 3 inferior leads (II, III, and aVF), the latter representing the strictly defined advanced IAB."[301]

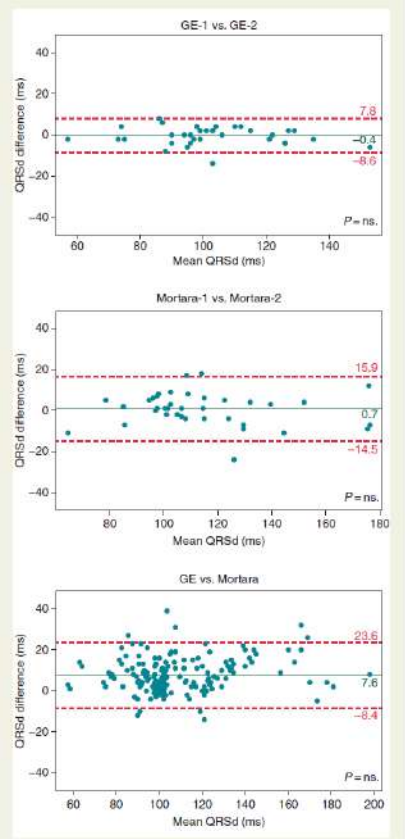
QRS DURATION REPRODUCIBILITY: COMPARISON TO OTHER VENDORS

"The study included randomly selected patients who were hospitalized in the department of cardiology of the University Hospital in Pilsen and had a clinical indication for a standard 12-lead ECG recording. Within a single day, they underwent separate ECG recording sessions, each with either one of the two MAC 5000 electrocardiographs (GE Medical Systems, Milwaukee, WI, USA), henceforth, GE-1 and GE-2 or one of the two Mortara ELI 350 electrocardiographs (Mortara Instrument, Inc., Milwaukee, WI, USA), henceforth Mortara-1 and Mortara-2."[297]

Below are the results of the pair-wise comparison, including intra-manufacture (first two Bland-Altman plots) and inter-manufacture (last Bland-Altman plot.) Note that there was systematic difference in QRSd of 7.6+8.1 ms with GE Healthcare being shorter than Mortara's.

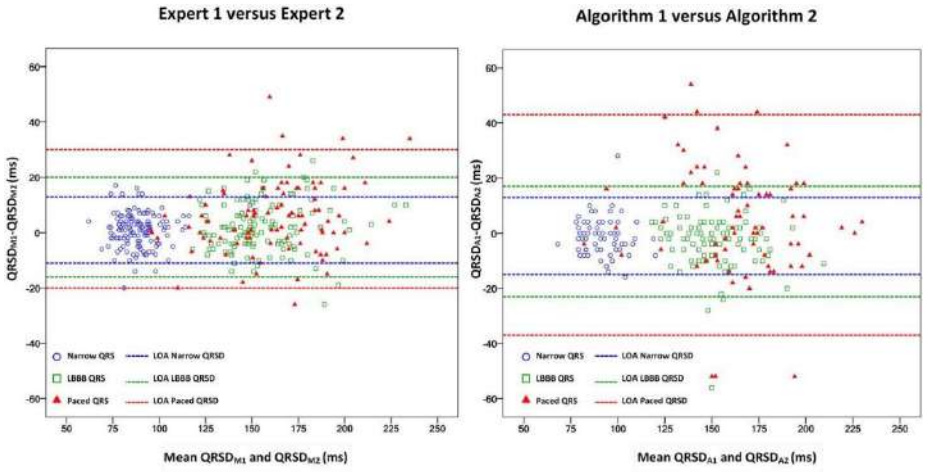
"Limited accuracy and precision of automated QRSd measurements have important clinical implications ... in risk stratification and selection of patients for specific therapies, particularly for CRT." "For the Mortara to achieve the QRSd precision comparable to that of a single GE Healthcare recording, a series of four to five ECGs would have to be recorded and QRSd averaged."[297]

Bland–Altman plots for inter-session agreement of QRSd



In another study, "QRSD was assessed in 377 digitally stored ECGs: 139 narrow QRS, 140 LBBB and 98 ventricular paced ECGs. Manual QRSD was measured as global QRSD, using digital calipers, by two independent observers. Computer-calculated QRSD was assessed by Marquette 12SL (GE Healthcare, Waukesha, WI, USA) and SEMA3 (Schiller, Baar, Switzerland)."[302]

Below are Bland-Altman plots comparing the experts to one another as well as the algorithms to one another. GE's Marquette 12SL™ program is referred to as algorithm 1 and the measurements from it as QRSDA1.



Differences among methods is insignificant when QRS's are narrow. In the presence of left bundle branch block (LBBB), small differences exist between 12SL™ and the manual readers (2 to 9 ms). In the presence of artificial pacing, the variance among all methods increases. See more details below:

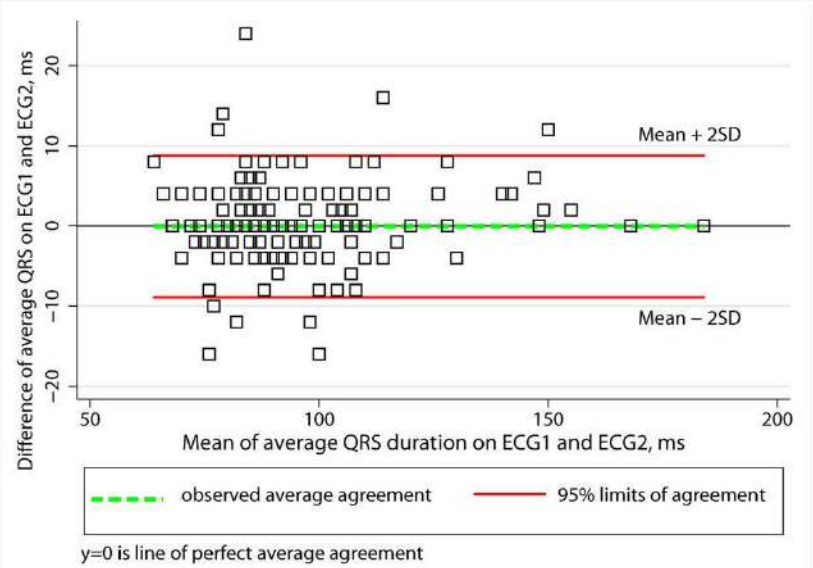
- In the presence of narrow QRS complexes, "analyzing QRSD within individual ECGs (pairwise), absolute differences in QRSD between the automated algorithms QRSDA1 versus QRSDA2 are 4 [2–9] ms (p = 0.010) and between QRSDM1 versus QRSDM2 4 [2–6] ms, p = NS. Absolute inter-manufacturer and interobserver variability were comparable in narrow QRS ECGs (4 [2–9] ms versus 4 [2–6], p=NS)."
- "Analyzing QRSD within individual LBBB ECGs (pairwise), absolute differences in QRSD between the automated algorithms QRSDA1 versus QRSDA2 are 7 [2–10] ms (p = 0.003), and between QRSDM1 versus QRSDM2 6 [3–12] ms (p = 0.006). … In LBBB ECGs, absolute inter-manufacturer and interobserver variability was comparable (7 [2–10] versus 6 [3–12] ms, p=NS). … Comparing manual versus automated QRSD measurements, absolute variability between QRSDMM and QRSDA1 was 4 [2–9] ms (p < 0.001) and between QRSDMM and QRSDA2 was 7 [3–10] ms (p = 0.044).
- In the presence of artificial ventricular pacing, variances between experts increases to 8 [4–18]ms, (p = 0.001). For manual versus automated QRSD measurements, "absolute variability between QRSDMM and QRSDA1 was 14 [7–25] ms (p = 0.005) and between QRSDMM and QRSDA2 was 14 [4–23] ms, (p = 0.001)."

JOHNS HOPKINS ARVD/C REGISTRY: SAME-DAY REPRODUCIBILITY

"Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C) is characterized by delay in depolarization of the right ventricle, detected by prolonged terminal activation duration (TAD) in V1–V3. Manual ECG measurements have shown moderate-to-low intra- and inter-reader agreement. The goal of this study was to assess reproducibility of automated ECG measurements in the right precordial leads."[303]

"Pairs of ECGs recorded in the same day from Johns Hopkins ARVD/C Registry participants [n=247, mean age 35.2±15.6 y, 58% men, 92% whites, 11(4.5%) with definite ARVD/C] were retrospectively analyzed. … Bland-Altman analysis revealed satisfactory reproducibility of tested parameters. V1 QRS duration bias was −0.10ms [95% limits of agreement −12.77 to 12.56ms], V2 QRS duration bias −0.09ms [−11.13 to 10.96ms]; V1 TAD bias 0.14ms [−13.23 to 13.51ms], V2 TAD bias 0.008ms [−12.42 to 12.44ms]."[303]

For global QRS duration, the following Bland-Altman diagram was provided:



FRAMINGHAM HEART STUDY: 12SL VERSUS DIGITAL CALIPERS

The Framingham Heart Study (FHS) data repository stored on GE Healthcare's MUSE™ system includes ECGs from 1986 to 2012. For this study, ECGs were randomly selected to account for temporal changes in ECG acquisition and recording techniques. ECGs were excluded if they had a paced rhythm, atrial fibrillation, or upon review had a technically inadequate tracing. The following measures were performed manually (using digital calipers by a single reader) and automatically via 12SL™: P wave duration, P wave amplitude, PR interval, QRS duration, R wave amplitude in lead V6 and QT interval in lead V5.

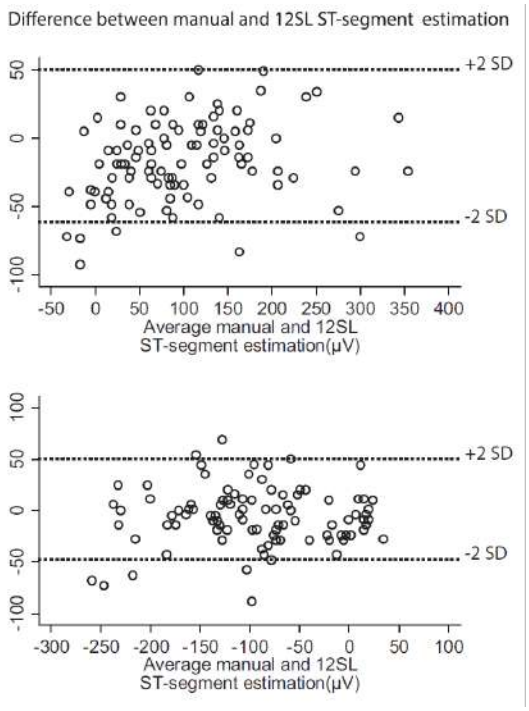
This showed "excellent correlation of automated [12SL™] and digital caliper measurements of PR interval, P wave amplitude, QRS duration, QT interval and R wave amplitude. P wave duration had more limited reproducibility." This study provided FHS "with strong confidence in introducing automated measures to Framingham Heart Study data. Integrating rapidly acquired waveforms through digital ECG platforms will enhance Framingham Heart Study data acquisition, save valuable investigator time, and permit novel analyses that may guide identification of cardiovascular disease and its risk factors."[247]

ST-SEGMENT DEVIATION:

ST deviations were evaluated in 69 consecutive patients suspected of an acute coronary syndrome (ACS).[304] Bland-Altman analysis demonstrated clinically acceptable limits of agreement comparing measurements of the J point and the T wave, but clinically inadequate limits of agreement with respect to ST-segment deviation, between the electrocardiographer and the computer. But as quoted from the study: "The difference between these 2 methods is mainly caused by different measurement points. There is no common agreement on what time point to use to measure ST amplitude. In this study, it was measured at 80 ms after the J point by manual measurement, while the computer selected a displacement at the midpoint of the ST segment." This 12SL measurement is known as STM, which is 1/8th of the average RR interval after the J-point. The measurement point for STM is corrected for heart rate. To get values at fixed interval from the J-point, use the expanded matrix capability available on the MUSE™ system.

In another study, "to evaluate the agreement between the 12SL algorithm and manual ST-segment measurement, a number of ECGs (N=200) were sampled."[305] In addition, "to explore the validity of the automated measurements also at the extremes of ST-segment deviations, ECGs were randomly sampled from each category of ST-deviation." The manual rater was blinded to results from the 12SL algorithm. See results of this evaluation in the figure below.

Bland Altman Results of ST deviation: 12SL Versus Manual Measurement



QT Interval

The assessment of automated QT measurements has undergone a great deal scrutiny since 2005 when the Food and Drug Administration (FDA) issued a new guidance document on the "design, conduct, analysis, and interpretation of clinical studies to assess the potential of a drug to delay cardiac repolarization."[306] An important implication of this guidance was that evaluators needed to be able to reproducibly detect a very small increase in QTc. A "through QT study" must be powered for the statistical detection of QTc interval changes that are as small as 6ms.[307] Automated measurements are desirable since they could reduce this effort.[308, 309] Measurements that are more consistent and accurate than manual measurements may result in a lower sample size and overall cost of a trial.[310]

GE Healthcare put considerable effort into improving its automated QT measurements, especially since leading investigators complained that 12SL™ was not accurate enough to eliminate manual measurement and would sometimes exhibit substantial errors in finding the end of the T-wave.[311] Fortunately, a new version of the 12SL™ program was released and evaluated by these same investigators. They found that the "accuracy of the 'new' 12SL™ algorithm is not only much greater than the accuracy previously observed with QT interval measurement by the 'old' 12SL algorithms, it also makes it feasible to use the modern equipment without any manual intervention in carefully selected parts of drug-development program."[32]

Similarly, in 2008, several cross-over, thorough-QT studies were used to evaluate the performance of GE's Marquette 12SL™ Program.[308] The variability associated with human measurements was generally 5–28% greater than that associated with automated methods. The performances of automated and human methods were comparable for demonstrating assay sensitivity in TQT studies with healthy volunteers.

In 2006, a large independent study evaluated the new QT algorithm for 12SL™, released in 2003 and now available in all current GE Healthcare electrocardiographs. Evaluation was done on over 45,000 resting ECGs obtained from two clinical trials, labeled as set "A" and "B". Set "A" (n=15,194 ECGs) exhibited substantially better signal quality than set "B" (n=29,866 ECGs). In set A, 95.9% of ECGs were measured automatically within 10 ms of the manual measurement. In set B, 83.9% of the automated measurements were within 10ms. "The study shows that (a) compared to the "old" version of the 12SL algorithm, the QT interval measurement by the "new" version implemented in the most recent GE Healthcare ECG equipment is

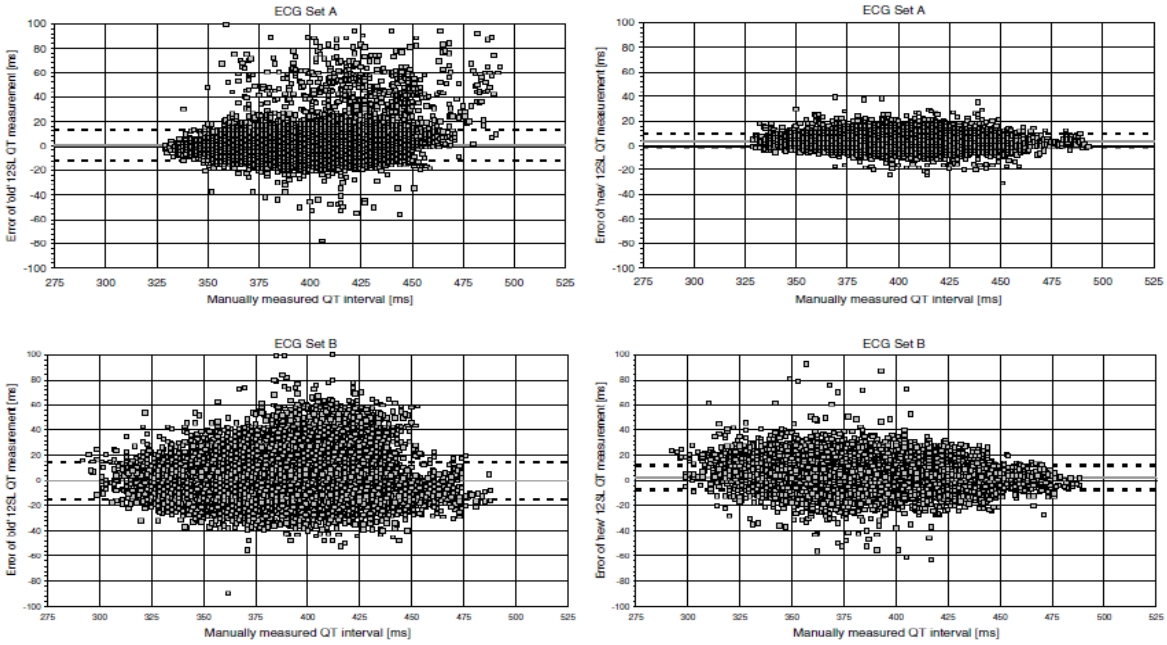
significantly better, and (b) the precision of automatic measurement by the 12SL algorithm is substantially dependent on the quality of processed ECG recordings."[32]

Percentages of ECGs with successful automatic QT measurement (n=45,060)[32]

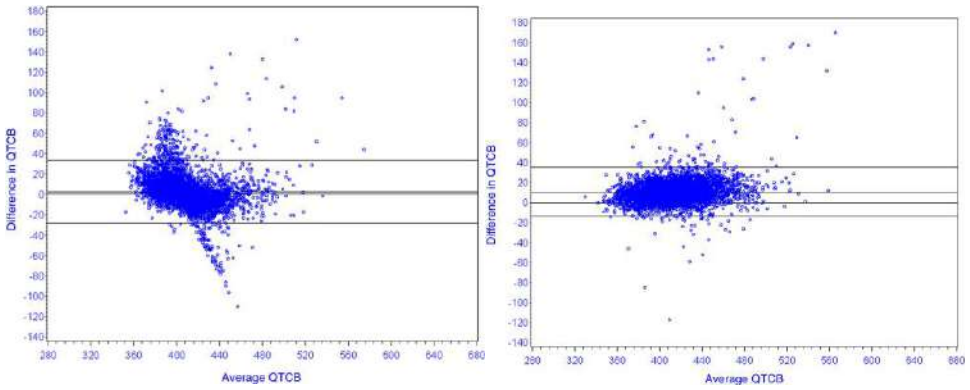
Absolute measurement error	***ECG set A***		***ECG set B***	
	"New" 12SL	***"Old" 12SL***	***"New" 12SL***	***"Old" 12SL***
≤ 5 ms	73.7	47.8	54.4	33.5
≤ 10 ms	95.9	76.6	83.9	59.5
≤ 15 ms	99.3	91.7	94.0	77.3

The table shows percentages of ECG tracings in which the error of automatic QT interval measurement was below the given threshold. For example, with a given threshold of 10ms, 95.9% of the ECGs in set A were within 10 ms of the manual measurement as opposed to only 76.6% of the ECGs with the "old" 12SL measurement algorithm.

Below are Bland-Altman plots of the older version of 12SL (on the left) versus the version of 12SL currently available GE Healthcare electrocardiographs (on the right). Clearly, the current version generates fewer errors; in fact, the agreement interval is cut in half.



Although the study by Hnatkova et. al. was large (N > 45,000), it was based on ECGs from clinical studies of normal subjects undergoing pharmaceutical testing. Tyl et. al.[312] decided there was a need to confirm these improvements on patients in a clinical environment. The two versions of 12SL were evaluated using "a total of 6,105 randomly selected electrocardiograms classified by the cardiologists as normal (4227), borderline (1254), abnormal (575), or not analyzable (49)."[312] Below are the Bland-Altman plots resulting from this study. Notice the latest version of 12SL (on the right) has the positive attribute of a narrower agreement interval versus the older version of 12SL (on the left).



Large comparative studies across the industry have demonstrated there is less agreement among ECG vendors when measuring ECGs from LQTS subjects versus normal subjects.[4, 298] It is important to know whether automated QT measurements are reliable when the QT becomes prolonged.

Fortunately, two large studies[32, 312] have evaluated the accuracy of GE's Marquette 12SL Program across a wide spectrum of QT values from 350 to 520ms and another specifically targeted the evaluation of 12SL when the QT was greater than 500ms.[313]

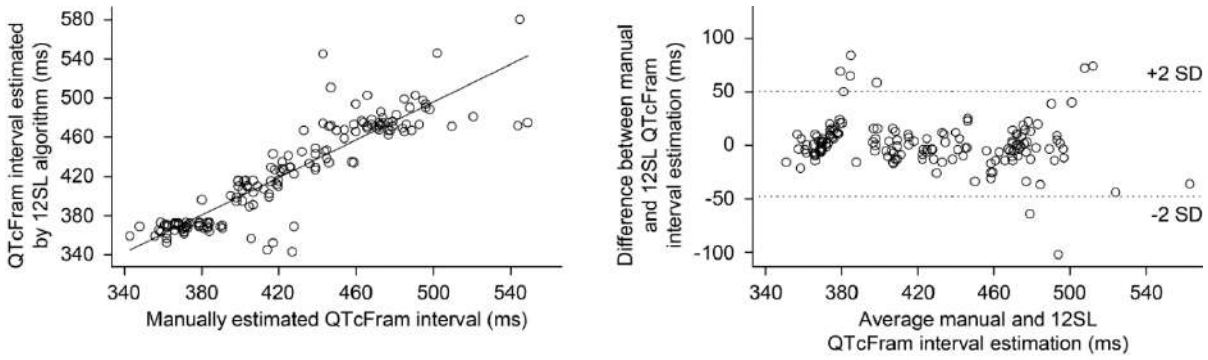
To assess agreement between two quantitative methods of measurement, Bland-Altman (B&A) scatter plots are recommended.[314] Each difference in milliseconds between the automated and manual QT measurement is presented on the vertical axis versus the manually measured QT along the horizontal axis.

One reason B&A plots are recommended for "assessing agreement between two methods of clinical measurement"[314] is because they reveal whether there is a systematic error or difference in measurement which changes over the spectrum of measurements required for clinical assessment. In this study, the mean difference between the manual and automated measurement forms a horizontal line throughout the spectrum of measurements. There is no measurement bias or error that becomes more pronounced anywhere along the spectrum of measurements.

In addition, B&A plots provide an agreement interval (see dashed lines) which indicates where 95% of the differences between the manual and automated measurements fall. This shows that "compared to careful manual QT interval readings in recording set A, the errors of the automatic QT interval measurement were (mean ± SD) +3.95 ± 5.50ms. ... In recording set B, these numbers were +2.41 ± 9.47ms."[32]

To specifically study the accuracy of automated 12SL QTc values at the extremes, and especially greater than 500ms, two large studies were performed – one from an out-of-hospital primary care population (173,529 ECGs from different patients) [315] and the other from a community hospital (225,117 ECGs from 63,286 unique patients).[316]

In the first instance, "50 ECGs were randomly sampled from the lowest 1st percentile, 100 ECGs were randomly sampled from 1st to 99th percentile, and 50 ECGs were randomly sampled from the upper 99th percentile. For all manually assessed ECGs, QTc_{Fram} intervals were measured manually in lead aVF, V2, and V5 at 10 times magnification and with the use of a digital caliper (MUSE™ Cardiology Information System, GE Healthcare, Wauwatosa, WI, USA). The mean of the manual QTc_{Fram} measurement from the three leads was used for the comparison. The manual rater (J.B.N.) was blinded to results from the 12SL algorithm. To evaluate agreement between manual and 12SL measured QTc_{Fram} intervals, results were summarized in a scatter-plot and in a Bland-Altman plot. Mean difference between manual and 12SL algorithm measurements was calculated together with the limits of agreement (±2 standard deviations)."[315] See figures below from the supplementary material provided in this paper.

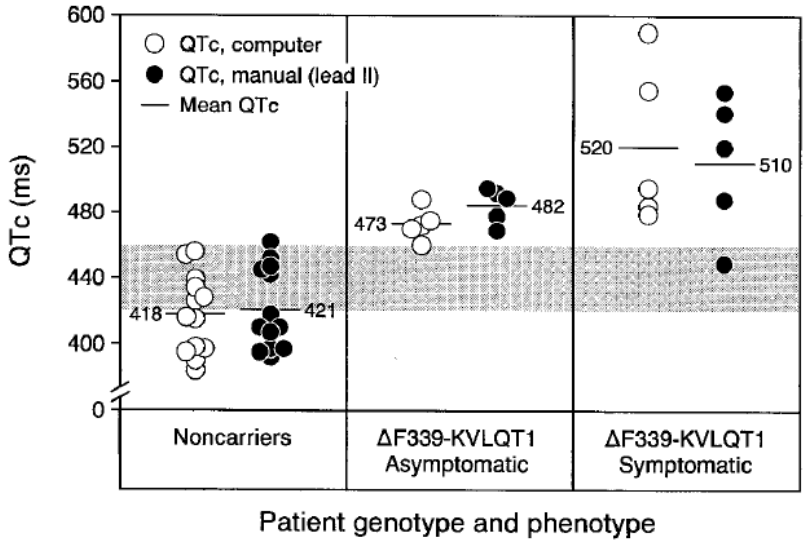


In the second instance, a GE Healthcare MUSE ECG database consisting of 225,117 ECGs from 63,286 unique patients collected over 11 years was searched using the following criteria: QTc (Bazett's formula) ≥ 500ms, QRS width ≤ 120ms, age 15 ≥ years, normal heart rate, no acute ST-elevation infarction, no atrial fibrillation, or atrial flutter. All ECGs resulting from this search were manually measured using the tangent method "in the lead showing the longest QT interval as the mean of three consecutive beats."[316] The automated QTc measurement was considered correct if it was within ± 10ms of the manual measurement, which was the case in 88% of ECGs exhibiting sinus rhythm and adequate technical quality.[313]

For QTc values ≥ 500ms, "correlation between manually and automatically measured QTc values was 0.97 (P< 0.001)."[316] This study also manually evaluated a random sample of 200 ECGs with automated QTc<500ms and found none that should have exceeded a QTc ≥ 500ms. "The manually measured median QTc was 430ms (range 339–499) vs. automatically measured median QTc 434ms (range 346–496). The correlation between the manually and the automatically measured QTc values was 0.91 (P<0.001)."[316]

In addition to these large studies, a smaller, yet important study evaluated the QTc measurement performance of 12SL versus expert cardiologists on ECG from patients who were evaluated for congenital LQTS (LQT1) with a range of QTc values from 390 to 600ms. The performance of the computer versus cardiologist measurement in lead II is presented below.

Comparison of QT measurements between cardiologist and computer in a study LQT1 patients.[317]



"Computer QTc and manual QTc (lead II) measurements. "The shaded area from 420 to 460 ms indicates the range for a 'borderline/equivocal' QTc."[317]

Several studies which exclusively evaluated 12SL,[32, 312, 313] stated there was better agreement between the automated and manual QT measurements when the ECG was of good quality. See specific details below:

- QT measurement errors (defined as > 15ms) were reduced from 8.3% to 0.7% when the ECG tracings were of high quality.[32]
- "Automated QT measurements were provided on all tracings; the readers judged some tracings as not interpretable, and QT measurements could not be performed, usually because of noisy recording or T-wave flattening."[312]
- "The biggest contributor to an incorrect QTc value was noise. In the presence of a technically inadequate ECG, the percent of ECGs where the manual and automated QTc values differed by more than 10ms was 8%."[313]

Given that ECG quality is a key requirement for quality QT measurements, it important that those acquiring ECGs leverage GE Healthcare's Hookup Advisor™ for real-time assessment and guidance regarding the quality of the waveform. In a study of 90,000 noisy ECGs, it was shown that when Hookup Advisor™ was green, the median difference was zero between the automated QT measurements by 12SL and manual measurements performed by CSE referees. The standard deviation of these differences decreased from 39 (when yellow) to 20.5ms (when green).[59]

Normals and patients with hypertrophic cardiomyopathy evaluated with the automatic QT measurements made by GE's Marquette 12SL™ Program were "more stable and reproducible than the manual measurements".[318]

The stability and consistency of the 12SL™ Program was leveraged for the measurement of QT in a large epidemiology study, because the QT variability of the 12SL Program "was smaller than that of the Dalhousie program."[319] This study derived normal limits from percentile distributions for QT as well as QT and T-wave subintervals in 22,311 participants in the Women's Health Initiative. This study advised considerable revision of the currently used limits for prolonged QT in women, with an additional race-specific adjustment in Asian women.

Similar normative values were established in another study, which was conducted on a large drug-induced trial patient population using 12SL™ Program measurements and medians, available for review by a cardiologist.[320] The analysis was performed on baseline (drug-free) ECG data. The final analysis included ECG recordings from 13,039 patients. Reference ranges from the study were stratified by important prognostic factors: age, sex, and overall ECG evaluation at baseline (normal or abnormal). From this study, proposed reference ranges were provided for patient management and data analyses in clinical drug development.

Predictive Value/Clinical Correlation of 12SL™ Measurements

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P-WAVE/PR INTERVAL: PREDICT ATRIAL FIBRILLATION, PULMONARY DEATH, ETC.

There has been considerable interest in long PR intervals and P-wave measurements for predicting which patients will ultimately suffer from atrial fibrillation (AF). To do this, normal reference ranges also had to be established. See examples below:

- In a study that included over 170K ECGs from primary care patients that were measured by GE's Marquette 12SL ECG Analysis Program, individuals with advanced intra-atrial block (IAB) defined as a P-wave duration > 120ms and biphasic P-waves in leads II, aVF, III had a higher risk of atrial fibrillation than patients with cardiovascular disease and no interatrial block.[301]
- A study by Veteran Affairs Healthcare Service (VAHS) found that after "5.3 years, 1,050 (2.4%) of patients were found to have AF on subsequent ECG recordings. Several ECG characteristics, such as P-wave dispersion (the difference between the widest and narrowest P waves), premature atrial contractions, and an abnormal P axis, were predictive of AF with hazard ratio of approximately 2 after correcting for age and sex."[321] Similar findings were also found across a large primary care population (n>150,000); P-wave measures provided by 12SL "were associated with increased hazards of AF, ischemic stroke, conduction disorder, and death from all causes."[322]
- A large negative terminal P-wave in lead V1 as measured by 12SL "suggests that an underlying atrial cardiopathy may cause left atrial thrombus formation and a subsequent stroke without intervening clinically recognized atrial fibrillation."[323]
- GE's Marquette 12SL™ program was used to measure the median PR interval, maximum P-wave duration, maximum P-wave area, and P-wave terminal force on ECGs from 3,110 Framingham Heart Study (FHS) and 8,254 Atherosclerosis Risk in Communities (ARIC) participants. "Over 10-years, 217 FHS and 458 ARIC participants developed atrial fibrillation (AF). In meta-analysis, P-wave duration >120 ms was significantly associated with AF (hazard ratio [HR] 1.55, 95% CI [confidence interval] 1.29 to 1.85) compared to ≤120ms. P-wave area was marginally but not significantly related to AF (HR1.31, 95% CI 0.95 to 1.80). P-wave terminal force was strongly associated with AF in ARIC but not FHS."[245]
- To establish reference ranges of PR duration and P-wave indices in individuals free of cardiovascular disease (CVD), ECGs from the Multi-Ethnic Study of Atherosclerosis (MESA) were used. "P-wave durations and amplitudes needed to calculate p-wave indices were automatically measured with the GE Marquette 12SL program 2001 version [GE Marquette, Milwaukee, WI]. A global single measure of PR interval was calculated from the beginning of the P-wave to the beginning of the QRS."[246] In individuals free of CVD and its risk factors, there are differences by age, sex and race in the distribution of PR and P-wave indices.

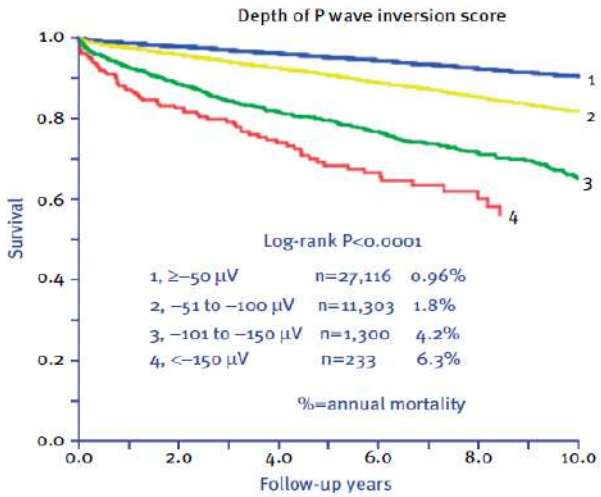
- Similarly, automated 12SL™ PR interval measurements on 50,870 patients of which 5,199 developed AF over 3.72 mean years of follow-up were used to define normative values. The study settled on "a PR interval value of 200 ms as a criterion in African Americans and Hispanics for the development of AF. A value of 200 ms may be less sensitive as a predictive measure for the development of AF in African Americans compared to non-Hispanic Whites."[324]

Using similar methods described above which rely on ECGs stored on a MUSE system and automated PR intervals from 12SL™, the following clinical correlates have also been established:

- Patients with genetic variants associated with AF have a longer PR Interval.[325]
- There is an "increased risk of AF for longer PR intervals for both women and men. With respect to short PR intervals, we also observed an increased risk of AF for women."[322]
- "During follow-up, we identified 34,783 deaths from all causes, 9,867 cardiovascular deaths, 9,526 cases of incident heart failure, and 1,805 pacemaker implantations. ... A long PR interval conferred an increased risk of heart failure (> 200 ms; HR, 1.31; 95% CI, 1.22-1.42; P < 0.001).[326]
- An increasing PR interval conferred an increased risk of pacemaker implantation, in a dose-response manner, with the highest risk associated with a PR interval > 200 ms (HR, 3.49; 95% CI, 2.96-4.11; P < 0.001). ... PR interval was significantly associated with the risk of the adverse outcomes investigated."[326]
- "Digital ECGs from 328,638 primary care patients were collected ... individuals with preexcitation had higher hazards of atrial fibrillation and heart failure."[327]

In addition, the Veterans Affairs Healthcare System (VAHS) has studied pulmonary death.

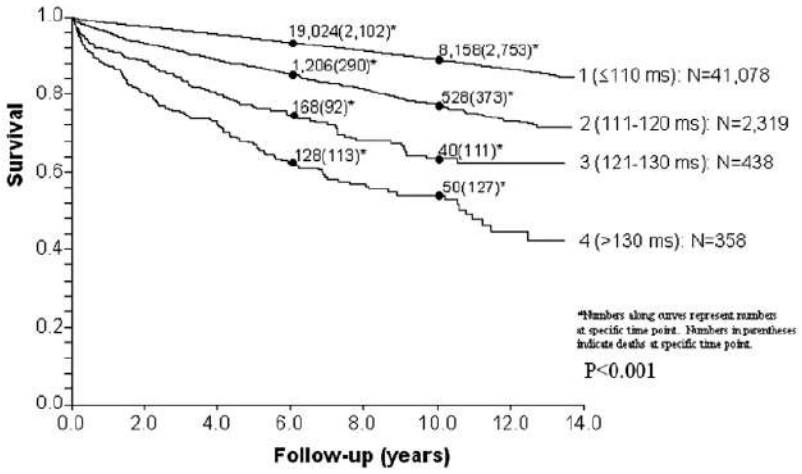
- "During a mean follow-up of 6 years there were 3,417 CV and 1,213 pulmonary deaths." P-wave amplitude in inferior leads, right axis deviation, left atrial abnormality and P-wave duration >120ms were all predictive of pulmonary death. "P-wave abnormalities are common findings that should not be ignored."[328]
- In the figure below, P-wave inversion score was evaluated against pulmonary mortality. The score was defined as the depth of P-wave (including terminal P-wave) in leads V1 or V2 (μV) of ≤ − 50 = 1; −51 to −100 = 2; −101 to −150 = 3; and < − 150 = 4. Note that although only 233 out 40,020 patients had a terminal P-wave in V1 or V2 < -150 μV, their annual mortality rate was 6.3%. "Each increment in the P-wave inversion score was associated with a 56% and 17% increase in CV and pulmonary death, respectively."[328] In a follow up study, "negative P waves (≤−100 μV) occurring in leads V1 or V2 with either a monophasic or biphasic pattern, and P waves with a duration of 140ms or longer, had significant associations with increased risk of CVD."[329]



QRS DURATION: SELECTING CANDIDATES FOR CRT, ETC.

Based on the QRS duration and QRS-T angle measurements made by GE's Marquette 12SL™ program, several studies have explored whether these measurements can predict death, heart failure, electrical/mechanical desynchrony or the optimum condition for cardiac resynchronization therapy.[76, 302, 330-340] Below are some quotes from the scientific literature with regards to the prognostic value of these measures:

- "Analyses were performed on the first electrocardiogram digitally recorded on 46,933 consecutive patients." Using computer generated QRS durations from 12SL™, the following conclusion was made: "QRS duration provides a simple method to stratify patients as to their risk of cardiovascular (CV) death. In a general medical sample, without BBB or paced rhythms, those with a QRS duration greater than 130 ms experience nearly twice the risk of cardiovascular death compared with those with a QRS duration of 110 ms or less. Similarly in patients with LBBB and RBBB, QRS duration greater than 150 ms is associated with greater risk of CV death."[337] See figure below:



- "The widest QRS duration on each ECG was manually measured after magnification. … Compared with computer measurements of QRS duration, the correlation coefficient (r) was 0.95, with a SE of 0.06, p < 0.0001"[334] The longer the QRS duration, the " higher positive likelihood ratio for predicting abnormal LV EF."[334]
- "Of the 4,033 patients, 252 died during a median follow-up of 3 years. The QRS duration was univariately associated with an increased risk of death (relative risk 8.5, 95% confidence interval CI 4.4 to 16.4, p <0.0001)" … "A QRS duration >105 ms best identified patients at increased risk. In conclusion, QRS duration is associated with an increased risk of death, even after adjustment for clinical factors, exercise capacity, left ventricular function, and exercise-induced myocardial ischemia."[338]
- "Prolonged QRS was associated with a significant increase in mortality (49.3% vs 34.0%, *P* = .0001) and sudden death (24.8% vs 17.4%, *P* = .0004)."[341]
- "A target population of 3,471 had" … "ECG data obtained from automated sources during the first year of diagnosis. " …. "Among the heart failure population, 20.8% of the subjects had a QRS duration > 120ms. A total of 425 men (24.7%) and 296 women (16.9%) had a prolonged QRS duration (p < 0.01). There was a linear relationship between increased QRS duration and decreased ejection fraction (p < 0.01). A prolonged QRS duration of 120 to 149 ms demonstrated increased mortality at 60 months (p = 0.001), when adjusted for age, sex, and race (p = 0.001). Systolic dysfunction was associated with graded increases in mortality across ascending levels of QRS prolongation."[339]
- Obstructive sleep apnea (OSA) and prolonged QRS duration are associated with hypertension, heart failure, and sudden cardiac death. A cross-sectional study of 221 patients concluded automated "QRS duration and OSA were significantly associated."[342]

ST-SEGMENT: LEFT VENTRICULAR HYPERTROPHY, RISK OF HEART FAILURE, ETC.

Obviously, ST segment deviation is associated acute myocardial infarction. There is a growing awareness that this measurement can be used for risk assessment in the presence of left ventricular hypertrophy or other chronic cardiovascular conditions. See examples below:

- "The predictive value of nonspecific ST depression as determined by visual and computerized [12SL™] Minnesota Code (MC) codes 4.2 or 4.3 were compared with computer-measured ST depression >or= 50 microvolts in 2,127 American Indian participants in the first Strong Heart Study examination." .... "CONCLUSIONS: Computer analysis of the ECG, using computerized MC and computer-measured ST depression, provides independent and additive risk stratification for cardiovascular and all-cause mortality, and improves risk stratification compared with visual MC."[343]
- In this study, computerized 12SL™ ST measurements were correlated with the presence of left ventricular hypertrophy (LVH). ECGs and echocardiograms (ECHO) were done on a total of 1,595 American Indian participants without evident coronary disease.[344] "The absolute magnitude of ST segment deviation above or below isoelectric baseline was measured by computer in leads V(5) and V(6), and participants were grouped according to gender-specific quartiles of maximal STdep. Left ventricular hypertrophy was defined by indexed LV mass >49.2 g/m (2.7) in men and >46.7 g/m (2.7) in women." ... "After controlling for clinical differences, increasing STdep remained strongly associated with increased prevalence of LVH (p = 0.0001). CONCLUSIONS: In the absence of evidence of coronary disease, increasing STdep in the lateral precordial leads is associated with increasing LV mass and increased prevalence of anatomic LVH."[344]
- Based on 12SL™ ST measurements from a total of 285,194 people, it was "found that ST-depressions were associated with a dose-responsive increased risk of CVD in nearly all the precordial leads. ST-elevations conferred an increased risk of CVD in women and regarding lead V1 also in men. ST-elevations in V2 to V3 were associated with a decreased risk of CVD in young men."[305] "This study also performed a validation analysis and found good agreement between manual and 12SL automated ST-segment measurements. Automated ST-segment depression in lead V6 compared with manual measurement showed a mean difference - 5.545μV (95% CI -11.07 to 0.02) with limits of agreement between -74.64 to 41.320μV."[305]
- Computerized assessment via 12SL™ of ST deviation and T-wave inversion identifies hypertensive patients at increased risk of developing congestive heart failure (CHF) and dying from it, even in the setting of aggressive blood pressure lowering.[345, 346]
- "MESA (Multi-Ethnic Study of Atherosclerosis) is a multicenter, prospective cohort of 6,441 participants (mean age, 62 years; 54% women). ... ECG interpretation was performed automatically with the GE Marquette 12SL™ program. ... ECG strain is independently associated with all-cause mortality, adverse cardiovascular events, development of LV concentric remodeling and systolic dysfunction, and myocardial scar over 10 years in multiethnic participants without past cardiovascular disease. ECG strain may be an early marker of LV structural remodeling that contributes to development of adverse cardiovascular events."[347]
- ST level was measured by 12SL in 29,281 patients. Early repolarization (ER) was defined as ST≥100μV. "Common patterns of ER without concomitant Q waves or T-wave inversion [as identified by 12SL] are not associated with increased risk of cardiovascular death; when either occurs with ER, there is a hazard ratio of 5.0 [348]

QT Interval: Overall Mortality, Sudden Cardiac Death (SCD), etc.

In addition to the question as to whether the computer can correctly measure QT, considerable study has been done to determine if a long QT interval - as measured by GE's Marquette 12SL™ Program - is predictive of poor outcome. See examples below:

- "QTc ≥ 500 ms was associated with high all-cause mortality with increased mortality in males compared with females. A new QTc mortality score [based on presence of drugs known to cause Torsade de Pointe, electrolyte abnormality, etc.] was constructed to predict mortality. Only a minority of cases with prolonged QTc > 500 ms were acknowledged in the medical records."[316]
- "86,107 ECGs were performed. ... Patients with QTc ≥ 500 ms had higher mortality than those with QTc < 500ms."[349]
- "Digital electrocardiograms from 17,529 primary care patients aged 50–90 years were collected. ... The accuracy of the personalized CVD prognosis can be improved when the QTc interval is introduced to a conventional risk model for CVD."[315]
- "Preoperative QT interval was an independent predictor of overall death and sudden cardiac death after isolated coronary bypass surgery."[350]
- "HIV+ patients have slightly but significantly longer QTc intervals compared to the general population."[351]

T-wave Morphology: Degree of IKr Block

In addition to automated QT interval measurements, GE Healthcare can quantify the shape of the T-wave in terms of the degree it is asymmetric, notched and/or flat. More specifically, this quantification is done via a product known as QT-Guard Plus, which relies on 12SL for measurement. See QT Guard Plus Physician's Guide for more details (2061747-001).

T-wave measurements available via QT Guard Plus have been correlated with many findings. See below:

- Sotalol is known for its profound effect on repolarization and its propensity to elicit Torsade de Pointes (TdP).[352] A linear combination of the T-wave shape measurements provided by GE Healthcare had a higher sensitivity than QTc to the dosage level of the drug.[38]
- "Longer T-peak to T-end interval (Tpe) implies increased risk for ventricular tachyarrhythmia (VT/VF) and mortality. ... We evaluated 305 patients with LVEF </= 35% and an implantable cardioverter-defibrillator implanted for primary prevention. ... Tpe was measured using seven different methods described in the literature, including six manual methods and the automated algorithm '12SL'. ... The automated 12SL method performs as well as any manual measurement."[353]
- "In this cohort, abnormal T wave morphology detected with the GE Healthcare QT Guard+™ accurately distinguished gene+ patients from healthy controls. This software can identify gene+ LQTS, even without QT prolongation. This may have important clinical application in ECG screening for LQTS, particularly when baseline QTc is normal."[354]
- GE Healthcare's QT dispersion and principal component analysis, have been correlated with overall mortality[244, 355-358] as well as acute ischemia.[22, 359-362]
- In an evaluation performed via the FDA, "T wave flatness, asymmetry, and the presence of notch were automatically assessed with QT Guard + (GE Healthcare, Milwaukee, WI)."[363] "T wave morphology changes are directly related to amount of hERG block; with quinidine and ranolazine, multichannel block did not prevent T wave morphology changes. A combined approach of assessing multiple ion channels, along with ECG intervals and T wave morphology may provide the greatest insight into drug-ion channel interactions and torsade de pointes risk."[363]

QRS-T Angle: Mortality in Presence of Heart Failure, etc.

QRS-T angle was first described early in the history of electrocardiography as a grave indicator.[364] Due to the difficultly of calculating it, it fell out of favor.[365] More recently, it has been confirmed to be a strong predictor of sudden cardiac death, etc.[366, 367] In any case, GE's Marquette 12SL™ Program can calculate QRS-T angle in the frontal plane or spatially. For spatial calculations, the algorithm uses a method for synthesizing XYZ that was derived from over 10,000 ECGs where both the standard scalar leads and Frank leads were simultaneously acquired for 10 seconds as described in this cited work.[37]

- "The spatial QRS-T angle, the angle between the directions of ventricular depolarization and repolarization, represents abnormal cardiac structure and electrical heterogeneities resulting in changes of the repolarization direction. Due to this, it is a strong marker of electrical instability and susceptibility to ventricular arrhythmias. ... ECGs were analyzed using the GE Marquette 12SL™ ECG Analysis Program. ... Baseline and follow-up QRS-T angle were calculated from the frontal QRS and T axis of the 12-lead surface ECG. Patients were followed for survival. A total of 2,929 heart failure (HF) patients were evaluated. Median interval between baseline ECG and follow-up ECG was 895 days, median follow-up time was 1,526 days. ... We analyzed the relation between the baseline QRS-T angle and LV systolic function. The QRS-T angle was associated with a reduction of systolic function. ... Conclusion: QRS-T angle is relatively stable in patients with HF and is a powerful predictor of outcome. Widening of the QRS-T angle has predictive value and is an ominous sign."[368]
- ECGs were analyzed with the use of the GE Marquette 12SL™ ECG Analysis Program (Marquette 12SL ECG Physician Guide). ... Frontal plane QRS-T angle was defined as the absolute value of the difference between the frontal plane QRS axis and T axis and was adjusted to an acute angle by (360°− angle) for an angle >180°. ... Patients admitted to a tertiary hospital with a clinical diagnosis of acute myocarditis were evaluated; 193 patients were included. Median follow-up was 5.7 years, 82% were male, and overall median age was 30 years (range 21–39). The most common clinical presentations were chest pain (77%) and fever (53%). ... Wide QRS-T angle (≥100°) was demonstrated in 13% of the patients and was associated with an increased mortality rate compared with patients with a narrow QRS-T angle (20% vs 4%; P = .007). The rate of heart failure among patients with a wide QRS-T angle was significantly higher (36% vs 10%; P = .001). ... QRS-T angle is a predictor of increased morbidity and mortality in acute myocarditis."[366]
- "During a mean follow-up of 6 years, a total of 4,127 cardiovascular deaths occurred. ... Spatial QRS-T angle is a significant and independent predictor of cardiovascular mortality that provides greater prognostic discrimination than any of the commonly utilized ECG diagnostic classifications."[369]
- Serial ECGs obtained from heart failure patients which exhibit a" widening of the QRS-T angle has predictive value and is an ominous sign."[370] This conclusion was reached based on ECGs collected and analyzed by GE's Marquette™ 12SL™ ECG Analysis Program at Israel's largest health maintenance organization, Clalit Health Services in Jerusalem. A total of 2,929 patients were evaluated. Median interval between baseline ECG and follow-up was 895 days; median follow-up time was 1,526 days. During this period, the overall mortality rate was 39.6% (1,159/2,929) Overall, the frontal plane QRS-T angle as calculated by 12SL "tended to be stable, with minor changes in the angle over time." However, those with more than 30° change in QRS-T angle were at much higher risk of death.

COMBINING 12SL™ MEASUREMENTS: PREDICTIVE SCORES

One of the first and best known scores in electrocardiography is called the "Selvester Score".[371] GE Marquette was the first to computerize this score and integrate it into an electrocardiograph. Results demonstrated that it "had a high correlation with manual application (r = 0.94) and was superior regarding time, training, reader bias, reproducibility and precision of measurement."[372]

The Selvester Score primarily relies on an analysis of QRS abnormalities, especially Q waves, for the assessment of myocardial infarction (MI) size. The score was originally based on autopsy data. Other damage scores, such as Cardiac Infarction Injury Score (CIIS) [373] have focused more on acute infarction and ST/T wave changes.

In 2005, these scores (based on measurements generated by 12SL) were evaluated on 46,933 patients in relation to cardiovascular mortality.[374] During a mean follow-up of 6 years, the CIIS outperformed all other ECG classifications in determining prognosis.

Due to the reliance the Selvester score places on the subtleties of a Q-wave and, in 2012, the introduction of the third universal definition of myocardial infarction (UDMI) which incorporates Q-waves as small as 20ms in leads V2-V3 leads or Q-waves in lead I, aVL, II, or aVF that are at least 30ms wide and 100µV tall, a large study (>43,000 ECGs) was undertaken to determine the prognostic value of UDMI Q-wave criteria versus conventional Q wave criteria ≥ 40ms for the identification of prior MI. "The GE 12SL program measurements of intervals, durations, and amplitudes were used to code the presence of both UDMI and ≥40msec Q waves in all leads."[375] "The study's population were an average age of 56 (± 15) years, 90% were male, 12% were of African descent, and 74% were outpatients. There were 3,929 cardiac deaths (9.0% of the population) over a mean follow-up of 7.6 (± 3.8) years. The annual all-cause mortality was 3.3% and the annual CV mortality was 1.1%"[375] "It was found that the UDMI Q wave criteria did not outperform ≥40msec Q wave criteria with respect to predicting CV death."[375] An analysis of prior work presented in this paper found only the presence/absence of Q-waves ≥40msec as significantly associated with infarct size as determined by cardiovascular magnetic resonance (CVMR).

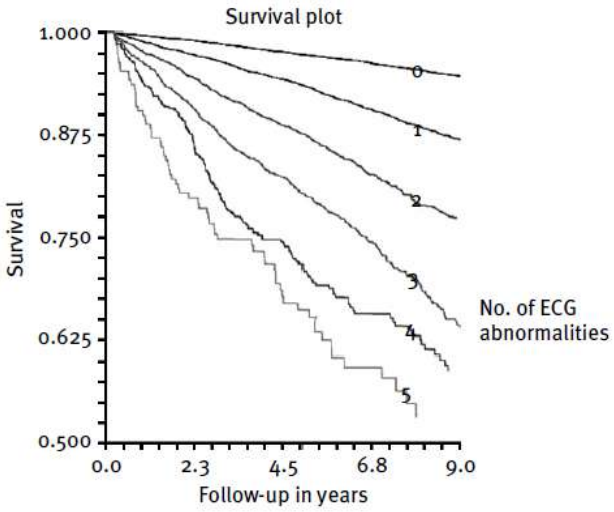
There is renewed interest in MI-sizing via ECG, since CVMR (as opposed to autopsy) provides a practical gold-standard reference for myocardial size.[376, 377] There continues to be a need for an inexpensive and accessible method for determining MI size it could have implications for finding patients which could be saved via the prophylactic use of an implantable cardiac defibrillator (ICD).[378]

Since the current method used for selecting patients for primary ICD therapy "misses ≈80% of patients who die suddenly", Strauss et. al. turned to the use of the 12-lead ECGs to test "the hypothesis that patients with elevated QRS-scores (index of myocardial scar) and wide QRS-T angles (index abnormal depolarization–repolarization relationship) would have high 1-year all-cause mortality and could be further risk stratified with clinical characteristics."[379] By leveraging MUSE, 12SL and GE Healthcare's Magellan ECG Research Workstation Software,[380] 19,750 ECGs were analyzed from patients who were not cared for in hospital areas known for a high risk of mortality (such as oncology, ICU, etc.). The study found that "QRS-scoring and QRS-T angle analysis identifies patients with high 1-year all-cause mortality and predominantly preserved left ventricular ejection fraction."[379] Based on the work published by Strauss et. al. in 2013, it appears feasible for "screening entire health system ECG databases to identify patients at increased risk of death."[379]

In addition to MI sizing, investigators with the U.S. Veteran Affairs Healthcare System (VAHS) have developed simplified predictive scores for cardiovascular mortality based on considerable study spanning more than two decades.[381, 382] This body of work is presented in over 20 peer-reviewed articles, some including patient cohorts exceeding 40,000 U.S. veterans who have been followed for more than a decade. The first was published in 2004;[244] the most recent, fall of 2018.[329] All these studies relied upon 12SL™ measurements and GE Healthcare's MUSE™ system for data mining and export of those measurements.[244, 321, 328, 329, 337, 348, 369, 374, 375, 381-395]

In any case, their simplest approach was to just add up the number of significant abnormalities in the ECG, such as atrial fibrillation, LVH, conduction defects, Q-waves, ST-segment depression, or prolonged QT. Known as the "Simplified ECG Score", "the annual mortality rates increased proportionally with the number of ECG abnormalities. In the group with no ECG abnormalities, the annual mortality rate was 0.54%. This increased

more than 10-fold in those with 5 or more abnormalities (6.7% annual mortality). After 10 y, almost 50% of the patients with an ECG score of 5 or more had died."[381] See figure below:



This could be given to primary care providers "to facilitate decision making regarding who should see a cardiologist. An elevated ECG score should heighten a physician's index of suspicion for CV risk in a patient and encourage an aggressive approach to diagnosis and patient management."[381]

Accuracy of Interpretive Statements: Reported Results

PURPOSE OF REPORTED RESULTS: REGULATORY REQUIREMENTS

The Statement of Validation and Accuracy is considered official product labeling and is reviewed by the Food and Drug Administration (FDA) and the International Electrotechnical Commission (IEC). This serves as a disclosure of the accuracy of the interpretive statements generated by GE's Marquette 12SL™ Program. This contrasts with a description of how interpretive statements are generated by the program; that is the purpose of another document, known as the 12SL™ Physician's Guide: Part I – Criteria and Methodology.

In 1991, the FDA recommended that such a document as *The Statement of Validation and Accuracy* be generated for the clearance of a 1500 Series Prehospital Defibrillator[20] that incorporated GE's Marquette 12SL™ Program as the first prehospital defibrillator to provide automated analysis of the prehospital 12-lead ECG.[17] Since 1991, *The Statement of Validation and Accuracy* has periodically been updated to keep abreast of the latest scientific findings regarding the 12SL™ Program. In 2003, the IEC issued a similar request for all manufacturers of ECG analysis equipment: that is, the IEC asked the manufacturers of ECG analysis programs and equipment to report the sensitivity, specificity, and positive predictive accuracy of the interpretive statements for each of the major diagnostic categories (see 60601-2-51© IEC 2003).[1] Like the FDA, the IEC also requested that these results be published and available to the consumer. *The Statement of Validation and Accuracy* fulfills this requirement.

The 12SL™ analysis program has continually evolved since it was first introduced in 1980. Each released version of the program contains one or more changes to it and is associated with a unique version number. This number appears on the ECG report printed by the analyzing electrocardiograph. The number is also printed on each ECG from the MUSE™ system. Encoded within this number are two elements: the actual 12SL™ version number and a product specific code, which refers to the type of product used for the analysis. The 12SL™ Physician's Guide contains a table that clarifies these codes and identifies the related 12SL™ version numbers.

The 12SL™ analysis program has continually evolved since it was first introduced; only portions of the program are changed per software version. The rest of the executable is tested to ensure that it generates the same results as the last version (see above description of the development and validation process for 12SL™). Based on the 12SL™ version number, the state of revision of each portion of the program can be determined.

Scientific references and results presented in this document span a variety of dates. Portions of the program that have not been recently changed can rely on reported results that are older, and yet, remain representative of the current state of that portion of the program. Sections of the program that have recently been enhanced require more recent publications. Depending upon which portion of the program is used for a diagnostic statement, different results reported in the literature can be used to characterize the performance of that statement as long as the results were generated subsequent to any substantial change to that portion of the program. Care has been taken to ensure that results from the literature and presented in this document are representative of the current version of the 12SL™ analysis program.

Although scientific references and results presented in this document reflect the current performance of the 12SL™ Program, it would be unwise to directly extrapolate these to what will occur in a specific clinical environment. These are statistical measures, not the performance that one should expect for a single patient.

Four key accuracy measures are explained below. These are used to disclose the accuracy of the 12SL™ program in accordance with IEC requirements.

It is assumed that the true diagnosis for a patient is known (that is, the "truth"). The ECG interpretation (classification) is called a "Test". The following designations are applied to characterize the performance of a test.

- "Normal" correctly classified as "Normal" is called "True normal" (TN)

- "Normal" incorrectly classified as "Pathologic" is called "False pathologic" (FP)
- "Pathologic" incorrectly classified as "Normal" is called "False normal" (FN)
- "Pathologic" correctly classified as "Pathologic" is called "True pathologic" (TP)

Tabulation of test results

Reference	Test	
	"Normal"	"Pathologic"
"Normal"	TN	FP
"Pathologic"	FN	TP

The following equations are calculated from a two (or multi-) category test:

Sensitivity: probability that a "True pathologic" would be classified as "Pathologic"

Sensitivity = TP / (TP+FN) x 100%

Specificity: probability that a "True normal" would be classified as "Normal".

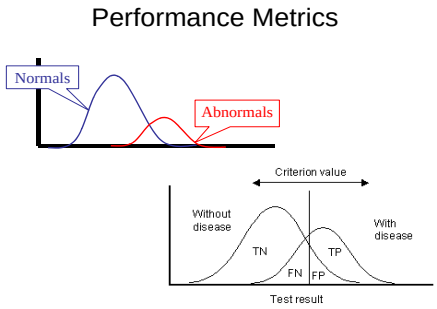
Specificity = TN / (TN+FP) x 100%

Positive predictive value (PPV): probability that a classified "Pathologic" is a "True pathologic".

PPV = TP / (TP+FP) x 100%

Negative predictive value (NPV): Probability that a classified "Normal" is a "True normal".

NPV = TN / (TN+FN) x 100%



To present performance metrics for GE's Marquette 12SL™ program, each study reported in this document uses one of the tables as presented in the following example. Note that the overall description of the study is presented in the header of the table, including the total number of ECGs for the study, the representative population or care environment where the ECGs were acquired for the study, and the independent scientific method used for verifying the disease or pathology. (See IEC 60601-2-51 clauses 50.102.3.1 and 50.102.3.2).

In the following example, 110 ECGs were collected in an emergency department from patients with chest pain of unknown origin. Each patient was tested for cardiac Troponin, a very sensitive and specific indicator of an acute myocardial infarction (AMI). Such details of the study and the method used to verify the diagnosis can be pursued via the bibliography reference associated with the title of the table. In this example, only 10 patients were positive for Troponin. As a result, under the column labeled "N", the number "10" appears in the row labeled as acute myocardial infarction. "N" is the number of patients that have been verified for a particular diagnosis, "N" has nothing to do with number of ECGs that were positive or negative for the recognition of AMI. In this specific example, the program correctly identified 4 of the 10 patients as having an AMI. As a result, the sensitivity for the program is listed as 40%. Note: this does not necessarily mean that the program made an ECG interpretation error on the other 6 patients. It could mean that the ECG did not reveal any ST elevation. From the remaining 100 patients that were negative for Troponin, the program falsely

recognized 1 as being an AMI. As a result, the specificity is listed as 99%. Since a total of 5 patients were called AMI by the program, but only 4 were correct, the positive predictive value is 80%.

Example: Study "A"[Ref A]

Representative test population:		Emergency department, patients with chest pain of unknown origin.		
Additional demographic data:		85 Men / 25 Women, ages 47- 84. Information on race is unavailable		
Total number of test ECGs:		110		
Method(s) used to verify diagnosis:		Troponin		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Acute Myocardial Infarction	10	40	99	80

Also notice that the tables indicate that this is a "test population" and that these are "test ECGs" or a validation set. This is an important distinction for the reporting of performance of the automated recognition of disease: that is, the term test ECG / validation set means that GE's Marquette 12SL™ program was not trained with the data that was collected for the study. The study provided results on a test set, not a training set. Typically, the performance of program will be worse on a test set than a training set.

The tables in this document report sensitivity, specificity, positive predictive accuracy (PPA) and, sometimes, negative predictive accuracy (NPA). Depending on the distribution and prevalence of disease in a population, a high-level of specificity may be more important than a high level of sensitivity. In the above example, there are only 10 individuals with the disease out of a population of 110. A 10-point drop in specificity would lead to many more mistakes (10% of 100 results in 10 mistakes) as opposed a 10-point drop in sensitivity (10% of 10, results in 1 mistake). It may be important to find every sick individual if a particular therapy can be applied that cures the disease but is not detrimental to the healthy individual. In this case, a high sensitivity, which typically results in a loss in specificity, may be warranted if there is no risk for treating a false positive, healthy individual. These issues are beyond the scope of this document but are discussed in the literature.[396, 397]

Interpretation of Rhythm: Reported Results

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This section provides performance metrics as reported in the literature regarding rhythm interpretations generated by GE's Marquette™ 12SL™ ECG Analysis Program. Results are reported for the following major rhythms: sinus, ectopic atrial rhythm, atrial tachycardia, atrial fibrillation, atrial flutter, junctional rhythm, and artificially paced. In addition, results are reported for the following rhythm modifiers: 1st degree AV block, 2nd AV block, 3rd AV block, and premature atrial / ventricular beats. The IEC also requires manufacturers to disclose rhythms, without reported results, due to their low rate of prevalence. (See IEC 60601-2-51 clause 50.102.4.1). For 12SL™, these include idioventricular rhythm, ventricular tachycardia, ventricular fibrillation, and wandering atrial pacemaker as well as statements regarding escape or fusion beats. Also, no reported results exist for interpretations regarding the rate or character of AV conduction during atrial fibrillation or atrial flutter.

ARTIFICIALLY PACED RHYTHMS

Several studies have evaluated the performance of GE's Marquette 12SL Program for appropriate detection and analysis of paced rhythms with and without GE Healthcare's high definition (HD) pacemaker detection technology. Regardless of whether HD technology is present, pacemaker detection is performed before any other rhythm analysis is performed.

Presented below is a comparison of pacemaker detection performance obtained during a prospective clinical trial, with and without high definition (HD) pacemaker detection technology. As opposed to other studies that have evaluated pacemaker detection performance based on what the human reader can see, the gold standard reference for measuring the accuracy of the detection was determined via information obtained from the pacemaker programmer. Notice when using HD, the sensitivity (SE) significantly increases with a 100% positive predictive value (PPV) in all recording environments.[36] With HD capability, 12SL can also state the presence of a biventricular pacing / cardiac resynchronization therapy (CRT).

Comparison of pace detection with and without HD technology[36]

All subjects		***High Definition***		***Conventional***	
Recording environment	# of ECGs	SE	PPV	SE	PPV
Baseline	88	100%	100%	76.4%	100%
Baseline + 2X settings	176	99.2%	100%	83.2%	99.9%
Extreme	352	88.7%	100%	41.5%	94.3%
Overall	528	92.4%	100%	56.0%	97.1%
CRT subjects only		***High Definition***		***Conventional***	
Recording environment	# of ECGs	SE	PPV	SE	PPV
Baseline	15	100%	100%	56.6%	100%
Baseline + 2X settings	30	98.8%	100%	69.6%	99.9%
Extreme	60	91.4%	100%	39.5%	96.1%
Non-CRT subjects only		***High Definition***		***Conventional***	
Recording environment	# of ECGs	SE	PPV	SE	PPV
Baseline	73	100%	100%	83.6%	100%

Baseline + 2X settings	146	99.3%	100%	91.1%	99.9%
Extreme	292	87.7%	100%	42.1%	93.8%

The recording environments included the following:

- "Baseline" implies routine clinical environment with patient's pacemaker settings at routine levels.
- "Baseline + 2X settings" means this is repeated at routine levels and at 2x their routine clinical levels in a pacemaker laboratory.
- "Extreme" includes 4 recordings. First the pacemaker settings are below their routine clinical settings then extreme noise is introduced into the ECG via the following three sources: turning on all 3 pacemaker programmers to generate RF noise, patient marching in place or V3 continuously tapped.

In addition to detecting biventricular pacing, 12SL version 22 and higher identifies the underlying rhythm. This is important to consider since, as reported by Guglin et. al., for ECGs with artificial pacing, "computer-drawn interpretations required revision by cardiologists in 61.3% of cases." In 18.4% of cases, a pacemaker was not detected. "The most common error in computer reading was the failure to identify an underlying rhythm."[89]

In 2001, before the advent of HD technology, 12SL was evaluated on 100 consecutive patients seen in a device clinic who were asked to participate in the study.

Evaluation of Pacemaker Detection without HD[398]

Representative test population:		Pacemaker clinic, Large hospital		
Additional demographic data:		Implanted devices included 44 single and 56 dual chamber devices (41 ICDs; 59 pacemakers; 92 bipolar leads). Pulse width settings ranged between 0.3 ms and 3.0 ms and voltage settings ranged between 0.9 and 6.0 V. Specific ages, gender and race are unavailable		
Total number of test ECGs:		372		
Method(s) used to verify diagnosis:		Patient History, Pacemaker Programmer		
Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Paced	200	87	100	100

Similarly, in 2002, a prospective trial was done at a different institution on 100 pacemaker clinic patients. ECGs

Evaluation of Pacemaker Detection without HD[399]

Representative test population:		Pacemaker clinic, Large hospital		
		Specific ages, gender and race are unavailable		
Total number of test ECGs:		389		
Method(s) used to verify diagnosis:		Patient History, Pacemaker Programmer		
Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Paced	235	87	99.4	99.5

In 2006, a large study was conducted that focused solely on pacemaker recognition and rhythm interpretation in the presence of electronic pacemakers without using HD technology. "Of the 7,834 consecutive ECGs screened, a pacemaker (PM) was identified by the computer, the cardiologists, or both in 205 ECGs. The cardiologists detected an electronic pacemaker in 201 tracings, whereas the computer detected one in 168 tracings. In 4 ECGs that were read as having an electronic pacemaker by computer, no pacemaker was present according to both cardiologists. In 164 (80.0%) of 205 ECGs, both computer and cardiologists agreed upon the presence of an electronic pacemaker. The sensitivity of recognizing a pacemaker by computer was 82.0%, and the specificity was 99.9%. In 37 cases, the algorithm failed to recognize the presence of a pacemaker. A common error was missing the ventricular spike (16 cases). Other errors included missing both the atrial and ventricular spikes (10 cases) and, rarely, the atrial spikes alone (4 cases)."[89]

Evaluation of computer analysis of pacemaker (PM) rhythms without HD[89]

Representative test population:		VA Hospital Inpatients & Outpatients		
Additional demographic data:		Specific ages, gender and race are unavailable		
Total number of test ECGs:		7834		
Method(s) used to verify diagnosis:		Confirmation by 2 cardiologists		
Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Paced ECG	205	82.0	99.9	96

The article concludes that, "automated computer ECG reading algorithms are useful tools for ECG interpretation, but they need further refinement in recognition of electronic pacemakers (PM). In 61.3% of ECGs with electronic PM, computer-drawn interpretation required revision by cardiologists. In 18.4% of cases, the ECG reading algorithm failed to recognize the presence of a PM. Misinterpretation of paced beats as intrinsic beats led to multiple secondary errors, including myocardial infarctions in varying localizations. The most common error in computer reading of ECGs with PMs is the failure to identify an underlying rhythm."[89]

Poon reported similar results for the analysis of paced tracings before the advent of HD. Quoting from the article: "The most common errors were related to interpretive statements involving patients with pacemakers: of 343 ECGs with pacemaker activity comprising 8.0% of the study ECGs, 75.2% (258/343) required revision, so that 45.7% of all inaccurate rhythm statements in this population occurred in patients with pacemakers. Overall, 13.2% (565/4297) of computer-based rhythm statements required revision, but excluding tracings with pacemakers, the revision rate was 7.8% (307/3954)."[88]

Given the need for improvement in both detection low energy artificial pacing as well as identification of underlying rhythms in the presence of artificial pacing, GE Healthcare developed and released the following:

- HD for detection of low energy pacing as well as bi-ventricular pacing.[36, 55-57]
- When HD technology is present, pacemaker annotations (including indications of biventricular pacing) are supplied at the MUSE™ system. In accordance with AHA/ACC/HRS recommendations, these annotations are supplied separately from the waveform in a "single row of the standard output tracing."[51] Some GE Healthcare electrocardiographs can supply this information, in real-time, while printing or displaying a rhythm strip.
- 12SL version 22 or higher for the detection and description of underlying rhythms in the presence of artificial pacing, regardless if HD technology is present.

NON-PACED RHYTHMS

Interpretation of cardiac rhythms is highly dependent on accurate detection of atrial activity. As a result, improved P wave detection has been a major pursuit of GE Healthcare.[400-402] Since 1998, a sophisticated tool, called MacRhythm, was incorporated into GE's Marquette 12SL™ Program for the detection of asynchronous P waves, hidden within the QRS or T wave.[105]

Previous versions of the program, which did not incorporate the QRS subtraction tool for P-wave detection, have been evaluated for rhythm interpretation accuracy and reported in the literature.[403, 404] The metrics in all tables presented below are from the later versions of the program, which incorporated MacRhythm.

The value of the QRS subtraction tool was prospectively tested on 10,761 ECGs.[26] Quoting from the study:

- "For three of the abnormal rhythms, namely, atrial fibrillation, junctional rhythms, and second-degree atrioventricular blocks, MAC-RHYTHM gave significantly higher sensitivity in both prospective (87.5%, 92.2%, and 80.8%, respectively) and retrospective (82.0%, 81.2%, and 79.6% respectively) testing than the [old program] (65.0%, 39.6%, and 12.0% respectively). Similarly, for sinus rhythms, MAC-RHYTHM had significantly higher specificity (prospective, 91.0% and retrospective, 91.7%) than the [old program] (86.5%). The specificity for the abnormal rhythms remained very high with MAC-RHYTHM (prospective, 99.4% to 99.7% and retrospective, 99.1% to 99.7%) compared to the [old program] (99.0% to 99.9%)."

Prospective study using MAC-RHYTHM.[26]

Representative test population:	Hospital, all departments
Additional demographic data:	Adult population Specific ages, gender and race are unavailable.
Total number of test ECGs:	10,761
Method(s) used to verify diagnosis:	Confirmed by experienced cardiologist.

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***NPA (%)***	***PPA (%)***
Sinus rhythms	9,324	98.7	91.0	91.5	98.6
Atrial fibrillation	832	87.5	99.4	99.0	92.4
Atrial flutter	106	76.4	99.7	99.8	71.7
Junctional	64	92.2	99.5	100.0	52.7, (72.8)•
2nd-degree AV blocks	26	80.8	99.6	100.0	32.8

Since the addition of the QRS subtraction tool, several enhancements were made to the P wave detector. This included spectral analysis for the detection of atrial flutter; optimal lead selection for P wave detection; and T wave alignment to reduce subtraction artifact in the residual signals used to create a P wave detection function.[106]

As published in the literature,

> *"Performance was assessed using a test set of 69,957 confirmed ECGs from four hospitals. The rhythm interpretation in the confirmed ECG was compared to the rhythm interpretations from the previous and new versions of the program. The rate of disagreements between the confirmed rhythm and the computerized interpretation decreased from 6.9% to 4.1%. Sensitivity improved for sinus,*

• After excluding paced ECGs with failed pace detection.

atrial fibrillation, atrial flutter, and junctional rhythms, while specificity and positive predictive value improved for all arrhythmias."[106]

Four hospitals, random selection of ECGs[106]

Representative test population:	Four hospitals, all departments
Additional demographic data:	Randomly selected, adult population. Specific ages, gender and race are unavailable.
Total number of test ECGs:	69,957
Method(s) used to verify diagnosis:	Routine confirmation by cardiologists

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Sinus	62397	98.2	85.5	98.3
Atrial fibrillation	5163	89.0	99.4	91.9
Ectopic atrial rhythm	1066	35.2	99.7	63.4
No P waves	635	63.1	99.1	38.1
Atrial flutter	576	55.0	99.6	50.7
2nd/3rd degree AVB	120	49.1	99.6	18.1

Recently, Poon[88] analyzed the interpretation performance for rhythm on 3,954 non-paced ECGs analyzed by 12SL. As quoted from the literature, "Our findings differ only modestly from the corresponding performance characteristics for sinus rhythm, atrial fibrillation, and atrial flutter recently reported by Farrell et al."

Evaluation in done in 2005 at NY Presbyterian Hospital [88]

Representative test population:	University hospital
Additional demographic data:	Consecutive inpatient and outpatient ECGs over a 3-week period. Specific ages, gender and race are unavailable.
Total number of test ECGs:	4297
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
PRIMARY RHYTHMS				
Sinus	3579	98.7	90.1	99.0
Atrial fibrillation	250	90.8	98.9	84.7
Atrial flutter	41	61.0	99.9	83.3
Atrial tachycardia	36	2.8	99.9	25.0
RHYTHM MODIFIERS				
Premature atrial complexes	212	64.2	99.5	87.2

Premature ventricular complexes	162	82.7	99.1	80.2

In another study, a total of 2,194 consecutive ECGs from 1,856 patients were collected from a tertiary care VA Hospital from both inpatients and outpatients. The results for rhythm analysis are summarized below. Not all rhythms, for example sinus rhythms, were reported in the study.

Evaluation of rhythm analysis done in 2006 at tertiary care, VA Hospital[219]

Representative test population:	Tertiary care, VA Hospital Inpatients & Outpatients
Additional demographic data:	Age ranged from 33 to 96 years (mean 73.5). Nearly all of them (98.3%) were male. Information on race is unavailable.
Total number of test ECGs:	2194 from 1856 patients
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
PRIMARY RHYTHMS				
Atrial fibrillation	67	76.1	99.6	85.0
Atrial flutter	41	65.9	99.9	93.1
Permanent pacemaker	56	73.2	99.9	93.2
2nd degree AV block	1	100	99.7	14.3
RHYTHM MODIFIERS				
1st degree AV block	138	97.8	99.7	95.7
Premature ventricular complexes	150	94.0	99.5	94.0
Premature atrial complexes	94	66.0	99.5	86.1

In another study, ECGs were acquired from symptomatic patients with isolated pulmonary hypertension. The blinded and un-blinded cardiologist and computer program analysis agreed regarding the rate and rhythm in each case (n=64). Sinus rhythm was present in 96.9% of patients; one patient had an ectopic atrial rhythm and one had a junctional rhythm. The heart rate averaged 84.1 ± 15.5 b/min. Sinus bradycardia was present in 5, sinus tachycardia in 6, and first degree atrioventricular block in 7 patients; 2 patients had a complete right bundle branch block.[405]

ECGs from symptomatic patients with pulmonary hypertension[405]

Representative test population:		University hospital, Patients with pulmonary hypertension		
Additional demographic data:		64 consecutive symptomatic patients. 12 M, 52 F, mean age 43 ± 13yr. Race is unavailable.		
Total number of test ECGs:		64		
Method(s) used to verify diagnosis:		Confirmation by 2 cardiologists		
Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
PRIMARY RHYTHMS				
Sinus	62	100	100	100
Ectopic atrial rhythm	1	100	100	100
Junctional Rhythm	1	100	100	100
RHYTHM MODIFIERS				
1st degree AV Block	7	100	100	100
BBB	2	100	100	100

Note that the studies yield similar results, despite the different locations and environments. This increases the confidence that these results will be reproducible in other populations.

In addition to these studies, an evaluation of the clinical consequences of misdiagnosed atrial fibrillation by a computer was performed at Henry Ford Hospital in Detroit, Michigan. A total of 2298 ECGs were identified with a computerized diagnosis of atrial fibrillation by GE Marquette 12SL™ Program. Of these 2,298 ECGs, 442 (or 19%) from 382 (35%) of the 1085 patients had been incorrectly interpreted as atrial fibrillation. The paper did not report the total number of true atrial fibrillation ECGs across the entire sampled population, only the number of "true positives" and "false positives" from the computerized interpretation. Only the positive predictive value may be calculated. In 92 patients (that is, 24% of the inaccurate computerized interpretations), the physician ordering the ECG, failed to correct the inaccurate interpretation. Clinical consequences of this misdiagnosis are presented in the paper as well as in this document (see Clinical Impact due to Computer Error). The conclusion of this work is that greater efforts should be directed toward educating physicians about the electrocardiographic appearance of atrial dysrhythmias and the recognition of confounding artifacts.

Evaluation of Misdiagnosis of Atrial Fibrillation by Computer[91]

Representative test population:		Large, university hospital
Additional demographic data:		The mean age of these 382 patients was 74 ± 14 years, and 49% (n =188) were men. Only a minority of patients complained of palpitations (n=22) or dizziness (n = 44) at the time of the index ECG; the remaining patients were asymptomatic. Thirty-one percent (n = 120) of patients had a prior history of atrial fibrillation. Information on race is unavailable.
Total number of test ECGs:		2298
Method(s) used to verify diagnosis:		Patient chart and follow-up
Rhythm category	***N***	***Positive predictive value (%)***
Atrial fibrillation	2298	81.0

This value of 81% for the positive predictive accuracy for the computerized recognition of atrial fibrillation is lower but comparable to the other studies presented here. Noise in the ECG tracing is a confounding factor in this study. Note that 38% of the misinterpretations by both the computer and physician were due to artifact.[91, 406] Quality control of noise is a critical factor for proper ECG interpretations by both the physician and computer.[33, 286] See Hookup Advisor™ for further insight on ECG quality and automated rhythm interpretation.

In contrast, in a community-based survey in China of 47,841 adults (age ≥45 years) which used 12SL for the identification of atrial fibrillation, "a cardiologist visually rechecked all the automatically detected AF ECGs and 500 randomly selected other ECGs without AF, with 100% agreement."[263] Of the "932 patients with a diagnosis of AF, 334 (35.8%) were unaware of its presence and only detected due to the ECG obtained during the study."

Community Health Survey to Determine Prevalence of Atrial Fibrillation in China[263]

Representative test population:		Community-based survey
Additional demographic data:		"Sample of representative 47,841 adults (age ≥45 years) was obtained through a two- stage, stratified cluster sampling design in the general population." "From each city or province, 4000 rural (1 to 13 representative villages) residents and 4000 urban (one to three representatives of communities in a capital city) residents (living in the area for >6 months) were surveyed." More women were sampled than men: men with AF (n=422) and without AF (n=18,073) versus women with AF (n=510) without AF (n=28,836).
Total number of test ECGs:		Total number of ECGs: 47,481.
Method(s) used to verify diagnosis:		Cardiologist reviewed. 932 positive cases of Afib identified by 12SL plus 500 randomly selected ECGs.
Rhythm category	***N***	***Positive predictive value (%)***
Atrial fibrillation	932	100.0

INTERPRETATION OF RHYTHM IN PEDIATRIC POPULATION

Recently, two studies have evaluated pediatric populations. The first was in an emergency department (ED); the other was across a large pediatric hospital.

In the first study, a total 294 cases were evaluated.[227] The patients ranged in age from 5 days to 21 years. The ED physicians interpreting the ECGs were directly involved in the patients' care and were familiar with the presenting complaint, past medical history, and physical examination. Physicians were allowed to use whatever means available to aid with ECG interpretation. The physicians were blinded to the computer interpretations. The reference standard was the ECG interpretation by a pediatric electrophysiologist.

Each electrocardiographic diagnosis, as well as the ECG as a whole, was assigned to one of the following predetermined classes: I, normal sinus rhythm; II, minimal clinical significance; III, indeterminate clinical significance; IV, those of definite clinical significance.

Both the computer and ED physician correctly interpreted all normal (class I) ECGs correctly (that is, normal sinus rhythm / normal ECG). The computer correctly diagnosed class II ECGs 82% of the time as compared to 67% by the ED physicians ($p<0.001$). The computer was also significantly more accurate than the ED physicians regarding the class III diagnoses, correctly interpreting 73% compared to 30% by the physicians ($p<0.001$). Regarding the individual class IV ECG diagnoses, the ED physicians were more accurate than the computer (28% vs 14%), but this difference did not reach significance ($p>0.3$).

Pediatric rhythm interpretation resulted in most computer errors in this study. "Despite its superior ability to accurately interpret many of the simple rhythm disturbances, the computer was less accurate than the ED physicians with regards to interpreting ECGs with abnormal supra-ventricular rhythms. Specifically, the computer failed to identify all 4 ECGs with junctional rhythm, 2 of 4 with supraventricular tachycardia, and 2 with intraatrial reentry tachycardia."[227]

This study did not assess specificity. "The over interpretation of ECGs by either the computer or ED physicians was not evaluated in this study."[227] As a result, the results of this study cannot be represented in the table recommended by the IEC.[1]

The second study evaluated 56,149 pediatric ECGs.[407] From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure balanced representation in terms of age, sex, etc. This resulted in a sample size of 1,147 ECGs. The reported results for rhythm are presented below:

Evaluation of pediatric rhythm interpretation[407]

Representative test population:		Large pediatric hospital		
Additional demographic data:		Median age at the time of ECG was 3.0yrs, in the heart disease group, and 6.0yrs, in the group without heart disease. Race and gender are unavailable.		
Total number of test ECGs:		1,147 (sampled from 56,149)		
Method(s) used to verify diagnosis:		Confirmation by 2 pediatric cardiologists		
Rhythm category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Sinus Rhythm in presence of Heart Disease	399	95.5	99	99

Sinus Rhythm in normal group	390	98.5	100	100
Sinus Arrhythmia in presence of Heart Disease	31	87	100	100
Sinus Arrhythmia in normal group	51	88	100	100
Sinus Rhythm with Ectopy in Heart Disease group	10	100	98.5	56
Sinus Rhythm with Ectopy in normal group	22	100	98	69

Contour Interpretation: Reported Results

Below are the reported results for the following abnormalities:

P-wave Abnormalities 182
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P-WAVE ABNORMALITIES

This section provides performance metrics, as reported in the literature, for interpretation of right and left atrial abnormalities.

Evaluation of right and left atrial abnormality at tertiary care, VA Hospital[219]

Representative test population:	Tertiary care, VA Hospital Inpatients & Outpatients
Additional demographic data:	Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.
Total number of test ECGs:	2,194 from 1,856 patients
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

P Wave Abnormality	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Right	29	100	99.9	97
Left	97	95.9	100	100

QRS ABNORMALITIES

This section provides performance metrics, as reported in the literature, for the computerized interpretation of QRS abnormalities. These include right bundle branch block (RBBB), left bundle branch block (LBBB), left ventricular hypertrophy (LVH), right ventricular hypertrophy (RVH) as well as healed anterior and/or inferior myocardial infarction.

The IEC also requires manufacturers to disclose those QRS abnormalities without reported results. (See IEC 60601-2-51 clause 50.102.3.1). These include the following statement categories: Wolff-Parkinson-White (WPW), QRS axis deviation abnormalities, hemi-blocks, low-voltage QRS, Brugada pattern and pulmonary disease pattern. In addition, isolated lateral or posterior myocardial infarctions have no reported results; instead, these statements are grouped with inferior or anterior myocardial infarctions.

At Mount Sinai Medical Center in New York City, over 39,000 ECGs were reviewed for computer accuracy.[220]. The cardiologist was used as the reference since interpretative statements regarding conduction are Type B statements.

A detailed inspection of the data from the Mount Sinai study showed that the cardiologist often changed the computer diagnosis to LBBB (n=97) from another conduction abnormality already stated by the program (like ILBBB or nonspecific intraventricular conduction block). If these other conduction abnormalities were included as part of the analysis, the sensitivity would increase from 78% to 88%.

Independent Assessment of Conduction Abnormalities[220]

Representative test population:	Hospital, all departments
Additional demographic data:	Ages, gender, and race are unavailable.
Total number of test ECGs:	39,000
Method(s) used to verify diagnosis:	Confirmed by cardiologists.

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RBBB	1661	90	100	100
LBBB	860	78	100	100
LBBB (grouped w/ ILBBB, IVCB)	860	88	100	100

At the Mayo clinic, the 12SL™ program was evaluated to determine whether it could replace an ECG program, based on XYZ Leads, with the 12SL™ program, which is based on the scalar 12-lead ECG.[408] In a similar fashion as the aforementioned study, over 12,000 ECGs were evaluated at the Mayo Clinic. See table below.

Independent Assessment of Conduction Abnormalities[409]

Representative test population:	Hospital, all departments
Additional demographic data:	Ages, gender, and race are unavailable.
Total number of test ECGs:	12,793
Method(s) used to verify diagnosis:	Confirmed by cardiologists.

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RBBB	391	91	100	100
LBBB	248	87	99.9	99.9

In another study,[219] ECGs were collected in a tertiary care facility from both inpatients (36.4%), outpatients (47.6%) and in the emergency room (16.0%). There were 2,194 consecutive ECGs recorded on 1856 patients. Two cardiologists read the ECGs. Of the 2,194 tracings, 122 were excluded from analysis because of a disagreement between the cardiologists' interpretations. Out of 2072 remaining cases, 776 (37.5%) the computer interpreted as normal and 1296 as abnormal. In 206 cases, there were discordances between the computer and cardiologists' interpretation (9.9%). There were no discordances in the ECGs interpreted as normal by the computer. The discordances occurred in 15.9 % of all ECGs read as abnormal. Conduction abnormalities were also evaluated as part of this study. The results are reported below:

Independent Assessment of Conduction Abnormalities by 2 Cardiologists[219]

Representative test population:	Hospital, all departments
Additional demographic data:	Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.
Total number of test ECGs:	2072
Method(s) used to verify diagnosis:	Confirmed by 2 cardiologists.

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RBBB	118	93.2	99.8	96.5
LBBB	33	90.9	99.9	90.9

RBBB in a pediatric population is exhibited in a narrow QRS. This diagnosis was evaluated at a pediatric hospital using 56,149 ECGs stored on a MUSE™ system. From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure a balanced representation. This resulted in a sample size of 1,147 ECGs. RBBB is a Type B statement and can be validated by a pediatric cardiologist.

Assessment of RBB in a Pediatric Population[407]

Representative test population:	Hospital, all departments
Additional demographic data:	Median age at the time of ECG was 3.0yrs, in the heart disease group, and 6.0yrs, in the group without heart disease. Race and gender are unavailable.
Total number of test ECGs:	1,147
Method(s) used to verify diagnosis:	Confirmed by 2 pediatric cardiologists.

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RBBB	123	79.6	99.8	99

Left ventricular hypertrophy (LVH) is often assumed to be little more than a marker of hypertension. LVH can occur in the normotensive, especially in the presence of other risk factors such as diabetes.[410] More importantly, it has been found in a large survey of over 7,000 individuals that although normotensives with LVH were rare, they had similar survival rates "to hypertensive adults with LVH and lower survival rates than normotensive and hypertensive adults with no LVH."[411] Not all patients with hypertension develop LVH. Yet once it has been identified in the hypertensive patient it is, other than age, "the most potent predictor of adverse cardiovascular outcomes."[412] Guidelines for the management of arterial hypertension now recognize the substantial clinical evidence of treatment-induced reductions in LVH accompanied by a reduced incidence of cardiovascular events,[413, 414] which makes the detection of LVH "advisable not only to quantify total cardiovascular risk initially but also to monitor treatment-induced protection."[415] It has become "increasingly important to identify left ventricular hypertrophy and prescribe a combination of therapies which facilitates regression to improve patients' symptoms and prognosis."[416]

When using echocardiography (ECHO) to detect LVH, the prevalence has been found to be high in the hypertensive population - from 20 to 60% - depending upon the presence of other risk factors and the setting where the test was done.[417] A review of ECG-based LVH criteria demonstrates that the ECG detects less

than half of those found positive via ECHO, leading to the conclusion that "electrocardiographic criteria should not be used to rule out left ventricular hypertrophy in patients with hypertension."[417]

The ECG continues to have an important role in care areas that neither can afford the ultrasound instrumentation nor the trained personnel to perform an accurate ECHO. Current care guidelines for the management of arterial hypertension define LVH as detected via the ECG as sufficient evidence to require different care pathway for specific patients versus that based on blood pressure alone.[415, 418]

It should also be appreciated that ECHO and ECG measure different aspects of LVH. Although an ECHO provides a macroscopic view of the enlarged heart, it does not provide a view of the microscopic changes in the cellular substrate, which can impact conduction and repolarization.[419-421] ECHO-LVH and ECG-LVH independently predict mortality as well as other cardiovascular events, "implying that ECHO-LVH and ECG-LVH carry different prognostic information."[422] This becomes especially apparent when the disease has progressed to the point where the ECG exhibits signs of electrocardiographic "strain", which is associated with an increased risk of mortality[390] as well as developing congestive heart failure (CHF) and "dying as a result of CHF, even in the setting of aggressive blood pressure lowering."[345] Even when an ECHO is available, some have concluded that both an ECHO and ECG are necessary for a complete assessment of the risk due to LVH.[422, 423]

For identifying LVH, the latest version[⊥] of GE's Marquette 12SL program incorporates the following commonly used criteria that have been extensively validated and reported in the literature:

- Sokolow-Lyon[*]
- Romhilt-Estes
- Cornell Product

A systematic review of the literature before 2007,[417] identified studies that assessed these aforementioned electrocardiographic criteria in hypertensive adults against echocardiography for whom sufficient data were available for not only reporting sensitivity and specificity but the actual number of true positives (TP), false positives (FP), true negatives (TN) and false negatives (FN) . The authors evaluated the quality of these studies based on "the methods of patient selection and data collection, completeness of descriptions of index and reference tests, completeness of blinding, and the likelihood of verification bias." Studies were ranked as being of high quality if they "described the setting (for example, family physicians referring patients to the clinic); collected data prospectively, with enrolment of consecutive patients and follow-up of all patients, including those who did not have echocardiography; and provided details on echocardiography and whether the assessor of the echocardiography was unaware of the electrocardiogram result or vice versa." In accordance with IEC requirements, below are the reported results from those studies of the highest quality that included at least 250 patients and evaluated more than one of the ECG-based LVH criteria used by 12SL.

[⊥] Previous versions of the 12SL program used a modification of the Romhilt-Estes criteria

[*] R in aVL > 11mm should be assumed to be part of the Sokolow-Lyon criteria

Sokolow-Lyon criteria versus ECHO (from Lee, 1992)[417]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 270 patients, mean age = 54, 69% men Prevalence of LVH = 23%		
Total number of test ECGs:		270		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 131; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	61	15	86	30

Cornell Product criteria versus ECHO (from Lee, 1992)[417]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 270 patients, mean age = 54, 69% men Prevalence of LVH = 23%		
Total number of test ECGs:		270		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 131; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	61	5	96	30

Romhilt Estes criteria ≥ 5 points versus ECHO (from Lee, 1992)[417]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 270 patients, mean age = 54, 69% men Prevalence of LVH = 23%		
Total number of test ECGs:		270		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 131; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	61	7	97	66

Sokolow-Lyon criteria versus ECHO (from Crow, 1995)[417]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 834 patients, mean age = 55, 61% men Prevalence of LVH = 15%		
Total number of test ECGs:		834		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 134; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	128	8	97	53

Cornell Product criteria versus ECHO (from Crow, 1995)[417]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 834 patients, mean age = 55, 61% men Prevalence of LVH = 15%		
Total number of test ECGs:		834		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 134; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	128	11	97	61

Romhilt-Estes ≥ 4 points versus ECHO (from Crow, 1995)[417]

Representative test population:		Primary Care / Office setting		
Additional demographic data:		Mixed black and Caucasian US population 834 patients, mean age = 55, 61% men Prevalence of LVH = 15%		
Total number of test ECGs:		834		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 134; women ≥ 110		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	128	16	98	54

Sokolow-Lyon criteria versus ECHO from Verdecchia, 2000[424]

Representative test population:		Hospital / tertiary care		
Additional demographic data:		Caucasian, Italy 947 patients, mean age = 60, 59% men Prevalence of LVH = 27%		
Total number of test ECGs:		947		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 125; women ≥ 125		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	258	16	93	45

Cornell Product criteria versus ECHO from Verdecchia, 2000[424]

Representative test population:		Hospital / tertiary care		
Additional demographic data:		Caucasian, Italy 947 patients, mean age = 60, 59% men Prevalence of LVH = 27%		
Total number of test ECGs:		947		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 125; women ≥ 125		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	258	20	91	46

Romhilt-Estes criteria versus ECHO from Verdecchia, 2000[424]

Representative test population:		Hospital / tertiary care		
Additional demographic data:		Caucasian, Italy 947 patients, mean age = 60, 59% men Prevalence of LVH = 27%		
Total number of test ECGs:		947		
Method(s) used to verify diagnosis:		ECHO LV Mass index (g/m^2) men ≥ 125; women ≥ 125		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	258	8	97	47

Skolow-Lyon criteria versus ECHO from Salles[425]

Representative test population:	Hospital / tertiary care			
Additional demographic data:	Caucasian and black, UK 471 patients, mean age = 60, 28% men Prevalence of LVH = 81%			
Total number of test ECGs:	471			
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 116; women ≥ 104			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	383	20	85	85

Cornell Product criteria versus ECHO from Salles[425]

Representative test population:	Hospital / tertiary care			
Additional demographic data:	Caucasian and black, UK 471 patients, mean age = 60, 28% men Prevalence of LVH = 81%			
Total number of test ECGs:	471			
Method(s) used to verify diagnosis:	ECHO LV Mass index (g/m^2) men ≥ 116; women ≥ 104			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
LVH	383	32	85	90

Subsequent to the review article published by Pewsner et al.,[417] it has been demonstrated that a composite of different voltage criteria used by 12SL™ for detecting LVH "may be a useful strategy to further increase the diagnostic ability of ECG." [426] In any case, the approach used by 12SL for the assessment of LVH conforms to the following recommendations made by the ACC:[427]

1. Interpretation of ECGs for LVH should utilize only validated criteria without deviation from the validated formulas
2. No single diagnostic criterion can be recommended for use compared with the others
3. Computer systems should utilize all criteria that are supported by valid evidence for identifying left ventricular hypertrophy.
4. Interpretations should specify which diagnostic criteria were used and which were abnormal (and thereby, by exclusion, which were examined but not found to be abnormal).

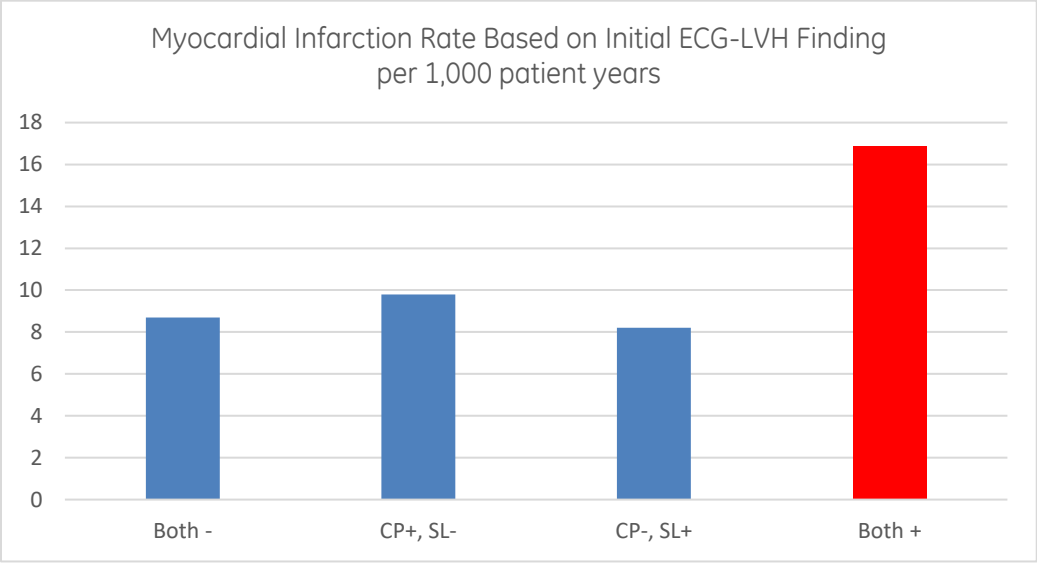
In 2017, a study by Okin et. al. found that in 9,193 patients followed 4.8±0.9 years, "persistence or development of ECG LVH by both Cornell product (CP) and Sokolow-Lyon (SL) voltage criteria during antihypertensive therapy is associated with markedly increased risks of cardiovascular end points and all-cause mortality."[49] "Compared with the absence of ECG LVH by both criteria, persistence or development of ECG LVH by both criteria entered as a time-varying covariate was associated with >3-fold increased risks of events in multivariable Cox analyses adjusting for randomized treatment, baseline risk factors, and on-

treatment heart rate and systolic and diastolic blood pressures. Patients with ECG LVH by either Cornell product or Sokolow-Lyon voltage had 45% to 140% higher risks of all end points."[49]

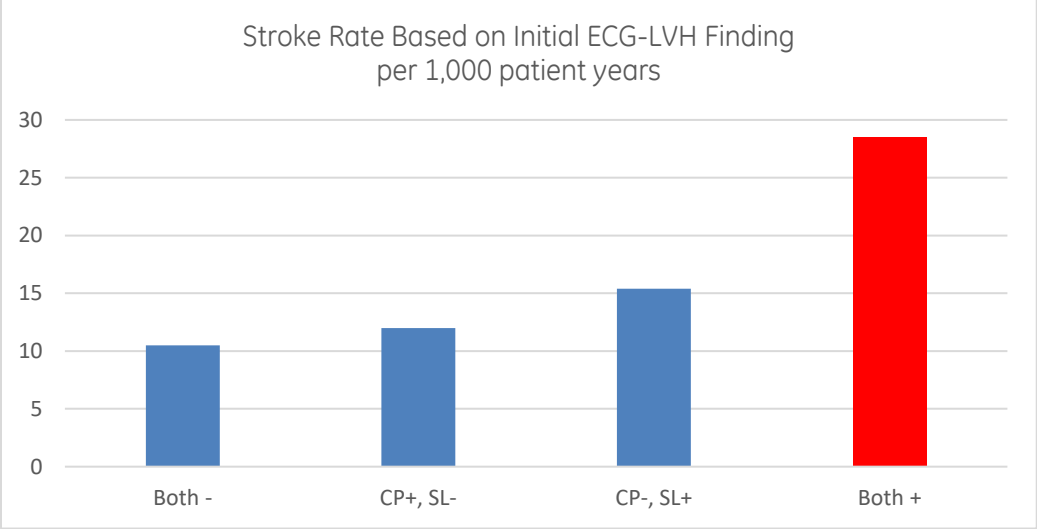
This paper by Okin et. al. also reiterated "the well-recognized limited sensitivity of any one ECG LVH criterion as compared with imaging modalities."[49] Given that serial ECG testing is inexpensive, this study suggests "that serial assessment of both CP and SL can improve risk stratification in patients with hypertension during treatment."[49]

Below, in graphical form, are some of the outcomes measured via this study. See full paper for completeness.[49]

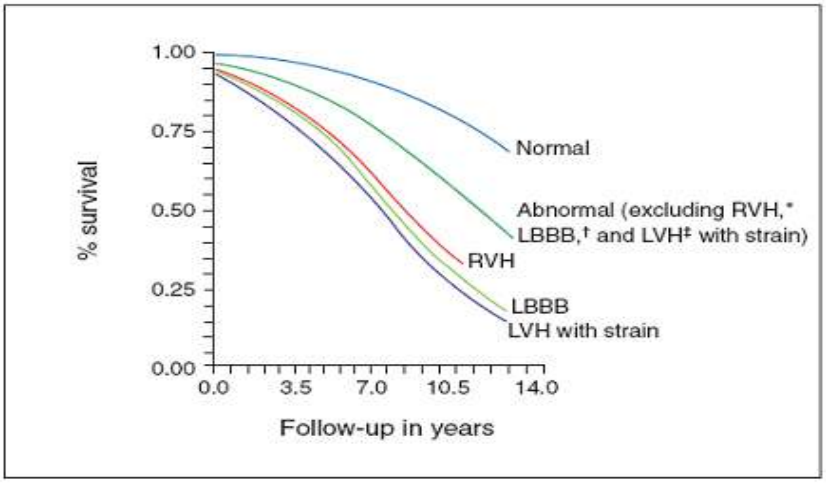
Impact of Combining Cornell and Sokolow Lyon: MI rate[49]



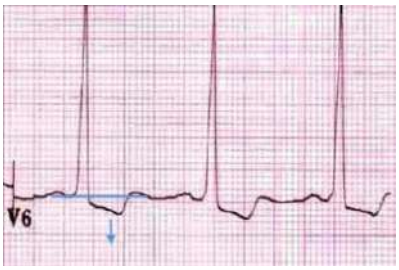
Impact of Combining Cornell and Sokolow Lyon: Stroke rate[49]



GE's Marquette 12SL™ interpretation was evaluated in terms of its prognostic value on 26,734 male and 3,737 female veterans.[244] The computerized interpretation was used without modification. Computer detected abnormalities associated with the lowest survival rates are presented below. Note that "LVH with strain" is the most predictive and that a normal ECG as defined by the 12SL program "is associated with extremely good survival".[244] This same finding was confirmed in a similar study that focused on Hispanics, although the prevalence of disease was lower."[388]



The term “LVH with strain” is an abbreviation for what the 12SL program states which is, “Left Ventricular Hypertrophy with repolarization abnormality.” The correlation between LV mass and QRS voltage has been extensively studied.[428] In any case, when the QRS voltage exceeds an age-adjusted threshold, the 12SL program states “LVH”. When 12SL states “LVH with strain”, it means the program has identified ST/T wave changes commensurate with LVH. The figure to the right is such an example. In lead V6, the QRS voltage is large, the ST-segment is abnormal (i.e. depressed, down slopping) and the T-wave inverted - a classic example of “LVH with strain”. As it turns out, it is the ECG-based characteristic referred to as “strain”, which is the most predictive of a poor clinical outcome in the VA population.[390]



In 2018,[394] investigators at VAHS took the additional step of determining whether QRS voltage could distinguish between physiological and pathological hypertrophy. Physiological hypertrophy implies increased LV mass but, in this case, it is due to positive influences, such as strenuous exercise followed by rest and recovery. Pathological hypertrophy infers the ventricle has grown in an abnormal fashion due to chronic stress and no longer has the cellular structure conducive to proper function.[419] Myocardial disarray makes the ventricle unable to properly relax or contract. This becomes a vicious cycle. As the heart becomes less effective, the body sends signals to the heart to grow more. Unfortunately, since in this case the drive to grow is not followed by rest or recovery, the growth will be abnormal, resulting in myocardial disarray. Distinguishing between the two forms of LVH is important due to the frequency of athletic training that occurs in the VA population. By studying ECGs of 16,253 veterans followed a median of 17.8 years, it was found that QRS voltage does “not reflect the same pathophysiological changes, and can be due to athletic training.”[394]

This is likely because the deadly changes associated with “strain” are not related to LV mass but, instead, are a reflection of the delayed conduction across the left ventricle due myocardial disarray, collagen and scar tissue that has formed as a consequence of chronic stress.[429] In any case, there is growing evidence that “ECG strain may be an early marker of LV structural remodeling that contributes to development of adverse cardiovascular events”,[347] including ventricular arrhythmias and sudden cardiac death.

Right ventricular hypertrophy (RVH) is less prevalent than LVH in the adult population. In any case, a large international study evaluated program performance for hypertrophy.[218] In this study there were a total of 1220 patients, 382 controls and 838 with cardiac disorders that were collected across five European centers. ECGs showing complete Left Bundle Branch Block (LBBB), Right Bundle Branch Block (RBBB) or other major intraventricular conduction defects were excluded; otherwise there were no other criteria for excluding ECGs. A normal individual (n=286) was defined as being free of significant cardiopulmonary disease on the basis of a health screening examination (negative history, normal physical exam, normal chest X-ray) or invasive cardiac study (n=96). Invasive studies usually entailed cardiac catheterization (CATH) for atypical chest pain

or ST/T abnormalities evident at rest or during exercise. LVH or RVH was based on CATH or ECHO or both. Specific details regarding the population are contained in the article.[218]

Performance of RVH by ECG, validated by CATH and ECHO[218]

Representative test population:	5 European Academic Centers, Hospitals			
Additional demographic data:	831 men, 389 women, all white, age 52±13 years			
Total number of test ECGs:	1220			
Method(s) used to verify diagnosis:	ECHO, CATH, Clinical History			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RVH	55	29.1	100	100

In another study, patients with pulmonary hypertension due to pulmonary vascular occlusive disease were evaluated in the Pulmonary Hypertension Clinic at the University of Michigan. Each underwent a thorough history, physical exam, ECG, echocardiogram, pulmonary function testing, and right heart catheterization. Symptoms (type and duration), effort tolerance, and New York Heart Association (NYHA) functional class were recorded during the initial visit. Pulmonary hypertension was defined as a mean pulmonary artery pressure > 25 mmHg. Patients were excluded if they presented with evidence of chronic lung disease, left ventricular hypertrophy, mitral or aortic valve disease, congenital heart disease, coronary artery disease or cardiomyopathy.[405]

Performance of RAE and RVH by ECG, validated by CATH and ECHO[405]

Representative test population:	Hospital, Academic Center			
Additional demographic data:	64 consecutive symptomatic patients; 12 M, 52 F, mean age 43 ± 13yr. Race is unavailable.			
Total number of test ECGs:	64			
Method(s) used to verify diagnosis:	ECHO, CATH, Pulmonary artery pressure			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RVH	64	39.1	100	100
Right Atrial Enlargement	13	46	100	100

The blinded cardiologist and computer program diagnosed RVH in 43.8 and 39.1% of patients, respectively; this is substantially lower than the 78.1%, as determined by the un-blinded reader that was provided the age and clinical parameters (i.e. symptoms associated with possible pulmonary hypertension). Right ventricular strain was present in 71.9% of patients and was most often characterized by the blinded cardiologist and the computer program as non-specific or inferior/anterior-lateral ischemia. The most common errors by the computer and blinded cardiologist were the diagnosis of an anterior-septal infarction based on the presence of a qR in V1 (10.9%), and of an inferior-posterior myocardial infarction because of the presence of a "pathologic" Q wave in II, III and aVF associated with a prominent R in V1 (6.2%)

The study concluded that the ECG does have a high specificity for the detection of RVH in symptomatic patients with pulmonary hypertension and that correlation with the clinical parameters is essential to

optimize the usefulness of the ECG. Without the clinical parameters, the computer program and blinded cardiologist often suggested myocardial infarction / ischemia.

In another study, two cardiologists were considered as the gold standard. As expected, performance metrics for the program are much higher when they are based on this human standard.

Evaluation of ventricular hypertrophy at tertiary care, VA Hospital[219]

Representative test population:	Tertiary care, VA Hospital Inpatients & Outpatients
Additional demographic data:	Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.
Total number of test ECGs:	2194 from 1856 patients
Method(s) used to verify diagnosis:	Confirmation by 2 cardiologists

Hypertrophy Category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Right Ventricle (RVH)	15	100	99.9	66.7

Criteria for RVH, in a pediatric patient, are defined by 16 different age categories.[430, 431] This diagnosis was evaluated at a pediatric hospital using 56,149 ECGs stored on a MUSE™ system. From this list, 2 groups of patients were selected: patients with heart disease and those without heart disease. The ECGs were systematically selected in the stratified groups to ensure balanced representation. This resulted in a sample size of 1,147 ECGs

Note that RVH is a Type A statement: that it typically requires non-ECG data for a reference gold-standard. In this case, the authors used the opinion of 2 pediatric cardiologists.

Assessment of RVH in a pediatric population[407]

Representative test population:	Hospital, all departments
Additional demographic data:	Median age at the time of ECG was 3.0yrs, in the heart disease group, and 6.0yrs, in the group without heart disease. Race and gender are unavailable.
Total number of test ECGs:	1,147
Method(s) used to verify diagnosis:	Confirmed by 2 pediatric cardiologists.

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
RVH	93	91.3	99.8	99

There are several independent studies that have evaluated the performance of GE's Marquette 12SL™ program to recognize healed myocardial infarction (MI).[432] The term "healed myocardial infarction" implies that this section is reporting results on the ability of the program to detect QRS abnormalities (like abnormal Q-waves) associated with necrosis. Computerized interpretation of a myocardial infarction is a Type A statement, requiring independent validation from non-ECG data.

The first series of evaluations of the 12SL™ program were done on ECGs from subjects that were selected from consecutive patients undergoing cardiac catheterization.[433, 434] The presence of an MI was determined via wall motion abnormalities associated with a 75% or greater obstruction of the relevant coronary artery. Patients with pulmonary disease, valvular disease, a history of previous MI, LV wall motion

abnormalities suggesting multiple MIs, and patients with a history of previous cardiac surgery were excluded. Normals were defined as having normal LV motion and coronary arteries. This resulted in a study population of 734 patients with an MI and 406 patients defined as normal. The infarction group consisted of 84% males with an average age of 55 years. The average age of the 121 female patients was 57 years. ECGs selected for analysis were obtained on average 3 days before the CATH in 92% of the infarction group patients. The remaining 8% were done within 30 days following the CATH procedure. The normal group consisted of 41% males with an average age of 46 years. The average age of the 238 female patients was 52 years. ECGs were obtained, on average, within 4 days before the CATH in 99% of the normal patients.

The results for the performance of the program versus CATH are presented below. Note that the physician had a similar level of sensitivity (69%) but maintained a higher level of specificity (97%).

Performance of MI: Group All Statements Indicating MI[433]

Representative test population:		Hospital		
Additional demographic data:		Specific ages, race, and gender information are unavailable.		
Total number of test ECGs:		1140		
Method(s) used to verify diagnosis:		CATH, Clinical History		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Myocardial Infarction	734	70	92	94

This same study also evaluated the performance of statements that were preceded by the modifiers "cannot rule out" and/or "possible". When these statements were not considered diagnostic for MI, the sensitivity was reduced to 54% while the specificity improved to 98%.

Performance MI Statements without Modifiers “Cannot Rule Out”, “Possible”[433]

Representative test population:		Hospital		
Additional demographic data:		Specific ages, race, and gender information are unavailable.		
Total number of test ECGs:		1140		
Method(s) used to verify diagnosis:		CATH, Clinical History		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Myocardial Infarction	734	54	98	98

Using the same aforementioned source of data, an evaluation of inferior MI was conducted,[434] which demonstrated that the 12SL program had a sensitivity of 76% and a specificity of 95% while the physician had a lower sensitivity (75%) but a higher specificity (97%) than the computer.

In a separate study conducted at a Veterans Administration hospital, 137 patients were evaluated via cardiac catheterization using similar methods for data acquisition and analysis as the study but, in this case, the focus was anterior myocardial infarction. Patients who had significant valvular heart disease, left bundle branch block, or paced rhythm were excluded. No attempt was made to identify and exclude patients with either left ventricular enlargement or chronic obstructive pulmonary disease, conditions that can reduce the specificity of ECG criteria for anterior myocardial infarction. All the ECGs were obtained on or near the day of

each patient's catheterization. Of the 137 patients, the normal group consisted of 82 patients and the anterior MI group consisted of 55 patients. Below are the reported results for the 12SL™ program:

Performance of Anterior MI by ECG, validated by CATH[435]

Representative test population:		Veterans Administration Hospital Adult population.		
Additional demographic data:		Specific ages, race, and gender information are unavailable.		
Total number of test ECGs:		137		
Method(s) used to verify diagnosis:		CATH		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Anterior MI	55	64	99	99

Another large international study also used CATH as the reference but relied solely on the assessment of wall motion abnormalities, not including coronary obstruction. The results are presented below:

Performance of Anterior and Inferior MI by ECG, validated by CATH [218]

Representative test population:		5 European Academic Centers, Hospitals		
Additional demographic data:		831 men, 389 women, all white, age 52±13 years		
Total number of test ECGs:		1220		
Method(s) used to verify diagnosis:		CATH, wall motion studies		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Anterior MI	170	66	98	84
Inferior MI	273	65	97	86

In another, two cardiologists were defined as the standard. As expected, the performance metrics of the program are markedly higher using this human standard.

Evaluation of old infarction at tertiary care, VA Hospital[219]

Representative test population:		Tertiary care, VA Hospital Inpatients & Outpatients		
Additional demographic data:		Patients age ranged from 33 to 96 years, mean 73.5. Nearly all of them (98.3%) were male. Race is unavailable.		
Total number of test ECGs:		2194 from 1856 patients		
Method(s) used to verify diagnosis:		Confirmation by 2 cardiologists		
Category	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Old myocardial infarctions	399	98.8	99.5	97.4

REPOLARIZATION ABNORMALITIES

Computer interpretations of a repolarization abnormality are composed of Type A and C statements. Recall that Type C statements refer to purely descriptive ECG features that usually cannot be documented by any other means. Examples of such statements include "non-specific ST-T abnormality". This document will primarily be reporting results of the Type A statements, which are verified by non-ECG data such as cardiac enzymes, patient outcomes, etc.

The recognition of ST-elevated acute myocardial infarction (STEMI) has been a major focus of GE Healthcare. This is because the ECG is so vital in selecting an appropriate treatment path for acute myocardial infarction[198] as well as reducing time-to-treatment for STEMI.[436]

GE Healthcare was the first to introduce a pre-hospital diagnostic 12 lead ECG as a small, compact unit for the ambulance that could acquire and transmit the ECG digitally so that there would be no distortion of the ST/T waveform.[165]This led to several studies that demonstrated that a prehospital ECGs can be practically acquired,[229] significantly cuts total time-to-treatment,[230-232] and has "the potential to significantly increase the diagnostic accuracy in chest pain patients."[233]

Based on data collected from the prehospital environment,[166] GE's Marquette 12SL™ Program was modified to recognize earlier forms of STEMI, using reciprocal depression as the primary discriminating characteristic to discern STEMI versus early repolarization.[17] This approach, combined with enhancements, allowed the sensitivity to double without a loss of specificity.[437, 438] Several tests have since verified that reciprocal depression is a highly specific marker of STEMI.[183, 439, 440]

GE's Marquette 12SL™ Program (Version 14) is used in prehospital defibrillators currently offered by other vendors (Medtronic-Physio Control, Zoll).[441, 442] GE Healthcare's resting electrocardiographs use a later version that includes such features as gender and age-specific criteria for the recognition of STEMI[443] and the detection of right ventricular involvement in the presence of an acute inferior infarction.[35] As a result, the following reported results for STEMI are presented in two groups: one that applies to the results of the program in the prehospital defibrillator and one for the results of the program in GE Healthcare's resting ECG equipment. Note that both versions of the program analyze data of the same fidelity and content, generating fiducial points and medians at 500 SPS.[19]

The following series of reported results are from prehospital ECGs and are representative of version 14 of the 12SL program.

In Australia, a GE Healthcare portable prehospital electrocardiograph[444] was used for the automatic diagnosis of acute myocardial infarction via GE's Marquette 12SL™ Program. "This automated program diagnosed acute evolving Q wave myocardial infarction with 71% sensitivity and 98% specificity. Specificity was 100% when patients with a known previous Q wave myocardial infarction were excluded."[440, 445]

Results from GE Healthcare's Prehospital Electrocardiograph[440]

Representative test population:	Prehospital ECGs
Additional demographic data:	Specific ages, race, and gender information are unavailable.
Total number of test ECGs:	526
Method(s) used to verify diagnosis:	Physician interpretation, serial ECG analysis, & clinical outcome.

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Acute MI	Unknown	71	98	Unknown
Acute MI, no previous MI	Unknown	71	100	100

As part of the NIH sponsored Myocardial Infarction Triage and Intervention (MITI) Project,[446] the 12SL™ Program accuracy for recognizing STEMI was evaluated. This was a large prehospital study (n=1,189) that acquired ECGs from patients within 6 hours of the onset of chest pain. This study used cardiac enzymes as the "gold standard". Their conclusion: "the positive predictive value of the computer- and physician-interpreted ECG was, respectively, 94% and 86% and the negative predictive value was 81% and 85%."[123]" The authors also stated: "The present algorithm is clearly adequate for first line screening of patients with chest pain by paramedics or in the emergency department. Its sensitivity is no worse than that of the emergency physician and its specificity is superior to the trained electrocardiographer." "Although more sensitive, the electrocardiographer had an overall incidence of a 5% false positive diagnosis, including a 22% incidence of false positive diagnoses in patients with isolated ST segment elevation. In contrast, the computer was nearly perfect at excluding patients without acute myocardial infarction but did so at the expense of diminished sensitivity." The raw numbers for algorithm performance are given in the following table.

Results from the MITI trial based on cardiac enzymes[123]

Representative test population:	Prehospital ECGs, large city			
Additional demographic data:	Age 60 ± 12 years, men 66%, race unknown			
Total number of test ECGs:	1,189			
Method(s) used to verify diagnosis:	Cardiac Enzymes			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Acute MI	391	52	98.5	94

The results of the MITI trial were also analyzed for the recognition of STEMI as opposed to solely using cardiac enzymes as the reference. That is, an analysis was done as to whether or not ST elevation was present along with the positive cardiac enzyme result. In this case, the program achieved a sensitivity of 71%. As stated in the literature: "The computer algorithm was developed to help differentiate early repolarization and nonspecific ECG changes from those of acute injury and, unlike the electrocardiographer, did not presume that ST elevation in a patient with chest pain was more likely than not to indicate acute infarction. Although more sensitive, the electrocardiographer has an overall incidence of 5% false positive diagnoses, including a 22% incidence of false positive diagnoses in patients with isolated ST segment elevation."[123]

Results from the MITI trial based on cardiac enzymes and presence of ST elevation[123]

Representative test population:	Prehospital ECGs, large city			
Additional demographic data:	Age 60 ± 12 years, men 66%, race unknown			
Total number of test ECGs:	1,189			
Method(s) used to verify diagnosis:	Cardiac Enzymes and ST elevation			
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
STEMI	286	71	98.5	94

In another study, clinical data, and ECG findings on 264 consecutive patients admitted to a coronary care unit with suspected acute myocardial infarction were prospectively evaluated with the same portable prehospital electrocardiograph as in the aforementioned prehospital studies. Eighty-six (86) patients (32.5%) had confirmed acute infarction and of these 85% had some form of ST elevation on their initial ECG. The area under the receiver operator curve (ROC) of the interpretations made by the 12SL™ program was 83.9%.[439]

A recent survey of 365 hospitals in the United States, found that hospitals that used the results of prehospital "electrocardiography, that were called in or transmitted by emergency medical services to activate the catheterization laboratory while the patient was still enroute to the hospital, had significantly faster door-to-balloon times than did hospitals that waited for the patient to arrive before activating the catheterization laboratory (P = 0.001)."[447] This survey found that "false alarms were reported to be infrequent."[447] The authors also stated that the perception "about the number of false alarms are probably as important" in determining "whether non-cardiologists are permitted to activate the catheterization laboratory."[447]

The following series of reported results are representative of the current version of the 12SL program.

"Identified patients who presented to Emergency Departments (EDs) in Winnipeg, Manitoba, Canada from January 2015 to September 2016 who were diagnosed with STEMI and sent to the regional CCL for primary PCI. We reviewed the ECGs that triggered CCL activation and determined the sensitivity and specificity of software interpretation of the ECG (Marquette 12SL, MUSE, GE Healthcare). A third physician's blinded interpretation of the ECG was considered the "gold standard" and 95% confidence intervals were calculated using Clopper-Pearson Method. ... Conclusion: Software interpretation of STEMI conferred a potential 17-minute reduction in D2D time. The reduction was greatest in those >75 years and women, populations that have longer D2D times and worse outcomes. Further study is needed to evaluate the real-world effect of such a system in the ED."[448] Further evidence of this work was published in 2020, stating that "in the 143,574 ECGs performed over the study period for suspected STEMI, the overall sensitivity and specificity of 12SL were 90.5% and 99.98%, respectively."[449]

In the following study, body surface mapping (80 leads) was compared with GE's Marquette 12SL™ Program for the recognition of acute myocardial infarction on ECGs taken over a 3-month period from 103 chest-pain patients in the ED.[450] Of these, 53 had an acute myocardial infarction as defined by positive enzymes. Only 24 met ECG criteria for STEMI.

The purpose of this study was to not only detect STEMI but to detect non-ST elevated acute myocardial infarction. The motivation of the study was to reveal that body surface mapping is superior because it can detect non-ST elevated acute myocardial infarction. Note that the 12SL™ Program is designed not to detect non-ST elevated acute myocardial infarction; it will indicate ST depression or T wave inversion. Based on the severity of these abnormalities, the current program will state, "marked ST depression, consider subendocardial injury" or "marked T wave abnormality, consider ischemia". It remains controversial as to whether the ECG can diagnose non-ST elevated acute myocardial infarction: this diagnosis is currently the sole domain of cardiac enzyme data.[451]

See the reported results of this study below. The admitting physician correctly diagnosed 24 patients with AMI (sensitivity 45%, specificity 94%). Of the 24 patients correctly diagnosed, 20 received thrombolytic therapy. According to care guidelines, thrombolytic therapy should only be applied in the case of a STEMI.[198] The automated analysis program correctly diagnosed 17 patients with STEMII (sensitivity 32%, specificity 98%).

Results for STEMI Based on Cardiac Enzymes[450]

Representative test population:	Emergency Department
Additional demographic data:	Age 64 ± 14 years, Men 74%, race unknown
Total number of test ECGs:	103
Method(s) used to verify diagnosis:	Cardiac Enzymes (CK-MB, Troponin)

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Acute MI	53	32	98	98

Results for STEMI based on cardiologist[450]

Representative test population:	Emergency Department
Additional demographic data:	Age 64 ± 14 years, Men 74%, race unknown
Total number of test ECGs:	103
Method(s) used to verify diagnosis:	Positive for STEMI by Cardiologist

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
STEMI	24	71	98	98

In the next study, 75 electrocardiograms were interpreted. “Two criteria were compared for thrombolysis eligibility: (1) measurement of > or =1 mm ST-segment elevation in 2 contiguous leads (measured) and (2) criterion 1 plus the subjective opinion that the changes represented acute transmural injury (interpretive). The results were compared with computerized interpretations by the Marquette 12SL system.”[452]

The ECGs for this study[452] were manually selected in a CCU and were roughly evenly divided among (1) normal, (2) those showing evidence of acute transmural injury, or (3) those showing other ST-segment or T-wave abnormalities (such as early repolarization, acute pericarditis, etc.) Note: this distribution of patient abnormalities is not representative of an ED, CCU or emergency medical service that typically has a much lower incidence of acute transmural injury (that is, on the order of 10-15%).[147]

This paper states that “strict reliance on measured electrocardiographic criteria alone would have resulted in overuse of thrombolysis among all 3 raters. Based on the consensus opinion, the absolute overuse of thrombolysis would have been approximately 15% (P <.0034).” In contrast, the computer had 100% specificity.

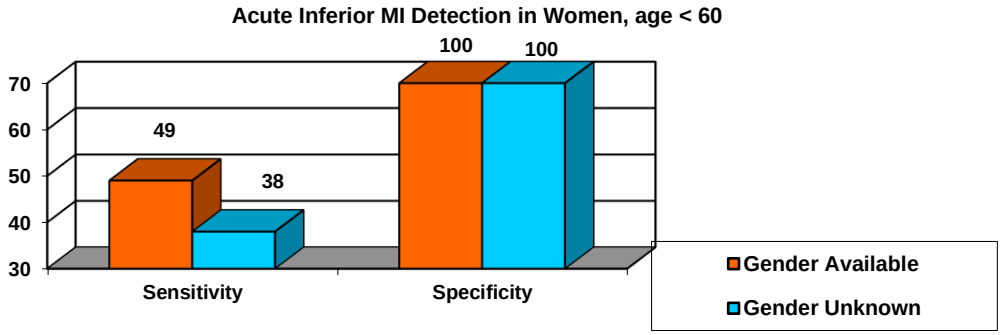
ECGs from cardiac care unit (CCU) evaluated by 3 cardiologists, consensus opinion[452]

Representative test population:	Emergency Department
Additional demographic data:	Specific ages, gender and race are unavailable.
Total number of test ECGs:	75
Method(s) used to verify diagnosis:	Consensus of 3 Cardiologists

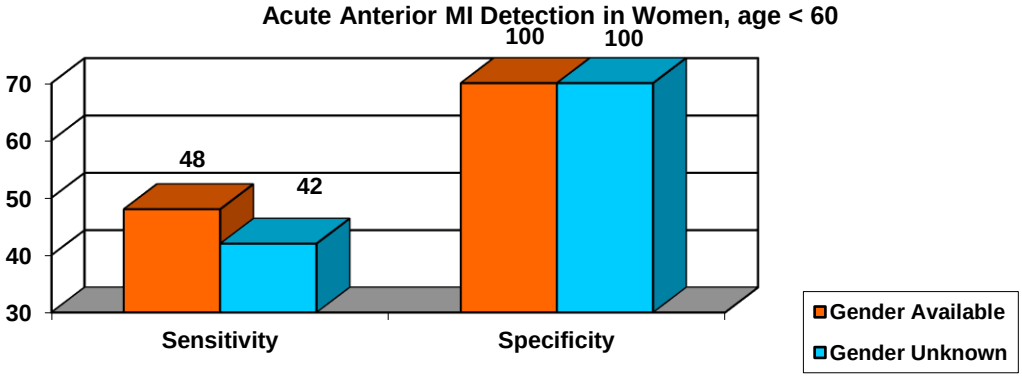
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
STEMI	26	61.5	100	100

GE Healthcare has done considerable research in gender specific differences in the ECG. Testing was done via data collected at the Mayo Clinic and the Medical College of Wisconsin. Results of testing, and an analysis of the ECG differences based on gender, have been broken down by location of myocardial infarction: that is, anterior versus inferior.

For acute inferior MI patients under age 60, women had lower ST elevation than men (lead II STJ average: 57µV for 99 females versus 86µV for 340 males, P value <.02). The opposite was true for patients over age 60. In the older patient population, women had larger ST elevation than men (lead AVF STJ average: 130µV for 378 females versus 84µV for 522 males, P value < .04). The figure below displays a comparison of the results, between the two program versions, for the recognition of acute inferior myocardial infarction in women less than 60 years of age.[27]



For acute anterior MI patients under age 60, women had lower ST elevations than men (lead V2 STE average, 307µV for females versus 432µV for males, P value < .007). Over age 60 years, this difference becomes less pronounced (lead V2 STE average, 336µV for females versus 421µV for males, P value < .009). The figure displays a comparison of the results between the two program versions for the recognition of acute anterior myocardial infarction in women less than 60 years of age.[453]



Test results show that the program is more sensitive for the recognition of acute myocardial infarction in women less than 60 years of age. For ages 60 and over, the program performance is the same as in previously published studies.

Results for STEMI for patients with new onset chest pain of unknown origin[27, 453]

Representative test population:	Emergency Department and Prehospital / Ambulance
Additional demographic data:	Acute inferior infarct: 477 Female (99 < 60 years), 862 Male (340 < 60 years); acute anterior infarct 450 Female (64 < 60 years), 699 Male (232 < 60 years). Controls are age and gender matched patients with new onset chest pain of non-cardiac origin.
Total number of test ECGs:	3,457
Method(s) used to verify diagnosis:	Cardiac Enzymes, Clinical Outcomes

Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Acute Inferior MI	1,339	49	100	100
Acute Anterior MI	1149	48	100	100

AHA / ACC guidelines recommend that patients with inferior STEMI and hemodynamic compromise should be assessed with a right precordial lead V4r to detect ST segment elevation to screen for right ventricular

(RV) infarction.[198] This is a class I recommendation, meaning that there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective. RV involvement in acute inferior infarction may be accompanied by significant hemodynamic consequences including a lowering of cardiac output and systemic blood pressure[454]. In addition, the in-hospital mortality of an acute inferior infarct is worsened when complicated by RV involvement.[455]

The 12SL ECG Analysis Program uses a threshold of 100 uV in lead V4r in interpreting all cases of right ventricular involvement, except under very specific circumstances.[35] Specifically, the program reduces the threshold to 50 uV in the presence of an acute inferior STEMI with high-degree AV block and a rightward ST vector (i.e., STE in III > II)[456-458] The prevalence of high-degree AV block (i.e., 2nd or 3rd degree AV block) in the general population is extremely rare and a person with an acute inferior STEMI and concomitant high-degree AV block is more than twice as likely to have RV involvement than not.[459]

ST elevation of 100 uV in lead V4r is a highly specific indicator of right ventricular involvement in the presence of acute inferior infarction. A threshold of 100 uV has been reported to have sensitivities of 57% - 100% and specificities of 68% - 100%, depending on the gold standard used (post-mortem examination, hemodynamic measures, angiography, etc).[460] A threshold of 50 uV has been reported to have sensitivities of 76% - 100% and specificities of 40% - 86%, again depending on the gold standard.[460, 461] Morgera[462] analyzed both thresholds in the same study with the same patient population and reported a specificity increase from 86% to 100% as the threshold went from 50 to 100 µV, with a sensitivity decrease from 76% to 57%. One should note that the diagnostic accuracy of right ventricular involvement has not been assessed in patients with certain conditions such as chronic lung disease and pericardial disease.

Although the lower ST elevation threshold in lead V4r will increase sensitivity and decrease specificity, this decreased specificity is offset by the requirement of concomitant ST elevation in lead III exceeding ST elevation in lead II and high-degree AV block, both of which are associated with right ventricular involvement. Using only the criteria of ST in III > II, Saw[456] reported a sensitivity of 97% and a specificity of 56% for the detection of right ventricular involvement in the presence of an acute inferior infarction. The reported incidence of high degree AV block in patients with RV involvement is 43%, compared to only 13% in patients with acute inferior infarction without RV involvement.[459]

GE Healthcare developed a 16-lead ECG database in conjunction with several chest-pain centers. A total of 1,343 16-lead ECGs were acquired and analyzed from 712 chest-pain patients. Each ECG record contained the standard 12-lead ECG, simultaneously acquired with leads V4r, V7, V8, and V9. GE Healthcare, in conjunction with the contributing investigators, analyzed and reported on the characteristics of the additional leads in relation to acute myocardial infarction and outcome.[463-465] The interpretation of GE's Marquette 12SL Program was compared to patient outcomes, as registered in this 16-lead ECG database. An acute STEMI was detected in 143 ECGs. Of these, 101 were diagnosed as being an acute inferior STEMI (including inferolateral and inferior-posterior). When V4r was withheld from the analysis, "consider RVI" was stated in 84 of the 101 IMI ECGs. When V4r was included in the analysis, the "with RVI" modifier was added in 34 of the 101 IMI ECGs. With one exception, all 12-lead ECGs that stated "consider RVI" also stated "with RVI" when V4r was added.

The sensitivity of the "consider RVI" statement for predicting positive ST elevation in V4r was 97% (33 / 34), while the positive predictive accuracy was 39% (33 / 84). The result here of 34% (34 / 101) of all acute inferior STEMIs having RVI is consistent with the percentages of 30 – 50% reported in the literature.[466]

How findings are stated can have a significant impact. One good example of this is when the program states "myocardial infarction, age unknown." This occurs when the program identifies pathological Q-waves but has insufficient ST/T changes to label it as acute. In this situation, a prior ECG is most helpful.[163] Dismissing the finding as not a STEMI can delay treatment if it is a STEMI, as shown in this referenced study.[275]

ACI-TIPI[467] uses the measurements of GE's Marquette 12SL™ program. Based on the presence of pathologic Q waves and/or the presence of repolarization abnormalities, the ACI-TIPI algorithm reports the probability of acute cardiac ischemia. The logistic regression formula used by ACI-TIPI[191] was implemented in all GE electrocardiographs and tested in the emergency department (ED)[197] as well as the prehospital environment.[21]

A large prospective trial was accomplished across 10 different emergency departments, with 30-day follow-up of clinical outcomes. A total of 10, 689 patients were evaluated: 8150 were not ischemic, 673 had stable

angina, and 1866 had acute cardiac ischemia (that is, unstable angina or an acute myocardial infarction. Quoting from the literature:[192]

> *"Reductions in admissions for patients without acute cardiac ischemia were greater among patients with ACI-TIPI-predicted ischemia probabilities in the lower ranges, reflecting a greater effect with stronger probabilistic advice not to admit (that is, a dose-response effect). Of note, in settings in which use of the ACI-TIPI reduced unnecessary admissions, appropriate hospital and CCU admission did not deteriorate for patients with true acute ischemia (unstable angina or acute infarction). Given these results of this "effectiveness" trial ACI-TIPI seems to be safe and effective for general use."*

ACI-TIPI had a larger impact when the attending physician was inexperienced (that is, an unsupervised resident). In this case, "use of ACI-TIPI was associated with a reduction in CCU admissions from 14% to 10%, a change of −32%(CI, −55% to 3%); a reduction in telemetry unit admissions from 39% to 31%, a change of −20%(CI, −34% to −2%) and an increase in discharges to home from 45% to 56%, a change of 25% (CI, 8% to 45%; overall P = 0.008)."

The purpose of this study was to measure the impact of care based on whether ACI-TIPI was available or not available. Within the same ED, ACI-TIPI was available on alternate months. The effect of improved triage with ACI-TIPI was reproducible, even after the physician had several months of experience with the device.

Using two cardiologists as the reference, the following results were reported for the interpretations of ischemia by computer:

Evaluation of ST/T abnormalities stated as ischemia at tertiary care, VA Hospital[219]

Representative test population:		Tertiary care, VA Hospital Inpatients & Outpatients		
Additional demographic data:		Age ranged from 33 to 96 years (mean 73.5). Nearly all of them (98.3%) were male. Information on race is unavailable.		
Total number of test ECGs:		2194 from 1856 patients		
Method(s) used to verify diagnosis:		Confirmation by 2 cardiologists		
ST/T Abnormality	***N***	***Sensitivity (%)***	***Specificity (%)***	***Positive predictive value (%)***
Ischemia	199	100	99.8	98

Due to the increased interest in early repolarization (ER) and whether it is predictive of sudden cardiac death, studies have evaluated the accuracy of ER as identified via 12SL. "To ensure diagnostic accuracy, a subset of 2,200 randomly selected electrocardiograms were carefully examined manually. The k value between automatically and manually determined ER in this subset was 0.82."[256]

PROLONGED QT

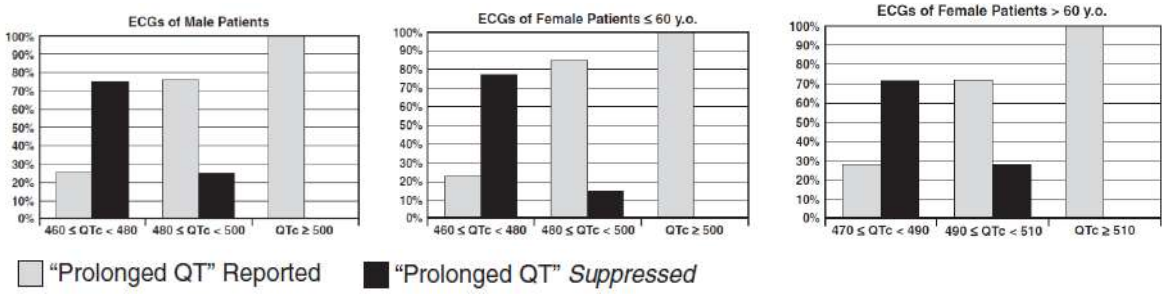
The diagnostic statement "Prolonged QT" is conditionally presented by 12SL even when the QTc is long (>450ms.) A study conducted by Garg et. al. evaluated the "extent to which automated censoring of a prolonged QT diagnosis occurs in large-scale clinical implementation of the 12SL program ... We observed that, of more than16,000 study ECGs for which the 12SL software calculated and displayed prolonged QTc values (≥470 ms in females >60 years old; or ≥460 ms in other sex/age groups), a prolonged QT diagnostic statement actually appeared on the computer-generated report in only 48% of these tracings, being algorithmically censored in the remaining 52% based on certain ECG waveform characteristics."[277] Gross results from this study are presented below:

Conditional presentation of "Prolonged QT" in presence of QTc > 470ms[277]

Representative test population:	Large, integrated health network
Additional demographic data:	Majority of ECGs were from females (51.8%), and most ECGs in each sex/age group were from white patients.
Total number of test ECGs:	97,046 ECGs from patients ≥18 years after exclusion criteria were applied: HR>100bpm or QRSD>120ms. Of these, 16,000 ECGs the 12SL program calculated and displayed prolonged QTc values (≥470 ms in females >60 years old; or ≥460 ms in other sex/age groups)
Method(s) used to verify diagnosis:	12SL statement issued versus different QTc values, from 460 to over 500ms.

QTC threshold & gender	***N***	***Suppressed***	***Reported***	***Percent reported***
Male 470ms ≤ QTc ≤ 500ms	3,370	1,576	1,794	53.2%
Male QTc > 500ms	997	0	997	100%
Female 480ms ≤ QTc ≤ 500ms	2,398	739	1,659	69.2%
Female > 500ms	1,301	63	1,238	95.2%

Percent of ECGs Identified as having "Prolonged QT".[277]



There are differing opinions as to when to identify "Prolonged QT". For instance, some recommend that certain populations be screened for prolonged QT, while others state this would be cost ineffective and would result in too many false positives.[10, 468-472] Some believe the statement should be issued starting at 440ms in men.[473] Others believe it only practical to begin stating it at ≥500ms, regardless of sex.[468, 474] Some insist the statement should be issued regardless of whether there is a conduction abnormality, evidence of myocardial infarction, paced rhythm, high heart rate, varying RR interval, low amplitude T-wave, poor ECG quality, etc. Others believe these conditions should preclude the statement from being issued. In any case, these tradeoffs can result in a wide swing in the prevalence of the statement "prolonged QT" in the typical hospital population, from 5 to 25%.

Using over 40,000 ECGs not analyzed by 12SL, an evaluation of cardiologists as to when they added the statement "prolonged QT" demonstrated that coexisting waveform abnormalities are considered.[475] This included bundle branch block, various ST segment or T wave abnormalities, arrhythmias, paced rhythms, myocardial ischemia or infarct. This study found that the prevalence of the statement "prolonged QT" would be 26.6% when a strict threshold of a QTc > 450ms was applied; across this same group of ECGs, cardiologists only added the statement ≈ 5% of the time.

In short, there is no easy answer as to when to state, "Prolonged QT". Apply strict thresholds below 500ms and approximately 25% of all ECGs will end up with the statement "Prolonged QT". Use higher thresholds or

restrict the conditions as to when the statement is generated, then ECGs from patients known to be at risk will not have the statement “Prolonged QT” as part of their computerized interpretation. The physician needs to take an active role in evaluating the ECG and determining the appropriate level of risk. As stated in an editorial in response to the work by Garg et. al, “computerized interpretation of ECGs is a supplement not a substitute.”[476]

In any case, there is a growing appreciation that QT/QTc alone is insufficient for determining risk. This is true for both congenital and drug-induced long QT syndrome (LQTS).

The criteria used by GE’s Marquette 12SL Program for when to issue “prolonged QT” has evolved. In general, thresholds for when to state it are increasing while the number of conditions that prevent the statement from being issued are being reduced. For instance, the criteria in the most recent version of the program (12SL v23), will identify prolonged QT at a faster heart rate (20 + age-adjusted threshold for sinus tachycardia). This change will address some instances in the literature that have reported that the 12SL program does not state “prolonged QT” even when the QTc>500ms, especially for pediatric patients.[227, 317]

It should also be kept in mind that a change in QTc can also be important. An increase of 60ms has been identified in an ACC/AHA consensus statement as an indicator of increased risk.[474] It is important to know that GE’s 12SL Serial Comparison program will identify when there is a change in QTc greater than 50ms.

Overall Classification: Reported Results

Several studies have addressed the issue if the computer can simply classify the ECG as either normal or abnormal. The following studies reported the following:

- "the program is reliable in diagnosing normality: even the disagreements are arguable."[243]
- A total of 855 triage ECGs in the emergency department (ED) were collected over 16 weeks. "Our data suggest that triage ECGs identified by the computer as normal are unlikely to have clinical significance that would change triage care."[173]
- "From a practical point of view, the eventual consensus opinion of the cardiologists was that only one tracing reported as normal by the system should have been reported as abnormal to a family doctor, resulting in a negative predictive value of 98.4%. In view of the cardiologists inter-observer variation with regard to what is normal, this may well be higher than an individual cardiologist's negative predictive value and suggests that the system examined may safely be used to exclude major abnormalities which would affect clinical management".[243]
- "A total of 39, 238 electrocardiograms were reviewed...The program placed the ECG into the following diagnostic classifications: normal 22%, otherwise normal 6%, borderline 5%, abnormal 66%. The reviewing physician agreed with this classification in 96.3% of all cases... The most striking information shows the agreement of the physicians with the computer diagnosis of an abnormal electrocardiogram in 97.7% of the 25,295 tracings. In only 204 records out of 25,987 tracings (.8%), the physicians edited a computer-called abnormal electrocardiogram and changed it to normal. In only 63 of 8,632 (.7%) tracings of which the computer called normal did the physicians edit this tracing to read abnormal."[220]

Overall classification via large database[220]

Representative test population:		Large hospital		
Additional demographic data:		Age, gender, and race information is unavailable		
Total number of test ECGs:		39,238		
Method(s) used to verify diagnosis:		Physician diagnosis		
Verified Diagnosis	***N***	***Sensitivity (%)***	***Specificity (%)***	***PPA (%)***
Normal ECG	8,632	99.9	100	99.9
Abnormal ECG	25,987	99.9	99.9	99.9

- As tested on 26,734 male and 3,737 female veterans, a classification of a normal ECG by the 12SL program "is associated with extremely good survival".[244]
- "Three ECG computer programs-Hewlett Packard analog program (HP), Telemed analog program (T) and Marquette 12 SL digital program (MAC) were evaluated and their accuracy of ECG reading compared with the reading of 4 experienced interpreters on 140 ECGs of patients with various clinical abnormalities. Major disagreement with effect on patient management, and minor disagreement were defined at a joint session with a senior (consensus). The computers identified all normal ECGs correctly (sensitivity 100%). The percentage of major agreements (full agreements and minor disagreements) between consensus and computer was 79% for HP, 90% for T and 93% for MAC."[217]
- "A total of 2194 ECGs were included for analysis in the study. One hundred twenty-two ECGs with a disagreement between the two cardiologists were excluded from analysis. Out of 2072

remaining cases, 776 (37.5%) were read by the computer as normal" ... "There were no discordances in the ECGs read as normal."[219]

- The computer correctly interpreted all normal ECGs.[227]
- "The quality of computer-assisted ECG interpretation was comparable to that of review provided by a cardiology service."[226]

Serial Comparison

The Serial Comparison program compares ECGs over time, appending interpretive statements to the report generated by GE's Marquette 12SL™ program. The Serial Comparison program is only available via the MUSE™ system and is described in the 12SL™ Physician's Guide.

The Serial Comparison program compares statements, measurements and waveforms.[13] The purpose of the program is to detect a significant clinical change and describe the change in terminology familiar to the cardiologist. Note that interpretive statements can change across serial ECGs, even though there is no significant clinical change in the ECGs. In this case, the program will not state a change.

The Serial Comparison program will compare ECGs that are analyzed by different versions of the 12SL™ program. This is because the Serial Comparison program re-analyzes historical ECGs. It compares the actual waveforms of the stored median complexes. It is critical this comparison be done on medians and fiducial point measurements generated by the same signal processing 12SL methodology, otherwise there will be a poor superimposition of the waveforms. This is important if an institution is going to compare and evaluate repolarization changes throughout the continuum of care, as recently demonstrated in a study that used 12SL measurements and waveforms to measure the potential significance of spontaneous and interventional ST-changes in patients transferred for primary percutaneous coronary intervention.[477]

GE Healthcare has developed specialized tools[65, 67, 360, 361, 478-480] for the collection, trending and comparison of serial 12-lead ECGs analyzed by the 12SL™ program for the assessment of the acute coronary syndrome patient as they migrate from the prehospital setting through to intervention and the CCU.

Conclusion

This document has presented the performance of GE's Marquette 12SL Program. The evidence came from the scientific literature and it is extensive. The gold standard data continues to be collected and the performance of the program evaluated.

Collection of data is an unending pursuit, for several reasons. The first, and most obvious, is that the program needs to be tested as improvements are made to it. Equally important, is that new gold standards become available that can fundamentally change our understanding of the ECG. Sometimes, ECG criteria that are well accepted and have been used for decades can be rejected, as recently demonstrated for atrial enlargement.[481] In addition, changes in clinical practice, can change the meaning of a gold standard, as in the case of evaluating Q-waves in an environment of aggressive treatment for STEMI. Clinical practice can also alter the use of the ECG or generate new manifestations of the ECG, as in the case of artificial pacing. The challenge is to keep abreast of these changes and, yet, have an interpretive program that is understandable to the practicing physician.

GE Healthcare is committed to continuous improvement of the program and obtaining the highest performance in the industry. GE Healthcare recognizes that data collection is key to this improvement and, as a result, collaborates across the globe with several centers in the collecting of ECGs correlated with gold standard data or other clinical input. Given the capabilities of the MUSE™ ECG storage system, most centers can investigate the performance of the program in a systematic fashion. GE Healthcare welcomes this activity and is interested in collaborating with those who are equally committed to the advancement of computerized electrocardiography. Feel free to contact us with your comments and insights.

Appendices: Statement Library, Pediatric Tables, and 12SL Versions

Appendix A: Statement Library Arranged by Statement Category

CRITICAL VALUES

Statement Number	Acronym	Text
1340	CRIT	*** Critical Test Result:
1342	CVHIHR	High HR
1343	CVLOHR	Low HR
1346	CVLQT	Long QTc
1360	CVSTEMI	STEMI
1361	CVACS	ACS / Ischemia
1362	CVAVB	AV Block
1363	CVARRHY	Arrhythmia

PREDOMINANT RHYTHM

Sinus Rhythms

Statement Number	Acronym	Text
19	SRTH	Sinus rhythm
21	SBRAD	Sinus bradycardia
22	NSR	Normal sinus rhythm
23	STACH	Sinus tachycardia
24	MSBRAD	Marked sinus bradycardia

Atrial Rhythms

Statement Number	Acronym	Text
25	RABRAD	Low right atrial bradycardia
26	RATACH	Low right atrial tachycardia
27	LABRAD	Left atrial bradycardia
28	LATACH	Left atrial tachycardia
29	RAR	Low light atrial rhythm
30	LAR	Left atrial rhythm
61	EABRAD	Unusual P axis, possible ectopic atrial bradycardia
62	EAR	Unusual P axis, possible ectopic atrial rhythm
63	EATACH	Unusual P axis, possible ectopic atrial tachycardia

Statement Number	Acronym	Text
64	EARO	Ectopic atrial rhythm
161	AFIB	Atrial fibrillation
162	FLUT	Atrial flutter
164	ATAC	Atrial tachycardia
271	SVT	Supraventricular tachycardia
279	PO-ATP	Possible wandering atrial pacemaker
280	MULT-AT	Multifocal atrial tachycardia
288	AFL-BL	Atrial flutter with 2 to 1 block

Junctional and Ventricular Rhythms

Statement Number	Acronym	Text
34	JUNBRAD	Junctional bradycardia
41	JBRAD	Unusual P axis and short PR, probably junctional bradycardia
42	JR	Unusual P axis and short PR, probably junctional rhythm
43	JTACH	Unusual P axis and short PR, probably junctional tachycardia
238	$SIVR	Idioventricular rhythm
248	#SVTACH	Ventricular tachycardia
249	$SFIB	Ventricular fibrillation
267	JUNCT-R	Junctional rhythm
268	IDIO-R	Idioventricular rhythm with AV block
269	VENT-RTH	Ventricular rhythm
270	J-TACH	Juncational tachycardia

Rhythm of Unknown Etiology

Statement Number	Acronym	Text
235	WQTACH	Wide QRS tachycardia
236	NQTACH	Narrow QRS tachycardia
237	$SWQR	Wide QRS rhythm
265	PR-SBRAD	Probably sinus bradycardia, verify AV conduction
272	VTACH	Ventricular tachycardia (ventricular or supraventricular with aberration)
282	AV-COND	Suspect AV conduction defect
287	LHR	Low heart rate, verify AV conduction.

Statement Number	Acronym	Text
299	UR	Undetermined rhythm

Pacemaker

Statement Number	Acronym	Text
183	APCX	atrial-paced complexes
184	VPCX	ventricular-paced complexes
185	AVPCX	AV dual-paced complexes
186	ASVPCX	atrial-sensed ventricular-paced complexes
289	BIVPCK	Biventricular pacemaker detected
290	PCK	Electronic ventricular pacemaker
291	DPCK	Demand pacemaker, interpretation is based on intrinsic rhythm
292	APCK	Electronic atrial pacemaker
293	AVPCK	AV sequential or dual chamber electronic pacemaker
294	EDP	Electronic demand pacing
295	APR	Atrial-paced rhythm
296	VPR	Ventricular-paced rhythm
297	ASVPR	Atrial-sensed ventricular-paced rhythm
298	AVDPR	AV dual-paced rhythm
326	WITH-DEM	with a demand pacemaker
1669	PMFAIL	*** Suspect unspecified pacemaker failure

RHYTHM MODIFIERS

Sinus Node

Statement Number	Acronym	Text
111	SABII	with 2nd degree SA block (Mobitz II)
112	SABI	with 2nd degree SA block (Mobitz I)
113	PAUSE	with sinus pause
187	SCX	sinus complexes
251	SAR	with sinus arrhythmia
252	MSAR	with marked sinus arrhythmia
284	SA-BLK	with SA block or transient AV block
285	SAB	with sinus arrest or transient AV block

AV Conduction

Statement Number	Acronym	Text
101	FAV	with 1st degree AV block
102	SPR	with short PR
103	MBZI	with 2nd degree AV block (Mobitz I)
104	MBZII	with 2nd degree AV block (Mobitz II)
105	SAV	with 2nd degree AV block
106	CHB	with complete heart block
107	VAVB	with variable AV block
108	AVDIS	with AV dissociation
141	W2T1	with 2:1 AV conduction
142	W3T1	with 3:1 AV conduction
143	W4T1	with 4:1 AV conduction
144	W5T1	with 5:1 AV conduction
190	PROAV	with prolonged AV conduction
245	$SRETC	with retrograde conduction
247	$SCAPTUR	sinus/atrial capture
278	WEKH	with Mobitz I (Wenckebach) block

Atrial Fib/Flutter

Statement Number	Acronym	Text
163	CRS	Coarse
171	RVR	with rapid ventricular response
172	SVR	with slow ventricular response
174	CJP	with a competing junctional pacemaker

Supraventricular Beats

Statement Number	Acronym	Text
188	SVCX	supraventricular complexes
189	INTRIN	intrinsic complexes
221	PSVC	premature supraventricular complexes
222	PAC	premature atrial complexes
223	PJC	premature junctional complexes

VENTRICULAR, ABERRANCY, OR FUSION

Statement Number	Acronym	Text
181	ABER	with premature ventricular or aberrantly conducted complexes
231	PVC	premature ventricular complexes
232	PVCF	premature ventricular and fusion complexes
234	BIGEM	in a pattern of bigeminy
244	$SFUS	fusion complexes
246	$SABCOND	aberrant conduction
274	VENT-FUS	with ventricular fusion
277	TVT	with transient ventricular tachycardia
283	AB-VENT	with intermittent aberrant ventricular conduction

ESCAPE

Statement Number	Acronym	Text
242	JESC	with junctional escape complexes
243	VESC	with ventricular escape complexes
275	J-ESC	with junctional escape
276	ESCBT	with escape beat

MISCELLANEOUS

Statement Number	Acronym	Text
175	IRREG	with undetermined rhythm irregularity
211	OCC	with occasional
212	FREQ	with frequent
233	CSEC	and consecutive
241	PEC	premature ectopic complexes

QRS AXIS AND VOLTAGE

Statement Number	Acronym	Text
307	DXTRO	Dextrocardia
370	LAD	Leftward axis
371	ALAD	Abnormal left axis deviation
372	LAD3	Left axis deviation
380	RAD	Rightward axis
381	ARAD	Abnormal right axis deviation

Statement Number	Acronym	Text
382	RSAD	Abnormal right superior axis deviation
383	RAD4	Right axis deviation
384	RAD5	Right superior axis deviation
390	INDAX	Indeterminate axis
391	NWA	Northwest axis
410	LOWV	Low voltage QRS
411	PULD	Pulmonary disease pattern

Intraventricular Conduction and Pre-excitation

Statement Number	Acronym	Text
300	WPWA	Ventricular pre-excitation, WPW pattern type A
302	WPWB	Ventricular pre-excitation, WPW pattern type B
303	ALTWPW	with fusion or intermittent ventricular pre-excitation (WPW)
304	WPW	Wolff-Parkinson-White
440	RBBB	Right bundle branch block
442	RBBRVH	Right bundle branch block -or- Right ventricular hypertrophy
445	IRBBB	Incomplete right bundle branch block
450	RSR	RSR' or QR pattern in V1 suggests right ventricular conduction delay
451	SRSRO	RSR' pattern in V1
460	LBBB	Left bundle branch block
465	ILBBB	Incomplete left bundle branch block
470	AFB	Left anterior fascicular block
471	PFB	Left posterior fascicular block
478	BIFB1	(RBBB and left anterior fascicular block)
479	BIFB2	(RBBB and left posterior fascicular block)
480	BIFB	*** Bifascicular block ***
481	TRIFB	Trifascicular block
482	IVCB	Nonspecific intraventricular block
487	IVCD	Nonspecific intraventricular conduction delay
782	MAFB	(masked by fascicular block?)

Chamber Hypertrophy or Enlargement

Statement Number	Acronym	Text
350	RAE	Right atrial enlargement
360	LAE	Left atrial enlargement

Statement Number	Acronym	Text
369	BAE	Biatrial enlargement
412	S1S2S3	S1-S2-S3 pattern, consider pulmonary disease, RVH, or normal variant
441	RVE+	, plus right ventricular hypertrophy
442	RBBRVH	Right bundle branch block -or- Right ventricular hypertrophy
520	RVH	Right ventricular hypertrophy
521	RVH-2ST	Right ventricular hypertrophy with repolarization abnormality
530	RAVL	R in AVL
531	SOKLYON	Sokolow-Lyon
532	CORNVOLT	Cornell Voltage
533	CORNPROD	Cornell Product
534	ROMESTES	Romhilt-Estes
540	LVH	Voltage criteria for left ventricular hypertrophy
541	LVH2	Left ventricular hypertrophy
542	QRSV	Minimal voltage criteria for LVH, may be normal variant
543	QRSW	with QRS widening
544	2ST	with repolarization abnormality
545	QRSW-2ST	with QRS widening and repolarization abnormality
548	LVH3	Moderate voltage criteria for LVH, may be normal variant
570	BIVH	Biventricular hypertrophy
571	PMDPV	Prominent mid-precordial voltage,
968	INJONV	ST elevation, consider injury or variant associated with LVH
1084	WSTR	with strain pattern

INFARCTION

Statement Number	Acronym	Text
700	SMI	Septal infarct
740	AMI	Anterior infarct
760	LMI	Lateral infarct
780	IMI	Inferior infarct
795	RVI	with right ventricular involvement
800	PXT	, with posterior extension
801	IPMI	Inferior-posterior infarct

Statement Number	Acronym	Text
802	POSTMI	Posterior infarct
803	QESPMI	Increased R/S ratio in V1, consider early transition or posterior infarct
805	RV4R	Inferior injury pattern suggests right ventricular involvement, recommend adding leads V3r and V4r to confirm
806	CRVI	Consider right ventricular involvement in acute inferior infarct
810	ASMI	Anteroseptal infarct
820	ALMI	Anterolateral infarct
821	STEMI	** ** ACUTE MI / STEMI ** **
822	NSTEMI	** ** ACUTE MI / non-STEMI ** **
827	LBBBNEW	** ** Consider ACUTE MI if LBBB is new ** **
827	LBBBAMI	** ** LBBB with primary ST elevation abnormality - PROBABLE ACUTE MI ** **
829	ACUMI	** ** ACUTE MI ** **
830	AC	, possibly acute
831	AU	, age undetermined
832	OLD	, old
833	NEW	, new
1423	ACUT	Acute

REPOLARIZATION ABNORMALITIES

ST Elevation

Statement Number	Acronym	Text
435	BRUG1	Brugada pattern, type 1
435	BRUG2	Brugada pattern, type 2
437	BRUG3	Brugada pattern, type 3
901	PCARD	Acute pericarditis
902	SERYR1	ST elevation, consider early repolarization, pericarditis, or injury
903	SERYR2	ST elevation, probably due to early repolarization
904	NSTE	Nonspecific ST elevation
963	IIOHAI	ST elevation, consider inferior injury or acute infarct
964	AIOHAI	ST elevation, consider anterior injury or acute infarct

Statement Number	Acronym	Text
965	LIOHAI	ST elevation, consider lateral injury or acute infarct
966	ALIHAI	ST elevation, consider anterolateral injury or acute infarct
967	ILIHAI	ST elevation, consider inferolateral injury or acute infarct
968	INJONV	ST elevation, consider injury or variant associated with LVH
1000	REPOL	Early repolarization
1083	STELIN	ST elevation in

ST Depression

Statement Number	Acronym	Text
1001	JSTN	Junctional ST depression, probably normal
1002	JST	Junctional ST depression, probably abnormal
1023	NSTD	Nonspecific ST depression
1024	STDEP2	ST depression, consider subendocardial injury
1082	STDPIN	ST depression in

Injury

Statement Number	Acronym	Text
920	SINJ	Septal injury pattern
930	AINJ	Anterior injury pattern
940	LINJ	Lateral injury pattern
950	IINJ	Inferior injury pattern
960	ASINJ	Anteroseptal injury pattern
961	ALINJ	Anterolateral injury pattern
962	ILINJ	Inferolateral injury pattern
1040	SSBINJ	Marked ST abnormality, possible septal subendocardial injury
1050	ASBINJ	Marked ST abnormality, possible anterior subendocardial injury
1060	LSBINJ	Marked ST abnormality, possible lateral subendocardial injury
1070	ISBINJ	Marked ST abnormality, possible inferior subendocardial injury
1071	MSTDIL	Marked ST abnormality, possible inferolateral subendocardial injury

Statement Number	Acronym	Text
1080	MSTDAS	Marked ST abnormality, possible anteroseptal subendocardial injury
1081	MSTDAL	Marked ST abnormality, possible anterolateral subendocardial injury

Other ST Effects

Statement Number	Acronym	Text
544	2ST	with repolarization abnormality
826	LBBBACS	** ** LBBB with primary ST-T abnormality - Consider ACUTE CORONARY SYNDROME (ACS) ** **
828	AIS	** ** Consider ACUTE CORONARY SYNDROME (ACS) ** **
900	NST	Nonspecific ST abnormality
1084	WSTR	with strain pattern
1100	ST&	ST &
1138	STABAND	ST abnormality and
1141	NSTT	Nonspecific ST and T wave abnormality
1460	ACSBCAUS	ECG interpretation of ACS is based on presence of symptoms and
1462	CROACS	ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings

T-Wave

Statement Number	Acronym	Text
1140	NT	Nonspecific T wave abnormality
1141	NSTT	Nonspecific ST and T wave abnormality
1141	NSTT	Nonspecific ST and T wave abnormality
1142	QRST	Abnormal QRS-T angle, consider primary T wave abnormality
1145	ILT	T wave abnormality, consider inferolateral ischemia
1150	AT	T wave abnormality, consider anterior ischemia
1151	MAT	Marked T wave abnormality, consider anterior ischemia
1160	LT	T wave abnormality, consider lateral ischemia
1161	MLT	Marked T wave abnormality, consider lateral ischemia
1170	IT	T wave abnormality, consider inferior ischemia

Statement Number	Acronym	Text
1171	MIT	Marked T wave abnormality, consider inferior ischemia
1172	MILT	Marked T wave abnormality, consider inferolateral ischemia
1180	ALT	T wave abnormality, consider anterolateral ischemia
1181	MALT	Marked T wave abnormality, consider anterolateral ischemia
1182	TINVIN	T wave inversion in

QT Interval

Statement Number	Acronym	Text
1139	SNDQA	, may be secondary to QRS abnormality
1143	LNGQT	Prolonged QT
1144	BOQTI	Borderline QT interval

NAMES

Measurement Names

Statement Number	Acronym	Text
100	PRINT	PR interval
322	VENT-RAT	Vent. rate
395	AXIS	QRS axis
1200	T-WAVE	T waves
1419	QRS	QRS
1420	QRS-DUR	QRS duration
1421	QRS-VOL	QRS voltage

Lead Groups

Statement Number	Acronym	Text
1450	SEP	Septal leads
1451	ANT	Anterior leads
1452	LAT	Lateral leads
1453	INF	Inferior leads
1454	POS	Posterior leads
1455	ANTSEP	Anteroseptal leads

Statement Number	Acronym	Text
1456	ANTLAT	Anterolateral leads
1457	INFPOS	Inferoposterior leads
1458	IFLAT	Inferolateral leads
1459	RECP	Reciprocal
1544	LD-LIMB	Limb lead

Lead Names

Statement Number	Acronym	Text
1550	LD-I	I
1551	LD-II	II
1552	LD-V1	V1
1553	LD-V2	V2
1554	LD-V3	V3
1555	LD-V4	V4
1556	LD-V5	V5
1557	LD-V6	V6
1558	LD-V7	V7
1559	LD-V8	V8
1560	LD-V9	V9
1562	LD-V2R	V2r
1563	LD-V3R	V3r
1564	LD-V4R	V4r
1565	LD-V5R	V5r
1566	LD-V6R	V6r
1567	LD-V7R	V7r
1568	LD-V8R	V8r
1569	LD-V9R	V9r
1570	LD-A1	A1
1571	LD-A2	A2
1572	LD-A3	A3
1573	LD-A4	A4
1574	LD-III	III
1575	LD-AVR	aVR
1576	LD-AVL	aVL
1577	LD-AVF	aVF
1579	LD-D	D
1580	LD-A	A

Statement Number	Acronym	Text
1581	LD-J	J
1582	LD-X	X
1583	LD-Y	Y
1584	LD-Z	Z

Electrode Names

Statement Number	Acronym	Text
1537	EL-NAP	NAP
1538	EL-NST	NST
1539	EL-NAX	NAX
1540	EL-RA	RA
1541	EL-LA	LA
1542	EL-RL	RL
1543	EL-LL	LL
1545	EL-H	H
1546	EL-E	E
1547	EL-I	I
1548	EL-M	M
1601	LD-R	R
1602	LD-L	L
1603	LD-N	N
1604	LD-F	F
1605	LD-C1	C1
1606	LD-C2	C2
1607	LD-C3	C3
1608	LD-C4	C4
1609	LD-C5	C5
1610	LD-C6	C6
1611	LD-C7	C7
1612	LD-C8	C8
1613	LD-C9	C9
1615	LD-C2R	C2r
1616	LD-C3R	C3r
1617	LD-C4R	C4r
1618	LD-C5R	C5r
1619	LD-C6R	C6r
1620	LD-C7R	C7r

Statement Number	Acronym	Text
1621	LD-C8R	C8r
1622	LD-C9R	C9r

ECG Classification

Statement Number	Acronym	Text
1684	NML	Normal ECG
1687	ABR	Otherwise normal ECG
1693	BORDE	Borderline ECG
1699	AB	Abnormal ECG

Technical Problems

Statement Number	Acronym	Text
1500	POOR	Poor data quality
1501	POWER	Powerline interference
1502	BASELINE	Baseline wander
1503	MUSCLE	Muscle tremor
1504	ELECTR	Electrode noise
1505	DISC	disconnected
1672	ARM	*** Suspect arm lead reversal, interpretation assumes no reversal
1673	QCERR	*** Poor data quality, interpretation may be adversely affected
1676	$SANLERR3	** Less than 4 QRS complexes detected, no interpretation possible **
1678	$SANLERR2	** No QRS complexes found, no ECG analysis possible **
1679	NSTDLDS	** Nonstandard lead placement, ECG interpretation not available **

Miscellaneous

Statement Number	Acronym	Text
2	PEDANL	** * Pediatric ECG analysis * **
5	DICTATION	Report dictated, transcription pending
20	ARAT	(Atrial rate=
31	NOPF	(no P-waves found)
32	BLKED	blocked

33	ACCEL	Accelerated
176	IRR	Irregular
177	$SWITH	with
178	$SOR	or
323	RHY	Rhythm
325	CONSEC	Consecutive
327	BASIC	Basic rhythm
843	CRI-FOR	Criteria for
845	MINI-CRIT	Minimal criteria for
846	BORD-CRIT	Borderline criteria for
1306	SUNCNF	(Unconfirmed)
1400	AND	and
1401	HOWEVER	however
1402	HWV-IT	however it
1459	RECP	Reciprocal
1510	LEAD	in lead
1511	LEADS	in leads
1665	LPAREN	(
1666	RPAREN	)
1680	PO	Possible
1682	CRO	Cannot rule out
1694	BO	Borderline

SERIAL COMPARISON

Technical

Statement Number	***Acronym***	***Text***
1301	COMPAR	When compared with ECG of
1300	NO-SERIAL	No previous ECGs available
1302	POOR-DAT	Poor data quality in current ECG precludes serial comparison
1303	NO-SERCMP	Serial comparison not performed; all previous tracings are of poor data quality
1304	DEMOGR	Warning: demographic data different

Rate

Statement Number	***Acronym***	***Text***
322	VENT-RAT	Vent. rate

Statement Number	Acronym	Text
1252	RAT-DEC	Although rate has decreased
1253	RAT-INC	Although rate has increased
1254	WITH-RATINC	with rate increase
1255	WITH-RATDEC	with rate decrease

QRS Axis

Statement Number	Acronym	Text
395	AXIS	QRS axis
396	SHFT-LFT	shifted left
397	SHFT-RGT	shifted right
842	QUE-INICHG	Questionable change in initial forces of

ST Segment

Statement Number	Acronym	Text
1104	ST-NOLDEP	ST no longer depressed in
1105	ST-LESDEP	ST less depressed in
1106	ST-MORDEP	ST more depressed in
1107	ST-NOWDEP	ST now depressed in
1108	ST-DEPREP	ST depression has replaced ST elevation in
1115	QUE-STCHG	Questionable change in ST segment
1116	ST-(INC)	Non-specific change in ST segment in
1120	ST-MORELV	ST more elevated in
1121	ST-LESELV	ST less elevated in
1122	ST-ELVPRS	ST elevation now present in
1123	ST-NOLELV	ST no longer elevated in
1124	ST-ELVREP	ST elevation has replaced ST depression in

T-Waves

Statement Number	Acronym	Text
1201	T-INC	T wave amplitude has increased in
1203	T-DEC	T wave amplitude has decreased in
1207	LOWT-INVT	Flat T waves have replaced inverted T waves in
1208	QUE-TCHG	Questionable change in T waves
1210	LOWT-NOL	Flat T waves no longer evident in

Statement Number	Acronym	Text
1211	LESS-FLTT	Fewer leads exhibit flat T waves in
1212	LOWT-NOW	Flat T waves now evident in
1213	MORE-FLTT	More leads exhibit flat T waves in
1214	NSTNL	Nonspecific T wave abnormality no longer evident in
1215	NSTNW	Nonspecific T wave abnormality now evident in
1216	NSTLS	Nonspecific T wave abnormality, improved in
1217	NSTMR	Nonspecific T wave abnormality, worse in
1218	NSTFT	Nonspecific T wave abnormality has replaced inverted T waves in
1219	NSTNF	Inverted T waves have replaced nonspecific T wave abnormality in
1220	T-INVNOW	T wave inversion now evident in
1221	T-INVMOR	T wave inversion more evident in
1222	INVT-LOWT	Inverted T waves have replaced flat T waves in
1223	T-LESINV	T wave inversion less evident in
1224	T-INVNOL	T wave inversion no longer evident in

Intervals

Statement Number	Acronym	Text
100	PRINT	PR interval
1250	QT-LONG	QT has lengthened
1251	QT-SHRT	QT has shortened
1420	QRS-DUR	QRS duration

Miscellaneous

Statement Number	Acronym	Text
840	INC-MI	Increased evidence of infarction in
844	CITED	(cited on or before
1305	NO-CHG	No significant change was found
1403	LFREQ	Less frequent
1404	MFREQ	More frequent
1405	NOLONG	is no longer
1406	NOW	is now
1407	HAS-CHG	has changed
1408	HAS-NOTCHG	has not changed
1409	ARE-NOW	are now

Statement Number	***Acronym***	***Text***
1410	PRESENT	present
1411	HAV-NOTCHG	have not changed
1412	HAV-CHG	have changed
1415	HAS-REP	has replaced
1416	HAS-INC	has increased
1417	HAS-DEC	has decreased
1418	ARE-NOL	are no longer
1422	QUE-CHG	Questionable change in
1424	EVO	Serial changes of evolving
1425	SERCHG	Serial changes of
1426	SNGCH	Significant changes have occurred

Appendix B: Statement Library Arranged by Statement Number

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1	SNF	STATEMENT NOT FOUND				N
2	PEDANL	** * Pediatric ECG analysis * **		X	X	N
3	AGSPAMI	*** Age and gender specific ECG analysis ***		X		N
4	$ACS	** Acute Cardiac Syndrome criteria **				N
5	DICTATION	Report dictated, transcription pending				N
6	$TWLVW	Leads V2, V3, V4, and V6 are interpolated		X		N
8	$VLDFMT	Waveform is valid only when viewed in 4x2.5 format with lead II as the rhythm lead				N
9	$5SECLD1	Only the first 5 seconds of lead I are valid				N
10	$RDBC1	Reserved for Database Conversion				N
11	$RDBC2	Reserved for Database Conversion				N
12	$RDBC3	Reserved for Database Conversion				N
13	$SERREM	The system removed serial comparison statements because				N
14	$NOT12SL	this ECG was not analyzed with 12SL				N
15	$NOT12SL2	the 1st previous ECG was not analyzed with 12SL				N
16	$NOT12SL3	this patient has a test analyzed with the HEART algorithm				N
19	SRTH	Sinus rhythm		X	X	N
20	ARAT	(Atrial rate=				N
21	SBRAD	Sinus bradycardia		X	X	O
22	NSR	Normal sinus rhythm		X	X	N
23	STACH	Sinus tachycardia		X	X	O
24	MSBRAD	Marked sinus bradycardia		X	X	A
25	RABRAD	Low right atrial bradycardia		X		A
26	RATACH	Low right atrial tachycardia		X		A
27	LABRAD	Left atrial bradycardia		X		A
28	LATACH	Left atrial tachycardia		X		A
29	RAR	Low right atrial rhythm		X		A
30	LAR	Left atrial rhythm		X		A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
31	NOPF	(no P-waves found)				A
32	BLKED	blocked		X		N
33	ACCEL	Accelerated		X		N
34	JUNBRAD	Junctional bradycardia		X	X	A
41	JBRAD	Unusual P axis and short PR, probable junctional bradycardia		X	X	A
42	JR	Unusual P axis and short PR, probable junctional rhythm		X	X	A
43	JTACH	Unusual P axis and short PR, probable junctional tachycardia		X	X	A
61	EABRAD	Unusual P axis, possible ectopic atrial bradycardia		X	X	A
62	EAR	Unusual P axis, possible ectopic atrial rhythm		X	X	A
63	EATACH	Unusual P axis, possible ectopic atrial tachycardia		X	X	A
64	EARO	Ectopic atrial rhythm			X	A
100	PRINT	PR interval			X	N
101	FAV	with 1st degree AV block		X	X	O
102	SPR	with short PR		X	X	O
103	MBZI	with 2nd degree AV block (Mobitz I)		X	X	A
104	MBZII	with 2nd degree AV block (Mobitz II)		X	X	A
105	SAV	with 2nd degree AV block		X	X	A
106	CHB	with complete heart block		X	X	A
107	VAVB	with variable AV block		X		A
108	AVDIS	with AV dissociation		X	X	A
111	SABII	with 2nd degree SA block (Mobitz II)			X	A
112	SABI	with 2nd degree SA block (Mobitz I)			X	A
113	PAUSE	with sinus pause			X	A
141	W2T1	with 2:1 AV conduction		X		A
142	W3T1	with 3:1 AV conduction		X		A
143	W4T1	with 4:1 AV conduction		X		A
144	W5T1	with 5:1 AV conduction		X		A
161	AFIB	Atrial fibrillation		X	X	A
162	FLUT	Atrial flutter		X	X	A
163	CRS	Coarse				N
164	ATAC	Atrial tachycardia			X	A
171	RVR	with rapid ventricular response		X		N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
172	SVR	with slow ventricular response		X		N
173	ABER2	with premature ventricular or aberrantly conducted complexes				A
174	CJP	with a competing junctional pacemaker		X	X	A
175	IRREG	with undetermined rhythm irregularity		X	X	O
176	IRR	Irregular		X		N
177	$SWITH	with		X		N
178	$SOR	or		X		N
179	$SAND	and		X		N
181	ABER	with premature ventricular or aberrantly conducted complexes		X	X	O
183	APCX	atrial-paced complexes		X	*	A
184	VPCX	ventricular-paced complexes		X	*	A
185	AVPCX	AV dual-paced complexes		X	*	A
186	ASVPCX	atrial-sensed ventricular-paced complexes		X	*	A
187	SCX	sinus complexes		X		N
188	SVCX	supraventricular complexes		X		N
189	INTRIN	intrinsic complexes		X		N
190	PROAV	with prolonged AV conduction		X		O
211	OCC	with occasional		X		N
212	FREQ	with frequent		X		N
221	PSVC	premature supraventricular complexes		X	X	O
222	PAC	premature atrial complexes		X	X	O
223	PJC	premature junctional complexes			X	O
231	PVC	premature ventricular complexes		X	X	O
232	PVCF	premature ventricular and fusion complexes			X	O
233	CSEC	and consecutive		X		A
234	BIGEM	in a pattern of bigeminy		X		O
235	WQTACH	Wide QRS tachycardia		X	X	A
236	NQTACH	Narrow QRS tachycardia		X		O
237	$SWQR	Wide QRS rhythm		X	X	O
238	$SIVR	Idioventricular rhythm		X	X	A
241	PEC	premature ectopic complexes			X	O
242	JESC	with junctional escape complexes		X	X	O
243	VESC	with ventricular escape complexes		X	X	O

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
244	$SFUS	fusion complexes		X	X	O
245	$SRETC	with retrograde conduction		X		O
246	$SABCOND	aberrant conduction		X	X	O
247	$SCAPTUR	sinus/atrial capture		X		N
248	$SVTACH	Ventricular tachycardia			X	A
249	$SVFIB	Ventricular fibrillation			X	A
251	SAR	with sinus arrhythmia		X		N
252	MSAR	with marked sinus arrhythmia		X	X	O
265	PR-SBRAD	Probable sinus bradycardia, verify AV conduction				N
266	SUP-TACH	Supraventricular tachycardia				O
267	JUNCT-R	Junctional rhythm		X	X	A
268	IDIO-R	Idioventricular rhythm with AV block				A
269	VENT-RTH	Ventricular rhythm				A
270	J-TACH	Junctional tachycardia			X	A
271	SVT	Supraventricular tachycardia		X	X	O
272	VTACH	Ventricular tachycardia (ventricular or supraventricular with aberration)				A
273	AFL	Atrial flutter			X	A
274	VENT-FUS	with ventricular fusion				O
275	J-ESC	with junctional escape				O
276	ESCBT	with escape beat				O
277	TVT	with transient ventricular tachycardia				O
278	WEKH	with Mobitz I (Wenckebach) block				O
279	PO-ATP	Possible wandering atrial pacemaker				O
280	MULT-AT	Multifocal atrial tachycardia				A
281	COMP-HB	Complete heart block				A
282	AV-COND	Suspect AV conduction defect				O
283	AB-VENT	with intermittent aberrant ventricular conduction				O
284	SA-BLK	with SA block or transient AV block				O
285	SAB	with sinus arrest or transient AV block				A
287	LHR	Low heart rate, verify AV conduction				O
288	AFL-BL	Atrial flutter with 2 to 1 block				A
289	BIVPCK	Biventricular pacemaker detected		X		N
290	PCK	Electronic ventricular pacemaker			X	N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
291	DPCK	Demand pacemaker, interpretation is based on intrinsic rhythm			X	N
292	APCK	Electronic atrial pacemaker			X	N
293	AVPCK	AV sequential or dual chamber electronic pacemaker			X	N
294	EDP	Electronic demand pacing			X	N
295	APR	Atrial-paced rhythm		X	*	A
296	VPR	Ventricular-paced rhythm		X	*	A
297	ASVPR	Atrial-sensed ventricular-paced rhythm		X	*	A
298	AVDPR	AV dual-paced rhythm		X	*	A
299	UR	Undetermined rhythm		X	X	O
300	WPWA	Ventricular pre-excitation, WPW pattern type A		X	X	A
302	WPWB	Ventricular pre-excitation, WPW pattern type B		X	X	A
303	ALTWPW	with fusion or intermittent ventricular pre- excitation (WPW)		X	X	A
304	WPW	Wolff-Parkinson-White		X	X	A
305	CWRT	Clockwise rotation of the heart, may invalidate criteria for ventricular hypertrophy				O
306	CCWRT	Counterclockwise rotation of the heart, may invalidate criteria for ventricular hypertrophy				O
307	DXTRO	Dextrocardia		X		A
320	CUR-UND	Current undetermined rhythm precludes rhythm comparison, needs review			X	O
321	PRV-UND	Previous ECG has undetermined rhythm, needs review			X	O
322	VENT-RAT	Vent. rate			X	O
323	RHY	Rhythm				O
324	PRM-CON	The premature contractions				O
325	CONSEC	Consecutive				O
326	WITH-DEM	with a demand pacemaker				O
327	BASIC	Basic rhythm				O
350	RAE	Right atrial enlargement		X		B
360	LAE	Left atrial enlargement		X		B
369	BAE	Biatrial enlargement		X		A
370	LAD	Leftward axis				B

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
371	ALAD	Abnormal left axis deviation				A
372	LAD3	Left axis deviation		X		A
380	RAD	Rightward axis		X		B
381	ARAD	Abnormal right axis deviation				A
382	RSAD	Abnormal right superior axis deviation				A
383	RAD4	Right axis deviation		X		A
384	RAD5	Right superior axis deviation		X		A
390	INDAX	Indeterminate axis		X		B
391	NWA	Northwest axis		X		A
395	AXIS	QRS axis			X	N
396	SHFT-LFT	shifted left			X	N
397	SHFT-RGT	shifted right			X	N
410	LOWV	Low voltage QRS		X		B
411	PULD	Pulmonary disease pattern		X		A
412	S1S2S3	S1-S2-S3 pattern, consider pulmonary disease, RVH, or normal variant				A
435	BRUG1	Brugada pattern, type 1		X		A
436	BRUG2	Brugada pattern, type 2		X		A
437	BRUG3	Brugada pattern, type 3		X		A
440	RBBB	Right bundle branch block		X	X	A
441	RVE+	, plus right ventricular hypertrophy		X		A
442	RBBRVH	Right bundle branch block -or- Right ventricular hypertrophy		X		A
445	IRBBB	Incomplete right bundle branch block		X	X	B
446	IRB-RVE	.				N
450	RSR	RSR' or QR pattern in V1 suggests right ventricular conduction delay		X	X	B
451	SRSRO	RSR' pattern in V1			X	N
460	LBBB	Left bundle branch block		X	X	A
465	ILBBB	Incomplete left bundle branch block		X	X	B
470	AFB	Left anterior fascicular block		X	X	A
471	PFB	Left posterior fascicular block		X	X	A
478	BIFB1	(RBBB and left anterior fascicular block)			X	A
479	BIFB2	(RBBB and left posterior fascicular block)			X	A
480	BIFB	*** Bifascicular block ***		X		A
481	TRIFB	Trifascicular block				A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
482	IVCB	Nonspecific intraventricular block		X	X	A
487	IVCD	Nonspecific intraventricular conduction delay		X	X	B
520	RVH	Right ventricular hypertrophy		X		A
521	RVH-2ST	Right ventricular hypertrophy with repolarization abnormality				A
530	RAVL	R in aVL		X		N
531	SOKOLYON	Sokolow-Lyon		X		N
532	CORNVOLT	Cornell Voltage		X		N
533	CORNPROD	Cornell Product		X		N
534	ROMESTES	Romhilt-Estes		X		N
540	LVH	Voltage criteria for left ventricular hypertrophy		X		A
541	LVH2	Left ventricular hypertrophy		X		A
542	QRSV	Minimal voltage criteria for LVH, may be normal variant		X		B
543	QRSW	with QRS widening		X		A
544	2ST	with repolarization abnormality		X		A
545	QRSW-2ST	with QRS widening and repolarization abnormality		X		A
548	LVH3	Moderate voltage criteria for LVH, may be normal variant		X		B
570	BIVH	Biventricular hypertrophy		X		A
571	PMDPV	Prominent mid-precordial voltage,		X		A
572	QV6	Deep Q wave in lead V6,		X		A
573	PPV	Prominent posterior voltage				A
574	PLV	Prominent lateral voltage				A
575	QIII	Deep Q in lead III				A
700	SMI	Septal infarct		X	X	A
701	SMI-LAE	.				N
740	AMI	Anterior infarct		X	X	A
760	LMI	Lateral infarct		X	X	A
780	IMI	Inferior infarct		X	X	A
782	MAFB	(masked by fascicular block?)		X	X	N
795	RVI	with right ventricular involvement		X		A
800	PXT	, with posterior extension			X	A
801	IPMI	Inferior-posterior infarct		X	X	A
802	POSTMI	Posterior infarct		X	X	A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
803	QESPMI	Increased R/S ratio in V1, consider early transition or posterior infarct		X		A
805	RV4R	Inferior injury pattern suggests right ventricular involvement, recommend adding leads V3r and V4r to confirm		X		N
806	CRVI	Consider right ventricular involvement in acute inferior infarct		X		N
810	ASMI	Anteroseptal infarct		X	X	A
820	ALMI	Anterolateral infarct		X	X	A
821	STEMI	** ** ACUTE MI / STEMI ** **		X		A
822	NSTEMI	** ** ACUTE MI / non-STEMI ** **				A
823	LBBBNEW	** ** Consider ACUTE MI if LBBB is new ** **		X		A
826	LBBBACS	** ** LBBB with primary ST-T abnormality - Consider ACUTE CORONARY SYNDROME (ACS) ** **		X		A
827	LBBBAMI	** ** LBBB with primary ST elevation abnormality - PROBABLE ACUTE MI ** **		X		A
828	AIS	** ** Consider ACUTE CORONARY SYNDROME (ACS) ** **		X		A
829	ACUMI	** ** ACUTE MI ** **				A
830	AC	, possibly acute		X		N
831	AU	, age undetermined		X	X	N
832	OLD	, old				A
833	NEW	, new			X	A
840	INC-MI	Increased evidence of infarction in				N
841	DEC-MI	Questionable change in initial forces of				N
842	QUE- INICHG	Questionable change in initial forces of			X	N
843	CRI-FOR	Criteria for			X	N
844	CITED	(cited on or before			X	N
845	MINI-CRIT	Minimal criteria for			X	N
846	BORD-CRIT	Borderline criteria for			X	N
880	MISIZ	*** QRS contour suggests infarct size is probably				N
881	VSMA	very small				N
882	SMA	small				N
883	MOD	moderate				N
884	LARG	large				N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
885	VLAR	very large				N
900	NST	Nonspecific ST abnormality		X		A
901	PCARD	Acute pericarditis		X		A
902	SERYR1	ST elevation, consider early repolarization, pericarditis, or injury		X		A
903	SERYR2	ST elevation, probably due to early repolarization		X		B
904	NSTE	Nonspecific ST elevation				A
920	SINJ	Septal injury pattern				A
930	AINJ	Anterior injury pattern		X		A
940	LINJ	Lateral injury pattern		X		A
950	IINJ	Inferior injury pattern		X		A
960	ASINJ	Anteroseptal injury pattern				A
961	ALINJ	Anterolateral injury pattern		X		A
962	ILINJ	Inferolateral injury pattern		X		A
963	IIOHAI	ST elevation, consider inferior injury or acute infarct		X		A
964	AIOHAI	ST elevation, consider anterior injury or acute infarct		X		A
965	LIOHAI	ST elevation, consider lateral injury or acute infarct		X		A
966	ALIHAI	ST elevation, consider anterolateral injury or acute infarct		X		A
967	ILIHAI	ST elevation, consider inferolateral injury or acute infarct		X		A
968	INJONV	ST elevation, consider injury or variant associated with LVH				A
1000	REPOL	Early repolarization		X		N
1001	JSTN	Junctional ST depression, probably normal		X		B
1002	JST	Junctional ST depression, probably abnormal		X		A
1020	STDIG	ST abnormality, possible digitalis effect				A
1021	NST2	Nonspecific ST abnormality				N
1022	STDEP	ST depression, consider subendocardial injury or digitalis effect				A
1023	NSTD	Nonspecific ST depression				A
1024	STDEP2	ST depression, consider subendocardial injury		X		A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1040	SSBINJ	Marked ST abnormality, possible septal subendocardial injury		X		A
1050	ASBINJ	Marked ST abnormality, possible anterior subendocardial injury		X		A
1060	LSBINJ	Marked ST abnormality, possible lateral subendocardial injury		X		A
1070	ISBINJ	Marked ST abnormality, possible inferior subendocardial injury		X		A
1071	MSTDIL	Marked ST abnormality, possible inferolateral subendocardial injury		X		A
1080	MSTDAS	Marked ST abnormality, possible anteroseptal subendocardial injury		X		A
1081	MSTDAL	Marked ST abnormality, possible anterolateral subendocardial injury		X		A
1082	STDPIN	ST depression in		X		A
1083	STELIN	ST elevation in		X		A
1084	WSTR	with strain pattern		X		A
1100	ST&	ST &		X		A
1104	ST-NOLDEP	ST no longer depressed in			X	N
1105	ST-LESDEP	ST less depressed in			X	N
1106	ST- MORDEP	ST more depressed in			X	N
1107	ST- NOWDEP	ST now depressed in			X	N
1108	ST-DEPREP	ST depression has replaced ST elevation in			X	N
1115	QUE- STCHG	Questionable change in ST segment				N
1116	ST-(INC)	Non-specific change in ST segment in			X	N
1117	ST-(DEC)	Non-specific change in ST segment in			X	N
1120	ST-MORELV	ST more elevated in			X	N
1121	ST-LESELV	ST less elevated in			X	N
1122	ST-ELVPRS	ST elevation now present in			X	N
1123	ST-NOLELV	ST no longer elevated in			X	N
1124	ST-ELVREP	ST elevation has replaced ST depression in			X	N
1138	STABAND	ST abnormality and		X		A
1139	SNDQA	, may be secondary to QRS abnormality		X		N
1140	NT	Nonspecific T wave abnormality		X		A
1141	NSTT	Nonspecific ST and T wave abnormality		X		A
1142	QRST	Abnormal QRS-T angle, consider primary T wave abnormality		X		A

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1143	LNGQT	Prolonged QT		X		A
1144	BOQTI	Borderline QT interval				A
1145	ILT	T wave abnormality, consider inferolateral ischemia		X		A
1150	AT	T wave abnormality, consider anterior ischemia		X		A
1151	MAT	Marked T wave abnormality, consider anterior ischemia		X		A
1160	LT	T wave abnormality, consider lateral ischemia		X		A
1161	MLT	Marked T wave abnormality, consider lateral ischemia		X		A
1170	IT	T wave abnormality, consider inferior ischemia		X		A
1171	MIT	Marked T wave abnormality, consider inferior ischemia		X		A
1172	MILT	Marked T wave abnormality, consider inferolateral ischemia		X		A
1180	ALT	T wave abnormality, consider anterolateral ischemia		X		A
1181	MALT	Marked T wave abnormality, consider anterolateral ischemia		X		A
1182	TINVIN	T wave inversion in		X		A
1200	T-WAVE	T waves				N
1201	T-INC	T wave amplitude has increased in			X	N
1203	T-DEC	T wave amplitude has decreased in			X	N
1207	LOWT-INVT	Flat T waves have replaced inverted T waves in				N
1208	QUE-TCHG	Questionable change in T waves				N
1210	LOWT-NOL	Flat T waves no longer evident in				N
1211	LESS-FLTT	Fewer leads exhibit flat T waves in				N
1212	LOWT-NOW	Flat T waves now evident in				N
1213	MORE-FLTT	More leads exhibit flat T waves in				N
1214	NSTNL	Nonspecific T wave abnormality no longer evident in			X	N
1215	NSTNW	Nonspecific T wave abnormality now evident in			X	N
1216	NSTLS	Nonspecific T wave abnormality, improved in			X	N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1217	NSTMR	Nonspecific T wave abnormality, worse in			X	N
1218	NSTFT	Nonspecific T wave abnormality has replaced inverted T waves in			X	N
1219	NSTNF	Inverted T waves have replaced nonspecific T wave abnormality in			X	N
1220	T-INVNOW	T wave inversion now evident in			X	N
1221	T-INVMOR	T wave inversion more evident in			X	N
1222	INVT-LOWT	Inverted T waves have replaced flat T waves in				N
1223	T-LESINV	T wave inversion less evident in			X	N
1224	T-INVNOL	T wave inversion no longer evident in			X	N
1250	QT-LONG	QT has lengthened			X	N
1251	QT-SHRT	QT has shortened			X	N
1252	RAT-DEC	Although rate has decreased				N
1253	RAT-INC	Although rate has increased				N
1254	WITH-RATINC	with rate increase				N
1255	WITH-RATDEC	with rate decrease				N
1300	NO-SERIAL	No previous ECGs available			X	N
1301	COMPAR	When compared with ECG of				N
1302	POOR-DAT	Poor data quality in current ECG precludes serial comparison				N
1303	NO- SERCMP	Serial comparison not performed; all previous tracings are of poor data quality				N
1304	DEMOGR	Warning: demographic data different				N
1305	NO-CHG	No significant change was found			X	N
1306	SUNCNF	(Unconfirmed)			X	N
1340	CRIT	*** Critical Test Result:		X		A
1342	CVHIHR	High HR		X		N
1343	CVLOHR	Low HR		X		N
1346	CVLQT	Long QTc		X		N
1360	CVSTEMI	STEMI		X		N
1361	CVACS	ACS / Ischemia		X		N
1362	CVAVB	AV Block		X		N
1363	CVARRHY	Arrhythmia		X		N
1400	AND	and				N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1401	HOWEVER	however				N
1402	HWV-IT	however it				N
1403	LFREQ	Less frequent				N
1404	MFREQ	More frequent				N
1405	NOLONG	is no longer			X	N
1406	NOW	is now			X	N
1407	HAS-CHG	has changed				N
1408	HAS- NOTCHG	has not changed			X	N
1409	ARE-NOW	are now			X	N
1410	PRESENT	present			X	N
1411	HAV- NOTCHG	have not changed				N
1412	HAV-CHG	have changed				N
1415	HAS-REP	has replaced			X	N
1416	HAS-INC	has increased			X	N
1417	HAS-DEC	has decreased			X	N
1418	ARE-NOL	are no longer			X	N
1419	QRS	QRS				N
1420	QRS-DUR	QRS duration			X	N
1421	QRS-VOL	QRS voltage			X	N
1422	QUE-CHG	Questionable change in			X	N
1423	ACUT	Acute			X	N
1424	EVO	Serial changes of evolving			X	N
1425	SERCHG	Serial changes of			X	N
1426	SNGCH	Significant changes have occurred			X	N
1427	DTOFF	Manual comparison required, data offline and on volume			X	N
1428	ANACP	Manual comparison required for analog tracing			X	N
1430	NOPHONE	Manual comparison required, cannot contact main system			X	N
1450	SEP	Septal leads		X	X	N
1451	ANT	Anterior leads		X	X	N
1452	LAT	Lateral leads		X	X	N
1453	INF	Inferior leads		X	X	N
1454	POS	Posterior leads			X	N
1455	ANTSEP	Anteroseptal leads		X	X	N
1456	ANTLAT	Anterolateral leads		X	X	N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1457	INFPOS	Inferoposterior leads			X	N
1458	IFLAT	Inferolateral leads		X		N
1459	RECP	reciprocal		X		N
1460	ACSBCAUS	ECG interpretation of ACS is based on presence of symptoms and		X		N
1462	CROACS	ECG not diagnostic for Acute Coronary Syndrome; consider clinical findings		X		N
1500	POOR	Poor data quality	X			N
1501	POWER	Powerline interference	X			N
1502	BASELINE	Baseline wander	X			N
1503	MUSCLE	Muscle tremor	X			N
1504	ELECTR	Electrode noise	X			N
1505	DISC	disconnected	X			N
1510	LEAD	in lead	X			N
1511	LEADS	in leads	X			N
1537	EL-NAP	NAP	X			N
1538	EL-NST	NST	X			N
1539	EL-NAX	NAX	X			N
1540	EL-RA	RA	X			N
1541	EL-LA	LA	X			N
1542	EL-RL	RL	X			N
1543	EL-LL	LL	X			N
1544	LD-LIMB	Limb lead	X			N
1545	EL-H	H	X			N
1546	EL-E	E	X			N
1547	EL-I	I	X			N
1548	EL-M	M	X			N
1550	LD-I	I	X			N
1551	LD-II	II	X			N
1552	LD-V1	V1	X			N
1553	LD-V2	V2	X			N
1554	LD-V3	V3	X			N
1555	LD-V4	V4	X			N
1556	LD-V5	V5	X			N
1557	LD-V6	V6	X			N
1558	LD-V7	V7	X			N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1559	LD-V8	V8	X			N
1560	LD-V9	V9	X			N
1562	LD-V2R	V2r	X			N
1563	LD-V3R	V3r	X			N
1564	LD-V4R	V4r	X			N
1565	LD-V5R	V5r	X			N
1566	LD-V6R	V6r	X			N
1567	LD-V7R	V7r	X			N
1568	LD-V8R	V8r	X			N
1569	LD-V9R	V9r	X			N
1570	LD-A1	A1	X			N
1571	LD-A2	A2	X			N
1572	LD-A3	A3	X			N
1573	LD-A4	A4	X			N
1574	LD-III	III	X			N
1575	LD-AVR	aVR	X			N
1576	LD-AVL	aVL	X			N
1577	LD-AVF	aVF	X			N
1578	LD-MVR	mVR	X			N
1579	LD-D	D	X			N
1580	LD-A	A	X			N
1581	LD-J	J	X			N
1582	LD-X	X	X			N
1583	LD-Y	Y	X			N
1584	LD-Z	Z	X			N
1585	LD-MY	mY	X			N
1586	LD-MZ	mZ	X			N
1587	LD-CC5	CC5	X			N
1588	LD-CM5	CM5	X			N
1601	LD-R	R	X			N
1602	LD-L	L	X			N
1603	LD-N	N	X			N
1604	LD-F	F	X			N
1605	LD-C1	C1	X			N
1606	LD-C2	C2	X			N
1607	LD-C3	C3	X			N

Code	MUSE Acronym	Text - English	Hookup Advisor[1]	12SL[2]	Serial Comparison[3]	Class[4]
1608	LD-C4	C4	X			N
1609	LD-C5	C5	X			N
1610	LD-C6	C6	X			N
1611	LD-C7	C7	X			N
1612	LD-C8	C8	X			N
1613	LD-C9	C9	X			N
1615	LD-C2R	C2r	X			N
1616	LD-C3R	C3r	X			N
1617	LD-C4R	C4r	X			N
1618	LD-C5R	C5r	X			N
1619	LD-C6R	C6r	X			N
1620	LD-C7R	C7r	X			N
1621	LD-C8R	C8r	X			N
1622	LD-C9R	C9r	X			N
1665	LPAREN	(		X		N
1666	RPAREN	)		X		N
1669	PMFAIL	*** Suspect unspecified pacemaker failure		X		N
1670	PDIG	, probably digitalis effect				N
1671	ODIG	or digitalis effect				N
1672	ARM	*** Suspect arm lead reversal, interpretation assumes no reversal		X		N
1673	QCERR	*** Poor data quality, interpretation may be adversely affected		X	X	N
1674	AHE	Acquisition hardware fault prevents reliable analysis, carefully check ECG record before interpreting		X		N
1675	MRR	Manual reading required due to inconsistent morphologies				N
1676	$SANLERR3	** Less than 4 QRS complexes detected, no interpretation possible **		X	X	N
1677	$SANLERR1	*** Memory allocation failure, no ECG interpretation possible ***			X	N
1678	$SANLERR2	** No QRS complexes found, no ECG analysis possible **		X	X	N
1679	NSTDLDS	** Nonstandard lead placement, ECG interpretation not available **		X		N
1680	PO	Possible		X	X	N

Code	*MUSE Acronym*	*Text - English*	*Hookup Advisor*[1]	*12SL*[2]	*Serial Comparison*[3]	*Class*[4]
1682	CRO	Cannot rule out		X		N
1683	COMMA	,		X		N
1684	NML	Normal ECG		X		N
1687	ABR	Otherwise normal ECG		X		O
1693	BORDE	Borderline ECG		X		B
1694	BO	Borderline		X		N
1699	AB	Abnormal ECG		X		A

Notes:

1. Hookup Advisor statements appear only on the screen during ECG acquisition on cardiographs that have the Hookup Advisor™ turned on. These statements never appear in an original interpretation (but may be used when editing).
2. "x" in this column applies only to 12SL V22. Older versions of 12SL may make additional statements that have been deprecated (e.g., certain pacemaker statements and statements that reference digitalis effect).
3. "*" in this column apply only to Serial Comparison in MUSE 8.0 and higher only. Earlier versions of MUSE are not aware of these statements.
4. N = normal ECG or not applicable; O = otherwise normal ECG; B = borderline ECG; A = abnormal ECG

Appendix C: Pediatric Tables

The normal values included in this appendix, and used by the pediatric analysis program, are those collected and published by Davignon et al. This data is based on more than 2,000 children who were found to have a normal physical examination. The total population was divided into 12 age groups, with 7 age groups in the first year of life to reflect the greater changes in the ECG during this time.

Less Than One Day Old

Item	*Value*	*Description*
Heart Rate	154	Upper heart rate
	93	Lower heart rate
Axis Limit	187	Right axis limit
	59	Left axis limit
	N/A	Northwest axis limit
PR Interval	80	Lower PR interval
	110	Mean PR interval
	160	Upper PR interval
QRS Duration	75	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	450	Large Q amplitude for III
	200	Large Q amplitude for V6
Lead V1	500	Small R amplitude for V1
	2600	Large R amplitude for V1
	1380	Mean R amplitude for V1
	NA	Small S amplitude for V1
	2300	Large S amplitude for V1
	850	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1100	Large R amplitude for V6
	NA	Small R amplitude for V6
	420	Mean R amplitude for V6
	950	Large S amplitude for V6
	320	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2800	V6 R amplitude + V1 S amplitude in horizontal
	5250	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

At Least a Day Old but Not More Than 2 Days Old

Item	*Value*	*Description*
Heart Rate	159	Upper heart rate
	91	Lower heart rate
Axis Limit	187	Right axis limit
	59	Left axis limit
	N/A	Northwest axis limit
PR Interval	80	Lower PR interval
	110	Mean PR interval
	160	Upper PR interval
QRS Duration	66	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	650	Large Q amplitude for III
	250	Large Q amplitude for V6
Lead V1	500	Small R amplitude for V1
	2700	Large R amplitude for V1
	1440	Mean R amplitude for V1
	NA	Small S amplitude for V1
	2100	Large S amplitude for V1
	850	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1200	Large R amplitude for V6
	NA	Small R amplitude for V6
	450	Mean R amplitude for V6
	950	Large S amplitude for V6
	300	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2900	V6 R amplitude + V1 S amplitude in horizontal
	5200	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

3 TO 6 DAYS OLD

Item	*Value*	*Description*
Heart Rate	166	Upper heart rate
	91	Lower heart rate
Axis Limit	187	Right axis limit
	77	Left axis limit
	N/A	Northwest axis limit
PR Interval	70	Lower PR interval
	100	Mean PR interval
	140	Upper PR interval
QRS Duration	68	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	550	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	2400	Large R amplitude for V1
	1290	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1700	Large S amplitude for V1
	660	Mean S amplitude for V1
	0.2	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1200	Large R amplitude for V6
	50	Small R amplitude for V6
	520	Mean R amplitude for V6
	1000	Large S amplitude for V6
	350	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2450	V6 R amplitude + V1 S amplitude in horizontal
	4900	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

1 TO 3 WEEKS OLD

Item	*Value*	*Description*
Heart Rate	182	Upper heart rate
	107	Lower heart rate
Axis Limit	161	Right axis limit
	65	Left axis limit
	NA	Northwest axis limit
PR Interval	70	Lower PR interval
	100	Mean PR interval
	140	Upper PR interval
QRS Duration	80	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	600	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	2100	Large R amplitude for V1
	1060	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1100	Large S amplitude for V1
	420	Mean S amplitude for V1
	1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	1650	Large R amplitude for V6
	250	Small R amplitude for V6
	760	Mean R amplitude for V6
	1000	Large S amplitude for V6
	340	Mean S amplitude for V6
	0.1	Lower R/S ratio in V6
Total Deflection	2100	V6 R amplitude + V1 S amplitude in horizontal
	4900	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

1 TO 2 MONTHS OLD

Item	*Value*	*Description*
Heart Rate	179	Upper heart rate
	121	Lower heart rate
Axis Limit	113	Right axis limit
	13	Left axis limit
	180	Northwest axis limit
PR Interval	70	Lower PR interval
	100	Mean PR interval
	130	Upper PR interval
QRS Duration	76	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	750	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	1800	Large R amplitude for V1
	950	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1200	Large S amplitude for V1
	500	Mean S amplitude for V1
	0.3	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	2150	Large R amplitude for V6
	500	Small R amplitude for V6
	1160	Mean R amplitude for V6
	650	Large S amplitude for V6
	270	Mean S amplitude for V6
	0.2	Lower R/S ratio in V6
Total Deflection	2900	V6 R amplitude + V1 S amplitude in horizontal
	5350	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

3 TO 5 MONTHS OLD

Item	*Value*	*Description*
Heart Rate	186	Upper heart rate
	106	Lower heart rate
Axis Limit	104	Right axis limit
	7	Left axis limit
	180	Northwest axis limit
PR Interval	70	Lower PR interval
	110	Mean PR interval
	150	Upper PR interval
QRS Duration	80	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	650	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	300	Small R amplitude for V1
	2000	Large R amplitude for V1
	980	Mean R amplitude for V1
	NA	Small S amplitude for V1
	1700	Large S amplitude for V1
	570	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	NA	Upper R/S ratio in V1
Lead V6	2250	Large R amplitude for V6
	650	Small R amplitude for V6
	1310	Mean R amplitude for V6
	1000	Large S amplitude for V6
	290	Mean S amplitude for V6
	0.2	Lower R/S ratio in V6
Total Deflection	3200	V6 R amplitude + V1 S amplitude in horizontal
	6150	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

6 TO 11 MONTHS OLD

Item	*Value*	*Description*
Heart Rate	169	Upper heart rate
	109	Lower heart rate
Axis Limit	99	Right axis limit
	6	Left axis limit
	180	Northwest axis limit
PR Interval	70	Lower PR interval
	110	Mean PR interval
	160	Upper PR interval
QRS Duration	76	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	850	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	150	Small R amplitude for V1
	2000	Large R amplitude for V1
	940	Mean R amplitude for V1
	50	Small S amplitude for V1
	1800	Large S amplitude for V1
	640	Mean S amplitude for V1
	0.1	Lower R/S ratio in V1
	3.9	Upper R/S ratio in V1
Lead V6	2250	Large R amplitude for V6
	600	Small R amplitude for V6
	1260	Mean R amplitude for V6
	700	Large S amplitude for V6
	210	Mean S amplitude for V6
	0.2	Lower R/S ratio in V6
Total Deflection	3200	V6 R amplitude + V1 S amplitude in horizontal
	5350	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

1 TO 2 YEARS OLD

Item	*Value*	*Description*
Heart Rate	151	Upper heart rate
	89	Lower heart rate
Axis Limit	101	Right axis limit
	7	Left axis limit
	180	Northwest axis limit
PR Interval	80	Lower PR interval
	110	Mean PR interval
	150	Upper PR interval
QRS Duration	76	98% confidence interval for QRS duration,
	90	Wide QRS
	110	Very wide QRS, block
Q Amplitude	600	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	250	Small R amplitude for V1
	1700	Large R amplitude for V1
	890	Mean R amplitude for V1
	60	Small S amplitude for V1
	2100	Large S amplitude for V1
	840	Mean S amplitude for V1
	0.05	Lower R/S ratio in V1
	4.3	Upper R/S ratio in V1
Lead V6	2250	Large R amplitude for V6
	600	Small R amplitude for V6
	1330	Mean R amplitude for V6
	650	Large S amplitude for V6
	190	Mean S amplitude for V6
	0.3	Lower R/S ratio in V6
Total Deflection	3900	V6 R amplitude + V1 S amplitude in horizontal
	4950	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

3 TO 4 YEARS OLD

Item	*Value*	*Description*
Heart Rate	137	Upper heart rate
	73	Lower heart rate
Axis Limit	104	Right axis limit
	6	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	120	Mean PR interval
	160	Upper PR interval
QRS Duration	72	98% confidence interval for QRS duration,
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	500	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	100	Small R amplitude for V1
	1800	Large R amplitude for V1
	810	Mean R amplitude for V1
	20	Small S amplitude for V1
	2100	Large S amplitude for V1
	1020	Mean S amplitude for V1
	0.03	Lower R/S ratio in V1
	2.8	Upper R/S ratio in V1
Lead V6	2450	Large R amplitude for V6
	800	Small R amplitude for V6
	1480	Mean R amplitude for V6
	500	Large S amplitude for V6
	150	Mean S amplitude for V6
	0.6	Lower R/S ratio in V6
Total Deflection	4200	V6 R amplitude + V1 S amplitude in horizontal
	5350	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

5 TO 7 YEARS OLD

Item	*Value*	*Description*
Heart Rate	133	Upper heart rate
	65	Lower heart rate
Axis Limit	143	Right axis limit
	11	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	120	Mean PR interval
	160	Upper PR interval
QRS Duration	79	98% confidence interval for QRS duration,
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	400	Large Q amplitude for III
	450	Large Q amplitude for V6
Lead V1	50	Small R amplitude for V1
	1400	Large R amplitude for V1
	670	Mean R amplitude for V1
	30	Small S amplitude for V1
	2400	Large S amplitude for V1
	1200	Mean S amplitude for V1
	0.02	Lower R/S ratio in V1
	2.0	Upper R/S ratio in V1
Lead V6	2650	Large R amplitude for V6
	850	Small R amplitude for V6
	1630	Mean R amplitude for V6
	400	Large S amplitude for V6
	120	Mean S amplitude for V6
	0.9	Lower R/S ratio in V6
Total Deflection	4700	V6 R amplitude + V1 S amplitude in horizontal
	5400	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

8 TO 11 YEARS OLD

Item	*Value*	*Description*
Heart Rate	130	Upper heart rate
	62	Lower heart rate
Axis Limit	114	Right axis limit
	9	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	130	Mean PR interval
	170	Upper PR interval
QRS Duration	85	98% confidence interval for QRS duration,
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	300	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	30	Small R amplitude for V1
	2500	Large R amplitude for V1
	540	Mean R amplitude for V1
	30	Small S amplitude for V1
	2500	Large S amplitude for V1
	1190	Mean S amplitude for V1
	NA	Lower R/S ratio in V1
	1.8	Upper R/S ratio in V1
Lead V6	2550	Large R amplitude for V6
	900	Small R amplitude for V6
	1630	Mean R amplitude for V6
	400	Large S amplitude for V6
	100	Mean S amplitude for V6
	1.5	Lower R/S ratio in V6
Total Deflection	4550	V6 R amplitude + V1 S amplitude in horizontal
	5300	R amplitude + S amplitude in V4

Amplitude in microvolts
Duration in milliseconds

12 TO 15 YEARS OLD

Item	*Value*	*Description*
Heart Rate	119	Upper heart rate
	50	Lower heart rate
Axis Limit	130	Right axis limit
	11	Left axis limit
	180	Northwest axis limit
PR Interval	90	Lower PR interval
	140	Mean PR interval
	180	Upper PR interval
QRS Duration	87	98% confidence interval for QRS duration,
	100	Wide QRS
	120	Very wide QRS, block
Q Amplitude	300	Large Q amplitude for III
	300	Large Q amplitude for V6
Lead V1	NA	Small R amplitude for V1
	1000	Large R amplitude for V1
	410	Mean R amplitude for V1
	30	Small S amplitude for V1
	2100	Large S amplitude for V1
	1080	Mean S amplitude for V1
	NA	Lower R/S ratio in V1
	1.7	Upper R/S ratio in V1
Lead V6	2300	Large R amplitude for V6
	650	Small R amplitude for V6
	1430	Mean R amplitude for V6
	400	Large S amplitude for V6
	80	Mean S amplitude for V6
	1.4	Lower R/S ratio in V6
Total Deflection	4100	V6 R amplitude + V1 S amplitude in horizontal
	5000	R amplitude + S amplitude in V4

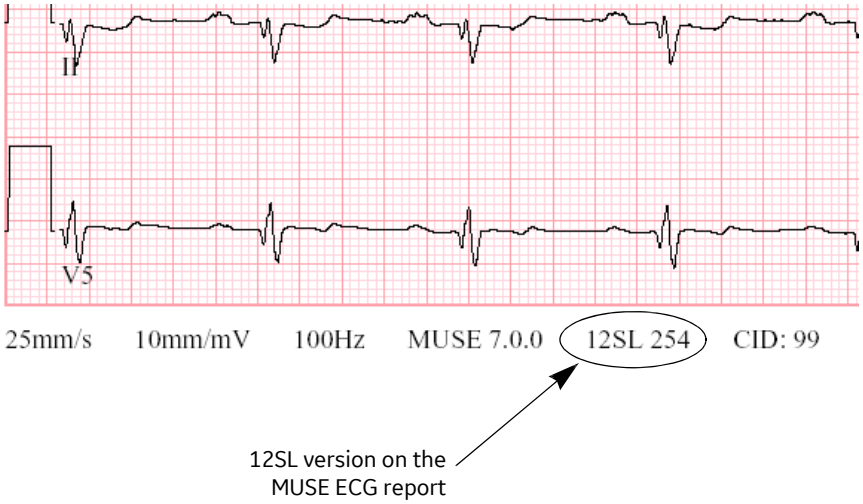
Amplitude in microvolts
Duration in milliseconds

Appendix D: 12SL Version Identification

INTRODUCTION

The 12SL analysis program has continually evolved since it was first introduced in 1980. Each released version of the program contains one or more changes to it and is associated with a unique version number.

A version number appears on the ECG report printed by an electrocardiograph or a MUSE system; encoded within this number are the actual 12SL version number and information about the specific platform on which the ECG was acquired.



CONVERSION TABLE

The following table can be used to convert the value displayed on the ECG report to the actual 12SL version number. Some values are reserved for future use. This table lists all possible values which may appear on the ECG report; not all of these values have been (or ever will be) used.

Version on Report	*Actual 12SL*	*Version on Report*	*Actual 12SL*	*Version on Report*	*Actual 12SL*	*Version on Report*	*Actual 12SL*
1	14	36	2	71	reserved	106	5
2	1	37	reserved	72	4	107	reserved
3	15	38	3	73	reserved	108	6
4	2	39	reserved	74	5	109	reserved
5	reserved	40	4	75	reserved	110	7
6	3	41	reserved	76	6	111	reserved
7	reserved	42	5	77	reserved	112	8
8	4	43	reserved	78	7	113	reserved
9	reserved	44	6	79	reserved	114	9
10	5	45	reserved	80	8	115	reserved
11	reserved	46	7	81	reserved	116	10
12	6	47	reserved	82	9	117	reserved
13	reserved	48	8	83	reserved	118	11
14	7	49	reserved	84	10	119	reserved

Version on Report	*Actual 12SL*	*Version on Report*	*Actual 12SL*	*Version on Report*	*Actual 12SL*	*Version on Report*	*Actual 12SL*
15	reserved	50	9	85	reserved	120	12
16	8	51	reserved	86	11	121	reserved
17	reserved	52	10	87	reserved	122	13
18	9	53	reserved	88	12	123	reserved
19	reserved	54	11	89	reserved	124	14
20	10	55	reserved	90	13	125	reserved
21	reserved	56	12	91	reserved	126	15
22	11	57	reserved	92	14	127	reserved
23	reserved	58	13	93	reserved	128	reserved
24	12	59	reserved	94	15	129	14
25	reserved	60	14	95	reserved	130	1
26	13	61	reserved	96	reserved	131	15
27	reserved	62	15	97	14	132	2
28	14	63	reserved	98	1	133	reserved
29	reserved	64	reserved	99	15	134	3
30	15	65	14	100	2	135	reserved
31	reserved	66	1	101	reserved	136	4
32	reserved	67	15	102	3	137	reserved
33	14	68	2	103	reserved	138	5
34	1	69	reserved	104	4	139	reserved
35	15	70	3	105	reserved	140	6
141	reserved	170	5	199	reserved	228	2
142	7	171	reserved	200	4	229	16
143	reserved	172	6	201	reserved	230	3
144	8	173	reserved	202	5	231	17
145	reserved	174	7	203	reserved	232	4
146	9	175	reserved	204	6	233	18
147	reserved	176	8	205	reserved	234	5
148	10	177	reserved	206	7	235	19
149	reserved	178	9	207	reserved	236	6
150	11	179	reserved	208	8	237	20
151	reserved	180	10	209	reserved	238	7
152	12	181	reserved	210	9	239	21
153	reserved	182	11	211	reserved	240	8
154	13	183	reserved	212	10	241	22
155	reserved	184	12	213	reserved	242	9
156	14	185	reserved	214	11	243	23
157	reserved	186	13	215	reserved	244	10

Version on Report	*Actual 12SL*	*Version on Report*	*Actual 12SL*	*Version on Report*	*Actual 12SL*	*Version on Report*	*Actual 12SL*
158	15	187	reserved	216	12	245	24
159	reserved	188	14	217	reserved	246	11
160	reserved	189	reserved	218	13	247	reserved
161	14	190	15	219	reserved	248	12
162	1	191	reserved	220	14	249	reserved
163	15	192	reserved	221	reserved	250	13
164	2	193	14	222	15	251	reserved
165	reserved	194	1	223	reserved	252	14
166	3	195	15	224	reserved	253	reserved
167	reserved	196	2	225	14	254	15
168	4	197	reserved	226	1	255	reserved
169	reserved	198	3	227	15		

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Dimensions (without resting ECG system)

A4 trolley (without resting ECG system)

Height	37.8 in (96 cm) 56.4 in (143 cm) with acquisition module and holder
Width	23.6 in (60 cm)
Depth	23.6 in (60 cm)
Weight	37 lbs (16.9 kg) — basic trolley 2.4 lbs (1.1 kg) — acquisition simply arm and barcode holder

A5 and Lite trolley (without resting ECG system)

Height	37.8 in (96 cm) 56.4 in (143 cm) with acquisition module and holder
Width	23.6 in (60 cm)
Depth	23.6 in (60 cm)
Weight	35 lbs (15.9 kg) — basic trolley 2.4 lbs (1.1 kg) — acquisition simply arm and barcode holder

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MAC 5

Optional accessories

KISS suction system (option where available)

Second tray

- Holds A4, A5 and letter size paper
- Inside dimensions of tray: 13 in (33 cm) x 4.3 in (110 cm) x 5.7 in (144 cm)

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