

Specificație Tehnică Completată

Anexa 1 Electrocardiograf cu 3 canale
Model: MAC 3 Reg. SDM: DM000870610
Producător: GE Healthcare

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Specificarea tehnică deplină solicitată, Standarde de referință	Specificația tehnică propusă de ofertant
Desriere: Electrocardiograf cu 3 canale, care inregistreaza, printeaza si interpreteaza ECG de la o singura sau mai multe derivatii simultan cu display color.	Desriere: Electrocardiograf cu 3 canale, care inregistreaza, printeaza si interpreteaza ECG de la o singura sau mai multe derivatii simultan cu display color. DA, ECG model MAC 3, pag.1 din Specificatie tehnica_MAC 3
Parametru Specificatia Tip pacient adult, pediatric	Parametru Specificatia Tip pacient adult, pediatric DA, pag.3 din Specificatie tehnica_MAC 3
Numarul de canale de procesare 3	Numarul de canale de procesare 3 DA, pag.3 din Specificatie tehnica_MAC 3
Configuratia: Portabil obligatoriu	Configuratia: Portabil obligatoriu DA, pag.1 din Specificatie tehnica_MAC 3
Derivatii: Tip imprimare auto si manual Sensitivitatea 2.5, 5, 10, 20, 10/5 mm/mv	Derivatii: Tip imprimare auto si manual DA, pag.53 din Manual de Operare Sensitivitatea 2.5, 5, 10, 20, 10/5 mm/mv DA, pag.2 din Specificatie tehnica_MAC 3
Semnal de calibrare 1 mV, +/- 3%	Semnal de calibrare 1 mV, +/- 3% DA, pag.78 din Manual de Operare, pag.147 din Physician Guide
Canal de frecventa: De diagnostic 0.05-150 Hz	Canal de frecventa: De diagnostic 0.01-150 Hz DA, pag.1 din Specificatie tehnica_MAC 3
Filtre miscventa obligatoriu	Filtre musculare obligatoriu DA, pag.19 din Physician Guide
Filtre frecventa joasa obligatoriu	Filtre frecventa joasa obligatoriu DA, pag.1 din Specificatie tehnica_MAC
Filtre frecventa inalta obligatoriu	Filtre frecventa inalta obligatoriu DA, pag.1 din Specificatie tehnica_MAC
Filtru de retea 50 Hz obligatoriu	Filtru de retea 50 Hz obligatoriu DA, pag.1 din Specificatie

Anexa 1

Impedanta de intrare > 10 M Ohm Gama de rejectie a modului comun la 50 Hz > 110 dB Curent analog-digital > 24 bit Scurgeri spre pacient prin electrozi <10 µA Detector de pacemaker obligatoriu Indicator deconectare electro acustic sau vizual obligatoriu Imprimanta: Termica incorporata Marime hartie > 80 mm Viteza de inscriere 5, (10 / 12.5), 25, 50 mm/s Derivatiile inscise minim 12 Numarul de derivatii inscise simultan > 3 Hârtia termică să fie compatibilă si de la alți producători de hartie si dispozitiv ECG- obligatoriu Display: Grafic, LCD/LED color – Obligatoriu Funcție Touchscreen – Obligatoriu Monitorizarea pe display: data, ora, sensibilitate, viteza de inscriere, filtru, derivatiile obligatoriu Mărime ecran > 5 inch Numărul de derivatii afisate simultan > 12	tehnica_MAC Impedanta de intrare > 10 M Ohm DA, pag.1 din Specificatie tehnica_MAC Gama de rejectie a modului comun la 50 Hz > 100 Db DA, pag.1 din Specificatie tehnica_MAC Curent analog-digital > 24 bit DA, pag.187 din Manual de Operare, pag.27 din Physician Guide Scurgeri spre pacient prin electrozi <10 µA DA, pag.3 din Specificatie tehnica_MAC Detector de pacemaker obligatoriu DA, pag.13 din Physician Guide Indicator deconectare electro acustic sau vizual obligatoriu DA, pag.154, 188 din Manual de Operare Imprimanta: DA, pag.2 din Specificatie tehnica_MAC Termica incorporata DA, pag.2 din Specificatie tehnica_MAC Marime hartie > 80 mm DA, pag.2 din Specificatie tehnica_MAC Viteza de inscriere 5, (10 / 12.5), 25, 50 mm/s DA, pag.2 din Specificatie tehnica_MAC Derivatiile inscise minim 12 DA, pag.191 din Manual de Operare Numarul de derivatii inscise simultan > 3 DA, pag.3 din Specificatie tehnica_MAC Hârtia termică să fie compatibilă si de la alți producători de hartie si dispozitiv ECG- obligatoriu DA, este indicat doar tipul de hartie.Imprimanta este una de tip termica, pag.2 din Specificatie tehnica_MAC Display: Grafic, LCD/LED color – Obligatoriu DA, pag.2 din Specificatie tehnica_MAC Funcție Touchscreen – Obligatoriu DA, pag.2 din Specificatie tehnica_MAC Monitorizarea pe display: data, ora, sensibilitate, viteza de inscriere, filtru, derivatiile obligatoriu DA, pag.2 din Specificatie tehnica_MAC Mărime ecran 5 inch DA, pag.2 din Specificatie tehnica_MAC

Posibilitatea transmiterii datelor la un sistem de management al datelor ECG. Card SD minim 5 GB Modul Wi-Fi Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vârsta, sex, greutate, înaltime Ajustarea automată a izolinei obligatoriu Comunicar cardiac Diapazon 30 -300 BPM Acuratețea ± 1BPM sau $\pm 1\%$ Interpretarea: Sistem de interpretare a datelor ECG obligatoriu Măsurări PR, QT, QTC, P, QRS, T, HR; Timpul interpretării minim 10 s Alimentarea 220 V, 50 Hz Baterie internă reîncărcabilă obligatoriu Timp operare autonomă > 4 ore Protecție defibrilator tip CF Accesorii (Nota: Modelele accesorii (coduri) sunt obligatorii a fi prezentate si ofertate de operatorul economic. Totodata operatorul economic are posibilitatea de a ajusta/completa aceste coduri/modele ca urmare a clarificărilor fără ca această ajustare să fie considerată modificare a ofertei initiale.) Cablul ECG original (de la producătorul ECG-ului) - 2 set. Electrod pectoral tip pară (set 6 buc.) - 2 set. Electrod pectoral tip pară (set 6 buc.) - 2 set. Geantă de transportare configurată pentru a permite transportul dispozitivului in siguranță - 1 buc. Termo-hârtie originala (compatibilă) - 5 set.	Numărul de derivatii afisate simultan 12 DA, pag.1 din Specificatie tehnica_MAC Posibilitatea transmiterii datelor la un sistem de management al datelor ECG.DA, pag.64 din Manual de Operare Card SD minim 5 GB DA: 200 inregistrari+ USB 5 GB Modul Wi-Fi DA, pag.128 din Manual de Operare Posibilitatea introducerii rapide a datelor pacientului Nume, ID, vârsta, sex, greutate, înaltime DA, pag. 39 din Manual de Operare Ajustarea automată a izolinei obligatoriu DA, pag.17 din Physician Guide Ritm cardiac Diapazon 30 -300 BPM DA, pag.3 din Specificatie tehnica_MAC Acuratețea $\pm 10\%$ / ± 5 BPM DA, conform IEC: EN 60601-2-25:2015, IEC 62366-1:2015, EN 62304:2006+A1:2015. Interpretarea: Sistem de interpretare a datelor ECG obligatoriu Măsurări PR, QT, QTC, P, QRS, T, HR; DA, pag. 162 din Manual de operare Timpul interpretării minim 10 s DA, pag.3 din Specificatie tehnica_MAC Alimentarea 220 V, 50 Hz DA, pag.2 din Specificatie tehnica_MAC Baterie internă reîncărcabilă obligatoriu DA, pag.2 din Specificatie tehnica_MAC Timp operare autonomă 5 ore DA, pag.2 din Specificatie tehnica_MAC Protecție defibrilator tip CF DA, pag.3 din Specificatie tehnica_MAC Accesorii (Nota: Modelele accesorii (coduri) sunt obligatorii a fi prezentate si ofertate de operatorul economic. Totodata operatorul economic are posibilitatea de a ajusta/completa aceste coduri/modele ca urmare a clarificărilor fără ca această ajustare să fie considerată modificare a ofertei initiale.)DA Cablul ECG original (de la producătorul ECG-ului) - 2 set. DA, Trunk cable 10-Lead IEC (2104722-001). Pag. 15 din Service manual

Anexa 1

	Electrod pectoral tip pară (set 6 buc.) - 2 set. DA Reusable value bulb electrode 6/set (2104783-001). Pag. 15 din Service manual Electrod pectoral tip pară (set 6 buc.) - 2 set. DA Reusable value bulb electrode 6/set (2104783-001). Pag. 15 din Service manual Geantă de transportare configurată pentru a permite transportul dispozitivului in siguranță - 1 buc. DA, cod: 27139 din Accesorii Termo-hârtie originala (compatibilă) - 5 set. DA, cod 48234000 din Accesorii



GE HealthCare

Resting ECG MAC 3

Easy. Reliable. Secure.

MAC™ 3 is built for the way you work — empowering clinicians to capture accurate ECGs quickly and precisely. Its compact, portable design lets you perform and transmit ECGs with minimal time and effort, streamlining your workflow. With an intuitive interface, accurate interpretation and secure connectivity, MAC 3 supports your ability to guide patients onto the right care pathway, right away.

Key features



Compact, portable, intuitive design: Capture and send reliable ECG data across a wide range of care settings.



Hookup Advisor™ and lead reversal detection: Help ensure proper lead connection for clean, accurate ECG acquisition.



12SL™ algorithm: Includes validated algorithms to support reliable measurements and consistent, accurate ECG interpretations.



Connected for timely care: Built-in Wi-Fi and easy integration with existing systems enable fast data sharing with care teams.



*Representative image only.

System specifications

Device physical

- Device type: Microprocessor augmented automatic electrocardiograph; 12-leadwire acquisition with programmable lead configuration.
- Height: 64 mm
- Width: 171 mm
- Depth: 294 mm
- Weight: 1.5 kg with battery installed but without paper.
- USB port: 1 USB 2.0 port supplying 0.5 amps of current.

Display

- Display: 5.0 inch (12.7 cm) diagonal graphics LED backlit.
- Touchscreen: Projected Capacitive (PCAP) multipoint touch input that works while wearing medical exam gloves.
- Resolution: 720 X 1280 pixels with scrolling waveform.
- Data:
 - Heart rate, patient ID, last name, first name, date of birth/age, date and time, battery power indicator, scrolling waveforms, lead labels, speed, gain and filter settings, warning messages, information messages, prompts, 12-leads standard display.

Printer

- Technology: Integrated thermal dot array
- Writer speed: 5, 12.5, 25 and 50 mm/s
- Number of traces: 3 leads + 1 rhythm or 3 leads; user selectable
- Sensitivity/gain: 2.5, 5, 10, 20 mm/mV and 10/5 mm/mV split gain
- Speed accuracy: $\pm 5\%$
- Amplitude accuracy: $\pm 5\%$
- Horizontal resolution: 40 dots/mm at 25 mm/s
- Vertical resolution: 8 dots/mm
- Paper type: Thermal. Z-fold perforated, 80 mm width, 280 sheets/pack

Electrical

- Power supply: AC mains or battery operation
- Input voltage: 100–240 VAC $\pm 10\%$
- Input current range: Maximum 0.6A @ 90 VAC, 0.3A @ 240 VAC
- Input frequency: 50/60 Hz ± 3 Hz

Battery

- Type: Replaceable and rechargeable internal battery.
- Charge time: Approximately 300 minutes from total discharge when device is off (standby).
- Battery capacity: 120 resting ECG recordings or 5 Hours (typical) of continuous monitoring without printing, at a minimum

Keypad

- Type: Membrane keyboard with tactile feedback

Other input device

- External USB barcode reader:
 - Symbolologies: 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

Report formats

- Thermal printer report formats:
 - 4 by 2.5s
 - 4 by 2.5s + 1 rhythm lead
 - 4 by 3s
 - 4 by 10s
 - Autorhythm (10-second ECG data for 3 leads)
 - Printing of 4 by 10s or Autorhythm for abnormal ECG
 - Continuous 3-channel rhythm
- PDF report format (A4 format):
 - 4 by 2.5s
 - 4 by 2.5s + 1 rhythm lead
 - 2 by 5s
 - 2 by 5s + 1 rhythm lead
 - 2 by 5s @ 50mm/s
 - 4 by 10s
 - Autorhythm (12-lead)

Patient information

- Supported patient information:
 - Patient ID
 - Visit number
 - Last name
 - First name
 - Date of birth
 - Gender
 - Technician ID
 - Secondary ID

ECG data processing specifications

- Storage: 200 records consisting of 10 seconds Resting ECG records on the device internal memory.
- External storage: USB-compliant flash drive supporting the FAT32 file system.
- Signal input
 - Defibrillation-proof type CF applied part.
 - Defibrillation protection: Per IEC 60601-2-25:2011.
- ECG interpretation: 12SL ECG Analysis Program for Adults and Pediatrics.
- Computerized measurements: 12-lead analysis
- ECG analysis frequency: 500 samples/second (sps)
- Digital sampling rate:
 - 2,000 samples/second/channel
 - Stored/transmitted ECG Waveform: Bandwidth: 0.01 to 150 Hz , Sample rate: 500 sps, Resolution: 4.88 μ V
- ECG on-screen preview: On-screen preview of acquired 10-second ECG waveform with 12SL measurement and optional 12SL interpretation.
- Acquisition mode: Pre-acquisition or post-acquisition, provide 10 seconds of instantaneous ECG acquisition.
- Dynamic range: AC Differential $\pm$ 5mV, DC offset $\pm$ 300 mV
- Resolution: 4.88 μ V/LSB @ 500 sps
- Frequency response: -3 dB @ 0.01 to 150 Hz
- Low cut-off frequency: 0.01 Hz, 0.02 Hz, 0.16 Hz or 0.32 Hz (-3 dB limits)
- High cut-off frequency: Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
- Adaptive AC filter: 47 Hz to 53 Hz when set to 50Hz, 57 Hz to 63 Hz when set to 60 Hz
- Common mode rejection: >100 dB (with AC filter switched on)
- Input impedance: >10M Ω @ 10 Hz, defibrillator protected
- Patient leakage: <10 μ A
- Special acquisition functions: Disconnected lead detection except RL, excessive AC noise, baseline wander and muscle tremor messages.
- Lead Reversal: Limb lead and chest lead reversal detection
- Heart rate meter: 30 to 300 BPM $\pm$ 10% or $\pm$ 5 BPM, whichever is greater. Heart rates outside this range will not be displayed.
- Start-up time: Less than 15 seconds

Environmental specifications

Operating Conditions

- Temperature: 5°C to 40°C (41°F to 104°F)
- Relative humidity (RH): 25% to 95% (non-condensing)
- Atmospheric pressure: 70 to 106kPa

Transport/storage conditions

- Temperature: -15°C to 50°C (59°F to 122°F)
- Relative humidity (RH): 25% to 95% (non-condensing)
- Atmospheric pressure: 50kPa to 106kPa

Safety specifications

- Standards complied with:
 - EN 60601-1:2006/A2:2021
 - EN 60601-1-2:2015/A1:2021
 - EN 60601-2-25: 2015
 - EN 60601-1-6:2010/A2:2021
 - EN 62366-1:2015/A1:2020
 - EN 62304:2006/A1:2015
 - EN ISO 15223-1:2016/A11:2021
- Type of protection against electrical shock: Class 1, internally powered
- Degree of protection against ingress of liquids: IP20
- 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: Defibrillation-proof type CF applied part

Network specifications

Wireless specifications

- 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
- Wireless standards:
 - 802.11a/b/g/n WLAN interfaces
 - Configured manually or via DHCP
- Authentication protocols:
 - Open
 - WPA
 - WPA2
- Authentication methods:
 - PSK
 - PEAP-MSCHAPV2
 - TTLS-MSCHAPV2

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

GSM network specifications

- GSM: Support 2G/3G/4G
- GSM bands:
Support:
 - LTE-FDD: B1/B2/B3/B4/B5/B7/B8/B12/B13/B18/B19/B20/B25/B26/B28
 - LTE-TDD: B38/B39/B40/B41
 - WCDMA: B1/B2/B4/B5/B6/B8/B19
 - GSM: B2/B3/B5/B8

Security and Privacy

- Encryption: All files containing PHI, and passwords
- Login authentication: Password
- Audit trail:
 - All login events, logouts and login failures, file deletions, file changes, file views, file acquisitions, file transmissions, file printouts, system configuration changes
- PHI access: Controlled by password-based authentication
- PHI access logs: Detailed and exportable logs of all PHI, viewing by users

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← Patient Data

♥ 99

Patient ID*

Visit number

Last name

First name

Date of birth

DD

MMM

YYYY

Gender

Male

Female

Technician ID

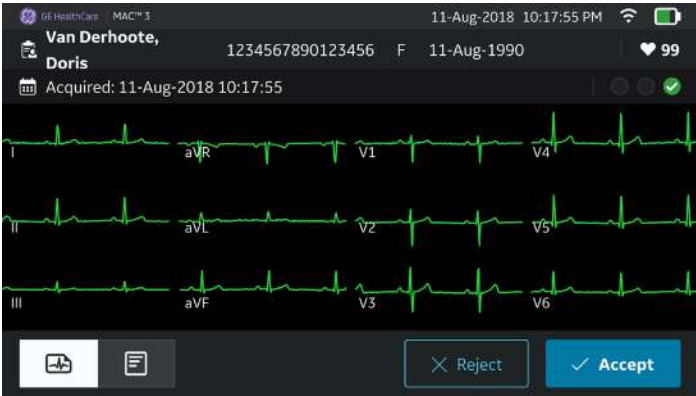
Order number

Location ID

Secondary ID

Save

Default patient entry screen (full-page view).



Example of ECG waveform preview.



Access SIM card and battery compartment.

¹Marquette 12SL ECG Analysis Program Physician's Guide DOC 2056246-007.

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MAC 3
DOC3185080



GE HealthCare

MAC[™] 3 Resting ECG Analysis System

Operator's Manual

Software Version 1.01



5918475-01
Revision 2
US English

General User Documentation

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Publication information

This document describes version 1.01 of the MAC™ 3 Resting ECG Analysis System, also referred to as the “product” or “system” or “device”. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this document are subject to change without notice.

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



Date of first CE mark - 2025.

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	23 June 2025	Initial release
2	19 November 2025	Updated content for Software V1.01

To access other GE HealthCare Diagnostic Cardiology documents, go to <https://www.gehealthcare.com/support/manuals>, search with product information or click **Browse by product** to filter the manuals by **Select Modality** list and **Select Product** list, and click **Apply**.

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

This document describes the MAC™ 3 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™ 3 Resting ECG Analysis system.

Installation should be performed by a qualified personnel.

The MAC™ 3 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 Emerge U Learning website <https://gehealthcare.sumtotal.host/rcore/c/dash/home/Home2?isDeepLink=1>.

For more self-paced course offerings, tools, and reference guides you may find useful, please visit the GE HealthCare Education at <https://www.gehealthcare.com/education>.

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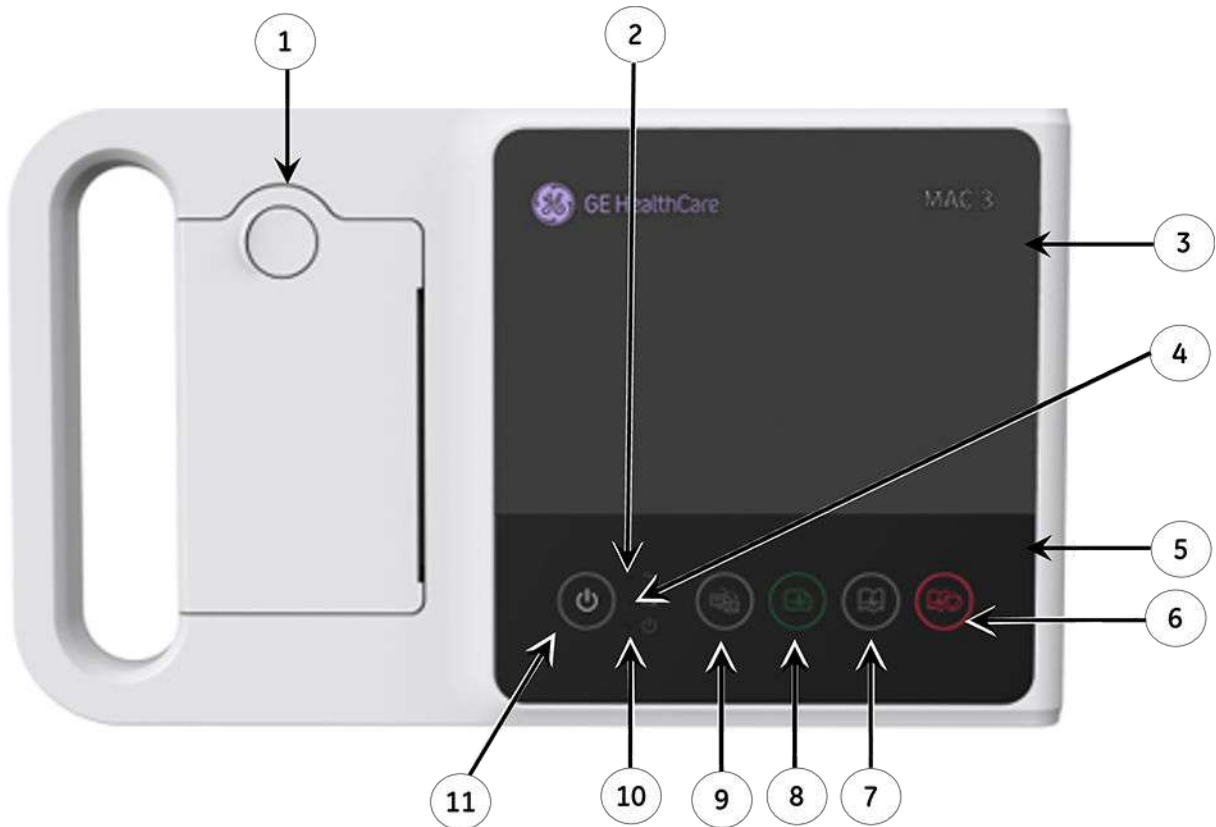
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1 Product overview

The MAC 3 Resting ECG Analysis System (referred to as "the device") is intended to acquire, analyze, display, and record electrocardiograph information for adult and pediatric populations. The basic system provides 3 or 12 lead ECGs and interpretive analysis. The transmission and receive of ECG and other clinical data, to and from, a central clinical information system is optional.

1.1 Front view

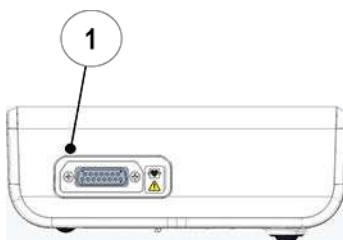


Item	Name	Description
1	Printer	Prints ECG reports.
2	AC Power LED	Shows if the device is on or off. - Green light - ON - external power connected. - No light - OFF - no external power.
3	Display	Displays waveform and text data. The touchscreen enables you to operate directly with the device through touch or tap.
4	Battery LED	Shows the battery status: - Amber light ON - battery charging. - Amber light blinking - battery low. - No light - battery is fully charged, not installed, or discharging.

Continues on the next page

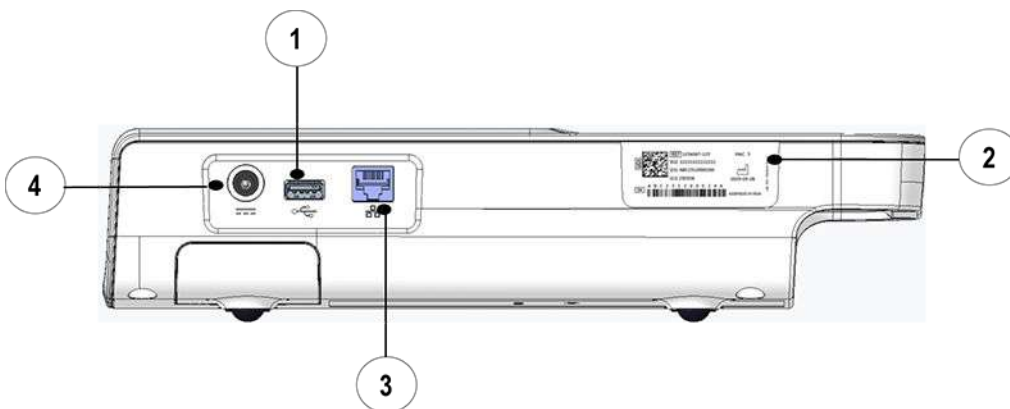
Item	Name	Description
5	Keysheet	Use the keysheet to: • Power on or off the device. • Start or stop the ECG acquisition. • Start or stop the rhythm record. • Start or stop to print the reports.
6	Stop print	Press this button to stop to print the ECG reports.
7	Start rhythm	Press this button to start the rhythm record.
8	Start ECG	Press this button to start the ECG acquisition.
9	Lead button	Press this button to configure the leads.
10	Power on LED	AC power status: • Green light - the device is plugged in and receiving power. • No light - the device is not plugged into AC power.
11	Power button	Turns the device on or off.

1.2 Side view



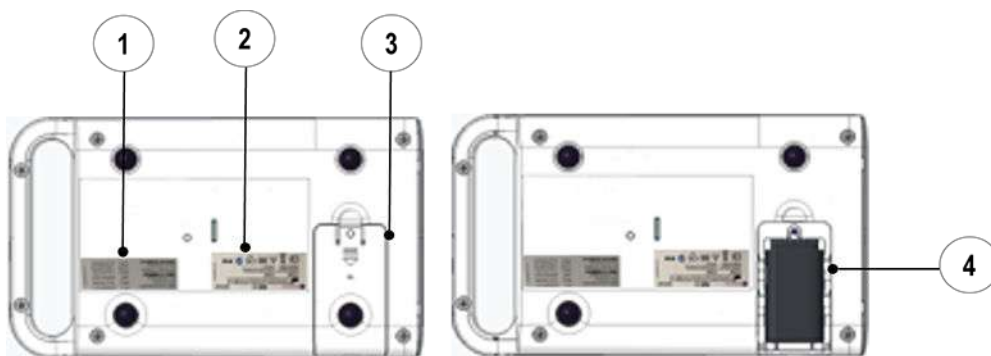
Item	Name	Description
1	Patient cable connector	Connect the patient cable to the device to acquire the ECG.

1.3 Rear view

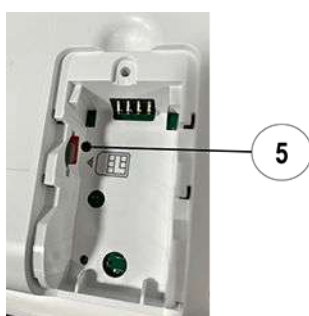


Item	Name	Description
1	USB port	Connect a USB flash drive or USB cable. You can connect a USB flash drive for a software update, backup/restore or export operations, or a barcode reader USB cable.
2	Serial number and UDI label	Shows the serial number and UDI label. For more information on the label details, see H.20 Serial number label on page 207 .
3	Ethernet/LAN port	Connect an Ethernet cable for LAN network connection.
4	AC/DC power inlet	Connect a GE HealthCare specified AC/DC power adapter.

1.4 Bottom view



Item	Name	Description
1	Serial number and UDI label	Shows the serial number and UDI label of the device. For more information on the serial number label details, see H.20 Serial number label on page 207 .
2	Product label	Shows the product label of the device. For more information on the device product label details, see H.21 Product label on page 208 .
3	Battery compartment	Holds the rechargeable Lithium-ion battery.
4	Battery	Rechargeable Lithium-ion battery.



Item	Name	Description
5	GSM SIM slot	Insert the SIM card to connect the device to the mobile network.

1.5 Acquisition screen overview



Table 1-1 Acquisition screen

Item	Name	Description
1	Patient information banner	Displays patient information such as the patient first name, surname, and gender. Select Tap to enter patient info 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 7.9 Configure the clock and language on page 136 .
3	Network status icon	Displays the wireless, LAN, or GSM (Cellular) connection status, see 7.8.5 Show network connection status on page 134 .
4	Battery or AC power icon	Displays the battery status.
5	Heart rate icon	Shows the real-time beats per minute (BPM). The shown heart rate updates whenever the heart rate calculation algorithm reports a change in the heart rate. The heart rate is not shown if it drops below 30 bpm, increases above 300 bpm, or the system is not getting ECG data. In cases where the heart rate is not shown, the symbols show instead of the heart rate:  .
6	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.
7	Settings icon	You can use this to configure the settings of the device, see 7.2 Settings screen overview on page 70 .
8	File manager icon	You can use this to view the stored files, see 6 Manage files on page 57 .

Continues on the next page

Table 1-1 Acquisition screen (Table continued)

Item	Name	Description
9	Gain	Displays the gain. You can select the gain from the drop-down list.  NOTE Any change to the test type and gain only applies to the current patient. For a new patient, the values are reset to the default settings.
10	Speed	Displays the speed of the lead. You can select the speed of the lead from the drop-down list.  NOTE Any change to the speed only applies to the current patient. For a new patient, the values are reset to the default settings.
11	Filter	Displays the filter. You can select the filters from the drop-down list.  NOTE Any change to the filter only applies to the current patient. For a new patient, the values are reset to the default settings.
12	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 hookup advisor is evaluating the waveform.

2 Equipment setup

2.1 Connect GSM (cellular network)

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [3.2 Power off the device on page 22](#).
- Disconnect the AC power cord from the device.

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 or LAN network, you can use a cellular network.



NOTE

This applies only if you use the device as a mobile device.

To connect to a cellular network:

1. Turn the device to view the bottom side.
2. Carefully lift the notch and move the battery cover in the direction shown on the cover to release from the battery compartment.



3. Remove the battery cover.



4. Remove the battery.
5. Put the SIM card in the slot in the direction to align to the SIM symbol on the battery compartment.



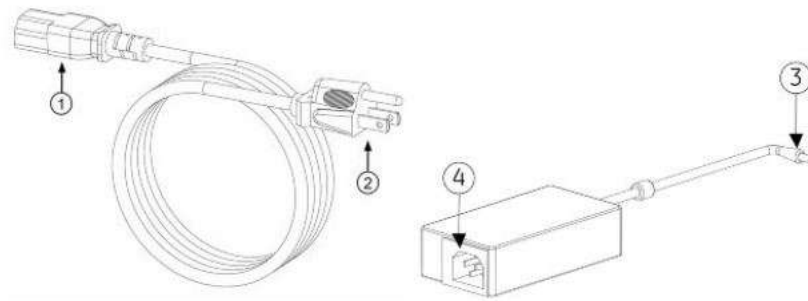
6. Configure the device to connect to a cellular network. See [7.8.4 Configure the GSM network on page 133](#).

2.2 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 you are not sure on the condition of the protective ground conductor, operate the unit from its battery.

**NOTE**

Unplug the AC power cord (Item 2) to disconnect the MAC 3 device from the AC outlet.

Table 2-1 Power cord parts

Item	Description
1	Female end of the AC power cord connected to the back of the AC/DC adapter.
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 device label. If does not match, do not connect the system to the power line until you adjust the power source to match the device 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.  **NOTE**
It is recommended that you connect the device into an uninterruptible power supply (UPS) or a surge suppressor.
Plug the male end of the power cord (2) into an AC outlet.
4. Check the AC Power LED. If the AC Power LED is green, the device is receiving power from the AC outlet.

2.3 Connect the external barcode reader

If you purchase the optional barcode reader with the device, connect it to the USB port on the device. Make sure that you enable the **USB** settings in **Settings > System > Hardware** screen.

-  **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.



Connect the barcode reader cable to the USB port of the device.



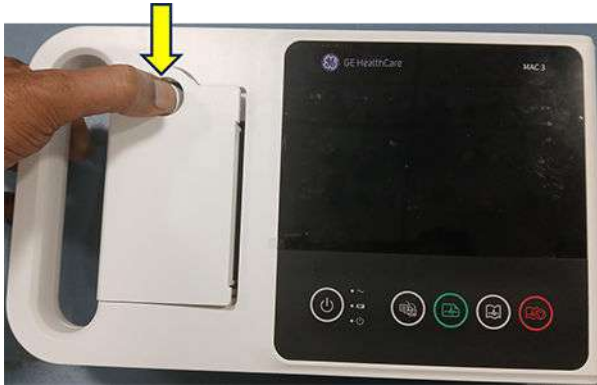
2.4 Insert the paper

Before you start this procedure, make sure that you:

- Power off the device. For more information on how to power off the device, see [3.2 Power off the device on page 22](#).
- Put the device on a flat surface.
- Use the Z-fold paper.

To insert the paper:

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



2. Pull the paper lifting tape and place the paper above it, but do not remove the paper lifting tape from the device. Then slide the paper into the device until it is fully inserted.

**NOTE**

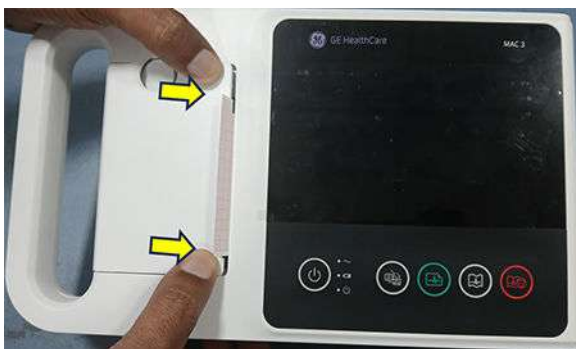
If the paper has Q marks, the Q marks must be on the top left side.



3. Advance the first sheet of paper.



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



2.5 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.



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.

To connect to a wired network:

- 1.



NOTE

GE HealthCare recommends that you connect the device into a LAN port with a LAN cable. The LAN cable must be less than 3 m.

Connect an Ethernet cable to the RJ45 port on the back side of the device.



2. Configure the device to connect to a wired network. See [7.8.3 Configure Ethernet network on page 131](#).

2.6 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 [7.6.3.2 Export settings to USB on page 95](#) and [7.6.3.1 Import settings from USB on page 93](#).

2.7 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:

1. Record and print a resting ECG.
2. Print a patient report. See [6.5 Print a patient report on page 63](#).
3. Transmit a patient report. See [6.6 Transmit a patient report to a configured destination on page 64](#).
4. Delete a patient report. See [6.7 Delete a patient report on page 65](#).

3 Login and security

3.1 Power on the 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.

**NOTE**

If you use the device for the first time, the activation screen displays. You must complete the self registration before you log in. For more information on how to do the self registration, see *MAC™ 3 Service Manual*.

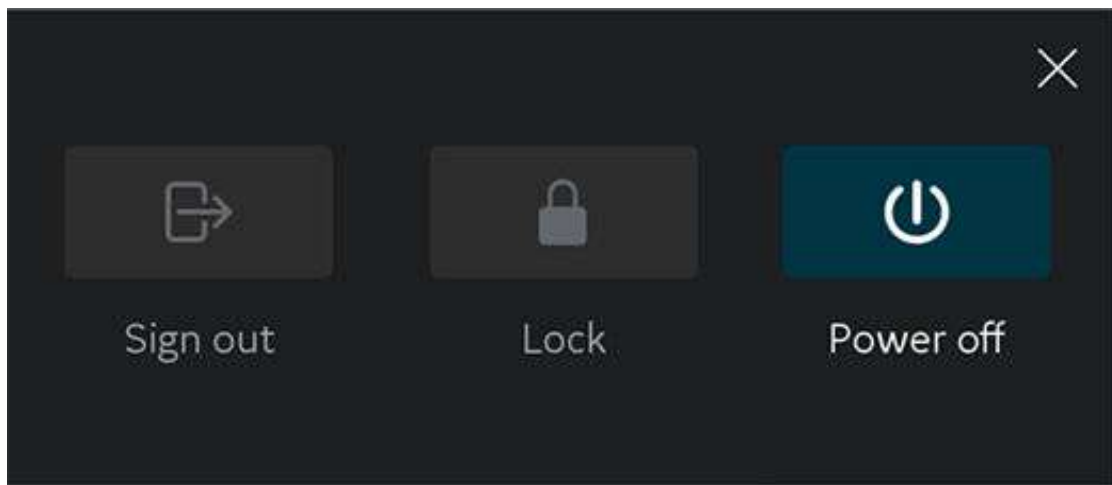
A notification message displays, if it is configured by the administrator.

2. Select **Accept**.
 - If you enable the **Device password**, you need to log on to the device.
 - If you disable the **Device password**, you can automatically logged on to the device.

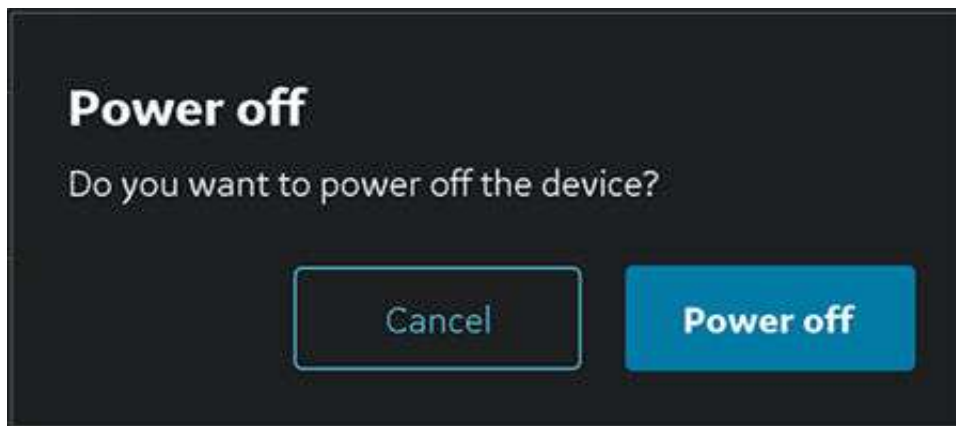
3.2 Power off the device

1. Before you power off the device, complete pending tasks, for example, acquire an ECG and save configuration settings.
2. Press the **Power** button on the front panel for a few seconds.

The **Power Options** display with **Sign out**, **Lock**, and **Power off** options.



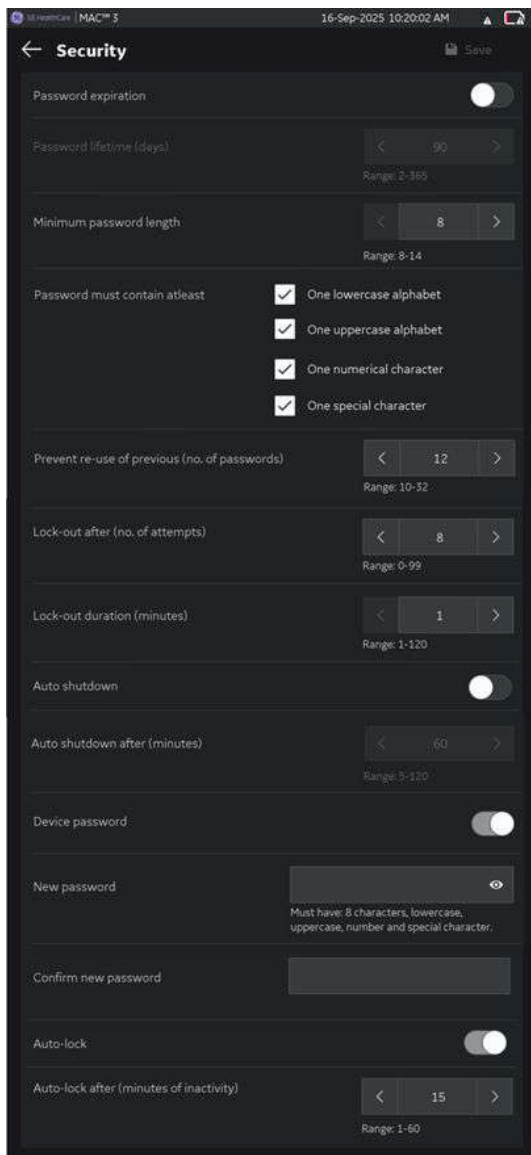
3. Select **Power off**.
The **Power off** confirmation displays.



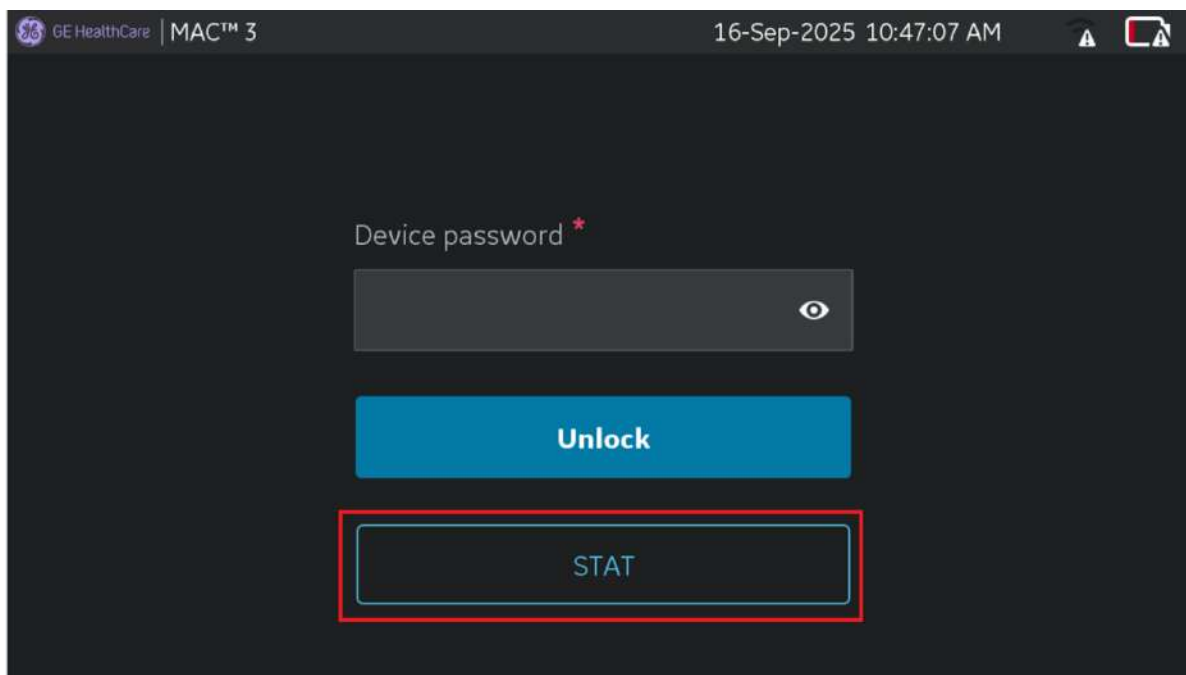
4. Select **Power off** to power off the device.
The device is off. The **Power on** LED on the front panel is off.
If you select **Cancel** the device does not power off.

3.3 Enter the device in STAT mode

If, you enable the **Device password** setting in **Settings > System > Security** screen. A STAT user can log on to the device to get a patient ECG in an emergency.

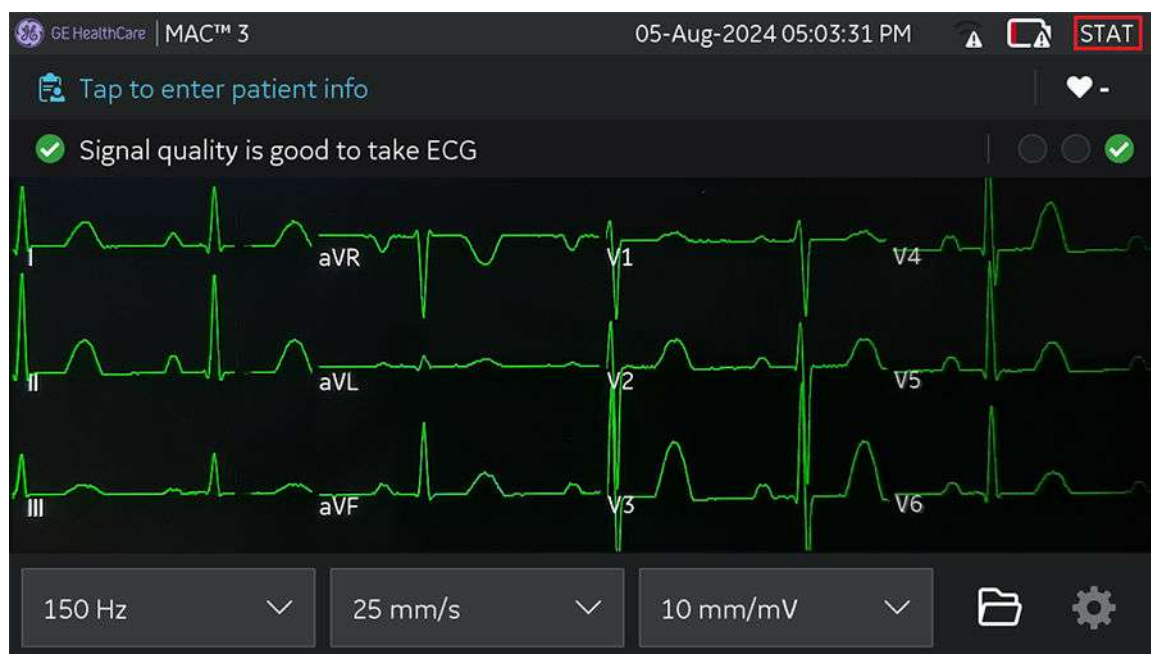


1. Press the **Power** button on the front panel for a few seconds to start the device.
The device is powered on. The **Power on** LED on the front panel is green. The login screen displays.



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

The **Acquisition** screen displays with **STAT** user.



You can do the below tasks in STAT mode:

- Enter patient information and acquire an ECG.
- If, you set the **Auto ECG Storage** to **All ECGs/Only abnormal ECG**, you can store the ECGs to file manager.
- Change the report format of the ECG in review screen, file manager, and retro review screen.
- Print the ECG report.
- Change the **Filter**, **Speed** and **Gain** in the Acquisition screen.

- Change the **Speed** and **Gain** in the review screen, file manager, and retro review screen.
- Enable/disable **Auto shift** and **Auto gain** in the review screen, file manager, and retro review screen.

You cannot do the below tasks in STAT mode:

- Configure the settings.
- Review the reports acquired in **Admin** user mode.
- Transmit the ECG reports.
- Export the ECG reports to USB flash drive.
- Delete the ECG reports.

3.4 Log on to the device

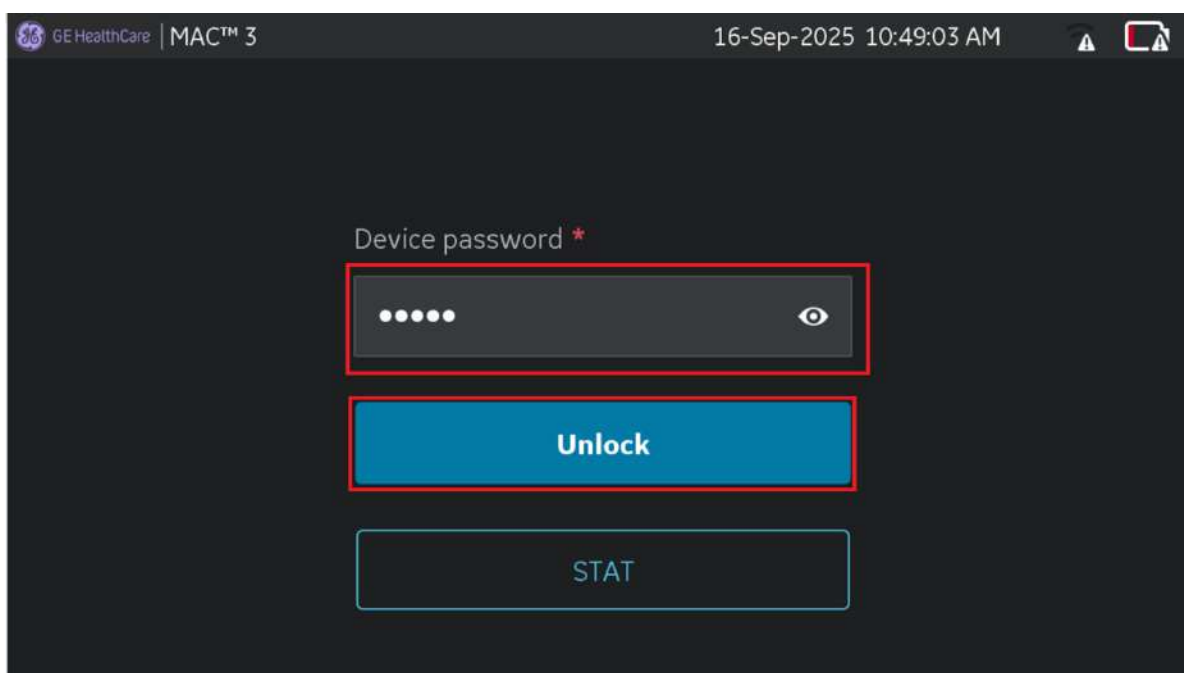
Make sure that you enable the **Device password** setting in **Settings > System > Security** screen. Enter the device password on the **Login** screen to enable user authentication to allow users to log on to the device.

Table 3-1 Types of device password

Type of password	Description
Device password	You can configure the device password in Security screen.
Admin password	You can change the default Admin password.

1. Do one of these steps:
 - If the device is shutdown, power on the device. See [3.1 Power on the device on page 22](#).
 - If the device is locked, unlock the device. See [3.7 Unlock the device on page 32](#).

The **Login** screen displays.



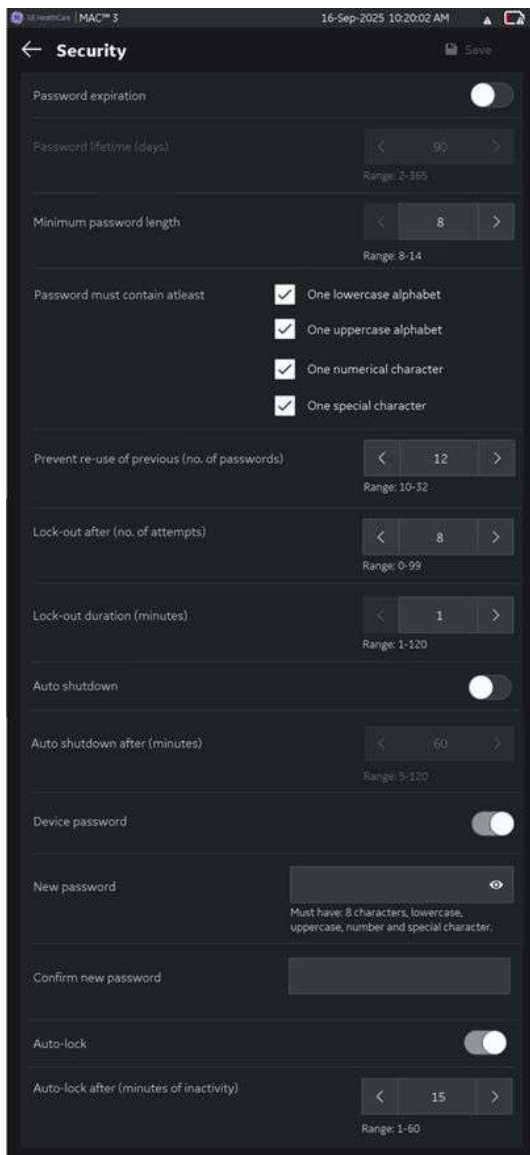
2. Enter the password.
 - To verify that you entered the correct password, select  icon to view the password.
 - Change the password immediately for security reasons.
 - If you are the Admin user and forgot your password, perform a system reset to reset the password to the default password. For more information, see [3.9 Perform system reset on page 36](#).
3. Select **Unlock**.
 - If the login credentials are correct, you are successfully logged on to the device.
 - If your login fails, see the table below:

Table 3-2 Login errors

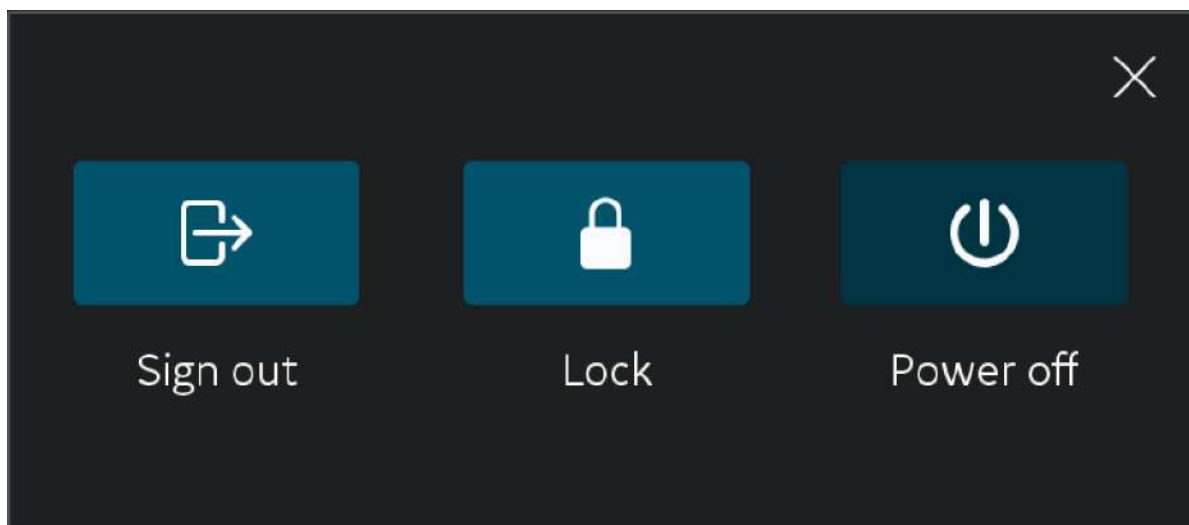
Error message	Cause	How to troubleshoot
Incorrect password	You entered your password incorrectly.	Re-enter your correct password again.
	You forgot your password.	Reset your password, then log on to the device again.
Change your password	Your password has expired.	Perform the procedure 3.8 Change the password on page 33 and log on to the device again.

3.5 Log out of the device

Log out of your user session when you complete to use the device. Make sure that you enable the **Device password** setting in **Settings > System > Security** screen.

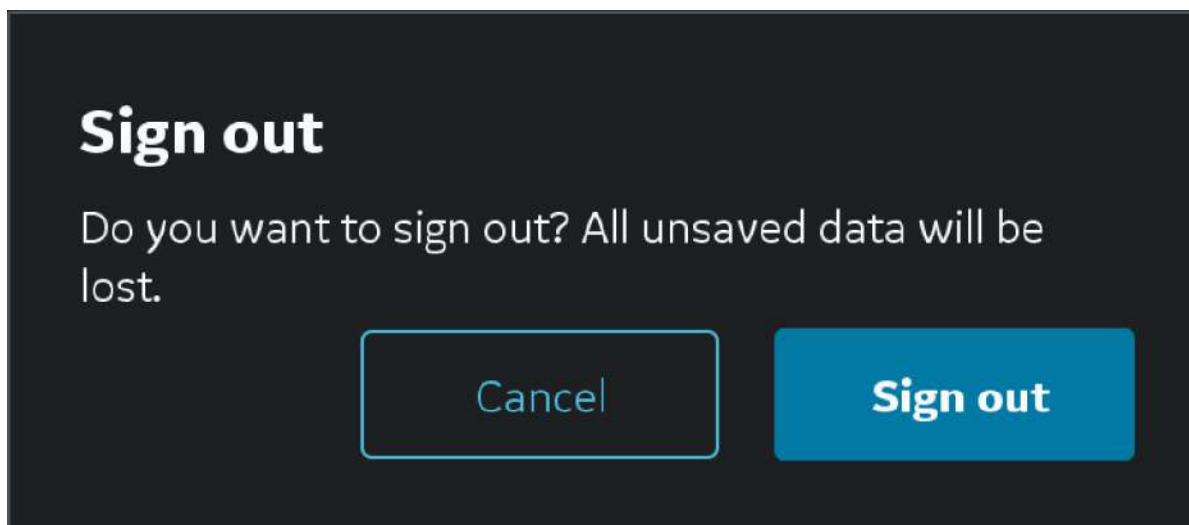


1. Complete pending tasks, for example, acquire an ECG or save the configuration settings, before you log off from your user session.
2. Press the **Power** button on the front panel for a few seconds.
The **Power options** display with **Sign out**, **Lock**, and **Power off** options enabled.



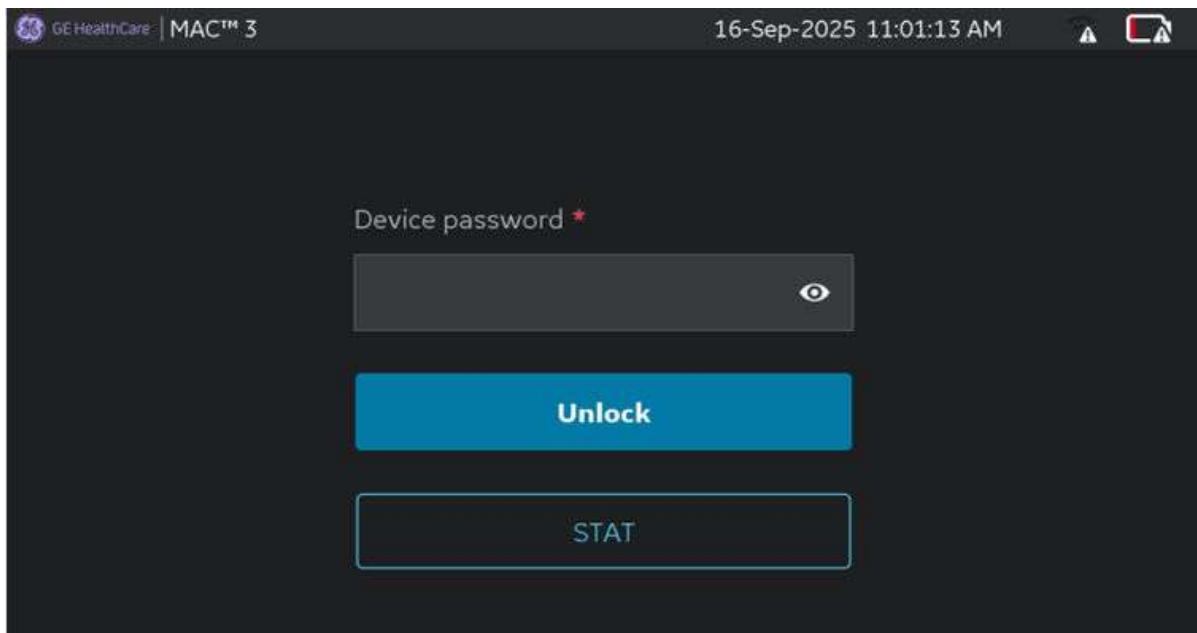
3. Select **Sign out**.

The **Sign out** confirmation displays.



4. Select **Sign out** to log out the device.

You will be logged out from your user session and displays the login screen.

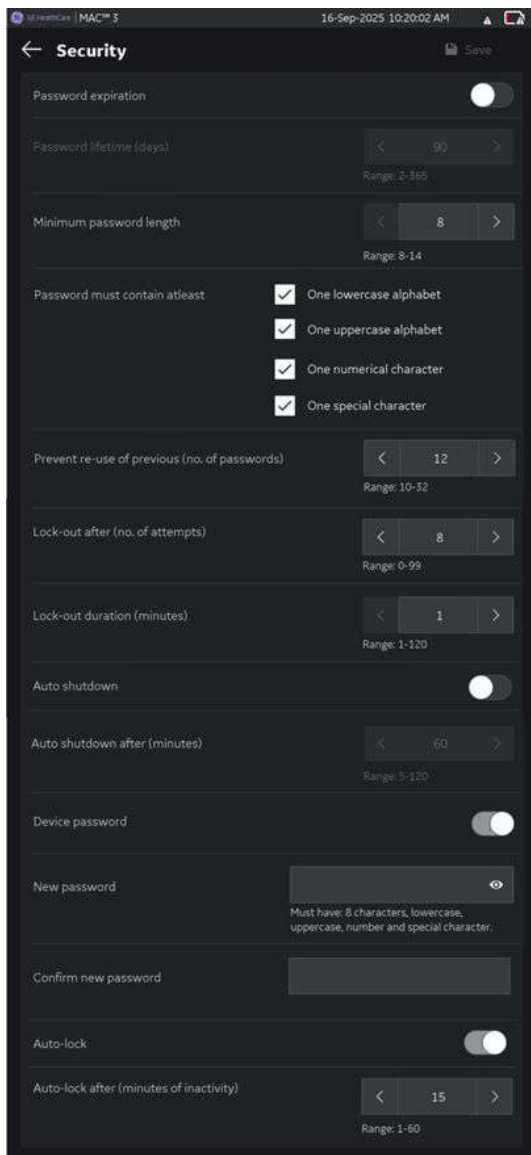


If you select **Cancel** the device does not sign out.

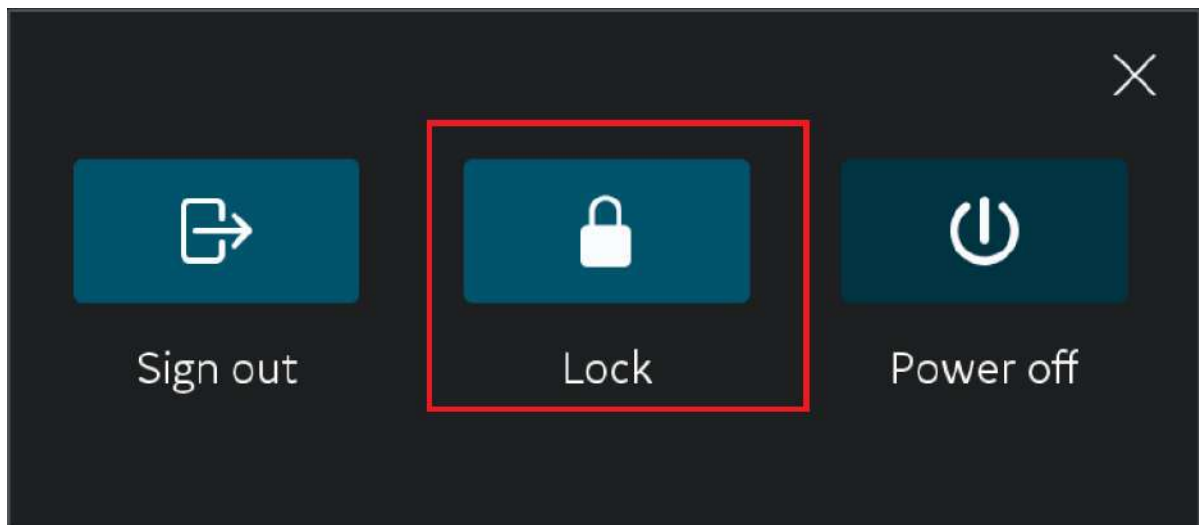
3.6 Lock the device

You cannot lock the device while the ECG or rhythm acquisition, or report print, transmission, deletion, saving of files, and export is in progress.

Make sure that you enable the **Device password** setting in **Settings > System > Security** screen.

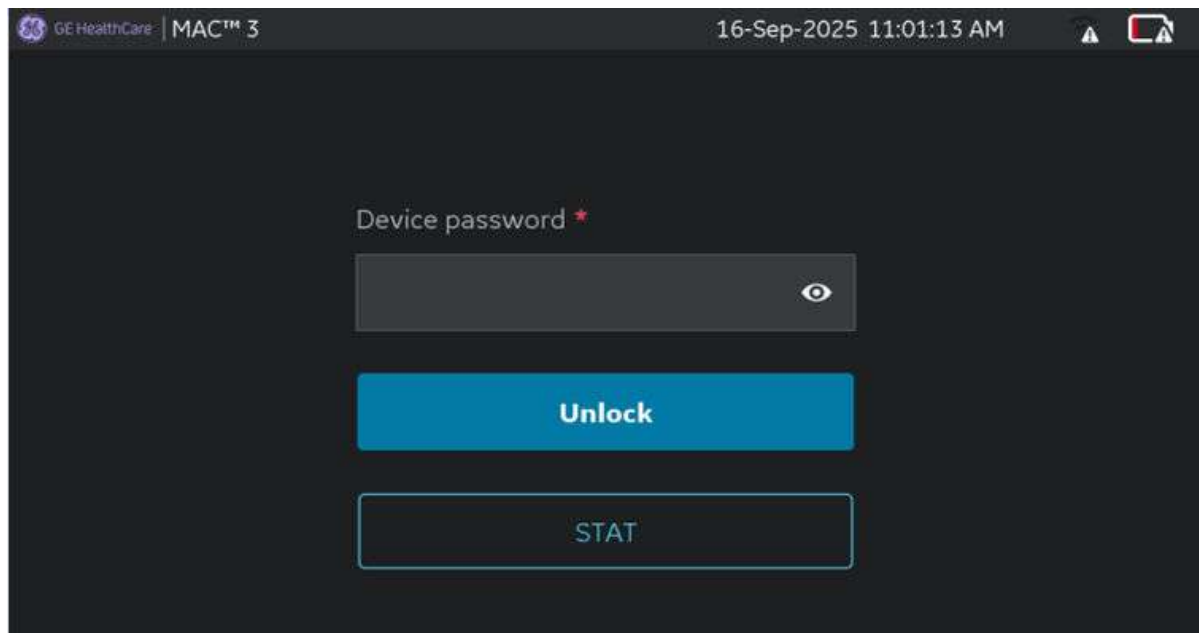


1. Complete your tasks.
2. Press the **Power** button on the front panel for a few seconds.
The **Power options** display with **Sign out**, **Lock**, and **Power off** options enabled.



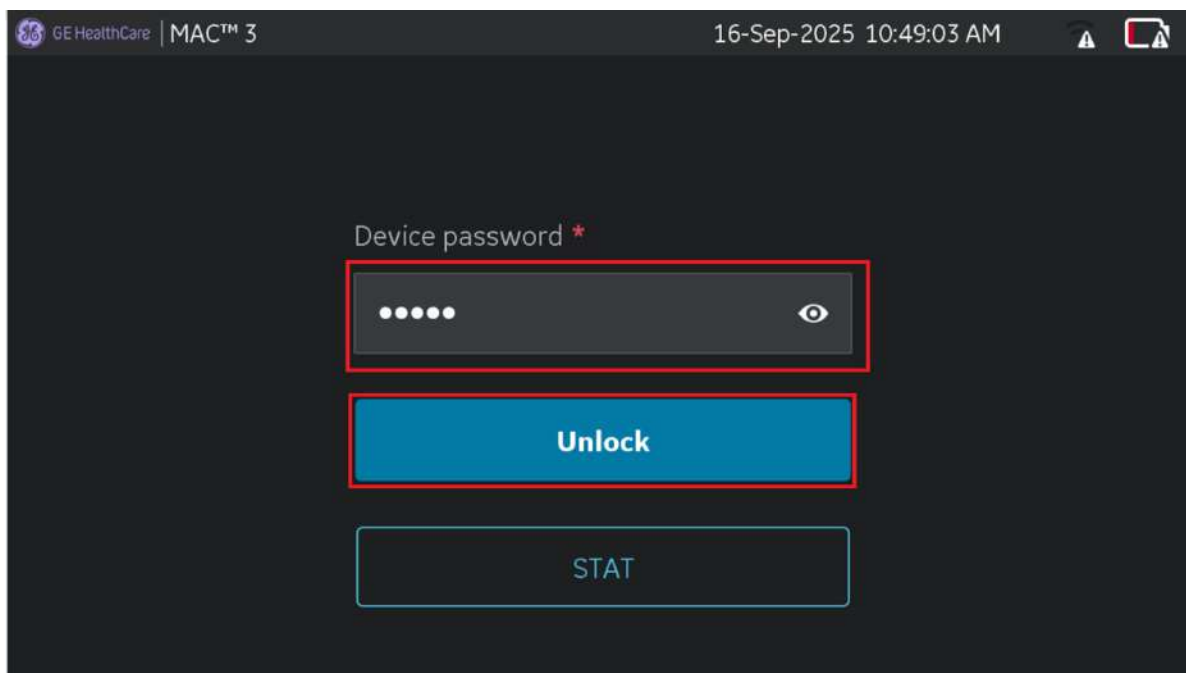
3. Select **Lock**.

The device is locked and the login screen displays.



3.7 Unlock the device

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



2. Enter the password.

3. Select **Unlock**.

If the login credentials are correct, you are successfully logged on to the device.

3.8 Change the password

This procedure applies to change the **Device password** and **Admin password**.

Make sure that the new password follows the password recommendations:

Password must contain at least 8 characters:

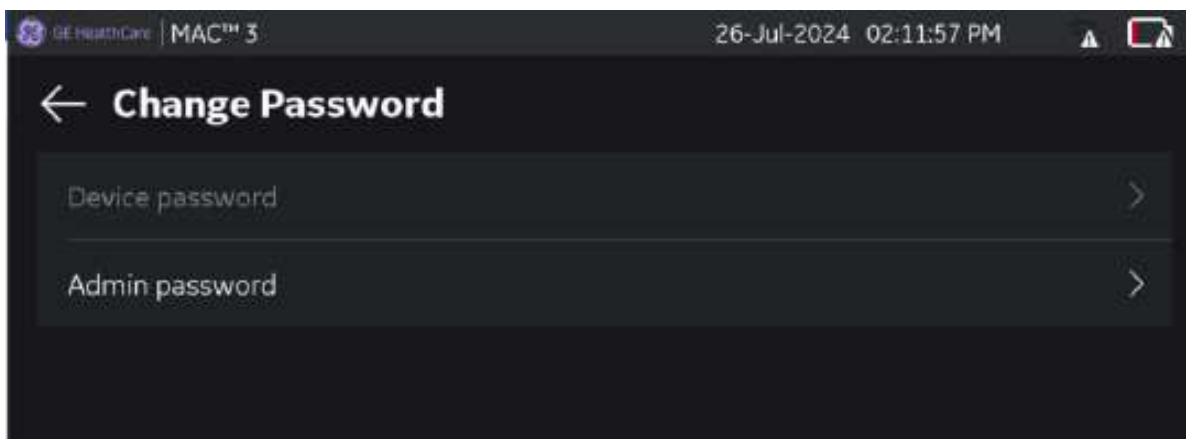
- One lowercase letter
- One uppercase letter
- One number
- One special character

3.8.1 Device password

You can change the device password from **Change Password** screen.

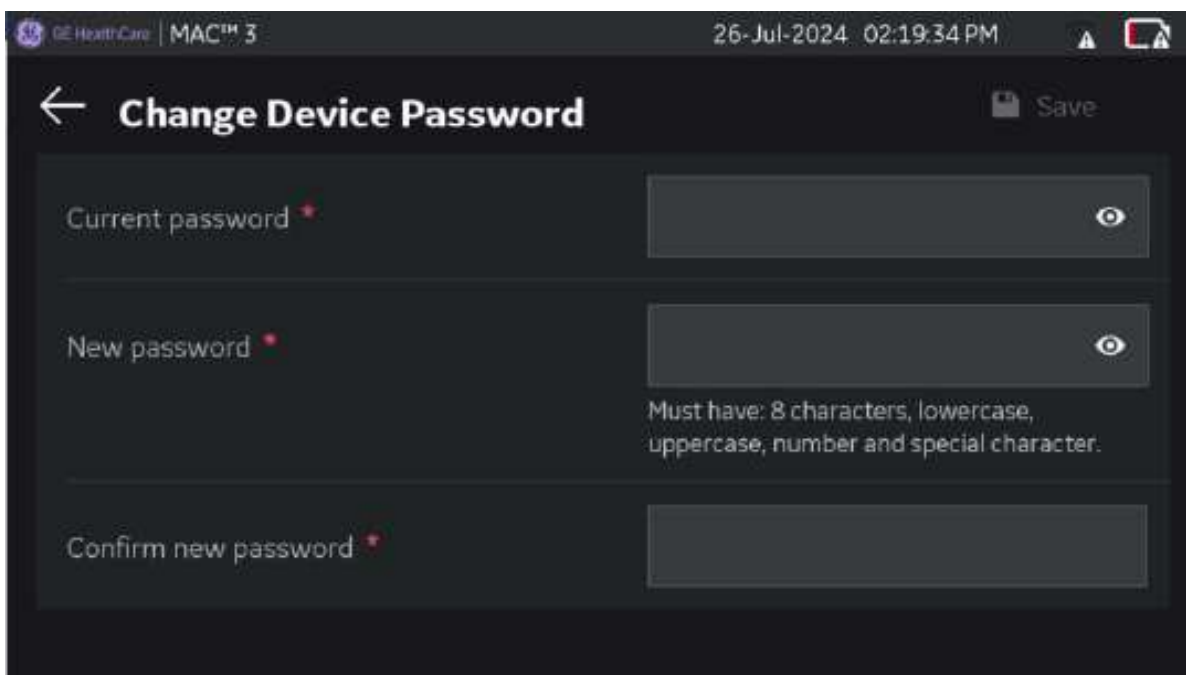
1. Select **Settings > System > Change Password**.

The **Change Password** screen displays.



2. Select **Device password** from the **Change Password** screen.

The **Change Device Password** screen displays.



3. Configure the fields as per the information in the table to change the device password.

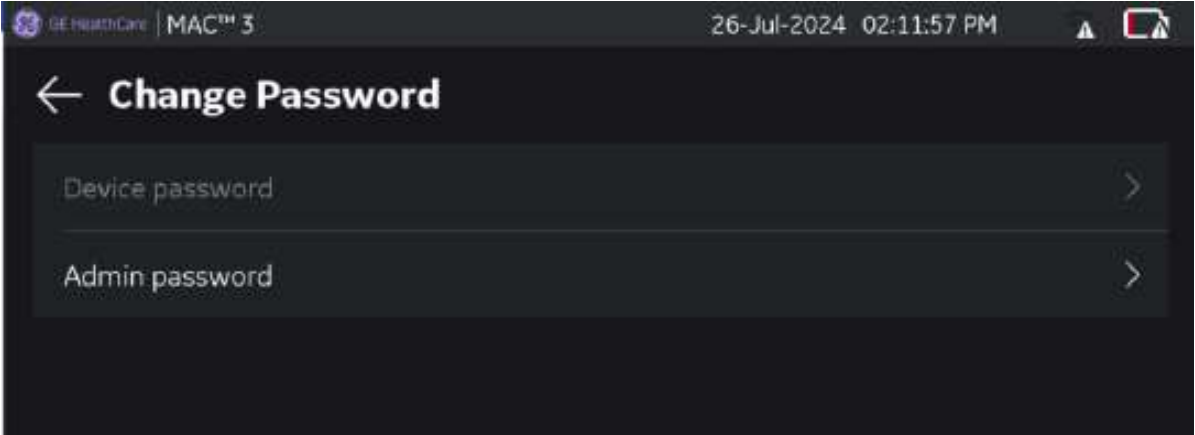
Table 3-3 Device password settings

Field	Action	Description
Current password	Enter current password.	Enter the current or expired device password.
New password	Enter new password.	The new password must contain at least 8 characters: • One lowercase letter • One uppercase letter • One number • One special character
Confirm new password	Enter the same new password.	Make sure that you enter the same new password to confirm.

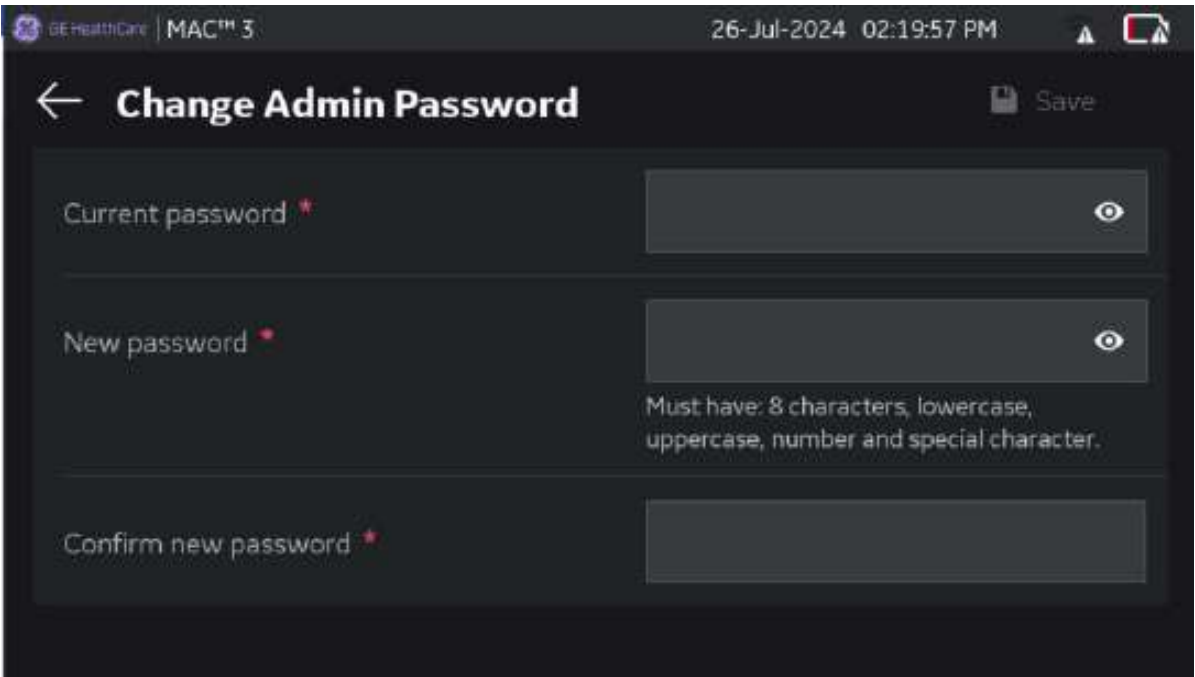
4. Select **Save**.

3.8.2 Admin password

1. Select **Settings > System > Change password**.
The **Change Password** screen displays.



2. Select **Admin Password** from the **Change password** screen.
The **Change Admin Password** screen displays.



3. Configure the fields as per the information in the table to change the Admin password.

Table 3-4 Admin password settings

Field	Action	Description
Current password	Enter current password.	Enter the current or expired Admin password.

Continues on the next page

Table 3-4 Admin password settings (Table continued)

Field	Action	Description
New password	Enter new password.	The new password must contain at least 8 characters: • One lowercase letter • One uppercase letter • One number • One special character
Confirm new password	Enter the same new password.	Make sure that you enter the same new password to confirm.

4. Select **Save**.

3.9 Perform system reset

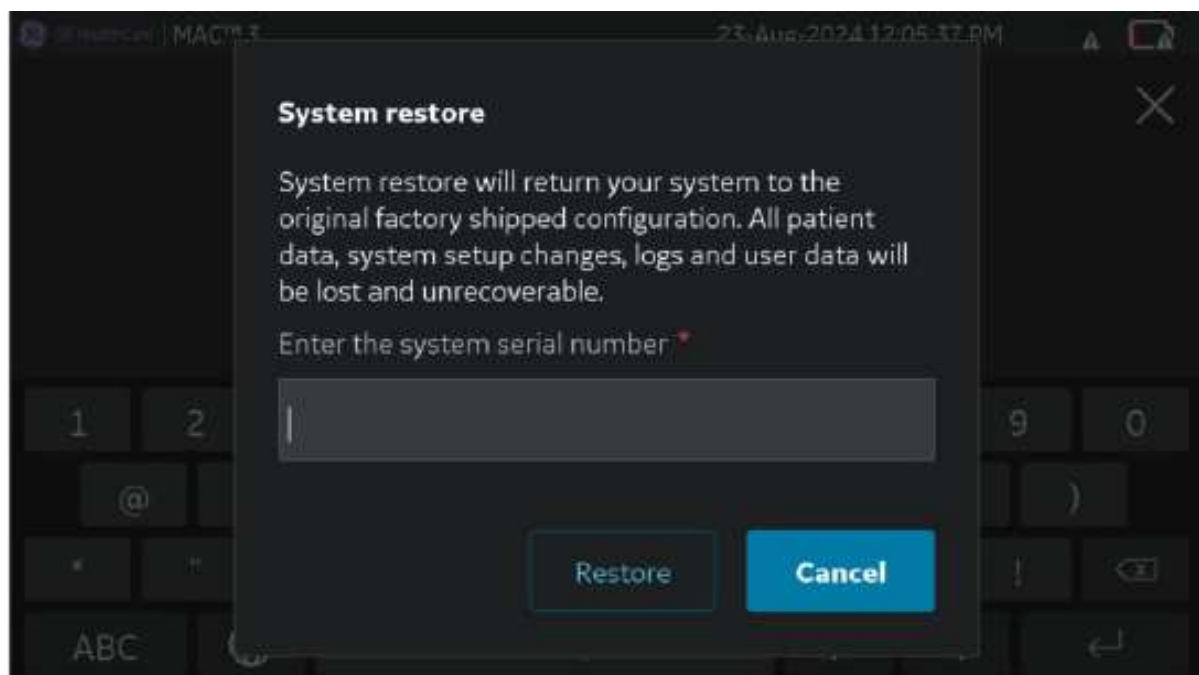
Before you start this procedure, make sure that:

- You have the serial number of the device.
- You connect the device to AC Power.
- Backup all the settings and data to USB flash drive.

Perform the below steps to reset the system to default settings, if you do not know the password.

1. When the **Login** screen opens, please contact the GE HealthCare Support team for assistance with system restore.

The **System restore** confirmation screen displays.



2. Enter the device serial number in the **Enter the system serial number** field.
The **Restore** button is enabled after you enter the correct serial number.
3. Select **Restore** to proceed with system restore.

The device restarts and set to factory default settings, all the patient data records and device certificate are deleted. You can access the device with **Admin** user credentials.

4. Select **Cancel** to cancel the system reset and continue to use the device with existed settings.

4 Patient information screen overview

The patient data helps you to identify the patient. You can view and make sure that the patient data is correct before you start an ECG.

You can update the patient information on the **Patient Data** screen.

- Read a patient barcode with a barcode scanner.
- Use a software keyboard to enter **Patient Data**.
- Do an Admission, Discharge, Transfer (ADT) query.

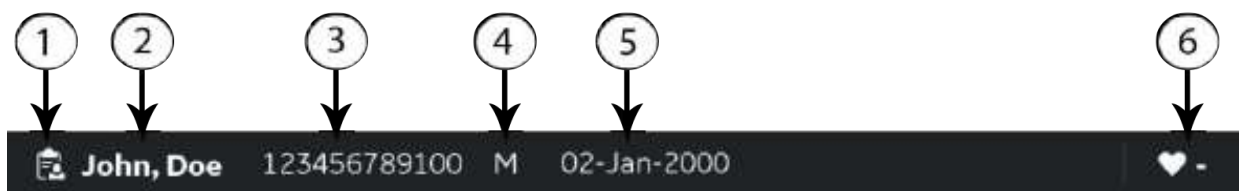
WARNING



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, you can find the patient information banner above the **Hookup Advisor** panel and shows the minimum patient information.



Item	Field	Description
1	Tap to enter patient info	Tap this option to open the Patient Data screen and to view the patient information.
2	Name	Shows the last name and first name of the patient.
3	Patient ID	Shows the unique identification number of the patient (patient ID).
4	Gender	Shows the patient gender.
5	DOB / (Age)	Shows the patient date of birth or age. If you enable the DOB in the Patient Data screen, only DOB shows on the bar. If you enable the Age in the Patient Data screen, only Age shows on the bar.
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, hyphen (-) symbol show instead of the heart rate.

Select the  icon or **Patient Information** banner to open the **Patient Data** screen. The fields set by your administrator display in the **Patient Data** screen.

GE Healthcare | MAC™ 3

17-Sep-2025 10:19:01 AM

← Patient Data

♥ -

Patient ID

Visit number

Last name

First name

Date of birth

DD

-

MMM

▼

-

YYYY

Gender

Male

Female

Technician ID

Acquiring Tech User

Location ID

Secondary ID

1

2

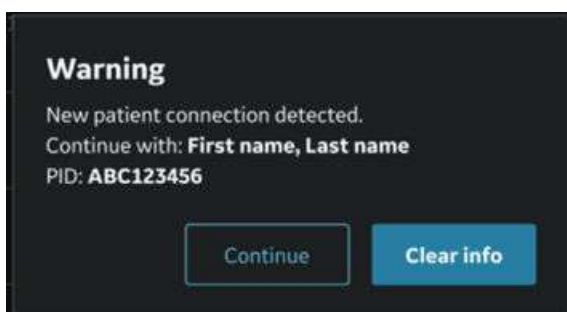
Save

Item	Field	Description
1	Patient Data	Enter the patient data, such as patient first name, last name, gender, age, and other information.
2	Save	Select Save to save the patient information.

If you cannot view the bottom fields of the **Patient Data** screen fully, scroll up through the screen. For information on updating data in the **Patient Data** screen, see [4.1.3 Use software keyboard to enter or edit patient data on page 43](#).

When patient details are entered (Patient ID/Secondary ID/Last Name/First Name/DOB/Age/Gender/Visit Number) and you connect lead wires to a patient after being disconnected for at least 30 seconds, a **New patient connection detected** warning message opens.

This occurs in the live waveform, patient data, preview, and review screens.



Select **Continue** if the patient information is correct.

Select **Clear info** if you need to start a new test with a new patient.

4.1 Enter patient data

Use a software keyboard to enter or update patient data in the **Patient Data** screen, see [4.1.3 Use software keyboard to enter or edit patient data on page 43](#).

4.1.1 Update patient data with a barcode reader

Use a barcode reader to easily enter and decrease the risks of errors while you enter the patient information. When you scan a patient ID with barcode reader, the device queries for the ADT data for patient demographics. You can then verify and modify the patient information.

You can scan a patient barcode with 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, see [2.3 Connect the external barcode reader on page 17](#).
 - The barcode symbology length aligns with the length of patient ID configured in the settings.
 - Perform the barcode reader diagnostic test to confirm the device is correctly configured to use the peripheral, see the *MAC™ 3 Service Manual*.
 - You are in the **Patient Data** screen.
 - You configure the DCP server in **Network** settings, see [7.7.2.1 Configure a DCP server on page 107](#).
 - An error message displays if you scan a barcode while you acquire the resting ECG or rhythm ECG for the patient.
1. Scan the patient barcode to populate the **Patient Data** screen.
Hold the button and put the barcode reader 10 cm to 15 cm (4 inches to 6 inches) above the barcode to scan.

The barcode scans automatically.



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

2. A message displays, if there is a mismatch between the scanned data from the barcode and existing patient data. Do one of the below steps:
 - a. Select **Use Scanned Data** to populate the barcode data into the relevant fields on the **Patient Data** screen, and confirm the data entered from the barcode is accurate.
 - b. Select **Use Current Data** to retain the manually entered information on the **Patient Data** screen, and enter or modify patient information as necessary.

4.1.2 Query ADT for patient demographics

Make sure that:

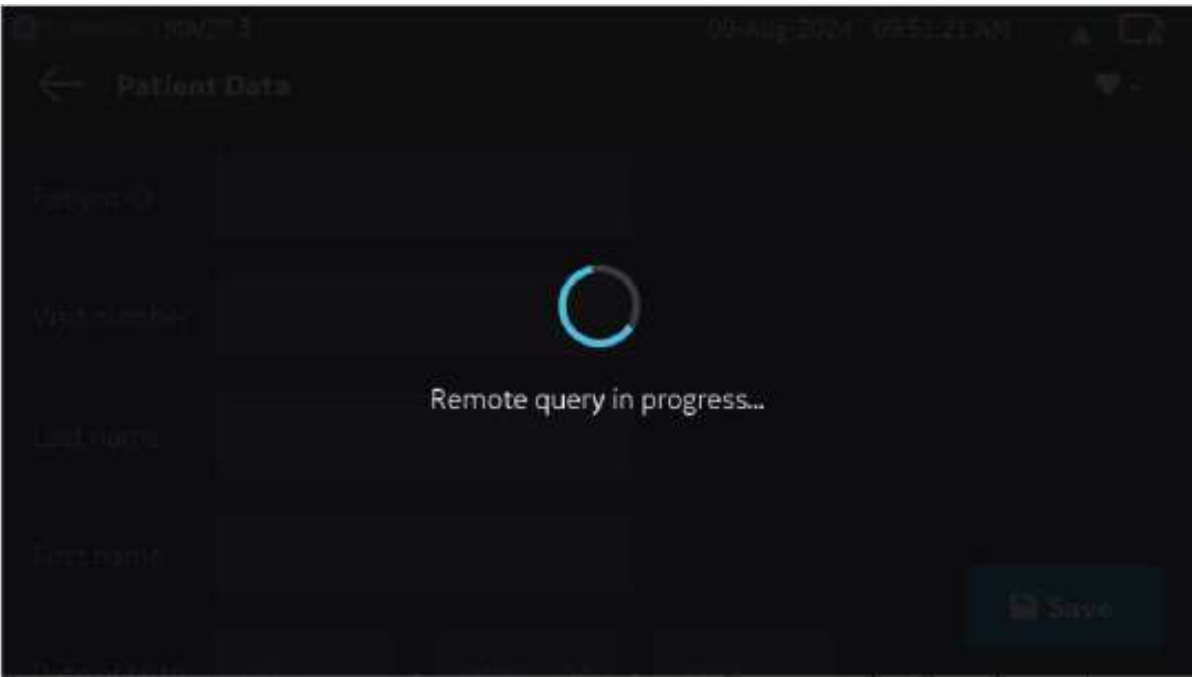
- Use ADT data to do remote patient query.
- You connect the barcode reader to the device, see [2.3 Connect the external barcode reader on page 17](#).
- Perform the barcode reader diagnostic test to confirm the device is correctly configured to use the peripheral, see the *MAC™ 3 Service Manual*.
- You configure the DCP server in **Network** settings, see [7.7.2.1 Configure a DCP server on page 107](#).



NOTE

- If the ADT query fails, only the **Patient ID** field will be populated.
 - The MAC 3 system supports only English alphabetic characters and numerical values for ADT query.
1. Open the **Patient Data** screen.
 2. Scan the patient barcode.

The device queries ADT data for matching patient information and populate the patient data.



- 3. Enter or change patient information, as necessary.

4.1.2.1 ADT query workflow

The device searches for ADT data in the DCP server with the Patient ID.

If	Then
An invalid Patient ID found on the DCP server.	An invalid patient ID message displays in the notification area.
A valid Patient ID found on the DCP server.	If there is no patient data in the screen, a remote query success message displays. The fields will be filled with new patient demographics on the Patient Data screen.
Multiple ADT records that match the Patient ID is found on the DCP server.	Scan another patient data. The Patient data mismatch message opens along with the query success message. A screenshot of a "Patient data mismatch" dialog box. It contains a table with two columns: "Current Patient Data" and "New Patient Data". The table has rows for "Patient ID", "Visit number", "Last name", and "First name". Below the table, there are two buttons: "Replace" and "Cancel". If you select Replace, the patient data fields will fill with the new patient information. If you select Cancel, the patient data fields will not be updated.
The patient query failed.	A message opens in the notification area that the patient query has failed.

4.1.3 Use software keyboard to enter or edit patient data

Use the software keyboard to enter or edit the patient information.



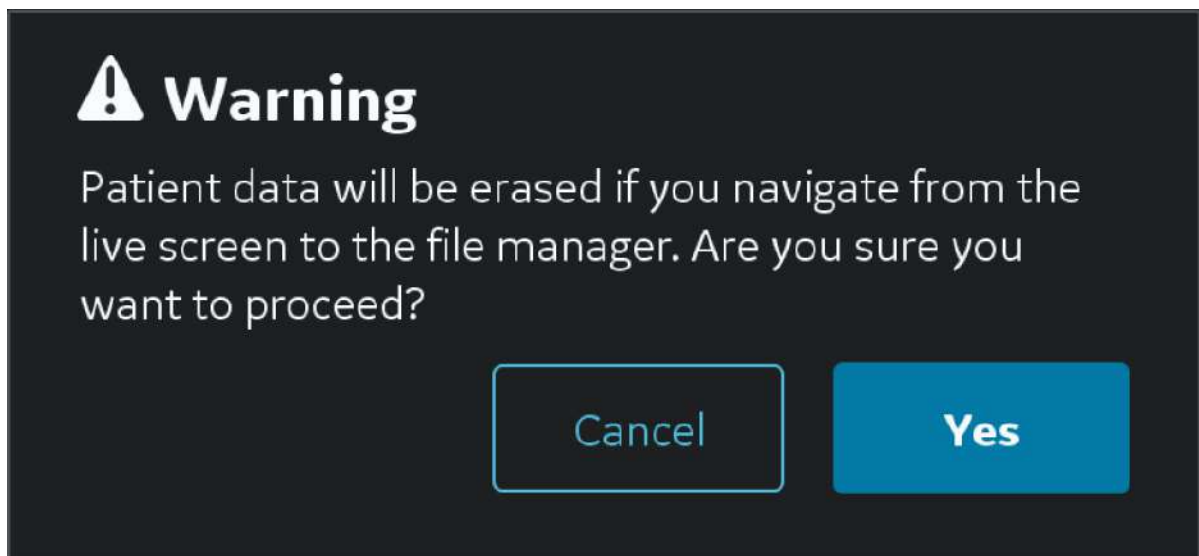
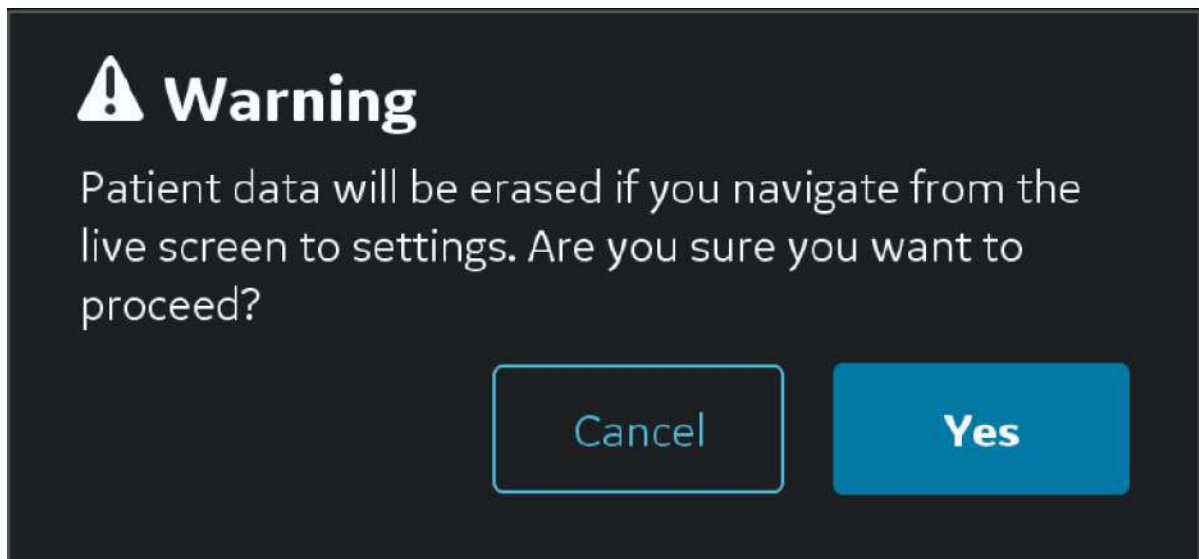
Item	Name	Description
1	Backspace	Deletes inputs.
2	Enter	Enters inputs.
3	Backward Arrow	Provides backward movement between columns.
4	Forward Arrow	Provides forward movement between columns.
5	Space	Adds a space between entered characters.
6	Input	Switches between different input methods.  NOTE If you use an English user interface, you cannot switch the input methods from English to Japanese characters.
7	Number	Switches to numbers and symbols.
8	Capitalization	Capitalizes a letter during entering.

- Use the software keyboard to enter data in the fields displayed in the **Patient Data** screen. Only fields that you configure for patient information displays in the **Patient Data** screen. See [D Patient data fields on page 180](#) for a list of fields that can display on the screen.
 - If you enter incorrect data in a field, the field border changes to red.
 - An asterisk (*) displays adjacent to mandatory fields in the **Patient Data**.



NOTE

A warning message display, if you go to the **Settings** or file manager screen before you complete a patient test.



2. If you select **Yes**, the data entered in the **Patient Data** screen clears when you go back to the **Acquisition** screen.
3. If you select **Cancel**, goes back to the **Patient Data** screen to complete the patient test.
4. To save your entries, select **Save**.
The information is saved and the **Patient Data** screen closes.

5 Record an ECG or rhythm

5.1 Hookup Advisor overview

The **Hookup Advisor** is a tool to monitor the lead signal quality and lead reversal during ECG acquisition. It can decrease or stop the occurrence of poor quality ECGs, save time, and prevent the need to restart the ECG.

The **Hookup Advisor** reports the status based on signals from each leadwire.

Table 5-1 Hookup Advisor panel

Item	Name	Description
1	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.
2	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 5-2 Hookup Advisor lead quality status indicators

Indicator	Description
Red 	Shows a lead fail condition or extreme baseline shifts or disconnected patient cable condition. 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, electrode noise, or possible lead reversal. 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 signal quality is good to acquire the ECG. 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 quality is good to acquire the ECG.



NOTE

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

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.

If the **Acquisition Module** is disconnected during ECG acquisition, the **Hookup Advisor** does not display the lead status or messages and ECG acquisition is stopped. An error message showing that

the acquisition module is disconnected displays in the waveform area of the [5.4 ECG acquisition overview on page 47](#) screen.

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.

Restart the ECG after the **Acquisition Module** is connected 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.

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.

5.1.1 Acquire an ECG based on the Hookup Advisor status in post-acquisition mode

In post-acquisition mode (refer to [5.4 ECG acquisition overview on page 47](#)), 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.

5.1.2 Acquire an ECG based on the Hookup Advisor status in Pre-acquisition mode

In pre-acquisition mode (refer to [5.4 ECG acquisition overview on page 47](#)), 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.

5.2 Change lead sets and lead formats

The **Acquisition** screen displays the waveform based on the configured lead format, lead set, speed, gain, and filter.

1. Press the **Leads** key to scroll through the leads.

**NOTE**

If the display shows more than 3 leads, the system will display 3 leads from the group configured as autorhythm.

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.

5.3 Change speed, gain, and filter

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

1. At the bottom of the **Acquisition** screen, select **Filter (Hz)**, **Speed (mm/s)**, and **Gain (mm/mV)** drop-down list.

**NOTE**

The 150 Hz acquisition bandwidth setting reduces signal frequencies above 150 Hz. Refer to the 12SL Physician's Guide for more information.

The 150 Hz filter is commonly used for adult patients.

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

5.4 ECG acquisition overview

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

Table 5-3 Table 5-4 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.

To record an ECG patient test manually, see [5.4.1 Manually start an ECG recording on page 48](#).

5.4.1 Manually start an ECG recording

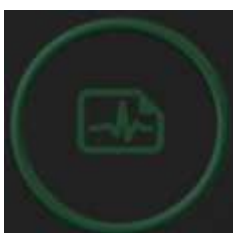
1. At the top of the **Acquisition** screen, click on **Tap to enter patient info**, enter patient data and select **Save** to start a test for a new patient.



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 [5.2 Change lead sets and lead formats on page 47](#), and [5.3 Change speed, gain, and filter on page 47](#).
3. Press the **Start ECG** icon in the keysheet 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 **Stop ECG** icon displays at the bottom of the Acquisition screen, the count of acquisition progress displays until you have recorded 10 seconds of data at the **Hookup Advisor** panel. You can cancel the acquisition before 10 seconds of data is recorded. For more information, see [5.4.2 Cancel an ECG on page 49](#).

In post-acquisition mode, the system starts recording the next 10 seconds of ECG data for analysis. The **Stop ECG** icon displays at the bottom of the Acquisition screen, the count of acquisition progress displays until you have recorded 10 seconds of data at the **Hookup Advisor** panel. You can cancel the acquisition before 10 seconds of data is recorded. For more information, see [5.4.2 Cancel an ECG on page 49](#).

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

If ...	Then ...
The Preview before print mode is enabled.	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 5.4.3 Accept or reject an ECG patient report on page 49
The Hookup Advisor status is Yellow or Red , a warning message displays before the preview screen.	
The Hookup Advisor status is Red , a warning message displays before the preview screen.	
The Hookup Advisor status is Green .	

Continues on the next page

If ...	Then ...
The Hookup Advisor status is Yellow or Red , a warning message displays before it goes for print.	The ECG patient report preview does not display. The ECG patient report is automatically accepted, saved in the file manager, and display for review. For more information, see Review an ECG Patient Report.
The Preview before print is disabled.	The report is automatically printed. For more information, see 5.4.4 Automatically print an ECG patient report on page 53 . If a destination is configured for ECG reports to be automatically sent after acquisition, the ECG report is automatically sent to the configured destination.

5.4.2 Cancel an ECG

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

1. Select the **Stop ECG** button at the bottom of the **Acquisition** screen to cancel the ECG acquisition:



The device stops recording the ECG data and goes to the waveform display in the **Acquisition** screen.

5.4.3 Accept or reject an ECG patient report

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

You can accept this preview to save the ECG patient report in the file manager, or reject it to go to the waveform display in the **Acquisition** screen.

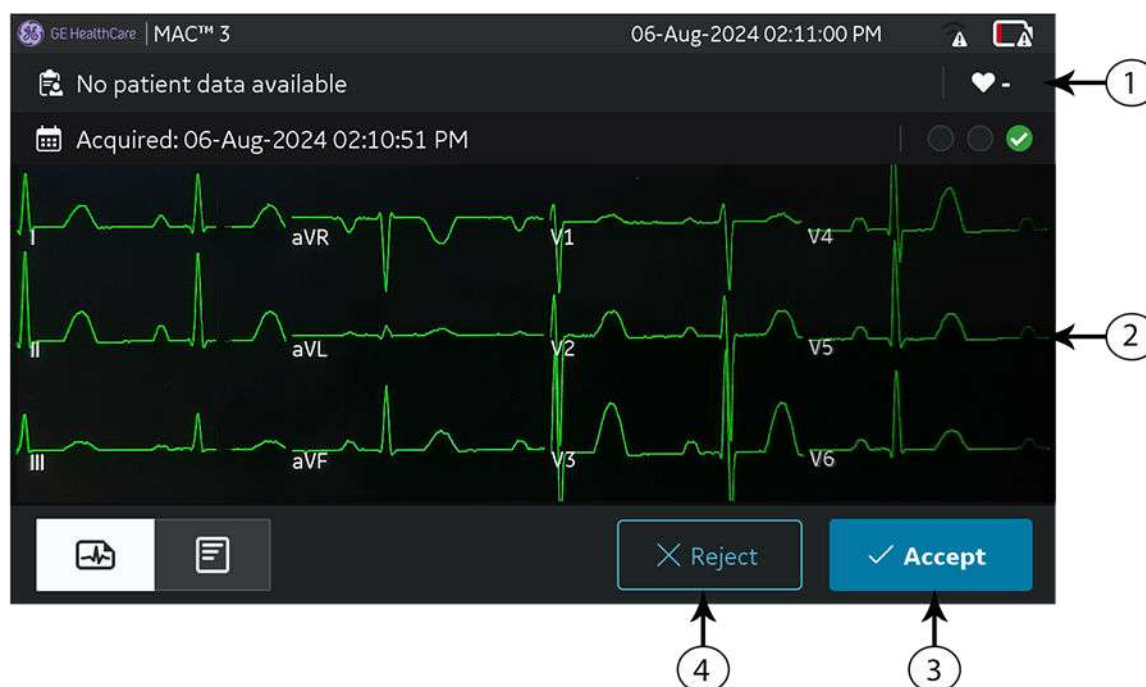


Table 5-4 Preview of the ECG patient report

Item	Name	Description
1	Patient Information banner	Displays patient information.
2	Preview of ECG patient report	The patient report preview is displayed as rhythm display output and analysis tab.  NOTE The preview of the ECG patient report is not available. For more information on the report formats and the standard layout of the ECG patient report, see B.1 ECG report formats on page 162.
3	Reject icon	Select the Reject icon to return to the 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 file manager.

To accept or reject the ECG preview, do the below steps:

1. Review the patient report on the preview screen and **Hookup Advisor** status.
2. Accept or reject the ECG preview based on the **Hookup Advisor** status.

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 3 device is inactive for 2 minutes.

Table 5-5 ECG tab displaying a preview of the ECG patient report

If ...	Then ...	Next Steps
Hookup Advisor status is green, the ECG signal quality is good.	Select the Accept icon:  The preview of the ECG patient report is accepted and saved in the file manager.	- Review the ECG patient report and decide on the next steps. - The ECG patient report is automatically printed. For more information, see 5.4.4 Automatically print an ECG patient report on page 53. - Transmission is initiated once accept is selected after the printing is done. Note the transmission is already auto enabled in system setup. 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.
Hookup Advisor status is yellow or red, there are issues with the ECG signal quality during the recording of this ECG.	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 5.4 ECG acquisition overview on page 47.

3. If you, accept the ECG preview, the **Review** screen displays.

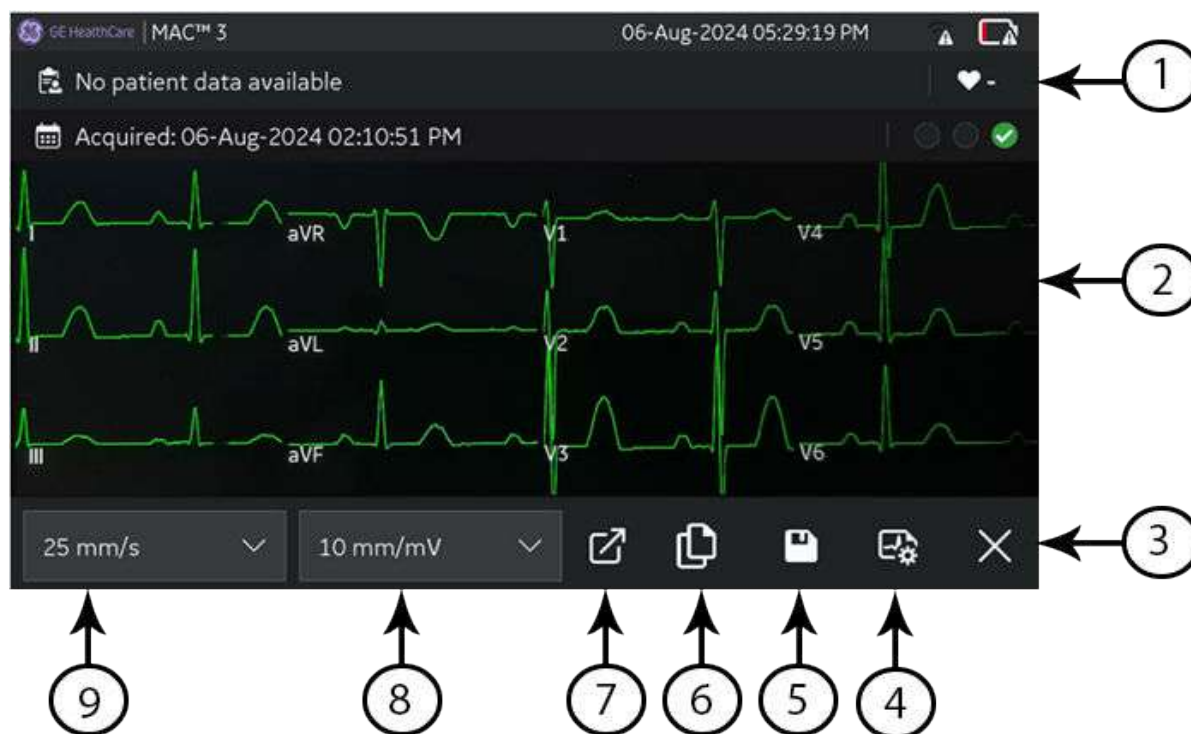


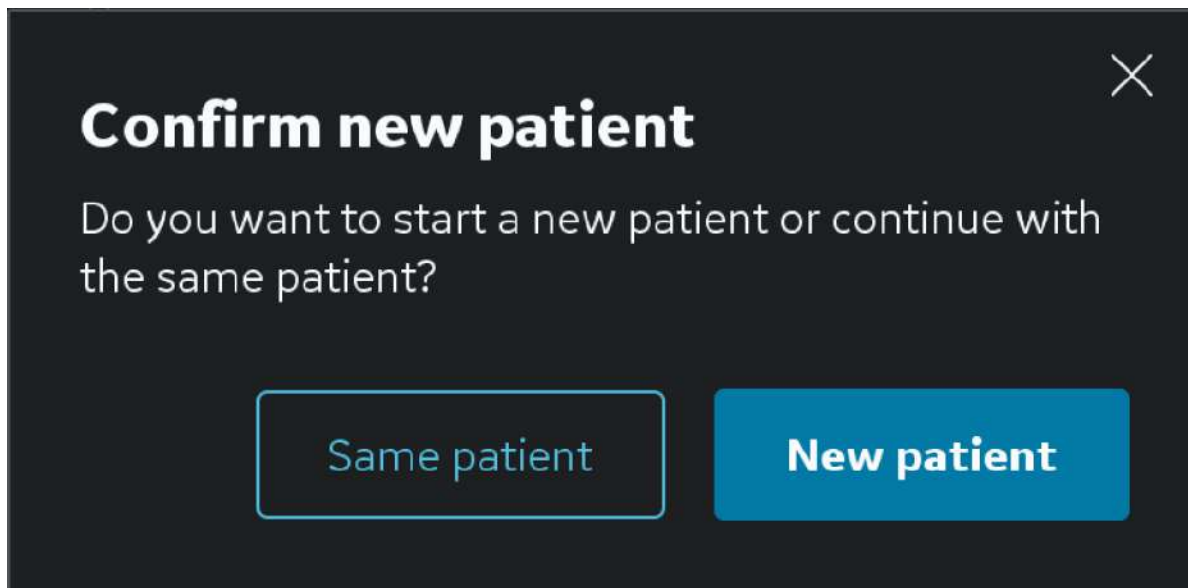
Table 5-6 Review of the ECG patient report

Item	Name	Description
1	Patient Information banner	Displays patient information.
2	Review of ECG patient report	The patient report review is displayed.
3	Close icon	Select the Close icon to close the patient report and return to the waveform display in the Acquisition screen.
4	Settings icon	Select the Settings icon to open the settings screens.
5	Save icon	Select the Save icon to save the changes of the patient report to the configured destination.
6	Copy icon	Select the Copy icon to print the duplicate of acquired ECG report.
7	Transmit icon	Select the Transmit icon to transmit the patient report to the configured destination.
8	Gain icon	Select the Gain icon to change the waveform gain.
9	Speed icon	Select the Speed icon to change the speed of the waveform.

When you disconnect patient leads and there is no activity with the MAC 3 device for 2 minutes, all ECG reports will automatically close.

- The system clears patient information and returns to live screen when review screen is auto closed due to inactivity and lead disconnection.
- The system auto close any of the messages opened in review screen before auto close of the review screen due to inactivity and lead disconnection.

- The system saves the acquired ECG to prevent loss of patient data before auto close of the review screen due to inactivity and lead disconnection. The save will happen regardless of the storage settings.
4. Select **Close** button  to close the review screen.
A **Confirm new patient message** displays.



5. Select **New patient** if you want to start with a new patient or **Same patient** to continue with the same patient.

5.4.4 Automatically print an ECG patient report

When you store a patient report in the file manager, 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

You will see the screen indicating the printing status.

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 [10.3 Printer errors on page 155](#).

To stop printing a patient report, press the **Stop print** key on the device.

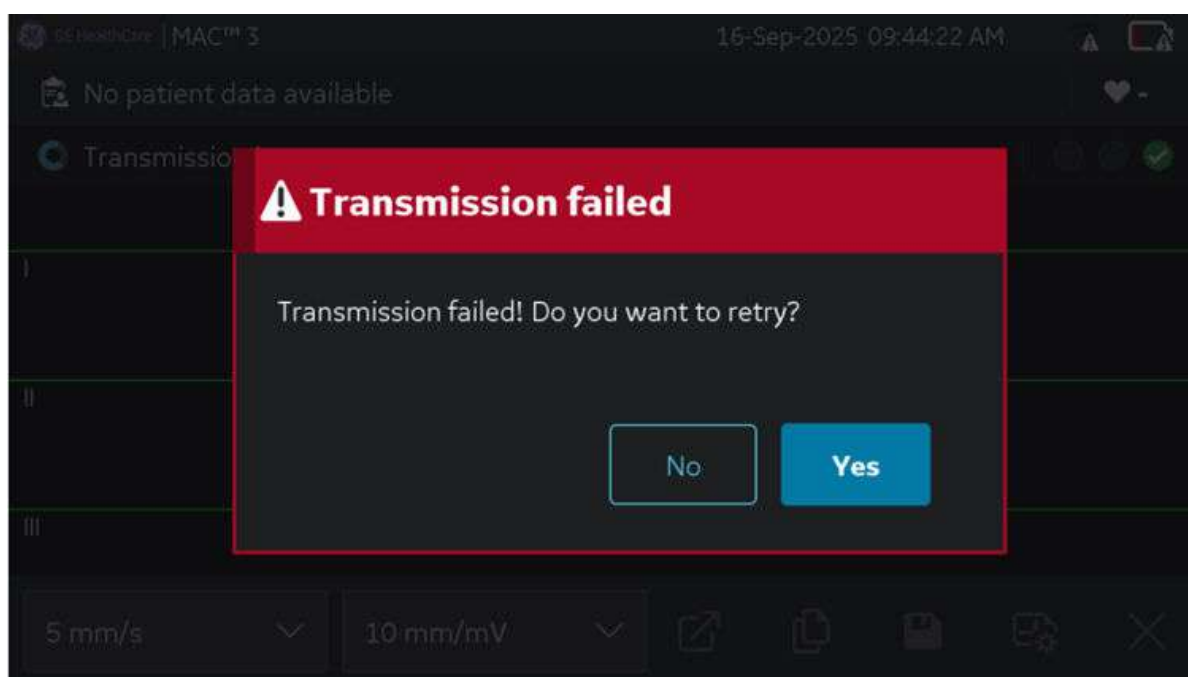


5.4.5 Retry transmission of a patient report

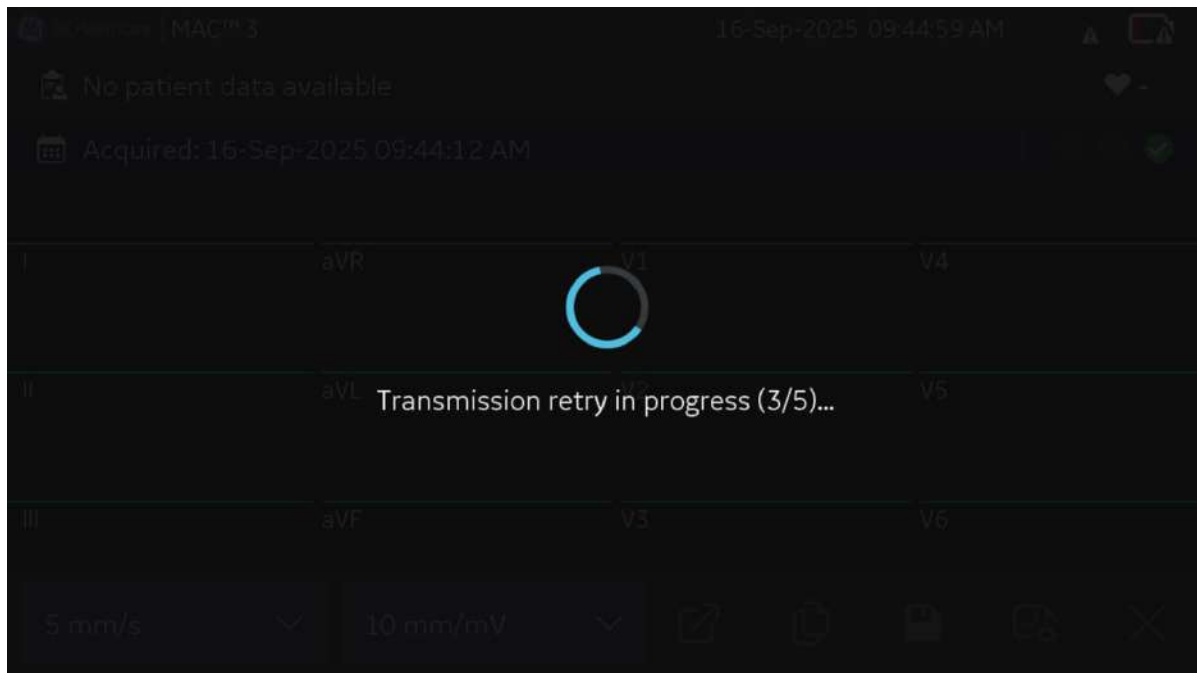
Make sure that you have the privilege to transmit Rhythm or ECG patient reports to a configured destination.

The system automatically tries to transmit a patient report.

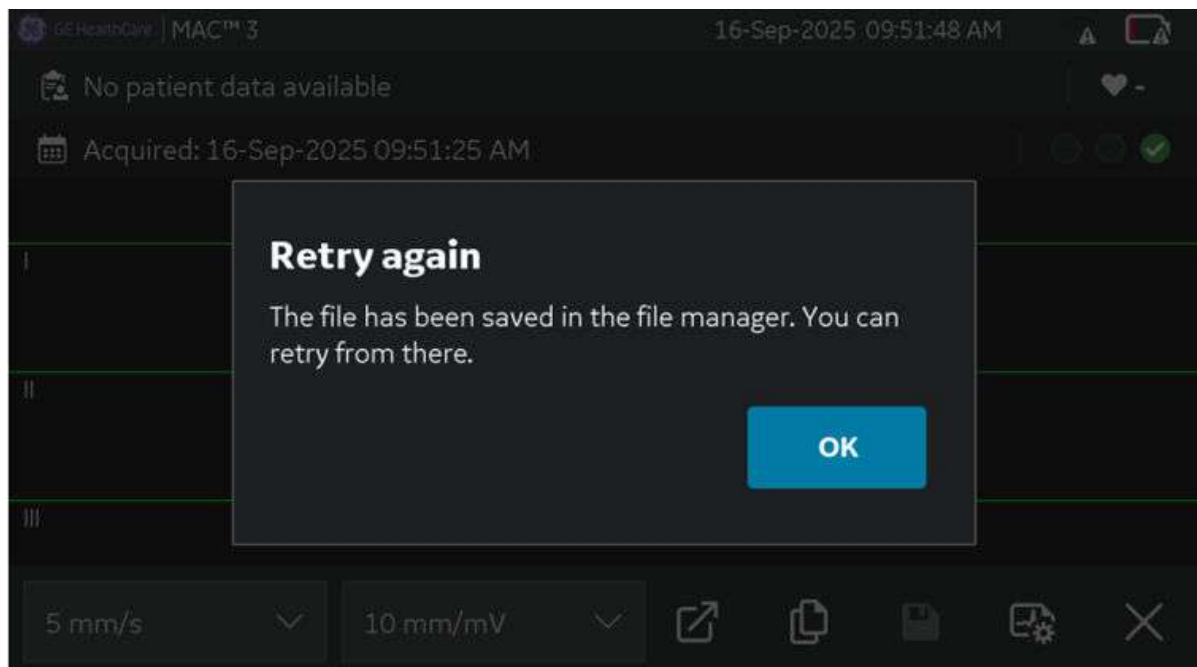
1. In case of failure of auto transmit, the retry transmission message displays, select **Yes**.



2. You can attempt 5 times to re-transmit the reports.



3. After all 5 attempts, the **Retry again** message displays.



4. Select the **OK**.
The report will be saved in the **File Manager**. You can retry from there to transmit the report.

5.5 Record a rhythm

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

1. Change the lead set or format, gain, speed, or filter, if required. See [5.2 Change lead sets and lead formats on page 47](#).
2. Press the **Start rhythm** on the keysheet of the device.



The rhythm is only printed. It is not digitally recorded.

Go to [Step 3](#) to stop printing the rhythm. If you do not stop printing the rhythm, printing continues until the paper tray is out of paper.

If a printer error occurs and rhythm printing is stopped, you need to troubleshoot the error. For more information, see [10.3 Printer errors on page 155](#).

3. Select the **Stop print** key on the device to stop printing the rhythm report.



4. Review the rhythm report.

6 Manage files

Select the file icon  on the right-corner of the **Acquisition** screen to open the file manager. The file manager displays a list of stored ECG reports. You need to enable **XMLO** and related network options from the **Options Manager** for USB export and transmission of files. When you enable the USB option, the file manager provides an interface to export the files to the system external storage. You can do the below tasks in the file manager:

- View stored reports
- View/update report format
- Print stored reports
- Transmit a patient report to a configured destination
- Export reports
- Delete stored reports
- Close report

The figure illustrates the file manager list.



	Name	Patient ID	Date and Time↓	Sent
	JOHN, DOE	123456789100	30-Jul-2022 23:35:48	
	JANE, DOE	123456789101	29-Jul-2022 23:35:48	
	JOHN, DOE	123456789103	28-Jul-2022 23:35:48	
	PATIENT, TEST	123456789104	27-Jul-2022 23:35:48	
	JOHN, DOE	123456789105	26-Jul-2022 23:35:48	

11 files available

Icons: Search, Share, Print, Delete, Settings, Close

Table 6-1 File manager list

Item	Name	Description
1	Name	Displays the patient first name and last name. You can use the patient name for identification and filter patient list.
2	Patient ID	Displays the unique ID assigned to the patient. You can use to get all related medical information for a specified patient, link records, and reports.

Continues on the next page

Table 6-1 File manager list (Table continued)

Item	Name	Description
3	Date and Time	Displays the date and time of the patient record.
4	Sent	Displays if you sent the patient record to another system or location.

6.1 Sort the files list

You can sort the files list in first 3 columns. Select one of the 3 column headers to sort the files list and select the order. The files list sort is in the order of priority:

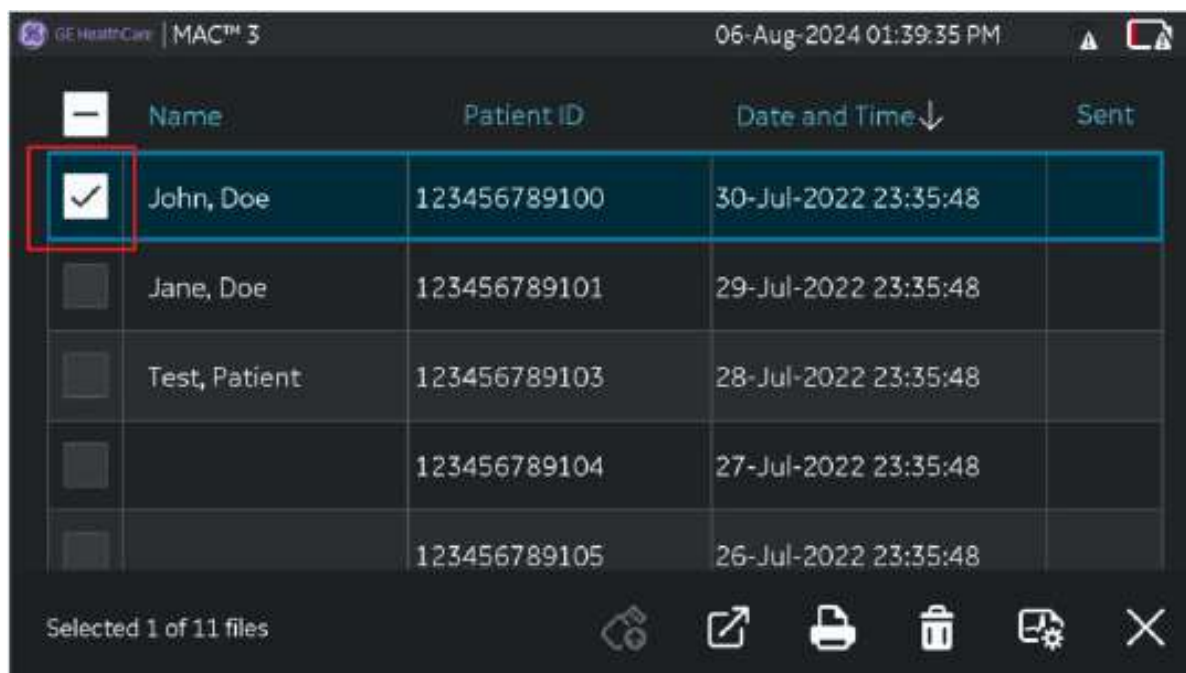
- First, the lowercase letters (a-z) will sort in each column.
- Next, the uppercase letters (A-Z) will sort after the lowercase letters in the same column.
- Last, the numeric characters (0-9) will sort in each column.

6.2 Select the file from the files list

To select the file from the files list:

1. Select the multiple selection checkbox in the first column of the file manager.

Automatically selects or unselects all the patients in the list. It helps you to quickly manage the large patient lists and perform more actions.



2. Select the checkbox of the individual patient from the list.

It changes the color and displays a tick mark and selects the patient from the list.

You can use this selection to perform more actions on a specified patient. The device allows you to select more than one patient, you can select their related checkboxes.

3. Click again on the selected patient.

The retro review screen opens for the selected patient specified information.

6.3 Export file

Before you start the procedure, make sure that:

- You enable the **USB** and **Allow USB storage** settings from **Settings > System > Hardware**. For more information on how to enable these settings, see [7.6.6 Configure hardware on page 102](#).
- You have connected the USB flash drive to the port.
- The USB flash drive supports the FAT32 file system.

6.3.1 Export file from File manager to USB

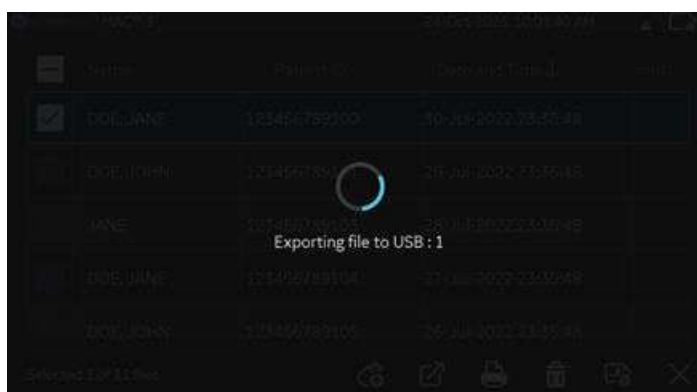
1. You can select a checkbox of the patient file or multiple checkboxes for more patient files to export.



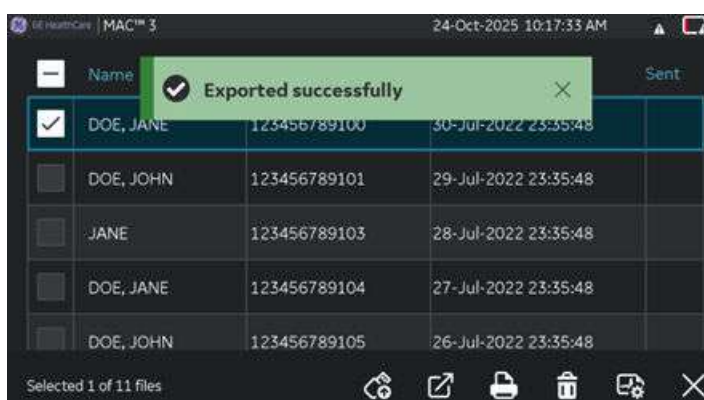
2. Select USB icon  to select the format of the file to export.



3. Select PDF or XML format to export.
Export progress screen displays.



If the file is exported to the USB flash drive, a message displays (**For Exported successfully**) .



If the below error messages display, troubleshoot the error to export the files:

- (**For User cancelled operation**) , you manually stopped the export process before it could complete. This error message appears when you press **Start ECG** key during export of file.
- (**For Failed to export**) , unknown system error, file export failed while the process is in progress.

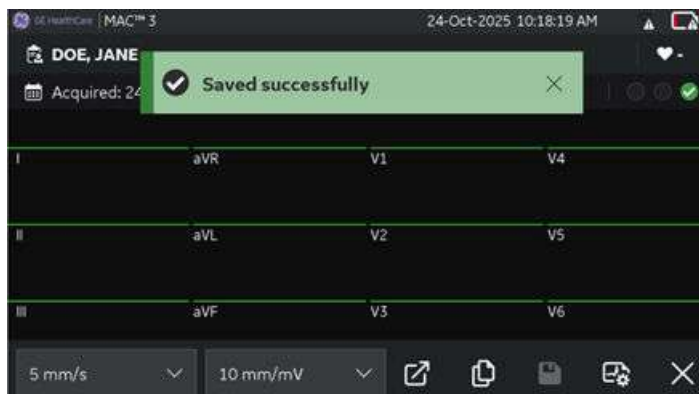
6.3.2 Save and export ECG reports to USB

1. You can save the patient report from the review screen to the USB.
2. Select **Save** to save the report to USB.

A message displays (**For Saving file to system...**) .



If the file is saved without errors, a message displays (**For Saved successfully**) .



If the file is saved to the USB flash drive without errors, a message displays (**For Exported successfully**) .



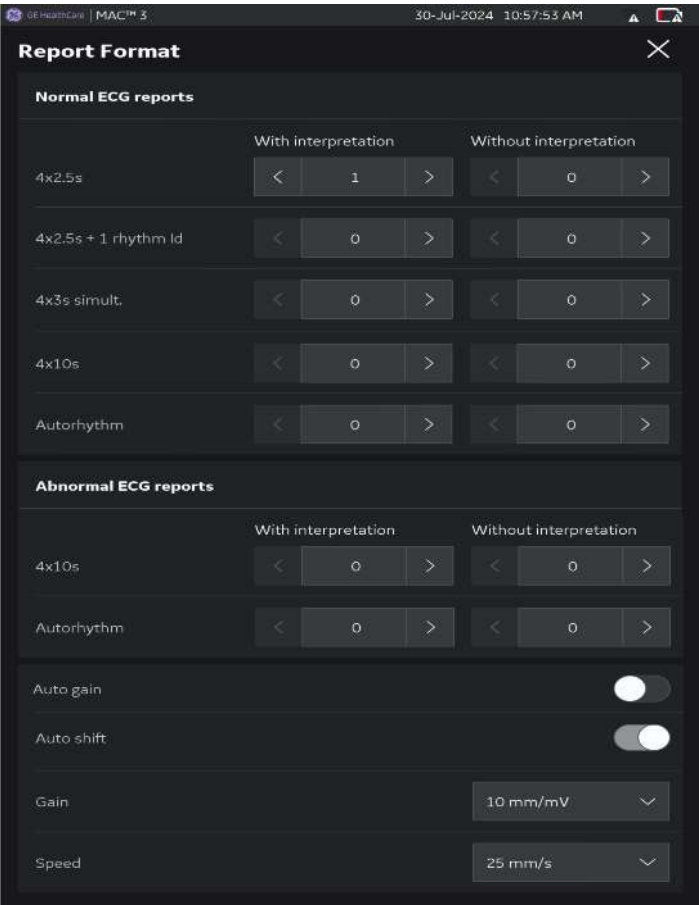
6.3.3 Save ECG reports to USB

1. Enable **Store XML format to USB drive** or **Store PDF format to USB drive** settings from **Settings > Workflow > Storage**.
2. You can save the patient report after you accept the ECG to the USB.

A message displays (**For Saved successfully**). The file is saved to the USB flash drive. If the below error messages display, troubleshoot the error to save the files:

- (**For User cancelled operation**), you manually stopped the export process before it could complete. This error message appears when you press **Start ECG** key during export of file.
- (**For Failed to export**), unknown system error, file export failed while the process is in progress.

6.4 Report format



The **Report Format** function helps you to specify the below parameters for the stored ECG patient reports to print:

- Report format
- Speed
- Gain
- Auto shift
- Auto gain

The below table provides the **Report Format** menus and functions.

Table 6-2 Report format menus and functions

Functions	Description
Report Format	You can set the report format to print a stored patient report.
Speed	You can change the printer speed setting.
Gain	You can change the printer gain setting.
Auto shift	You can enable or disable the auto shift setting for the printer.
Auto gain	You can enable or disable the auto gain setting for the printer.

To select the report format to print a stored ECG patient report, do the below procedure:

**NOTE**

The changes made here affect only the current ECG patient report. When you start to record a new ECG, the reports specification in the system setup use to print the report.

1. Select **Report Format** icon .
The **Report Format** window opens.
2. Enter the number of copies of the report for the necessary report format.
3. Change the settings for **Auto gain** and **Auto shift**.
4. Change the settings for **Gain** and **Speed**.
5. Select the close icon  on top to exit the **Report Format** window and go back to file manager screen.

6.5 Print a patient report

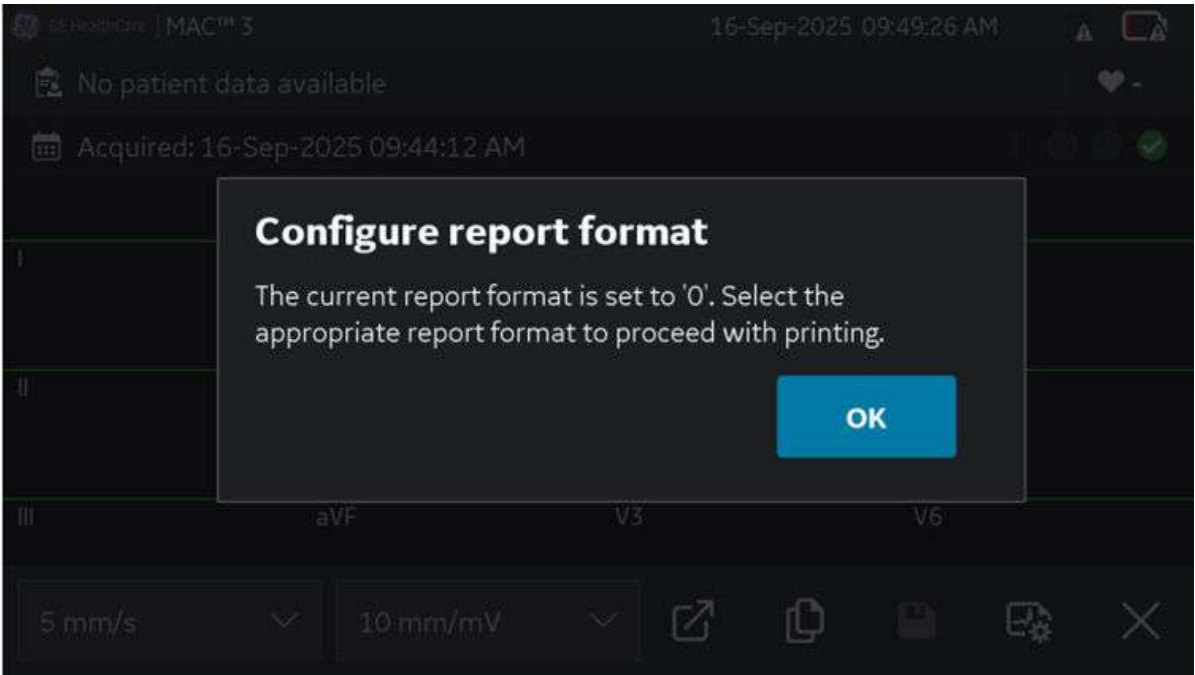
You can print a copy of a stored ECG patient report in one of the configured report format via thermal printer.

1. Before you print a copy of the report, review the patient report and verify:
 - The patient information in the patient report is correct.
 - The ECG report is acquired with the necessary gain and filter.
2. Select a file/files and click on the print option .

The file prints in the selected report format. While, you print all other options disable. After you print the report, the file manager list will enable.

If a printer error occurs, the error message display. The print restarts automatically after the error is resolved. For more information on printer errors, see [10.3 Printer errors on page 155](#).

If you set the report format to zero, a **Configure report format** screen displays.



3. Select **OK** to set the correct report format before you print the report.
4. To stop printing a patient report, press the stop print key on the keysheet of the device.



6.6 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 (MUSE v9, or MUSE NX, or Cardio-Soft V7)	Hilltop format
Resting ECG	CareIntellect MUSE server	Hilltop format
Resting ECG	HTTPS server	Hilltop and XML formats.
Resting ECG	SFTP server	PDF, Hilltop, and XML formats.

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

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

2. Select the transmit icon  to expand the transmission options.
3. Select **PDF** or **Hilltop** or **XML** file format to transmit the report to a default destination.

A transmission progress displays. If no errors, the report is transmitted and displays a message **(For Transmitted successfully)** . If the transmission fails, a message display **Transmission failed**, resolve the errors to transmit the report.

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

6.7 Delete a patient report

Make sure that you have the privilege to delete ECG patient report from the files manager list.

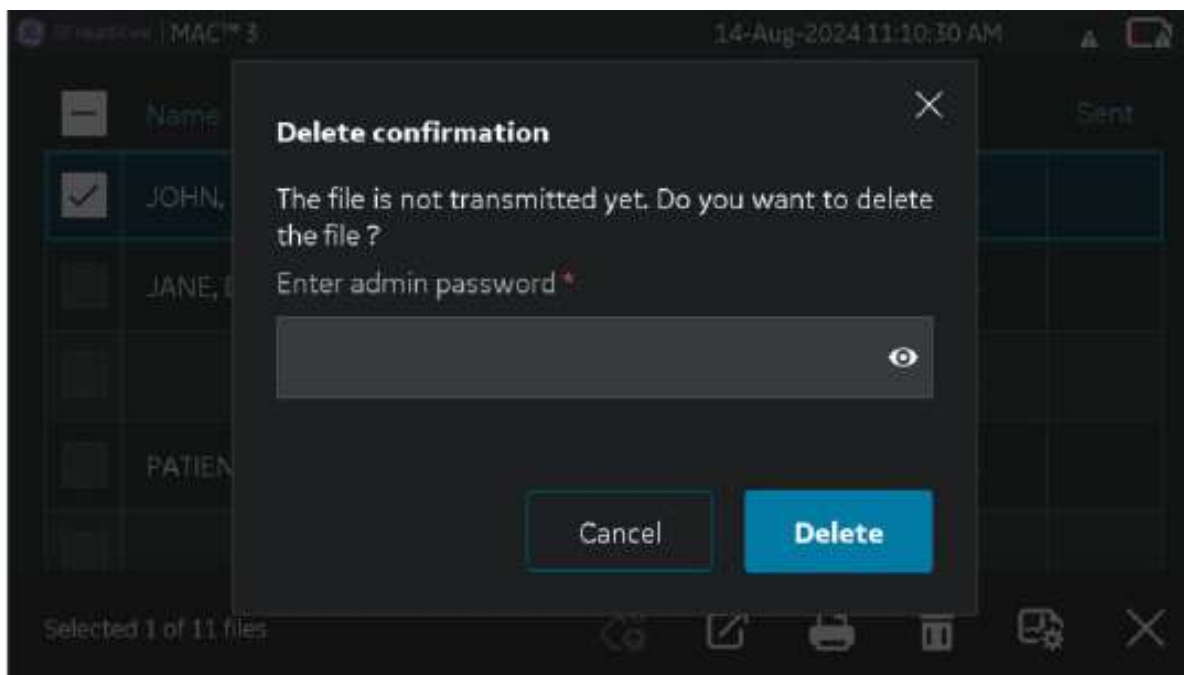


NOTE

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

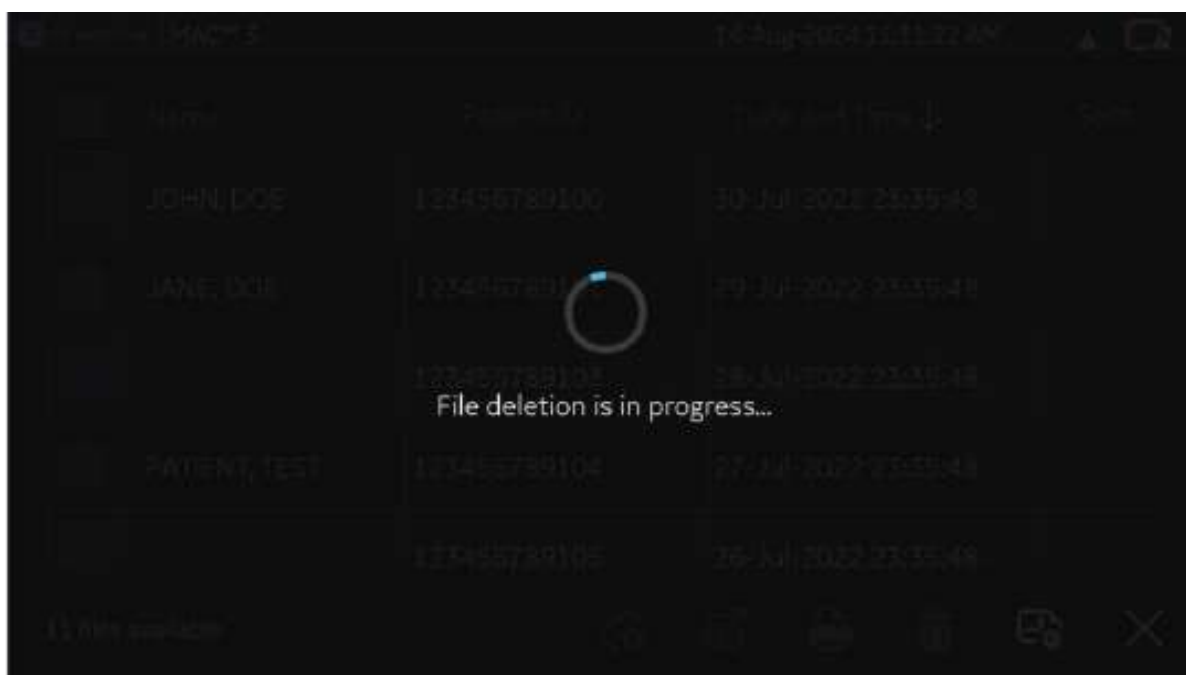
1. Select the file/files to delete and click delete icon .

A **Delete confirmation** message display, to confirm the file is not transmitted, if you need to delete the file permanently.

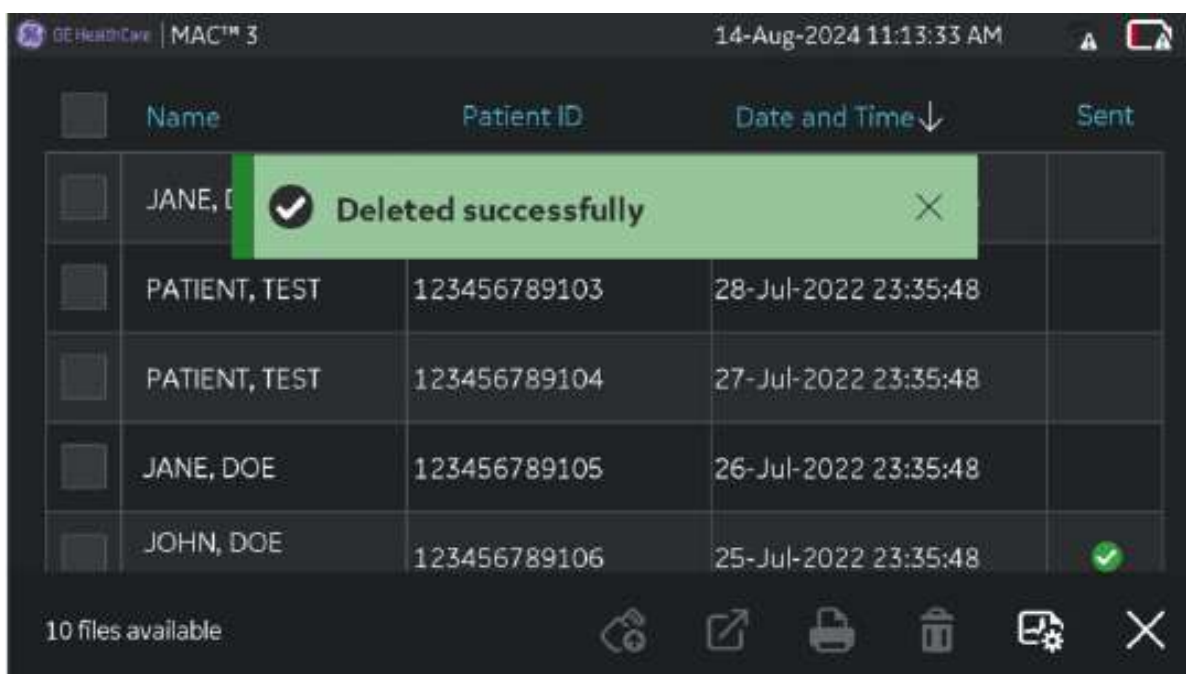


2. Type the Admin password.
3. Select **Delete** to delete the selected patient report.

A progress window displays.



If no errors, a successful message display.



The selected patient report will delete from the files manager list.

4. Select **Cancel** to cancel the deletion of the selected patient report.

The selected patient report is not deleted from the list and go back to files manager list.

6.8 Close the files manager

1. Transmit, export, report setup, delete, or print the patient report.
2. After you complete your tasks, select the  icon to close the files manager list.

The files manager list closes and goes back to the **Acquisition** screen.

6.9 Review a stored patient report

You can review a stored patient report in retro review screen.

1. Select a file and tap on the file to review the stored patient report.

A retro review screen displays.

2. Click on the waveform icon  to review the ECG waveform of the stored patient report.

A stored ECG waveform retro review screen displays.

3. Click on the parameters and description icon  to review the measurements and interpretation statements.

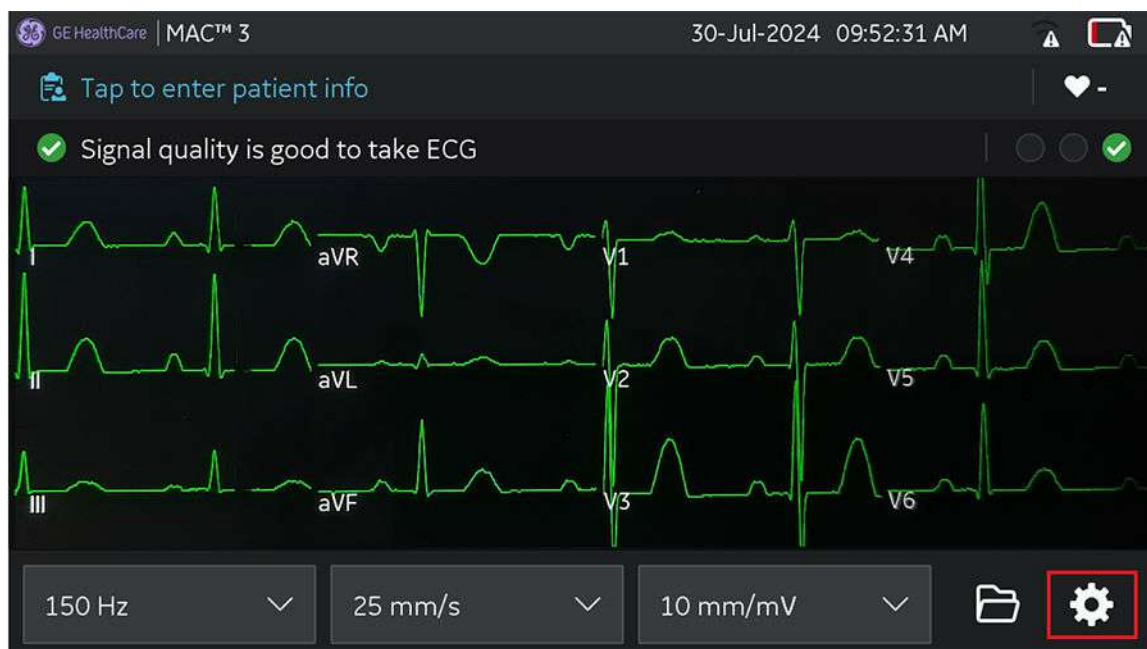
You can start all the below functions that is available in the retro review screen.

- Export the stored patient report in PDF or XML format.
 - Transmission of the stored patient report.
 - Print a stored patient report.
 - Change the auto shift and auto gain.
 - Change the settings for gain and speed.
 - Delete a stored patient report.
 - Change the stored patient report format.
 - Close the retro review screen to go back to the files manager list.
4. You can select the other file and repeat [Step 1](#) to [Step 3](#) to continue the review of other stored patient report.

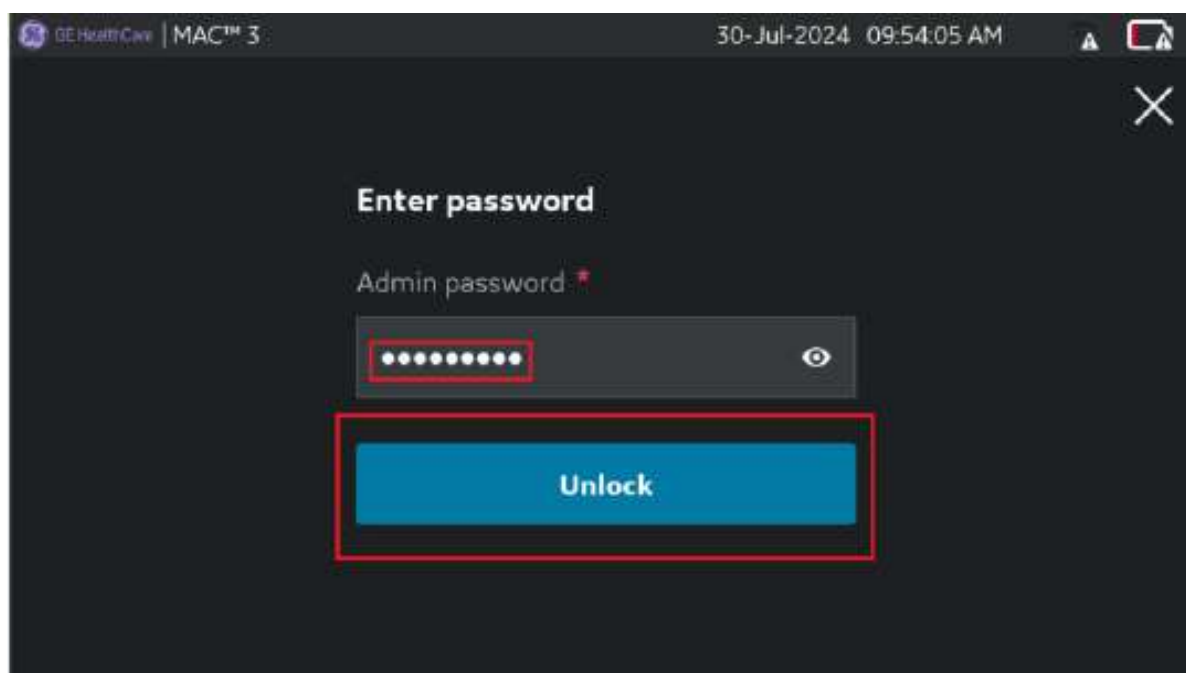
7 Configure settings

7.1 Open the settings screen

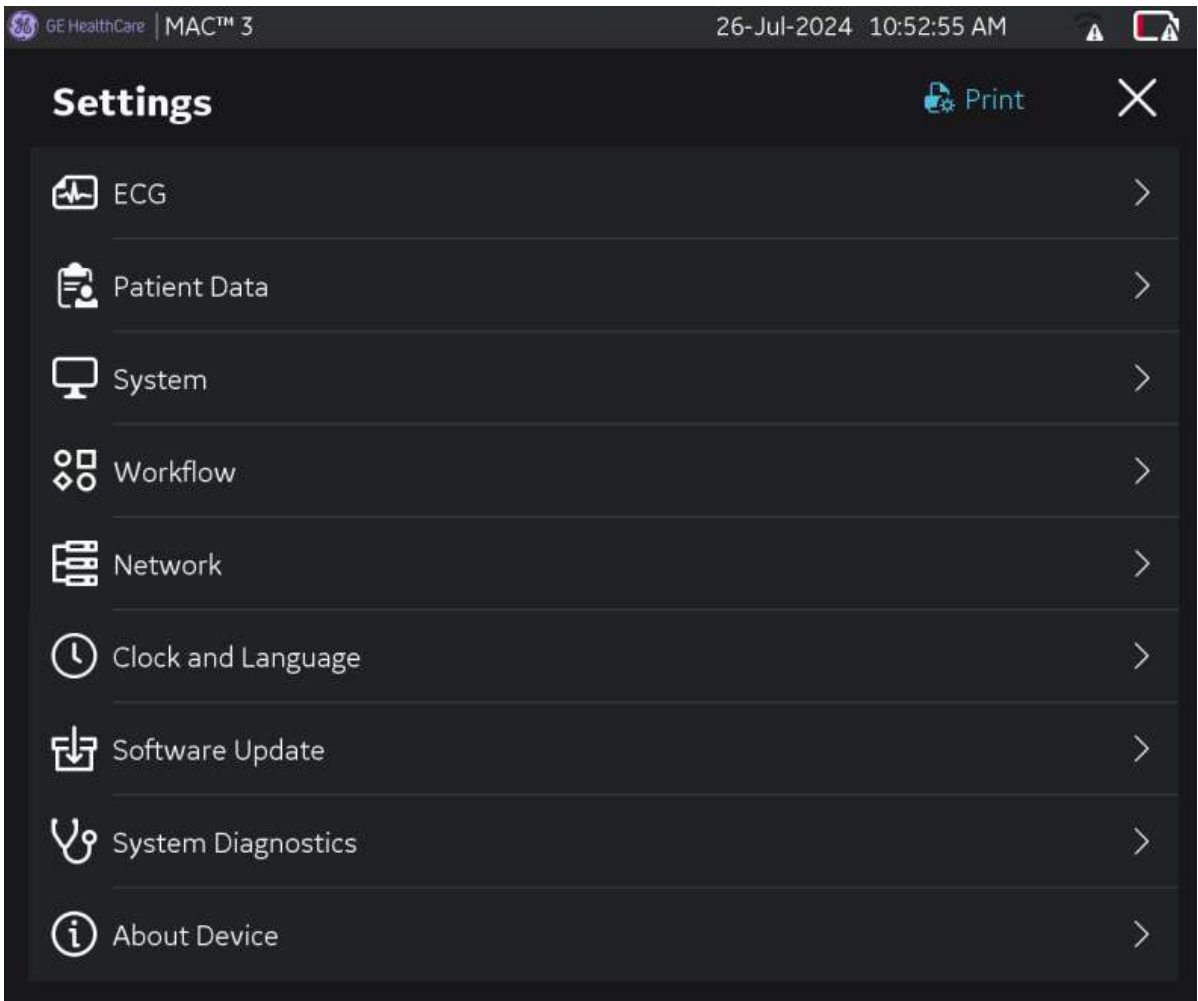
1. Select the settings  icon from the **Acquisition** screen.



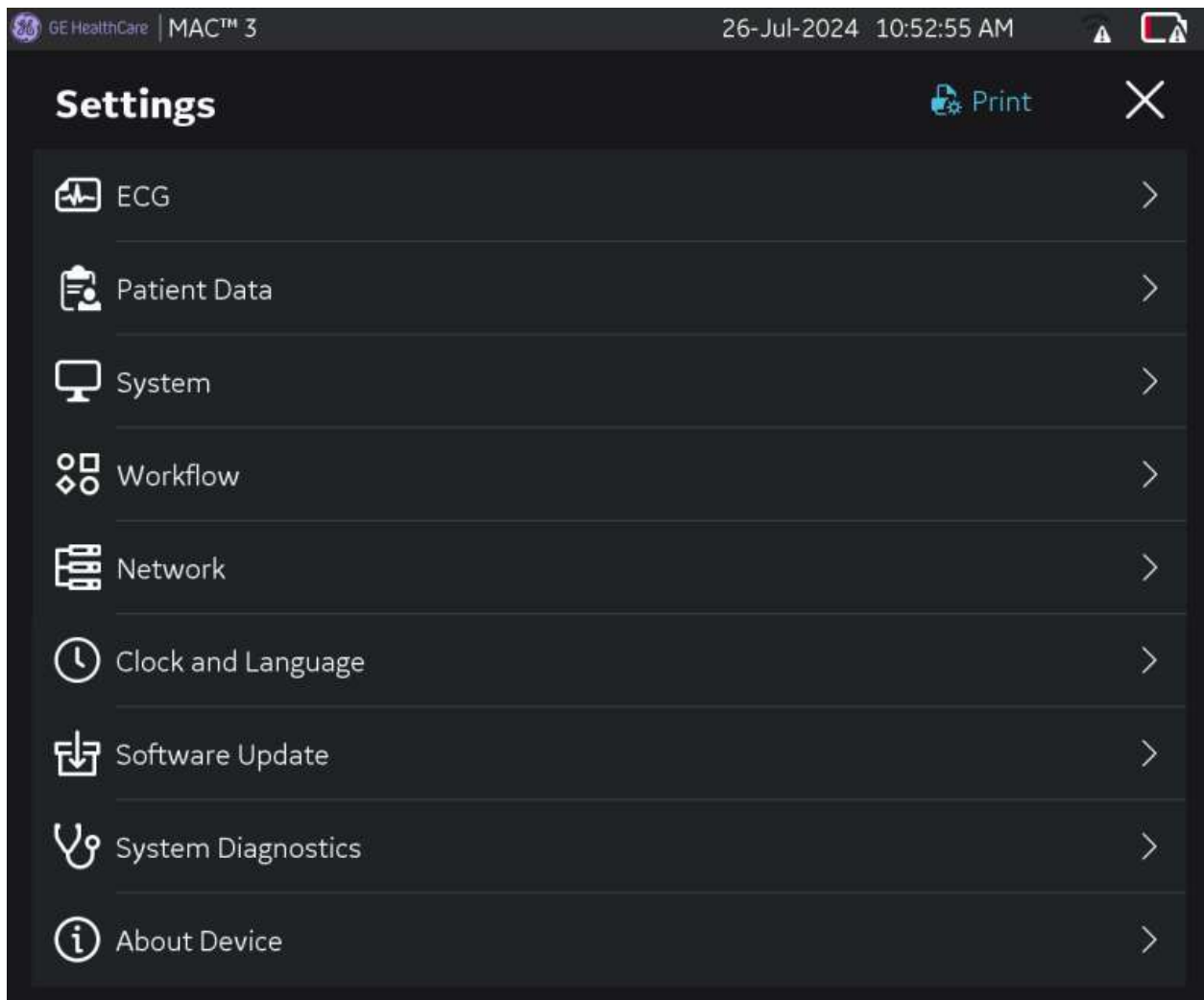
2. Enter the **Admin password** and click **Unlock** to view the setup options.



The settings screen opens.



7.2 Settings screen overview



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

- ECG - to configure the ECG settings.
- Patient Data - to configure the patient information settings.
- System - to configure the system settings.
- Workflow - to configure the storage and transmission settings.
- Network - to configure the network settings.
- Clock and Language - to configure the date, time, and the language settings.
- Software Update - to update the software.
- System Diagnostics - to test the system.
- About Device - to verify the device and system information.
- Print - to print the configuration of the system including ECG, Patient Data, System, Workflow, Network, Clock and Language settings and system information.

7.3 Configure general tasks

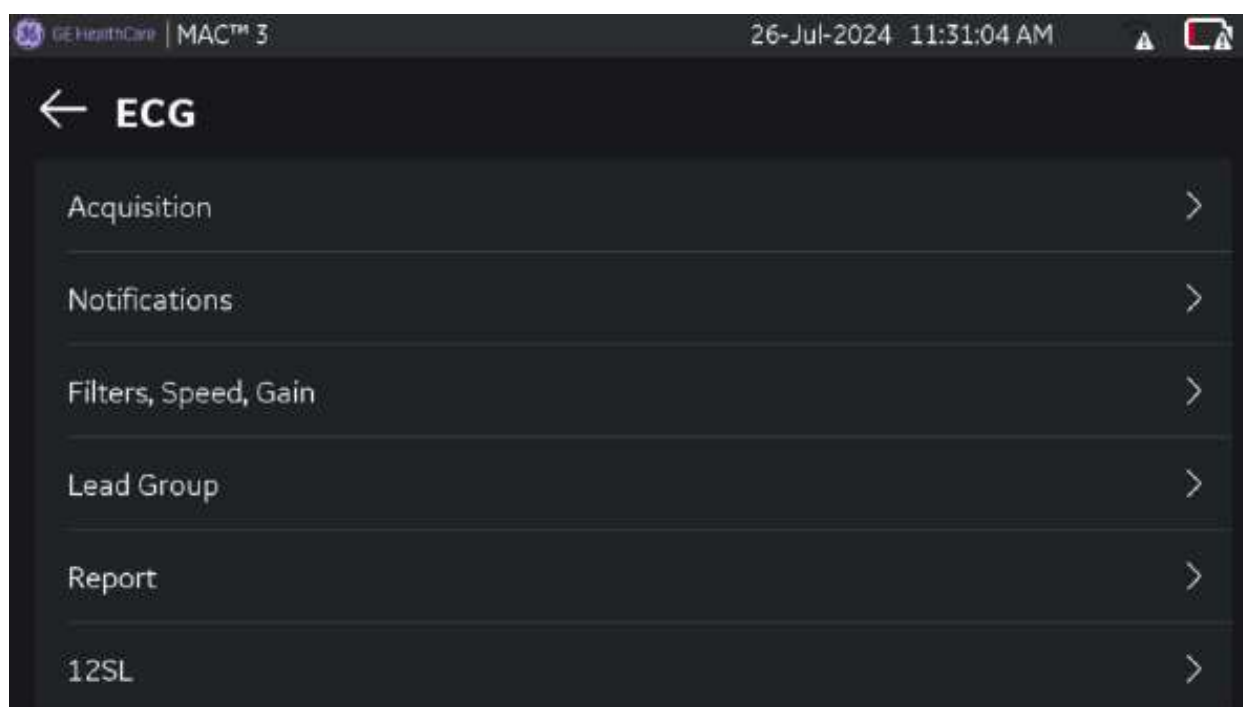
Perform general tasks, as per the information in the below table:

Table 7-1 Configure general tasks

Button	Action
Save	Select this setting to save the system settings. - If it is successful, a success message displays (For Saved successfully) . - If it is failed because of an error, a failed message displays (For Failed to save) . Troubleshoot the error and save the system settings.
Changes	A confirmation dialog displays with a message indicating your changes are not saved and will be lost. Select Discard to discard the changes and move to the other screen. Select Stay to review and save the changes before moving to other screen.

7.4 Configure ECG

Select **Settings > ECG** menu to configure.



- Acquisition - [7.4.1 Configure ECG acquisition on page 72](#)
- Notifications - [7.4.2 Configure notifications on page 73](#)
- Filters, Speed, Gain - [7.4.3 Configure Filters, Speed, and Gain on page 74](#)
- Lead Group - [7.4.4 Configure lead groups on page 78](#)
- Report - [7.4.5 Configure report on page 80](#)
- 12SL - [7.4.6 Configure 12SL interpretations on page 81](#)

7.4.1 Configure ECG acquisition

1. Select **Settings > ECG > Acquisition**.

The **Acquisition** settings screen displays.

The screenshot shows the 'Acquisition' settings screen on a GE HealthCare MAC 3 device. The screen has a dark background with white text. At the top, there is a status bar with the GE HealthCare logo, 'MAC™ 3', the date and time '16-Sep-2025 10:26:21 AM', and a battery icon. Below the status bar is a header with a back arrow and the title 'Acquisition', and a 'Save' button with a floppy disk icon. The settings are organized into four rows, each with a label on the left and a control on the right:

- Lead label type:** Two buttons, 'AHA' and 'IEC'. The 'IEC' button is highlighted with a white border.
- Lead sequence:** A dropdown menu showing 'Standard' with a downward arrow.
- Acquisition mode:** A dropdown menu showing 'Post-acquisition' with a downward arrow.
- Simulated patient data:** A toggle switch that is currently turned off (white circle on the left).

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

Table 7-2 Acquisition settings

Field	Action	Description
Lead label type	Select AHA or IEC to configure the lead label type.	The supported lead labels are from the American Heart Association (AHA) and International Electrotechnical Commission (IEC).
Lead sequence	Select a value from the drop-down list to configure the lead sequence.	To select Standard or Cabrera lead sequence. The leads identified in the Lead Groups change to the related lead sequence when you set the lead sequence settings. Default value: Standard
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: Post-acquisition

Continues on the next page

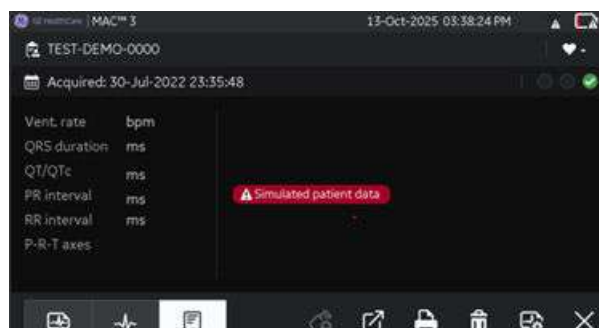
Table 7-2 Acquisition settings (Table continued)

Field	Action	Description
Simulated patient data	Enable or disable the simulated patient data setting.  NOTE This setting will be disabled when the system resumes from a power off state.	If this setting is enabled, you can use simulated patient data for demonstrations or troubleshooting. The system generates and displays simulated ECG waveforms on the Acquisition screen only when you disconnect the patient cable from the device. The label at the middle of the screen and the label at the top of printed report 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

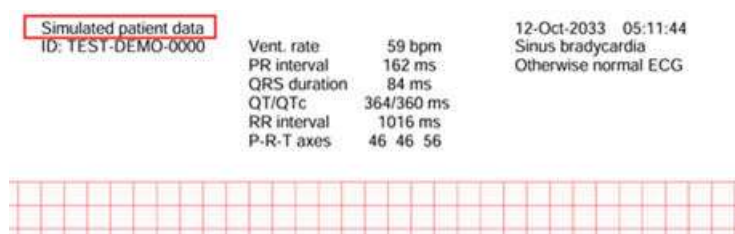
- Click **Save**.

Simulated patient data screens:

File manager



PDF report



7.4.2 Configure notifications

- Select **Settings > ECG > Notifications**.

The **Notifications** setting screen displays.



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

Table 7-3 Notifications setting

Field	Action	Description
Auto gain check	Enable or disable this auto gain check setting.	Enable this setting to display a message after you press the ECG key, if the gain of the recorded ECG data is either too high or too low. You can then manually adjust the gain. Default value: Enable
Baseline wander warning	Enable or disable this baseline wander warning setting.	Enable this setting to display a screen message when the system detects a wandering baseline. Default value: Disable
Muscle tremor warning	Enable or disable this muscle tremor warning setting.	Enable this setting to display a screen message when the system detects muscle tremor. Default value: Disable
AC noise level warning	Enable or disable this AC noise level warning setting.	Enable this setting to program the system to check for powerline interference when recording an ECG. Default value: Enable

3. Click **Save**.

7.4.3 Configure Filters, Speed, and Gain

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

GE HealthCare | MAC™ 3 26-Jul-2024 12:56:39 PM

← Filters, Speed, Gain Save

AC filter	Off 60 Hz 50 Hz
AC adaptive filter	☐
Baseline roll filter	0.16 Hz ▼
Default display filter	150 Hz ▼
Default display speed	12.5 mm/s ▼
Default gain	10 mm/mV ▼

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

Table 7-4 Filters, Speed, Gain setting

Field	Action	Description
AC filter	Select a value from the list to configure the AC filter type.	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: • Off • 60Hz • 50Hz
AC Adaptive filter	Enable or disable this AC adaptive filter setting.	To enable or disable the AC Adaptive filter .
Baseline roll filter	Select a value from the drop-down list to configure the baseline roll filter.	Use the baseline roll filter to remove low frequency components such as motion artifact, respiratory variation, and baseline shift. The higher the setting, the more the filter smooths out a wandering baseline. This filter does NOT distort the ST segment displayed on the ECG reports. Default value: 0.16 Hz

Continues on the next page

Table 7-4 Filters, Speed, Gain setting (Table continued)

Field	Action	Description
Default display filter	Select a value from the drop-down list to configure the default display 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
Default display speed	Select a value from the drop-down list, to configure the default display 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 mm/s Allowed values: • 5 mm/s • 12.5 mm/s • 25 mm/s • 50 mm/s

Continues on the next page

Table 7-4 Filters, Speed, Gain setting (Table continued)

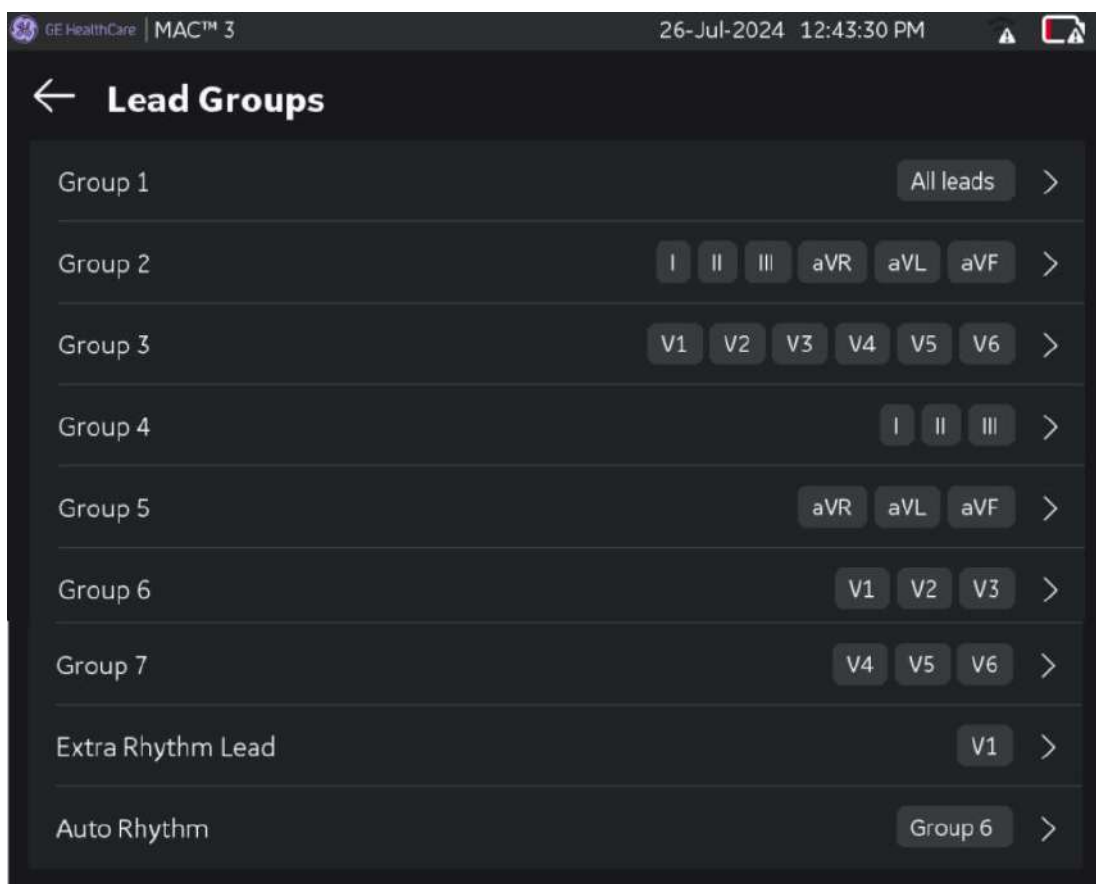
Field	Action	Description
Default gain	Select a value from the drop-down list, to configure the default gain of the ECG waveform to display on the Acquisition screen.	Gain indicates how many mm represent 1 mV of sample data on the printout. Changing the gain changes the amplitude of the waveforms. A higher 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 1mm 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 mm/mV Allowed values: • 2.5 mm/mV • 5 mm/mV • 10 mm/mV • 20 mm/mV • 10/5 mm/mV

3. Click **Save**.

7.4.4 Configure lead groups

1. Select **Settings > ECG > Lead Groups**.

The **Lead Groups** setting screen displays.



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

Table 7-5 Lead groups setting

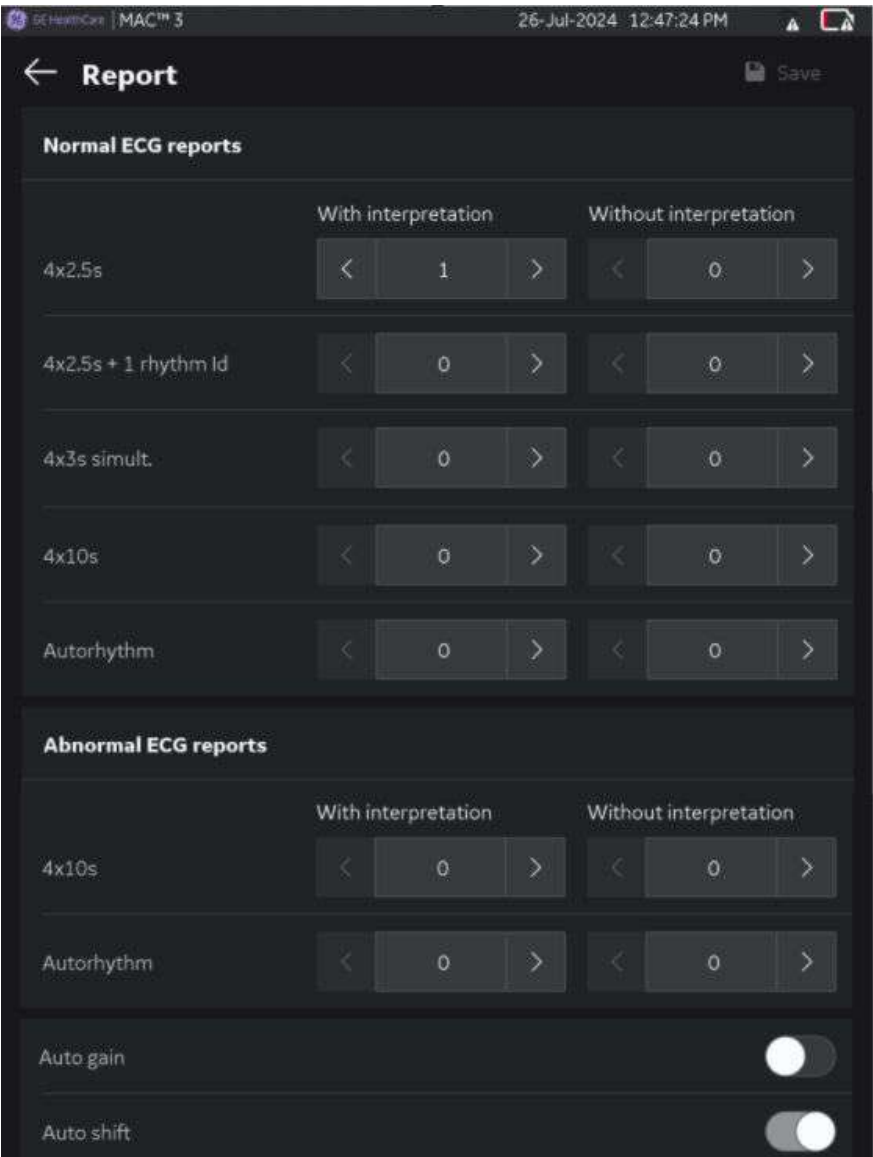
Field	Action	Description
Group 1 – Group 3	Select the lead to define the lead group.	The lead groups are only displayed on the screen. The options available under the leads displayed are: All Leads and 6 leads . Default value: All Leads for Group 1 and 6 leads for Group 2 and Group 3 .
Group 4 – Group 7	Select the lead to define the lead group.	The lead groups for rhythm printing and display. The number of leads that can be selected is three. Default value: 3 leads
Extra Rhythm Lead	Select the rhythm lead to define the format.	Select the rhythm lead for the 4 by 2.5 + 1 rhythm ld report format. Default value: Lead V1 .
Auto Rhythm	Select the lead group to define the rhythm report.	Select the group (from Group 4 to Group 7) to print in the Auto rhythm report.

3. Click **Save**.

7.4.5 Configure report

- 1. Select **Settings > ECG > Report**.

The **Report** setting screen displays.



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

Table 7-6 Report settings

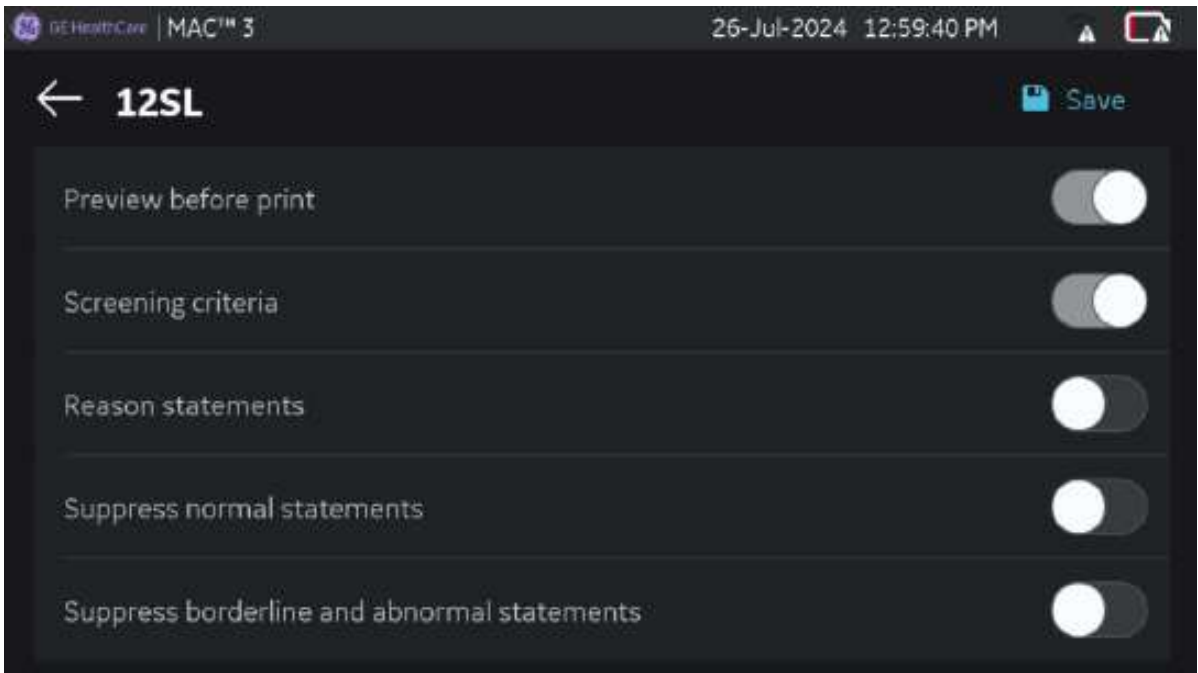
Field	Action	Description
Normal ECG reports	Choose the report formats your system automatically prints after you press the Start ECG key.	- Select whether you want the report to print with or without interpretation (12SL analysis statements). - Enter the number of copies you want to print for each report (0 - 10 copies). The available report formats are: 4 by 2.5s 4 by 2.5s + 1 rhythm ld 4 x 3 silumt 4 by 10s Autorhythm  NOTE The default report format is one copy with interpretation for 4 by 2.5.
Abnormal ECG reports	Choose the report formats your system automatically prints when an ECG is interpreted as abnormal.	- Select whether you want the report to print with or without interpretation (12SL analysis statements). - Enter the number of copies you want to print for each report (0 - 10 copies). The available report formats are: 4 by 10s Autorhythm By default, no extra report is printed.
Auto gain	Enable or disable the Auto gain feature.	Enable Auto gain setting to adjust the gain to minimize waveform overlap. You can apply the Auto gain to all leads or only to Thorax leads if the waveform overlap is maximum. Default value: Disable.
Auto shift	Enable or disable the Auto shift feature.	Enable Auto shift setting to automatically shift the waveforms vertically to avoid (or minimize) waveform overlap between rows. Default value: Enable.

3. Click **Save**.

7.4.6 Configure 12SL interpretations

1. Select **Settings > ECG > 12SL**.

The **12SL** setting screen displays.



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

Table 7-7 12SL settings

Field	Action	Description
Preview before print	Enable or disable this setting.	If you enable this setting, displays the 10 second ECG preview report before you print. If you disable this setting, the screen does not show the preview report before you print. Default value: Enabled
Screening criteria	Enable or disable this setting.	Enable this setting to prevent the 12SL analysis specified statements to show from the reports. For the list of these statements, see A 12SL statements on page 160 . If you disable this setting, the device runs the 12SL algorithm in normal analysis mode and report shows all statements. Default value: Disabled
Reason statements	Enable or disable this setting.	Enable this setting to include the reason statements in the report. If you disable this setting, no reason statements included in the report. Default value: Disabled

Continues on the next page

Table 7-7 12SL settings (Table continued)

Field	Action	Description
Suppress normal statements	Enable or disable this setting.	Enable this setting to prevent the Normal ECG 12SL analysis statement to show from the report. If you disable this setting, the Normal ECG 12SL analysis statement displays on the report. Default value: Disabled
Suppress border line and abnormal statements	Enable or disable this setting.	Enable this setting to prevent the Abnormal ECG and Borderline ECG 12SL analysis statement to show from the report. If you disable this setting, the Abnormal ECG and Borderline ECG 12SL analysis statement display on the report. Default value: Disabled

3. Click **Save**.

7.5 Configure patient information

1. Select **Settings > Patient Data**.

The **Patient Data** setting screen displays.

GE HealthCare | MAC™ 3

26-May-2025 03:20:01 PM

← Patient Data

Save

Mandatory fields

None

Patient ID length

< 10 >

Range 3-16

☒ Patient ID

☒ Visit number

☒ Last name

☒ First name

☒ Date of Birth/Age

DOB

Age

☒ Gender

☒ Technician ID

☒ Acquiring Tech User

☐ Location ID

☐ Secondary ID

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

Table 7-8 Patient data settings

Field	Action	Description
Mandatory fields	Select a value from the drop-down list to configure the mandatory field.	You can set the mandatory fields from the list. Allowed values: None, Patient ID, and All field. Default value: None.
Patient ID length	Enter the number to configure the length of the patient identification number.	You can select the value from 3 to 16. This field is always set to enable. Default value: 12
Visit number	Select or unselect this field.	If you select the Visit number , displays the field in the patient information screen. If you do not select the Visit number , hides the field in the patient information screen.

Continues on the next page

Table 7-8 Patient data settings (Table continued)

Field	Action	Description
Last name	Select or unselect this field.	If you select the Last name , displays the field in the patient information screen. If you do not select the Last name , hides the field in the patient information screen.
First name	Select or unselect this field.	If you select the First name , displays the field in the patient information screen. If you do not select the First name , hides the field in the patient information screen.
Date of Birth/Age	Select or unselect this field.	If you select the DOB , displays the field in the patient information screen. If you select the Age , displays the field in the patient information screen. Default value: DOB.
Gender	Select or unselect this field.	If you select the Gender , displays the field in the patient information screen. If you do not select the Gender , hides the field in the patient information screen.
Technician ID	Select or unselect this field.	If you select the Technician ID , displays the field in the patient information screen. If you do not select the Technician ID , hides the field in the patient information screen.
Acquiring Tech User	Select or unselect this field.	If you select the Acquiring Tech User , displays the field in the patient information screen. If you do not select the Acquiring Tech User , hides the field in the patient information screen.
Location ID	Select or unselect this field.	If you select the Location ID , displays the field in the patient information screen. If you do not select the Location ID , hides the field in the patient information screen.
Secondary ID	Select or unselect this field.	If you select the Secondary ID , displays the field in the patient information screen. If you do not select the Secondary ID , hides the field in the patient information screen.

- Click **Save**.

7.6 Configure system

Select **Settings > System** menu to configure.



Device - [7.6.1 Configure device on page 86](#)

Security - [7.6.2 Configure security on page 87](#)

Change Password - [3.8.2 Admin password on page 35](#)

Settings Backup - [7.6.3 Settings backup on page 92](#)

Option Manager - [7.6.4 Enable options on page 98](#)

Buzzer - [7.6.5 Configure buzzer on page 101](#)

Hardware - [7.6.6 Configure hardware on page 102](#)

Audit Logs, Event Logs, and Remote Configuration - Refer to *MAC™ 3 Service Manual*.

7.6.1 Configure device

1. Select **Settings** > **System** > **Device**.

The device setting screen displays.

GE Healthcare | MAC™ 3 17-Sep-2025 11:08:02 AM

← Device Save

Cart ID 1 Range 0-255

Default location ID 0 Range 0-9999

Site 1 Range 1-65535

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

Table 7-9 Device settings

Field	Action	Description
Cart ID	Set the device ID.	The device number is unique for each ECG device. Default value: 1
Default location ID	Set the default location ID.	For each patient test, the location ID is populated in the Location field of the Patient Data screen. Default value: 0
Site	Set the site number.	Default value: 1

- Select **Save**.

7.6.2 Configure security

- Select **Settings > System > Security**.

The **Security** setting screen displays.

16-Sep-2025 10:20:02 AM

← Security

Save

Password expiration: ☐

Password lifetime (days): Range: 2-365

Minimum password length: Range: 8-14

Password must contain atleast:

- ☒ One lowercase alphabet
- ☒ One uppercase alphabet
- ☒ One numerical character
- ☒ One special character

Prevent re-use of previous (no. of passwords): Range: 10-32

Lock-out after (no. of attempts): Range: 0-99

Lock-out duration (minutes): Range: 1-120

Auto shutdown: ☐

Auto shutdown after (minutes): Range: 5-120

Device password: ☒

New password: 
Must have: 8 characters, lowercase, uppercase, number and special character.

Confirm new password:

Auto-lock: ☒

Auto-lock after (minutes of inactivity): Range: 1-60

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

Table 7-10 Security settings

Field	Action	Description
Password expiration	Enable or disable this setting.	If you enable this setting, set the duration for password expiration in the Password lifetime (days) field. The password expires after the configured duration, and a message displays to the user to set a new password. If you disable this setting, the password does not expire. Default value: Enabled
Password lifetime (days)	Set the password expiration duration in days, if Password expiration setting is enabled.	This specifies the number of day a password needs to stay 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. • 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. Allowed values: 2 and 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. Allowed values: 8 to 14 characters
Password must contain atleast	Select what a user password must contain.	The password must contain: • One lowercase alphabet. • One uppercase alphabet • One numerical character • One speical character

Continues on the next page

Table 7-10 Security settings (Table continued)

Field	Action	Description
One lowercase alphabet	Select or unselect this setting.	If you select this setting, the lower alphabet characters are required to be used in the password. If you unselect this setting, the lower alphabet characters are not required to be used in the password. Default value: Enabled
One uppercase alphabet	Select or unselect this setting.	If you select this setting, the upper alphabet characters are required to be used in the password. If you unselect this setting, the upper alphabet characters are not required to be used in the password. Default value: Enabled
One numerical character	Select or unselect this setting.	If you select this setting, the numeric characters are required to be used in the password. If you unselect this setting, the numeric characters are not required to be used in the password. Default value: Enabled
One speical character	Select or unselect this setting.	If you select this setting, the special characters are required to be used in the password. If you unselect this setting, the special characters are not required to be used in the password. Default value: Enabled
Prevent re-use of previous (no. of passwords)	Set a value 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: 12 Allowed values: 10 to 32
Lockout after (no. of attempts)	Enter the number of failed logon attempts after which the system must be automatically locked, if the Lock-out setting is enabled.	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: 8 Allowed values: 0 to 99

Continues on the next page

Table 7-10 Security settings (Table continued)

Field	Action	Description
Lockout duration (minutes)	Enter the duration of inactivity (in minutes) after which the system must be automatically locked, if the Lock-out setting is enabled.	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. Allowed values: 1 to 120
Auto shutdown	Enable or disable this setting.	If you enable this setting, set the duration in minutes for system to automatically shutdown in the Auto shutdown after (minutes) field. If you disable this setting, the system does not shutdown automatically. Default value: Disabled
Auto shutdown after (minutes)	Enter the duration in minutes after which the system must automatically shutdown, if the Auto shutdown setting is enabled.	This specifies to configure the duration in minutes to shutdown the system automatically. If it is set to 60 minutes then the system automatically shutdown after 1 hour. Default value: 60 Allowed values: 5 to 120
Device password	Enable or disable this setting.	If you enable this setting, the New password and Confirm new password fields display. Enter the new password. Make sure that the new password follows the password recommendations: • One lowercase letter • One uppercase letter • One number • One special character Make sure that you enter the same new password to confirm. If you disable this setting, you cannot change the device password but you can change the Admin password, see 3.8.2 Admin password on page 35 .

Continues on the next page

Table 7-10 Security settings (Table continued)

Field	Action	Description
Auto lock	Enable or disable this setting.	If you enable this setting, the device is automatically locked after a configured duration of inactivity in the Auto lock after (minutes of inactivity) field. If you disable this setting, the device is not locked automatically. Default value: Disabled
Auto lock after (minutes of inactivity)	Enter the duration of inactivity (in minutes) after which the system must be automatically locked, if the Auto lock setting is enabled.	This specifies to configure the duration of inactivity in minutes to automatically lock the system. If it is set to 10 minutes then the system automatically lock after 10 minutes of inactivity. Default value: 15 Allowed values: 1 to 60

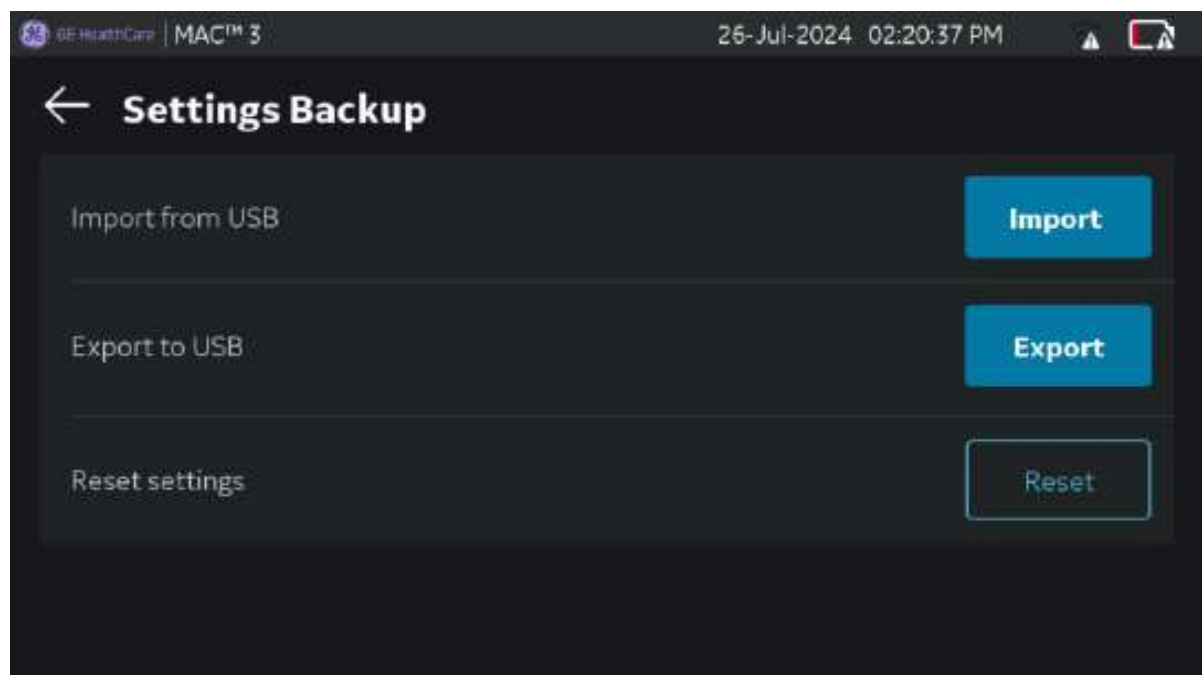
3. Select **Save**.

7.6.3 Settings backup

Make sure that you backup the settings before you upgrade the software or reset the settings.

1. Select **Settings > System > Settings Backup**.

The **Settings Backup** screen displays.



2. Select the below options to import, export, and reset the settings.

Table 7-11 Backup settings

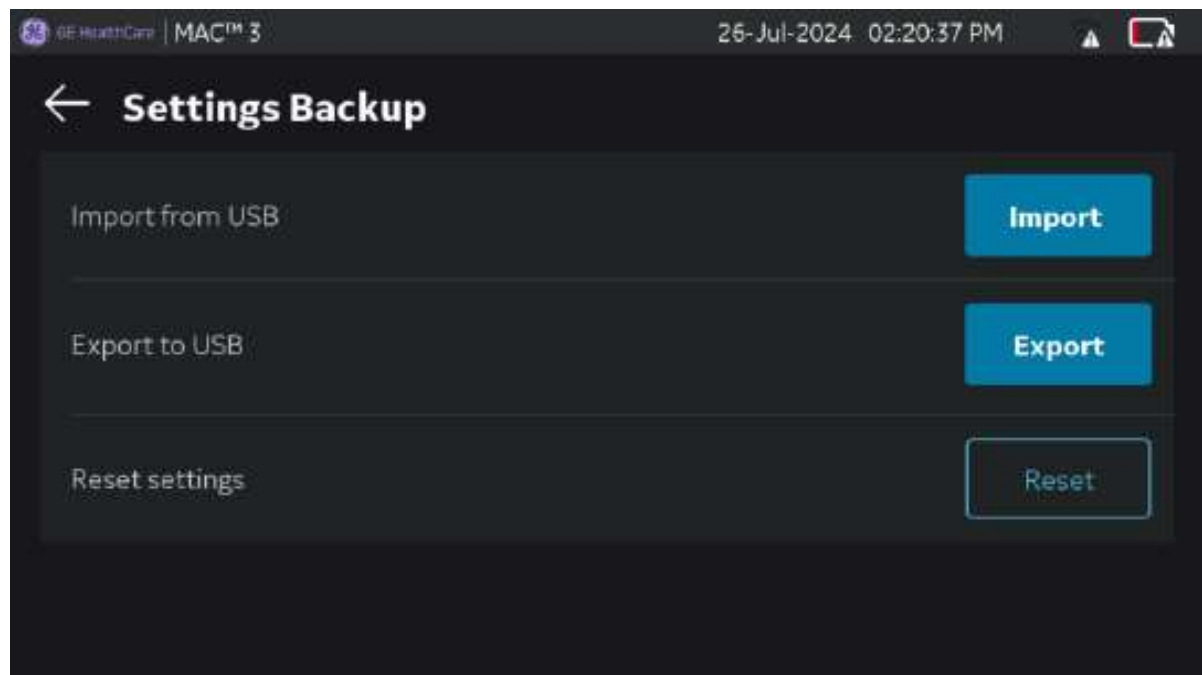
Field	Action	Description
Import from USB	Select Import .	Import settings from the USB flash drive. Only an Admin user can import from USB.
Export to USB	Select Export .	Export settings to the USB flash drive. Only an Admin user can export to USB.
Reset settings	Select Reset settings .	Reset the settings. Only an Admin user can reset the settings.

7.6.3.1 Import settings from USB

Make sure that you connect the USB flash drive in the USB port. The USB flash drive must have the correct file format.

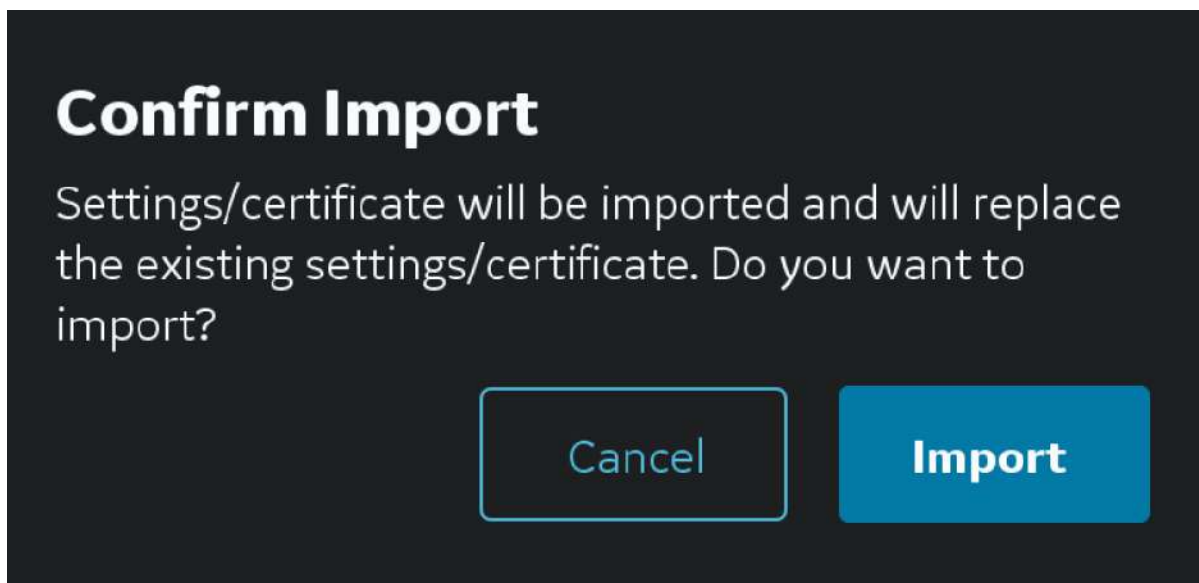
1. Select **Settings > System > Settings Backup**.

The **Settings Backup** screen displays.



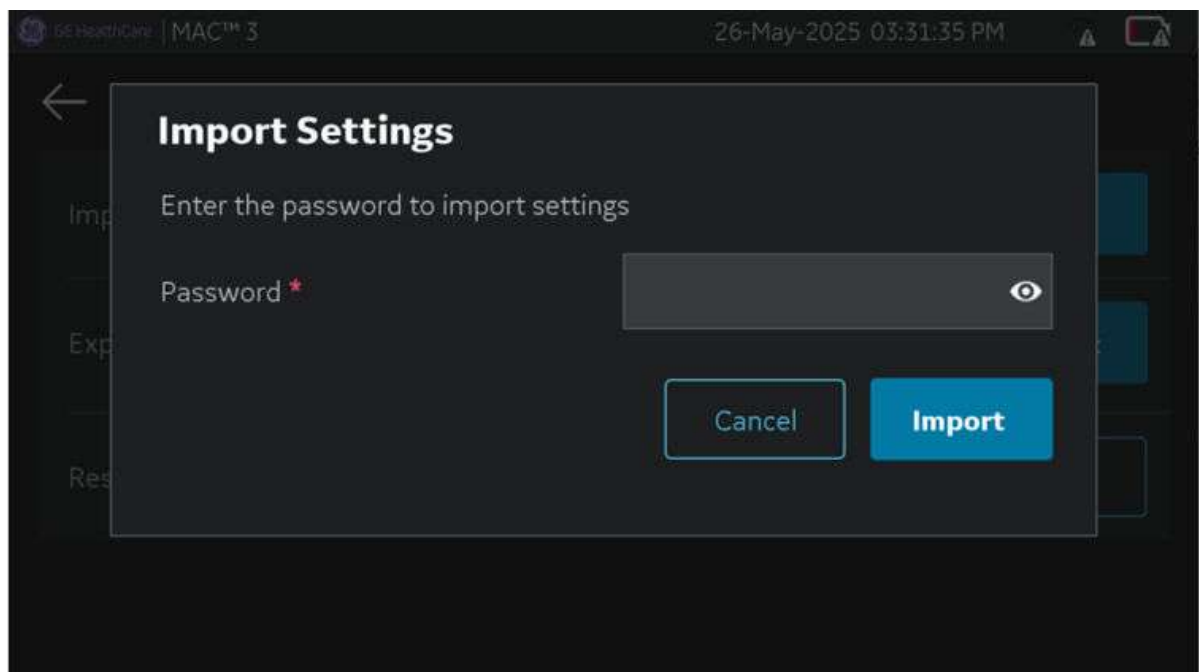
2. Select **Import** to confirm the action

The **Confirm Import** screen displays.



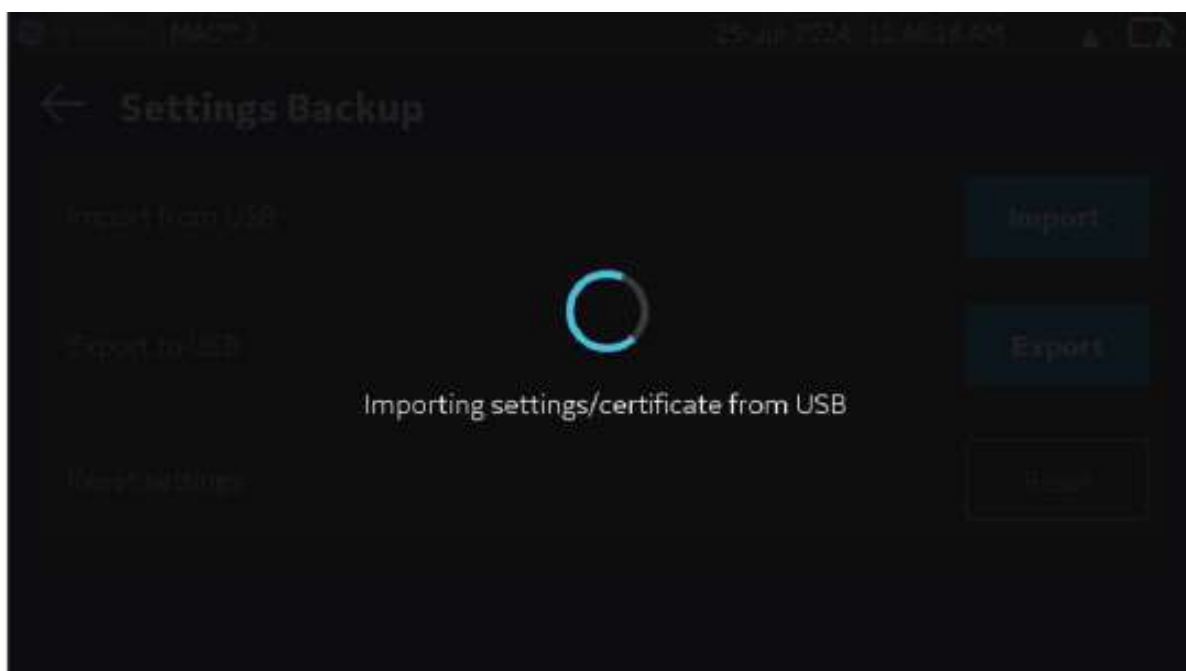
3. Enter the same password previously you use to export the configuration file and select **Import** to import the settings from USB flash drive.

The password confirmation screen displays.



4. Select **Import** to confirm and continue to import the settings.

The import settings progress screen displays.



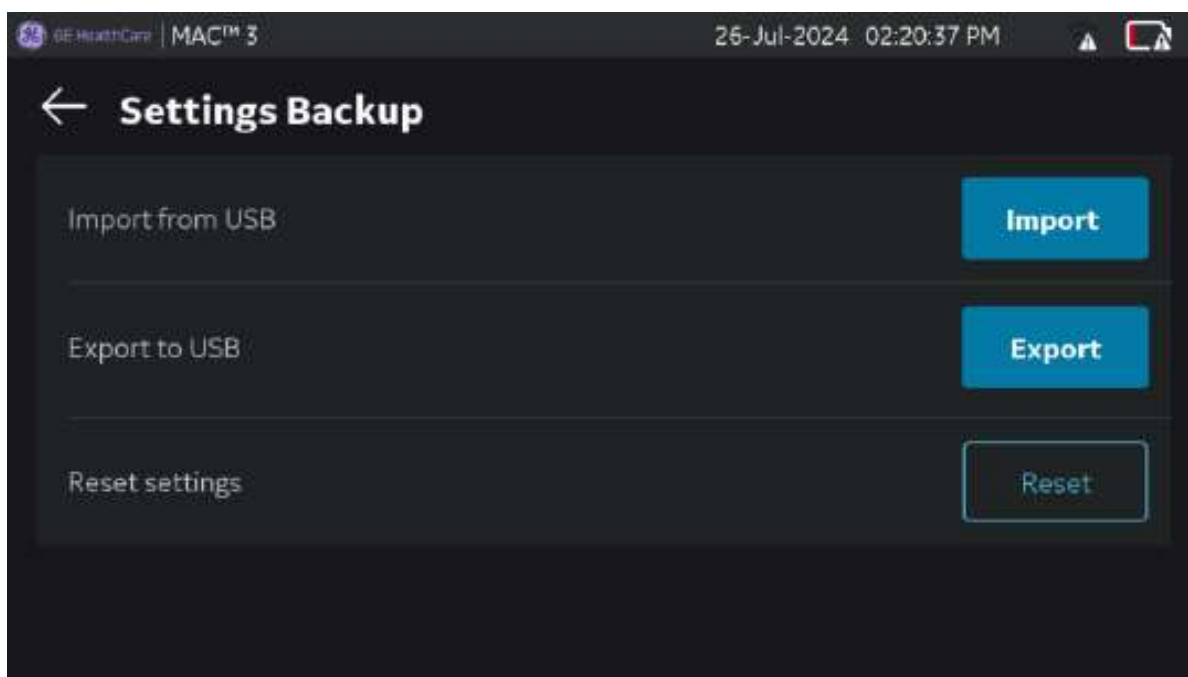
5. Select **Cancel** to cancel import and go back to **Settings Backup** screen.

7.6.3.2 Export settings to USB

Make sure that you connect the USB flash drive in the USB port.

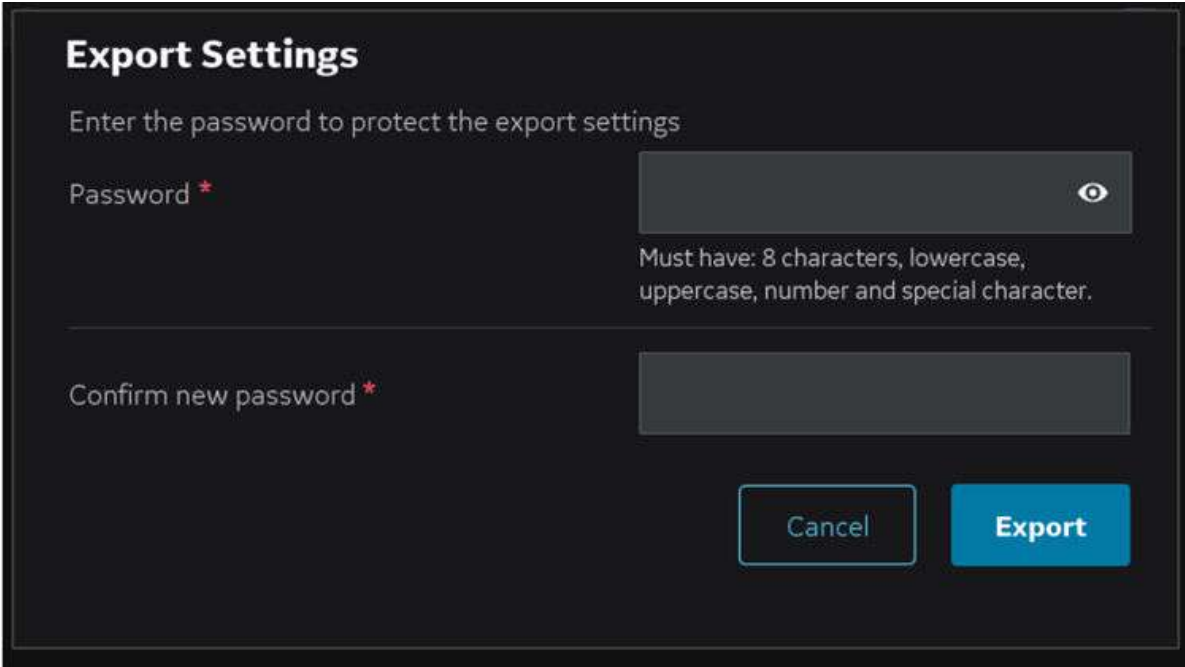
1. Select **Settings > System > Settings Backup**.

The **Settings Backup** screen displays.



2. Select **Export** to export the settings to the USB flash drive.

The password confirmation screen displays.



Export Settings

Enter the password to protect the export settings

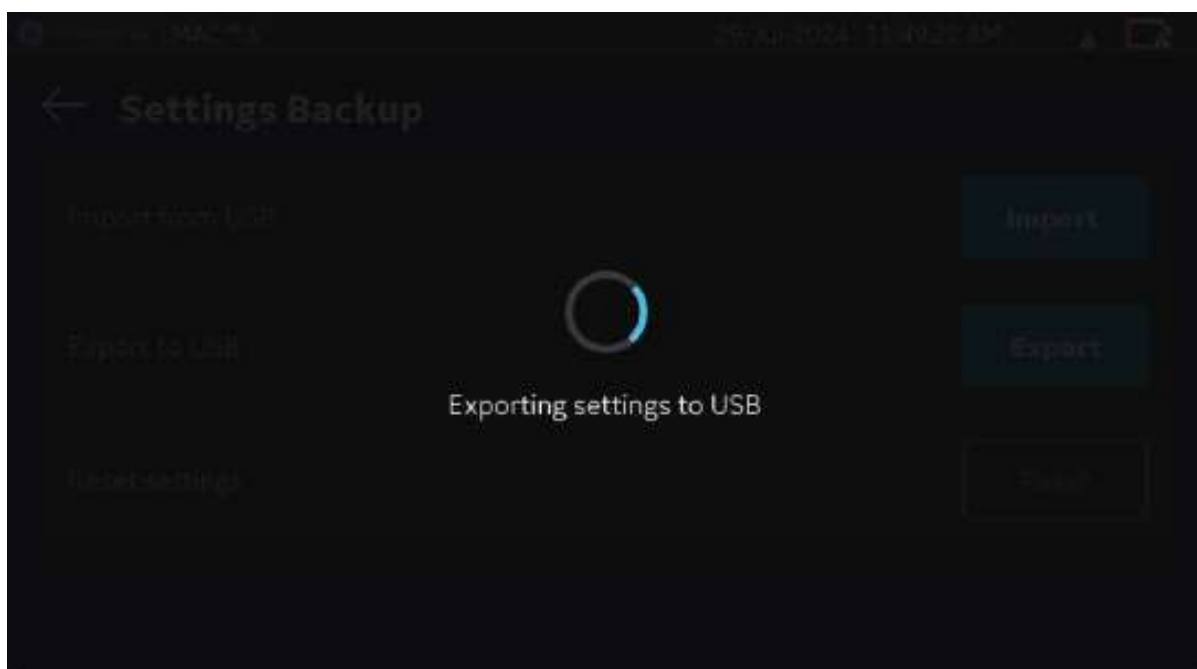
Password *

Must have: 8 characters, lowercase, uppercase, number and special character.

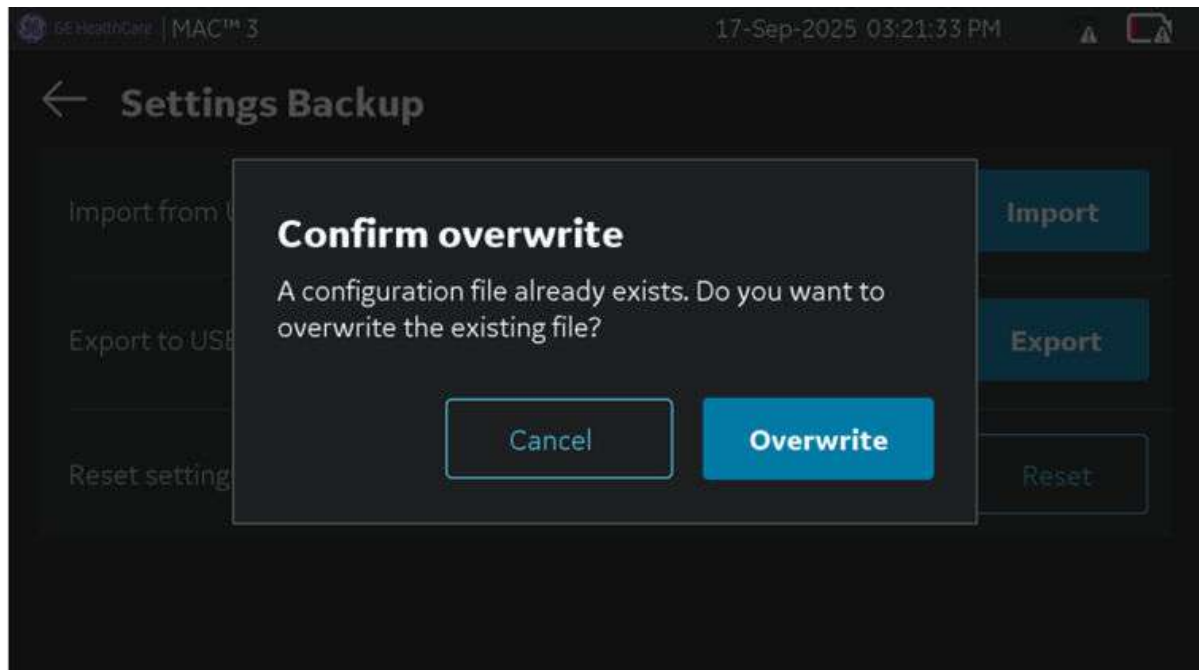
Confirm new password *

- The password characters display with asterisks. The  icon enable/disable you to view the entered password or confirmed password field text.
 - Enter a password which meets the password requirements that display in the confirmation window. Type again the same password to confirm the **Password** field.
 - Select the **Cancel** button to stop the export of the configuration settings.
 - The device does not authenticate for duplicate passwords. You can use the same password for any number of exports.
3. Select **Export**.

The export settings progress screen displays.



If you connect a USB with existing configuration file, the overwrite confirmation screen displays.



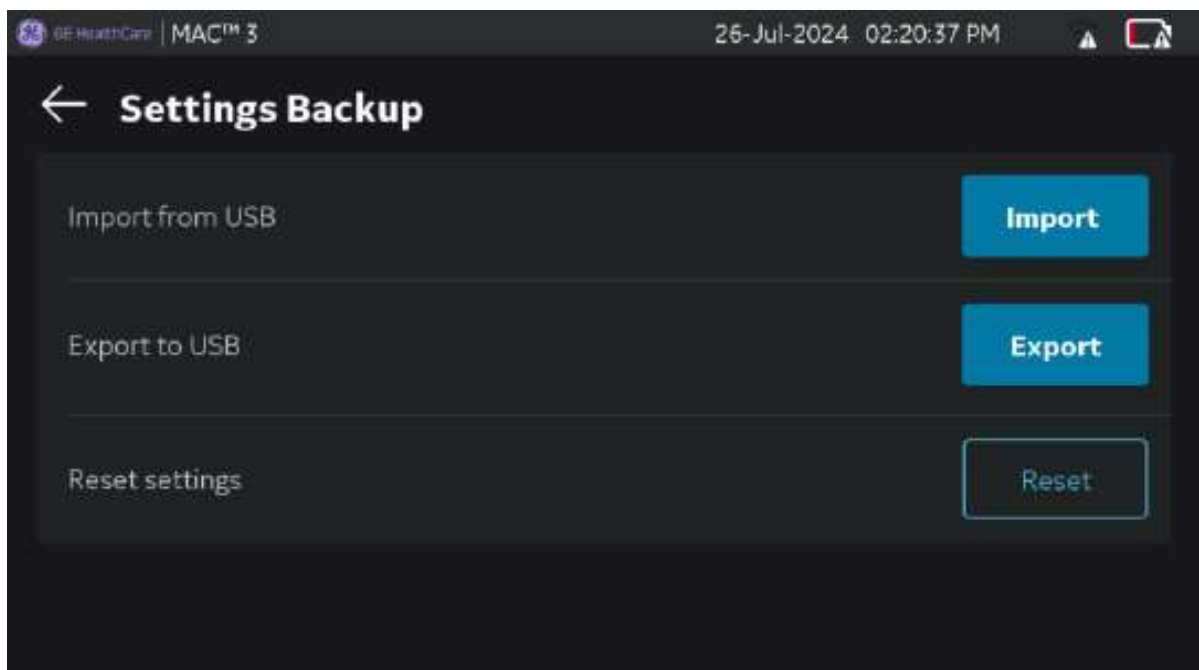
4. Select **Overwrite** to overwrite the existing file.
5. Select **Cancel** to cancel to overwrite the existing file.

7.6.3.3 Reset settings to factory defaults

Make sure that you exported the settings to USB flash drive before you reset to factory defaults.

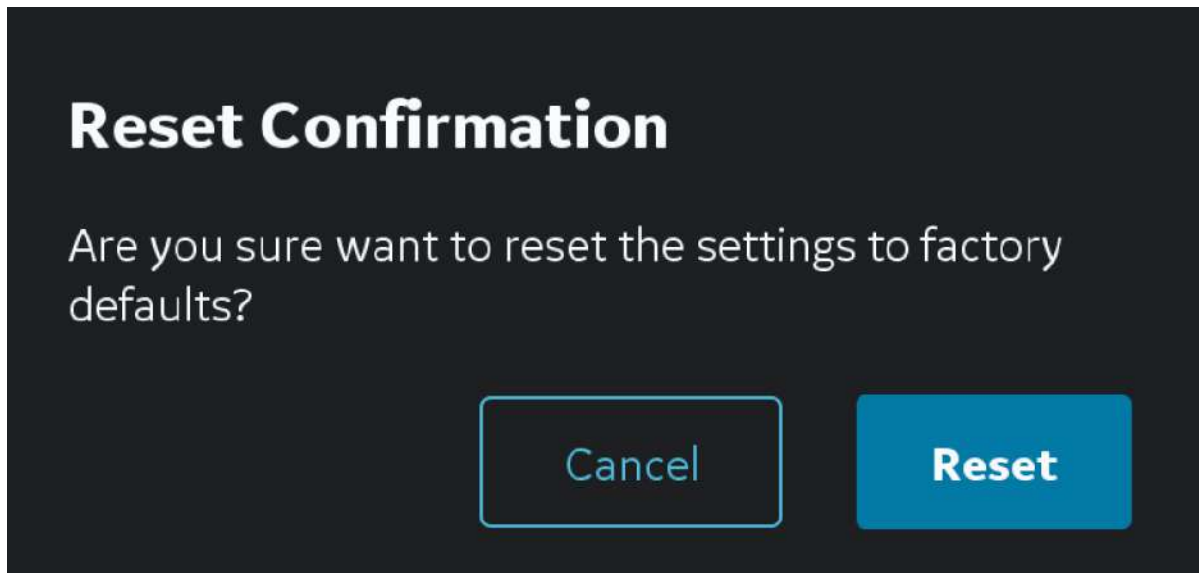
1. Select **Settings > System > Settings Backup**.

The **Settings Backup** screen displays.



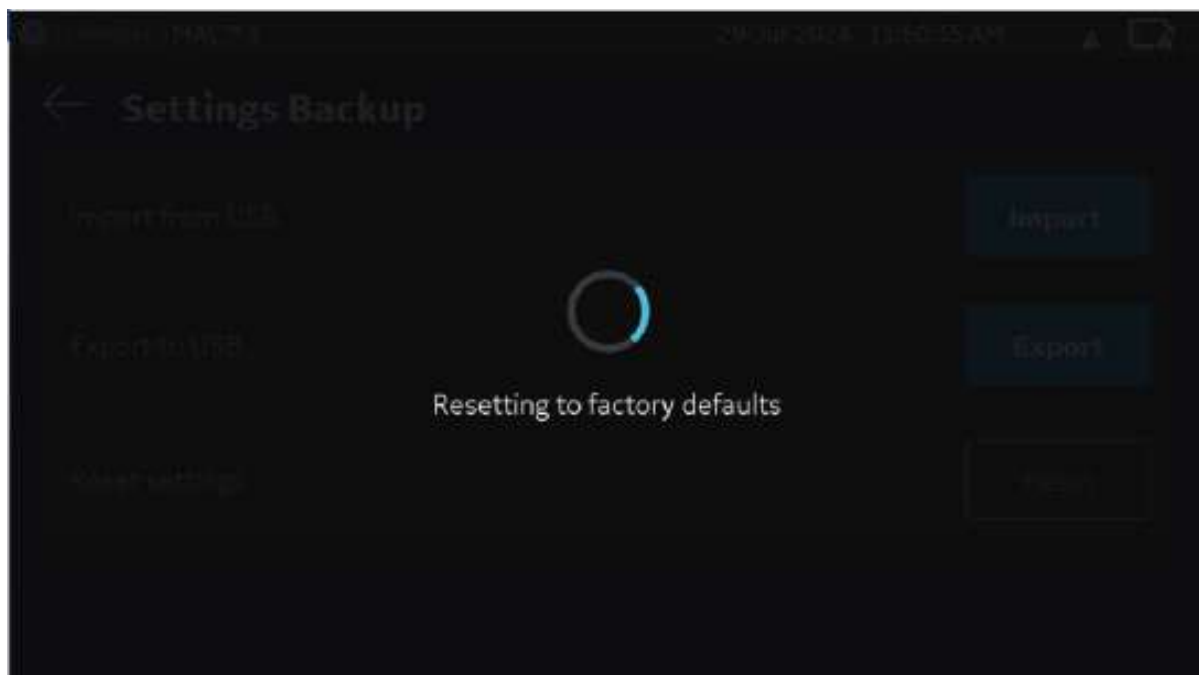
2. Select **Reset** to reset the settings to factory defaults.

The **Reset Confirmation** screen displays.



3. Select **Reset** to confirm and continue to reset the settings to factory defaults.

The resetting to factory defaults progress screen displays.



4. Select **Cancel** to cancel reset the settings to factory defaults and go back to **Settings Backup** screen.

7.6.4 Enable options

Before you begin this procedure, make sure that:

- The serial number of the device is configured. See Installation procedure upon replacing the main PWA.

- You obtain the required option codes. Contact your GE HealthCare Service Support representative to obtain the unique code for your device. You cannot enable the options without the appropriate code.

**NOTE**

The enabled options are not reset when the device is reset to factory default settings.

- Select **Settings > System > Option Manager**.

The **Option Manager** screen displays.

- From the below option list, select the option you want to enable.

Table 7-12 Available device options

Option	Description
MI12 - 12SL interpretation	12SL interpretation
XMLO - Export to USB	You can save Sapphire XML formatted record files to USB flash drive.
WRLS - Transmission over Wi-Fi	You can configure the default wireless network to transmit the ECG reports through Wi-Fi.
LANT - Transmission over Ethernet	You can configure the default Ethernet network to transmit the ECG reports through LAN.

Continues on the next page

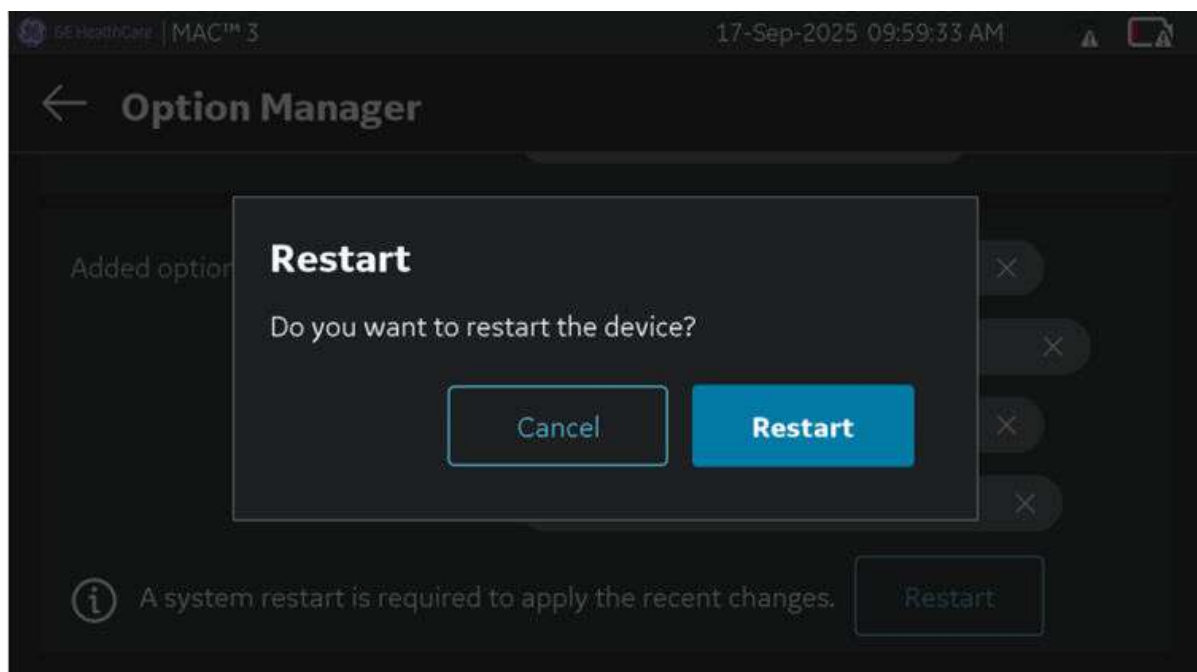
Table 7-12 Available device options (Table continued)

Option	Description
GSMM - Transmission over GSM	You can configure the below default cellular network, to transmit the ECG reports through GSM. • LTE only • 3g only • 2g only • LTE/3g/2g(auto-connect)
BRCD - Barcode reader	You can enter the patient information through a barcode reader.

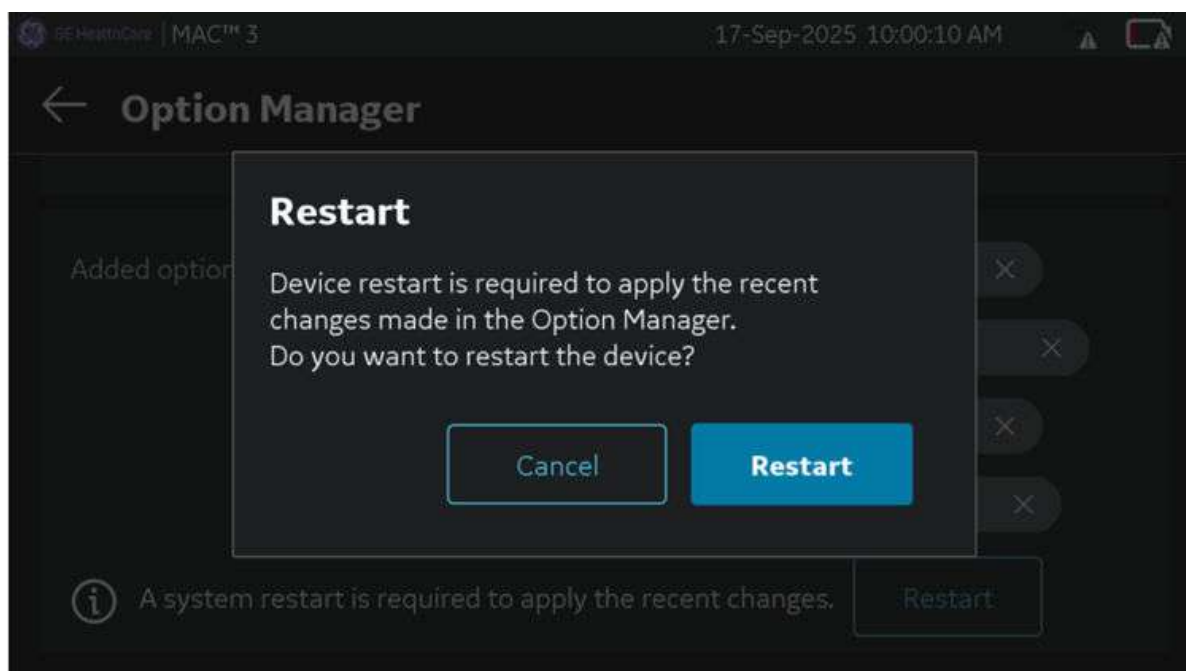
3.  **NOTE**
Because each option has a unique option code, you can enable only one option at a time.

Enter the option code for the selected option in the **Option Code** field.

4. Select **Add** to enable the selected option.
An error message displays if you enter an invalid option code.
A **Restart** confirmation screen displays.



5. Select **Restart** to restart the device and to apply the changes.
After restart of the device, the selected option is added to the **Added options** list.
6. Repeat [Step 3](#) to [Step 5](#) for each option you want to enable.
7. If you cancel the added option or switch to other screen.
A **Restart** confirmation screen displays.



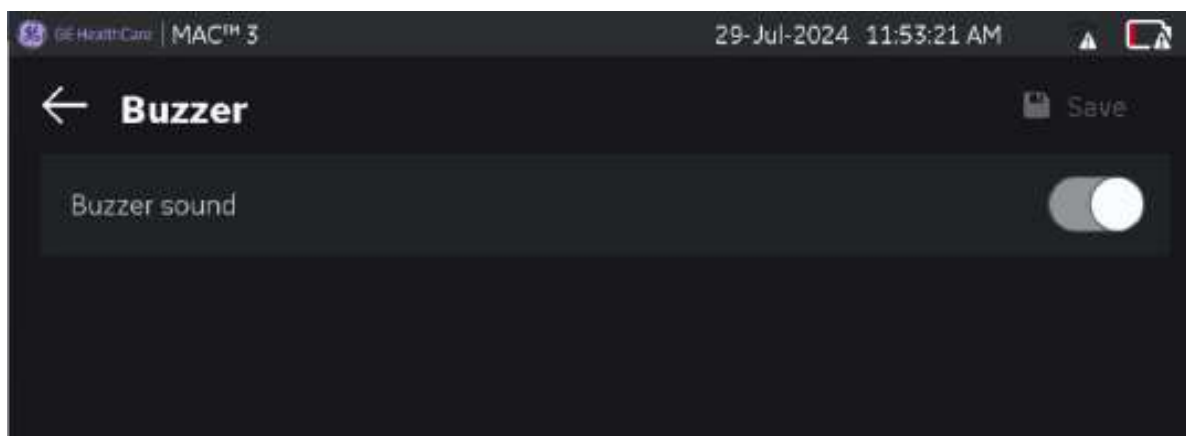
8. Select **Restart** to restart the device and to apply the changes.

After restart of the device, the selected option is deleted from the **Added options** list.

7.6.5 Configure buzzer

1. Select **Settings > System > Buzzer**.

The **Buzzer** setting screen displays.

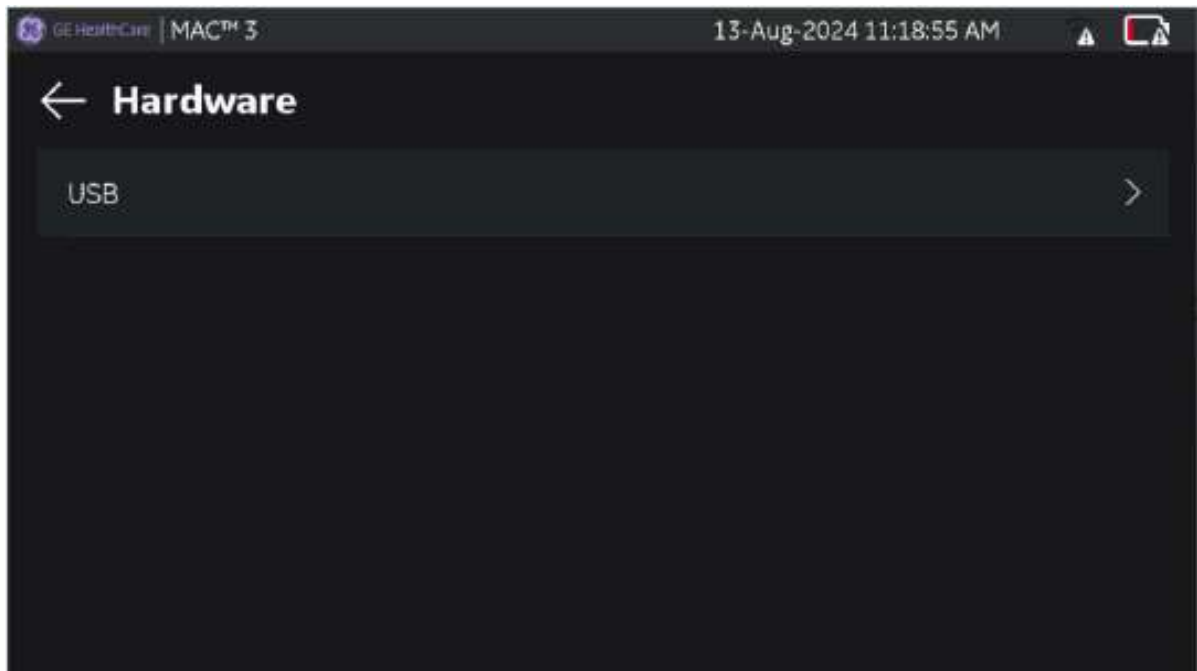


2.  **NOTE**
The buzzer option is always set on in the device. You can enable or disable this option.
Enable the **Buzzer sound** option to activate the buzzer sound of hard key press.
3. Disable the **Buzzer sound** option to not activate the buzzer sound of the hard key press.
4. Select **Save**.

7.6.6 Configure hardware

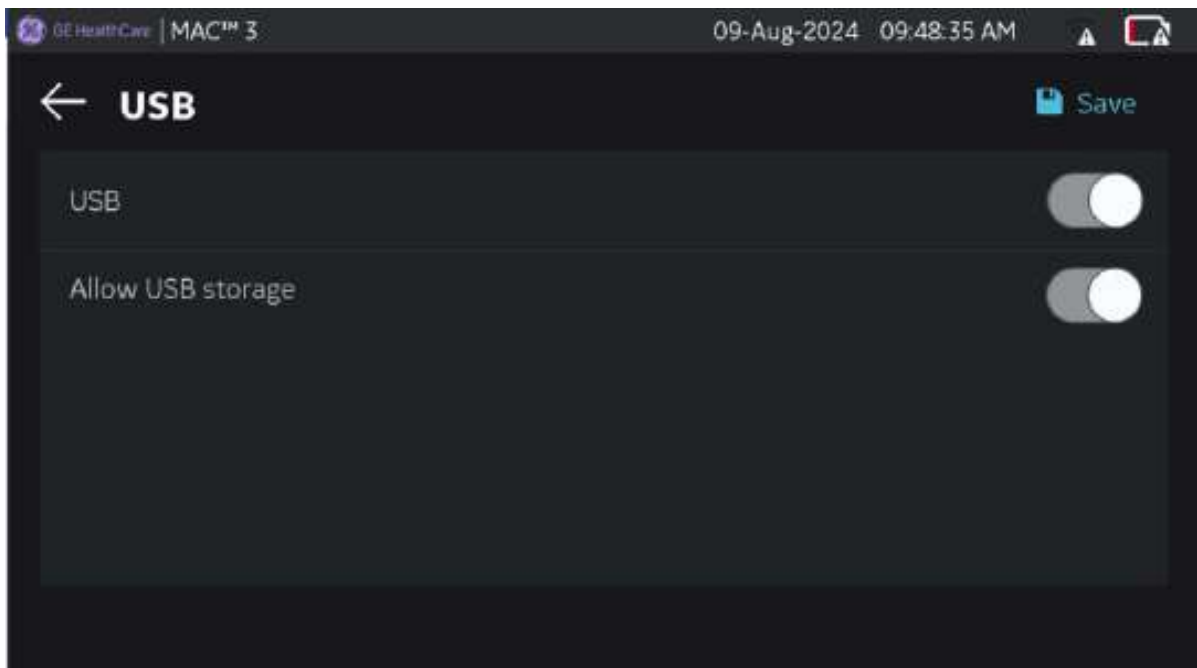
1. Select **Settings > System > Hardware**.

The **Hardware** setting screen displays.



2. Select **USB**.

The USB settings screen displays.



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

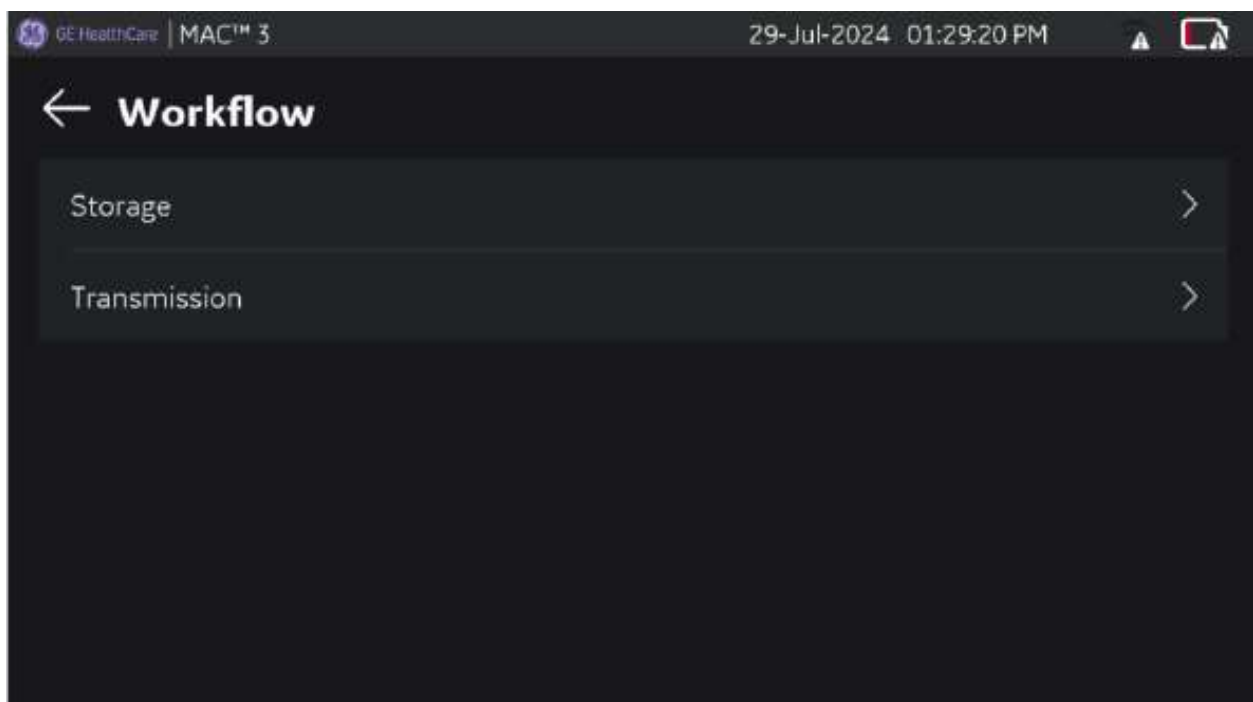
Table 7-13 USB settings

Field	Action	Description
USB	Enable or disable this setting.	If you enable this setting, the USB port will enable to use the USB flash drive. Default value: Disabled
Allow USB storage	Enable or disable this setting.	If you enable this setting, you can do the below tasks with USB flash drive: - Export settings, logs, diagnostic test results, and files - Import settings and certificates. - Transmit ECG reports. Default value: Disabled

- Select **Save**.

7.7 Configure workflow

Select **Settings > Workflow** menu to configure storage and transmission.



Storage - [7.7.1 Configure storage on page 103](#)

Transmission - [7.7.2 Configure transmission on page 106](#)

7.7.1 Configure storage

- Select **Settings > Workflow > Storage**.

The **Storage** screen displays.

GE Healthcare | MAC™ 3

29-Jul-2024 01:29:59 PM

←

Storage

Save

Auto ECG storage

No ECGs

Storage Format

500Hz

Store XML format to USB drive

☐

Store PDF format to USB drive

☐

PDF grid

☐

PDF report format

4x2.5s

PDF file name configuration

☒ Patient ID

☒ Secondary ID

☒ Date of birth

☒ Date and Time

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

Table 7-14 Storage settings

Field	Action	Description
Auto ECG storage	Select the value from drop-down list to configure the field.	Select the type of ECGs you want the system to automatically store. Default value: No ECGs Allowed values: • All ECGs • No ECGs • Only abnormal ECG If you select All ECGs or Only abnormal ECG, the 10 seconds ECG will be stored to the configured server.
Storage Format	Select the value from drop-down list to configure the field.	Select the type of storage format for the recorded ECG.  NOTE The recorded ECG is encrypted. Default value: 500Hz Allowed values: • 500Hz • 500Hz DVS Select 500Hz if you want to send the ECGs to the MUSE system with software versions NX R1 or higher. Select 500Hz DVS to store the ECGs and print again with the device that receives the ECG with initial resolution. The MUSE system must use the software versions NX R1 or higher.
Store XML format to USB drive	Enable or disable this setting.	If you enable this setting, each ECG saves automatically in XML format, while you use the standard proprietary GE HealthCare format. For more information, see 6.3.2 Save and export ECG reports to USB on page 60. Default value: Disabled
Store PDF format to USB drive	Enable or disable this setting.	If you enable this setting, each ECG saves automatically in PDF format, while you use the standard proprietary GE HealthCare format. For more information, see 6.3.2 Save and export ECG reports to USB on page 60. Default value: Disabled
PDF grid	Enable or disable this setting.	If you enable this setting, the grid lines show in the exported PDF file.
PDF report format	Select the value from the drop-down list to configure the field.	Select the report format for the ECG stored in PDF format. Default value: 4x2.5s Allowed values: • 4x2.5s + 1rhythm ld • 2x5s • 2x5s + 1rhythm ld • 2x5s @50mm/s • 4x10s • Autorhythm (12 lead)

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Table 7-14 Storage settings (Table continued)

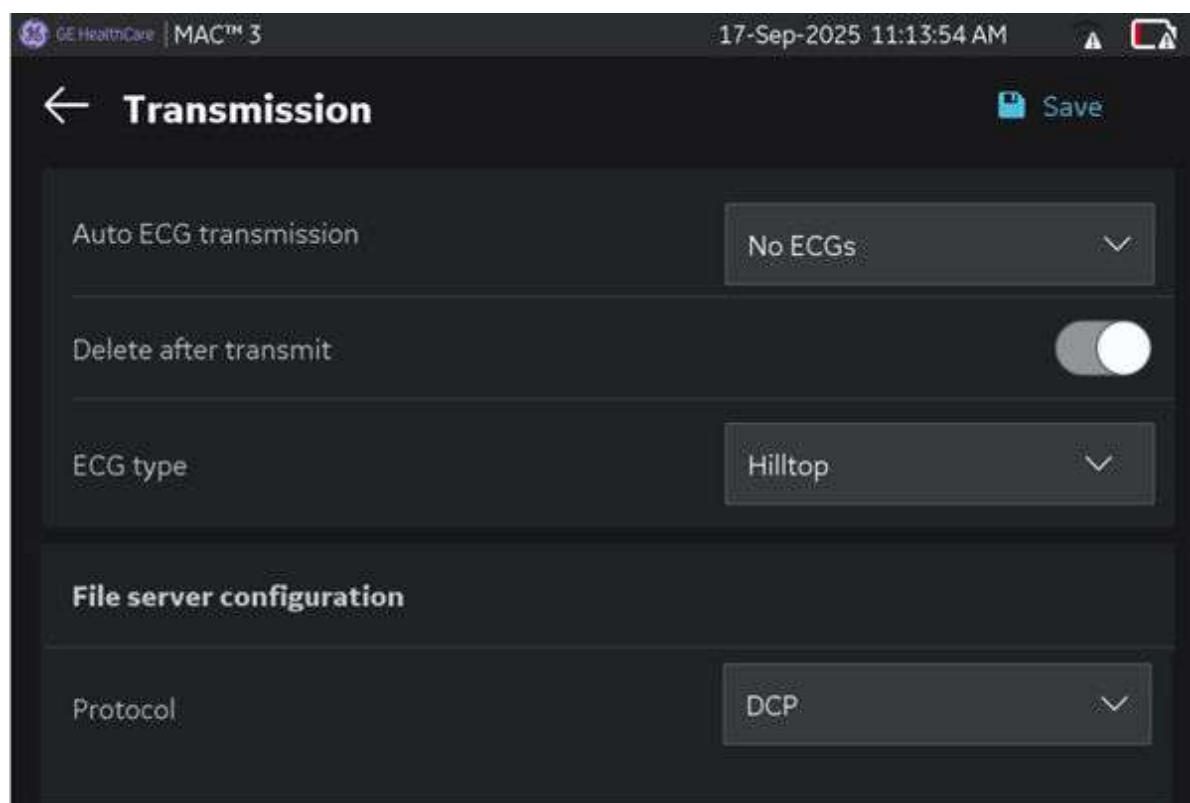
Field	Action	Description
PDF File name configuration	Select the options to configure the PDF file name.	Select the options how you want to configure the PDF file name. You can configure all the below options or one of the below options for the PDF file name: • Patient ID - select the checkbox to include the patient ID in the file name. Default value: Selected the checkbox. • Secondary ID - select the checkbox to include the patient secondary ID in the file name. Default value: Selected the checkbox. • Date of birth - select the checkbox to include the patient date of birth in the file name. Default value: Selected the checkbox. • Date and Time - select the checkbox to include the date and time of the recorded ECG in the file name. Default value: Selected the checkbox. If you select all the options for the PDF file name, the PDF file name format will be PID_SID_DOB_DE_TE.pdf.  NOTE If you do not select any of the options for the PDF file name, then the PDF file name format will be DE_TE.pdf.

3. Select **Save**.

7.7.2 Configure transmission

1. Select **Settings > Workflow > Transmission**.

The **Transmission** setting screen displays.



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

Table 7-15 Transmission settings

Field	Action	Description
Auto ECG transmission	Select the value from drop-down list to configure the field.	Select the type of ECGs that you want to transmit automatically after you acquire the ECGs to an external device. Default value: No ECGs Allowed values: • All ECGs • No ECGs • Only abnormal ECGs If you select All ECGs or Only abnormal ECG, the 10 seconds ECG will be transmitted to the configured server.
Delete after transmit	Enable or disable this setting.	If you enable this setting, deletes the files from the file manager list after you transmit the ECGs to an external device. Default value: Enabled
ECG type	Select the value from drop-down list to configure the field.	Select the default file type to transmit. Default value: Hilltop Allowed values: • Hilltop • XML  NOTE Other options are available to configure only when you change the mode of file server configuration. See 7.7.2.2 Configure HTTPS server on page 115 and 7.7.2.3 Configure an SFTP server on page 118 on how to configure the HTTPS and SFTP servers to transmit the files.
Protocol	Select the value from drop-down list to configure the field.	Select the type of protocol to transmit the files. Default value: DCP Allowed values: • DCP • HTTPS • SFTP • CareIntellect MUSE See 7.7.2.2 Configure HTTPS server on page 115, 7.7.2.3 Configure an SFTP server on page 118, and 7.7.2.4 Configure the CareIntellect MUSE server on page 120 on how to configure the HTTPS, SFTP, and CareIntellect MUSE protocols to transmit the files.

3. Select **Save**.

7.7.2.1 Configure a DCP server

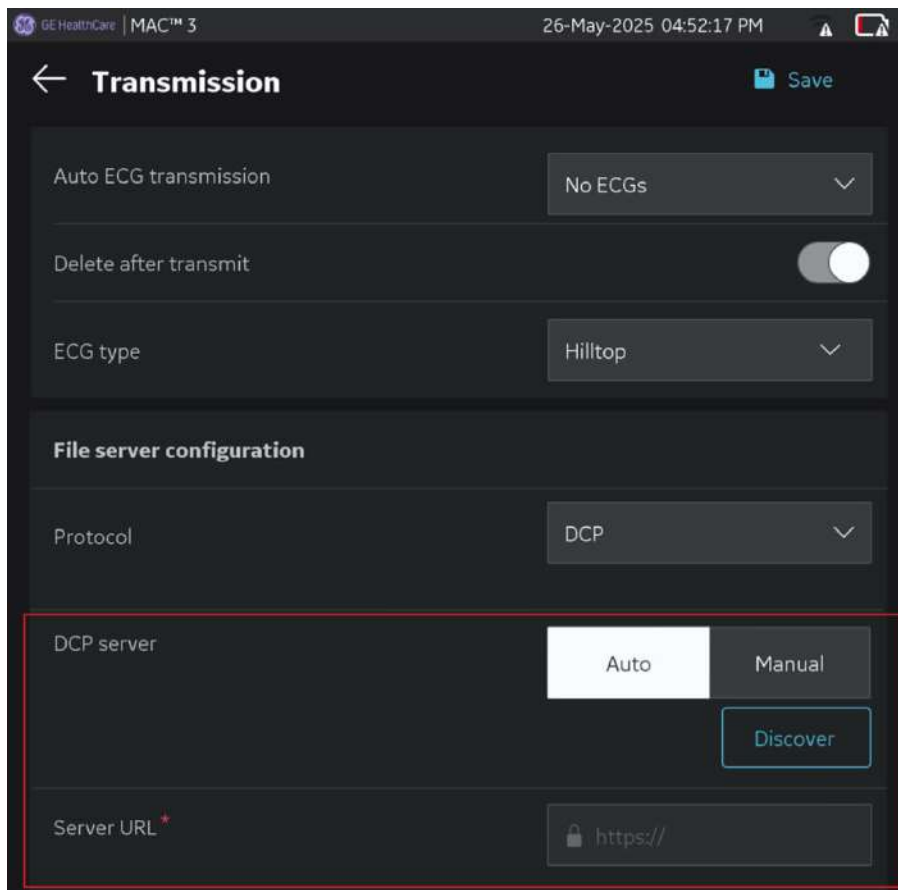
Make sure that you set the **Wi-Fi** or **Ethernet** network mode in **Settings > Network** screen to configure the DCP server. For more information, see [7.8.1 Configure Wi-Fi on page 126](#) and [7.8.3 Configure Ethernet network on page 131](#).

1. Select **Settings > Workflow > Transmission**.

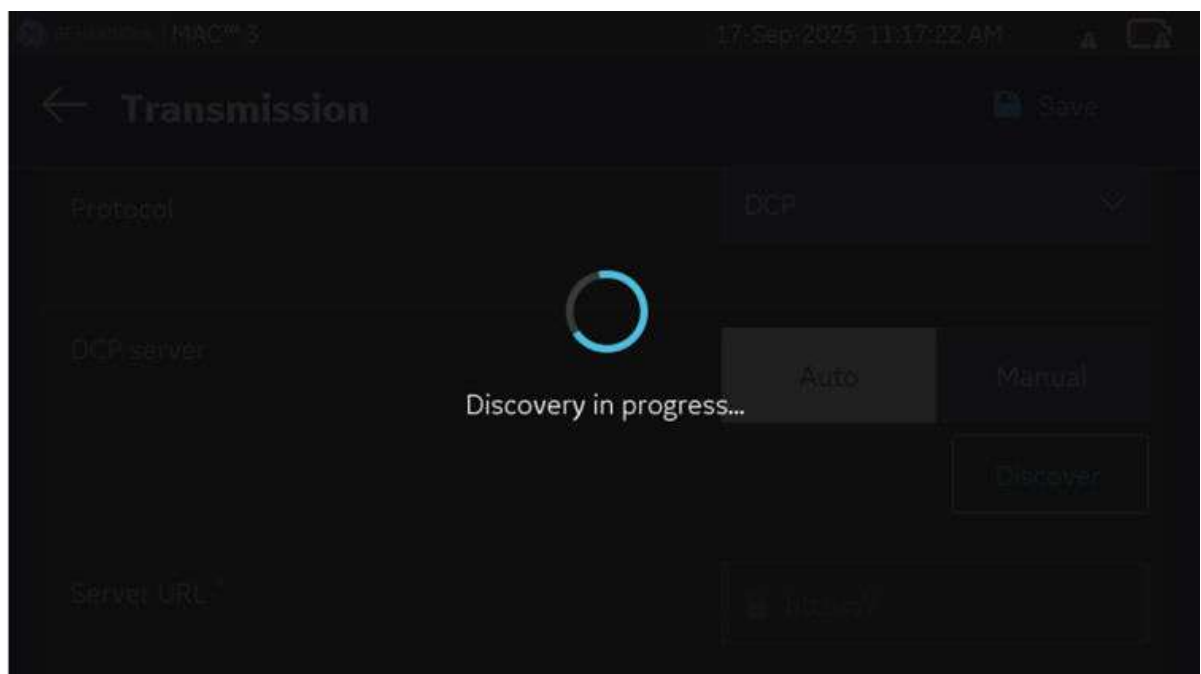
The **Transmission** setting screen displays.

The screenshot shows the 'Transmission' configuration screen in the GE HealthCare MAC 3 interface. The top bar includes the GE HealthCare logo, 'MAC™ 3', the date and time '17-Sep-2025 11:13:54 AM', and a 'Save' button. The main content area has a dark background with white text. It features three settings: 'Auto ECG transmission' set to 'No ECGs', 'Delete after transmit' set to 'On' (indicated by a white toggle), and 'ECG type' set to 'Hilltop'. Below these is a section titled 'File server configuration' which contains a 'Protocol' dropdown menu currently set to 'DCP'.

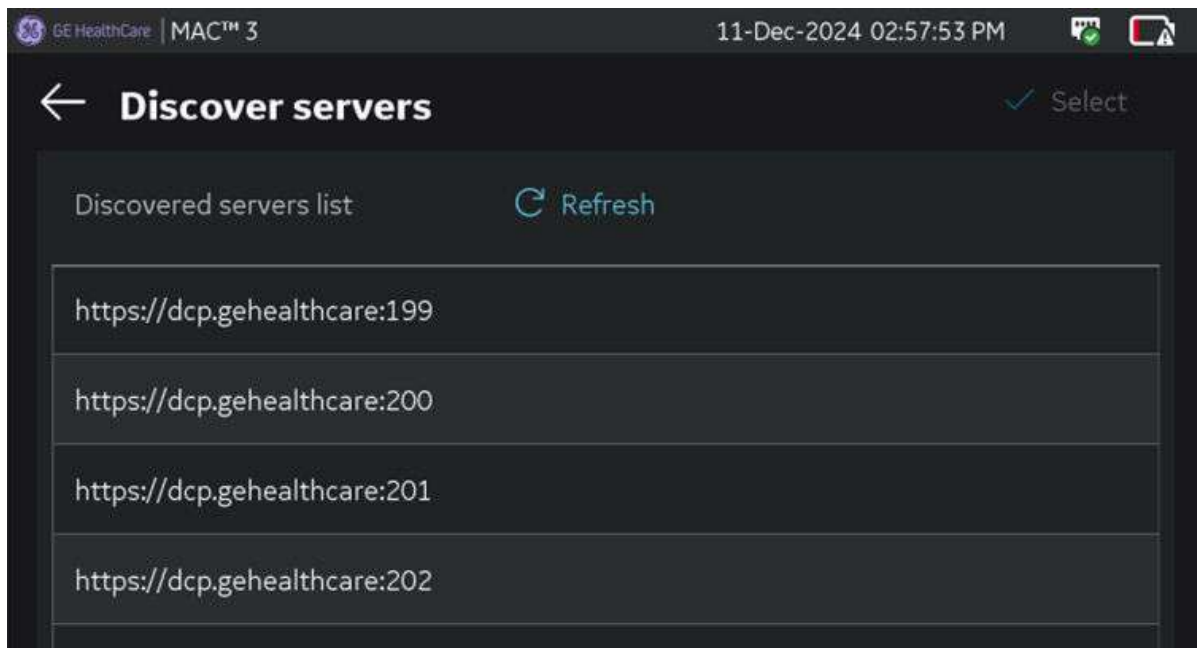
2. Select the **DCP** from the **Protocol** drop-down list of **File server configuration**.
The **DCP** file server configuration screen displays.



3. Select **Discover** to obtain automatically the DCP server URL from the network.
A progress screen displays.



If no errors, a list of available servers in the network display.

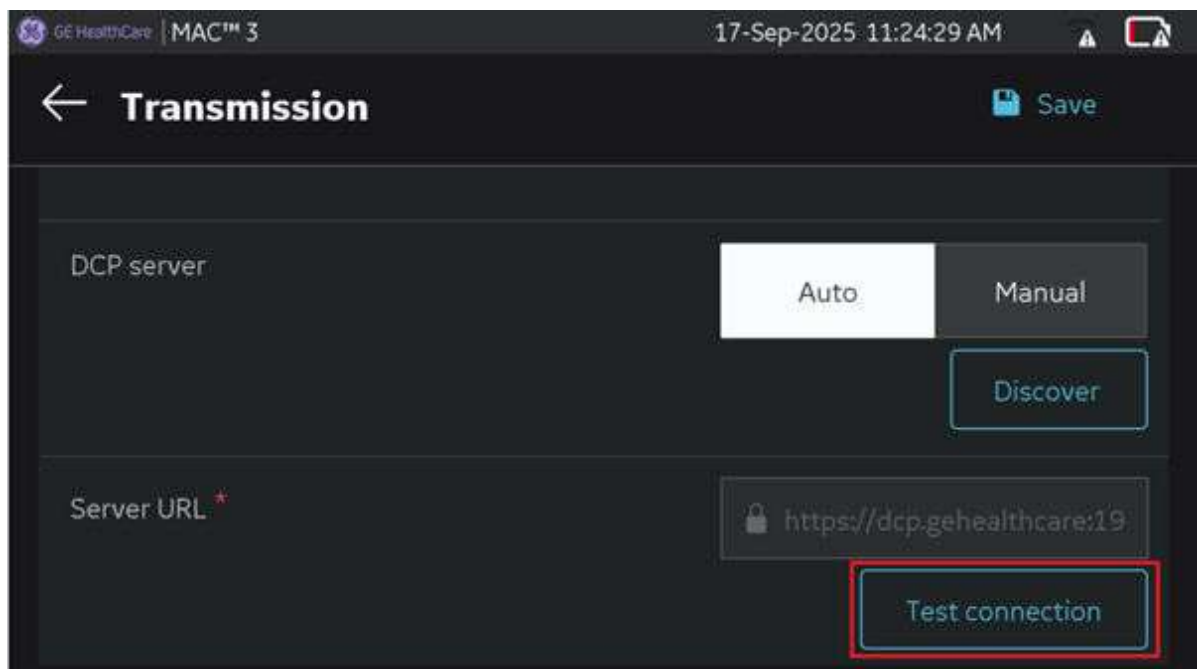


4. If you select unsecured server with `http://` url from the list, continue to [Step 5](#) without importing the certificate for DCP transmission.

OR

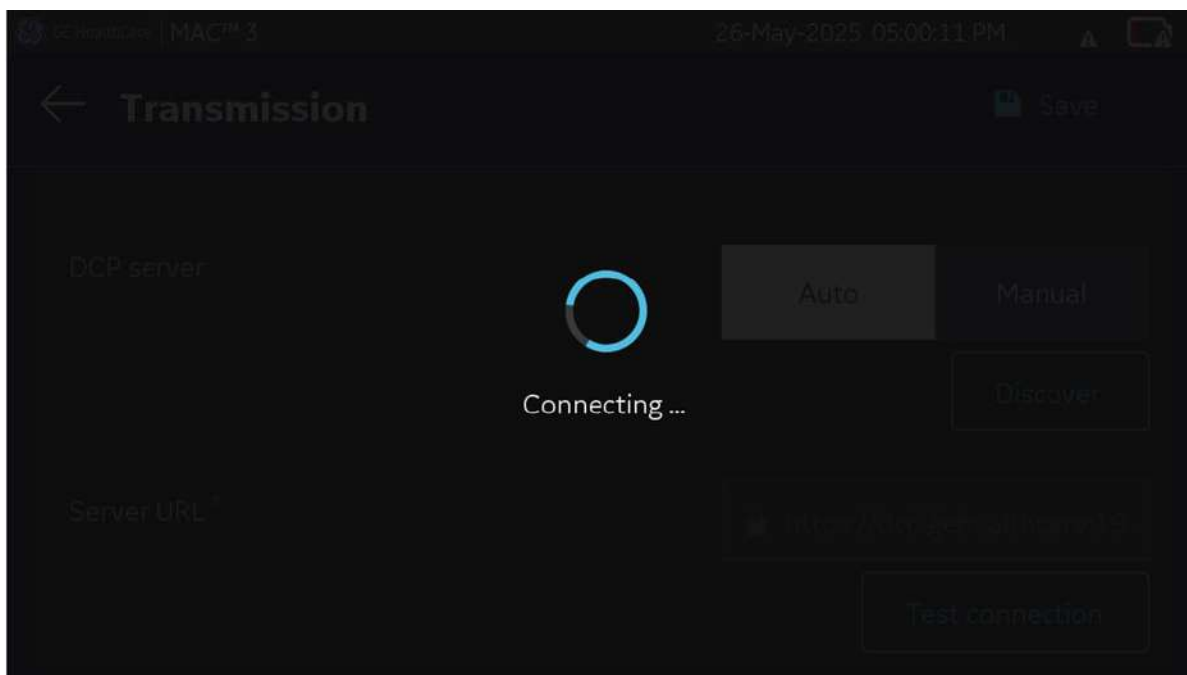
If you select a secured server with `https://` url from the list, continue to [Step 5](#) after you import the certificate for a secured DCP transmission. See [7.8.2 Install certificates on page 129](#).

The **Server URL** field automatically fills the URL information and enable the **Test** button.

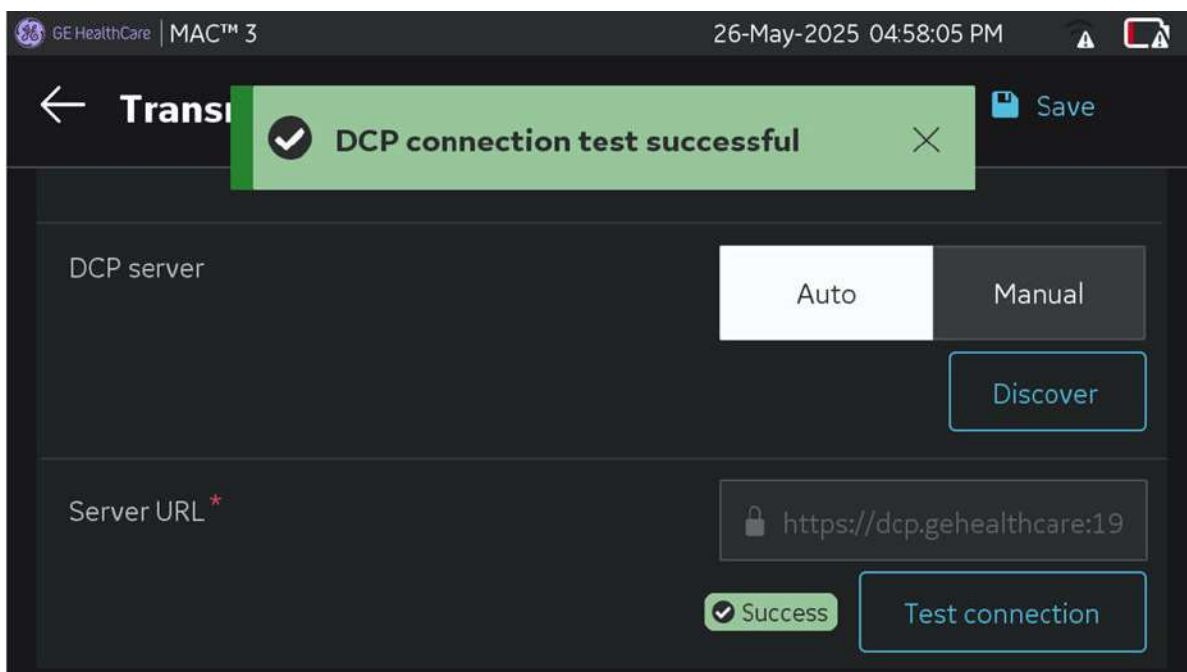


5. Select the **Test connection** button to test the connection.

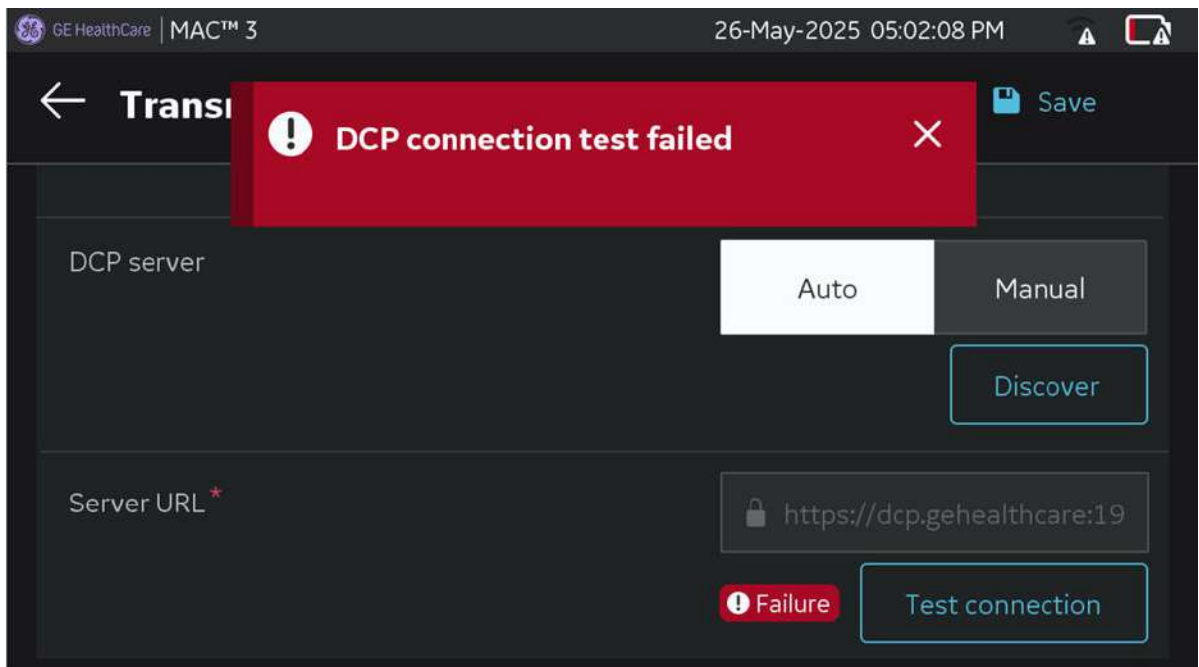
The connection status message Connecting, Connected, Disconnecting, or Disconnected to the DCP server display.



If the test connection is successful, the **DCP connection test successful** message display.



If the test connection is not successful, the **DCP connection test failed** message display.



6. Select **Save** to save the DCP server configuration.
7. Select the **Manual** for **DCP server**.
The DCP server display to set the server URL manually.

GE HealthCare | MAC™ 3 26-May-2025 05:02:55 PM

← Transmission Save

Auto ECG transmission No ECGs

Delete after transmit ☒

ECG type Hilltop

File server configuration

Protocol DCP

DCP server Auto Manual

Server URL ^{*} https://

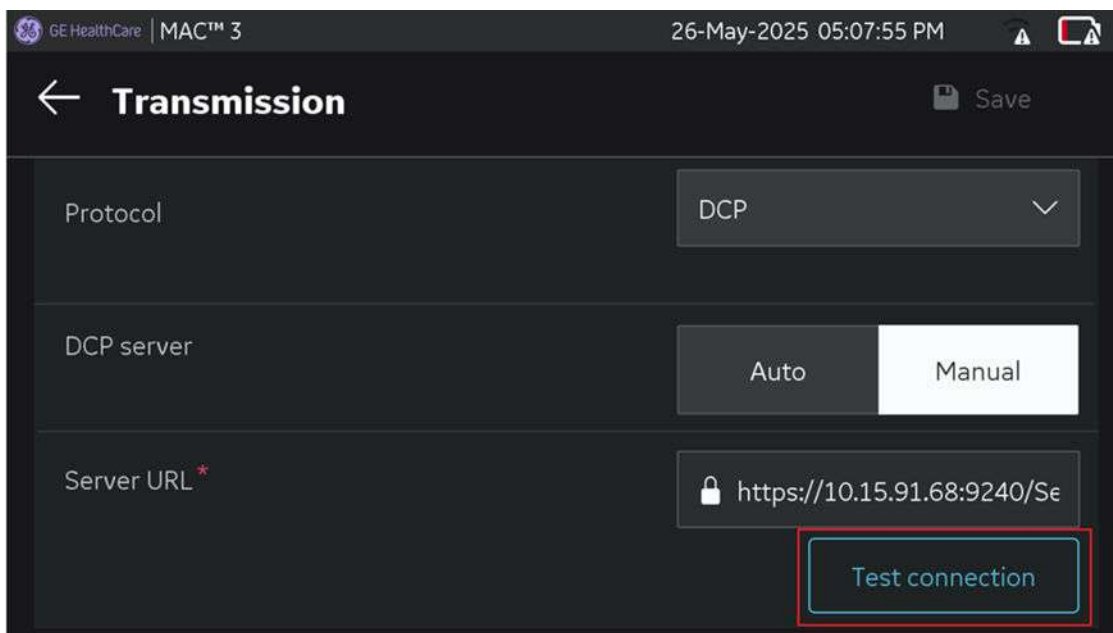
8. Manually enter the DCP server URL in the **Server URL** field.

If you enter the unsecured server with `http://` url, continue to [Step 9](#) without importing the certificate for DCP transmission.

OR

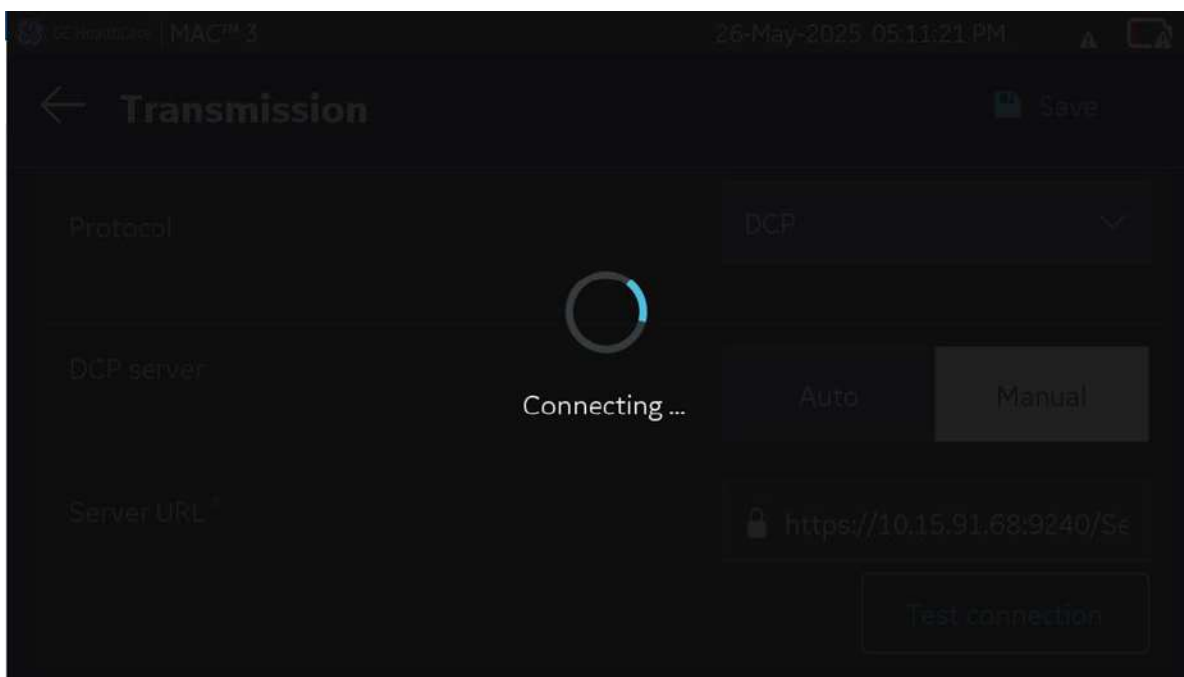
If you enter a secured server with `https://` url, continue to [Step 9](#) after you import the certificate for a secured DCP transmission. See [7.8.2 Install certificates on page 129](#).

After you enter the DCP server URL information, the **Test** button enables automatically.

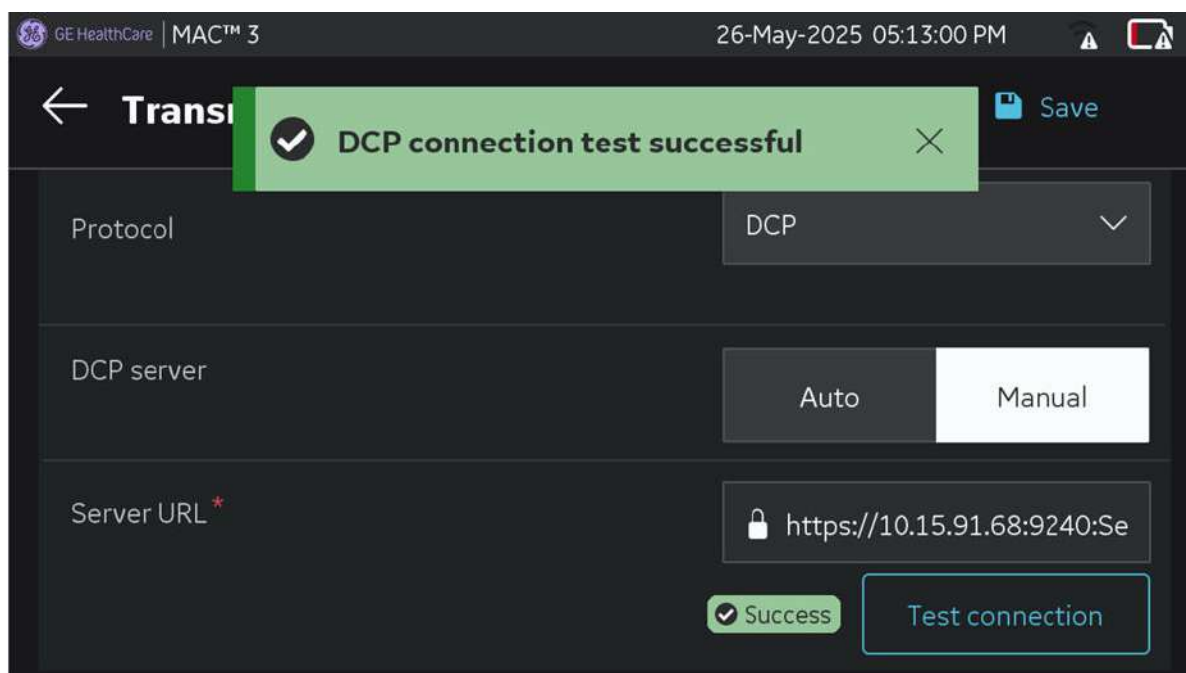


9. Select the **Test connection** button to test the connection.

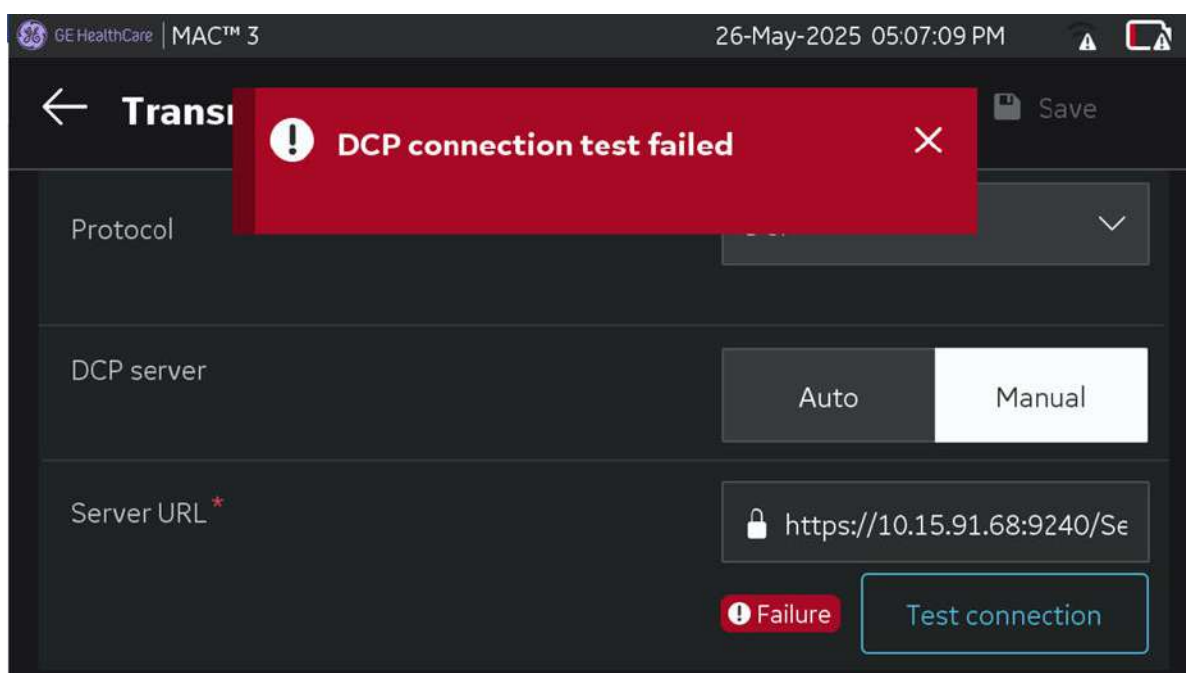
The connection status message Connecting, Connected, Disconnecting, or Disconnected to the DCP server display.



If the test connection is successful, the **DCP connection test successful** message display.



If the test connection is not successful, the **DCP connection test failed** message display.



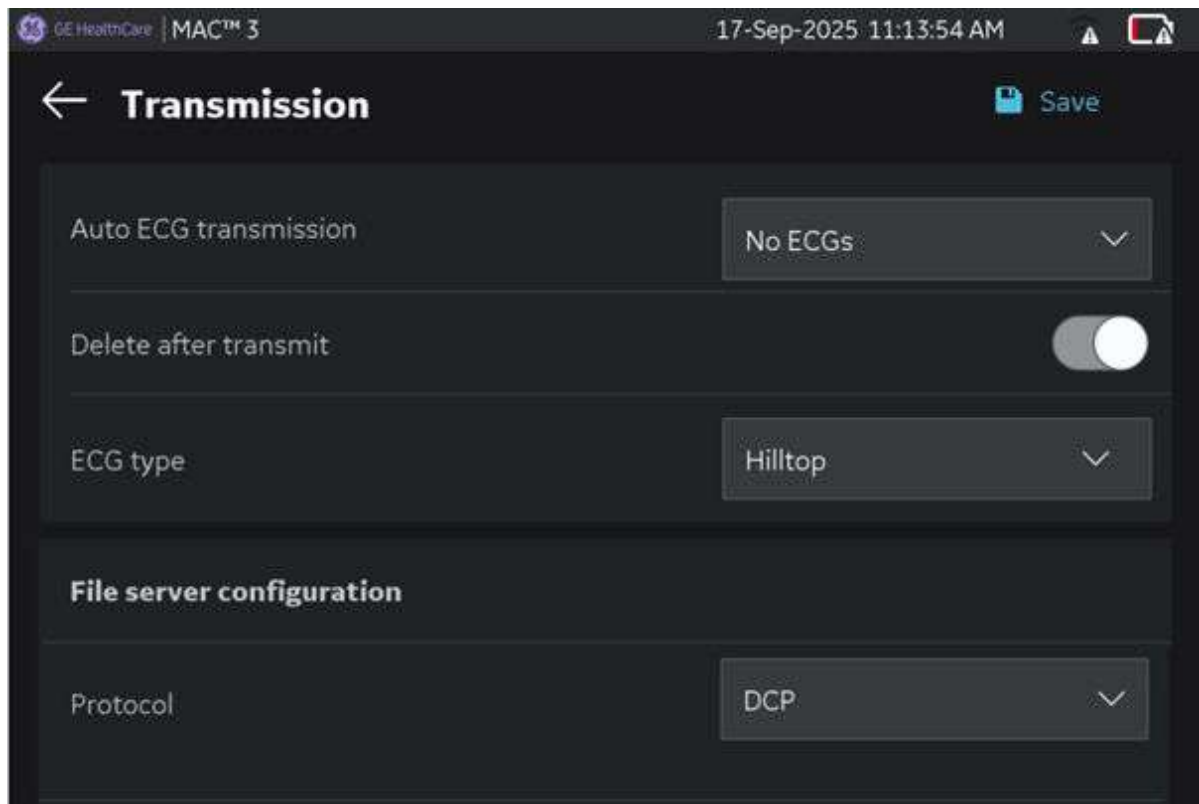
10. Select **Save** to save the DCP server configuration.

7.7.2.2 Configure HTTPS server

Make sure that you set the **Ethernet**, **Wi-Fi**, or **GSM** network mode in **Settings > Network** screen to configure the HTTPS server. For more information, see [7.8.3 Configure Ethernet network on page 131](#), [7.8.1 Configure Wi-Fi on page 126](#), and [7.8.4 Configure the GSM network on page 133](#).

1. Select **Settings > Workflow > Transmission**.

The **Transmission** setting screen displays.



2. Select the **HTTPS** from the **Protocol** drop-down list of **File server configuration**.
The **HTTPS** file server configuration screen displays.

GE HealthCare | MAC™ 3 26-May-2025 03:39:59 PM

← **Transmission** Save

Auto ECG transmission No ECGs

Delete after transmit ☒

ECG type Hilltop

File server configuration

Protocol HTTPS

Server URL * https://

Port number *

UserName

Password

- Configure the fields as per the information in table.

Table 7-16 HTTPS server settings

Field	Action	Description
Server URL	Enter the server URL. This is a mandatory field.	Enter the server URL to transmit the files through HTTPS protocol. If you configure a https URL, a valid PEM certificate is required to authenticate and connect to the HTTPS server. Install the PEM certificate. See 7.8.2 Install certificates on page 129 .
Port number	Enter the HTTPS server port number. This is a mandatory field.	Enter the HTTPS port number to transmit the file through HTTPS server.
UserName	Enter the username for the HTTPS server.	Enter the username to transmit the file thorough HTTPS server.
Password	Enter the password for the HTTPS server.	Enter the password to transmit the file through HTTPS server.

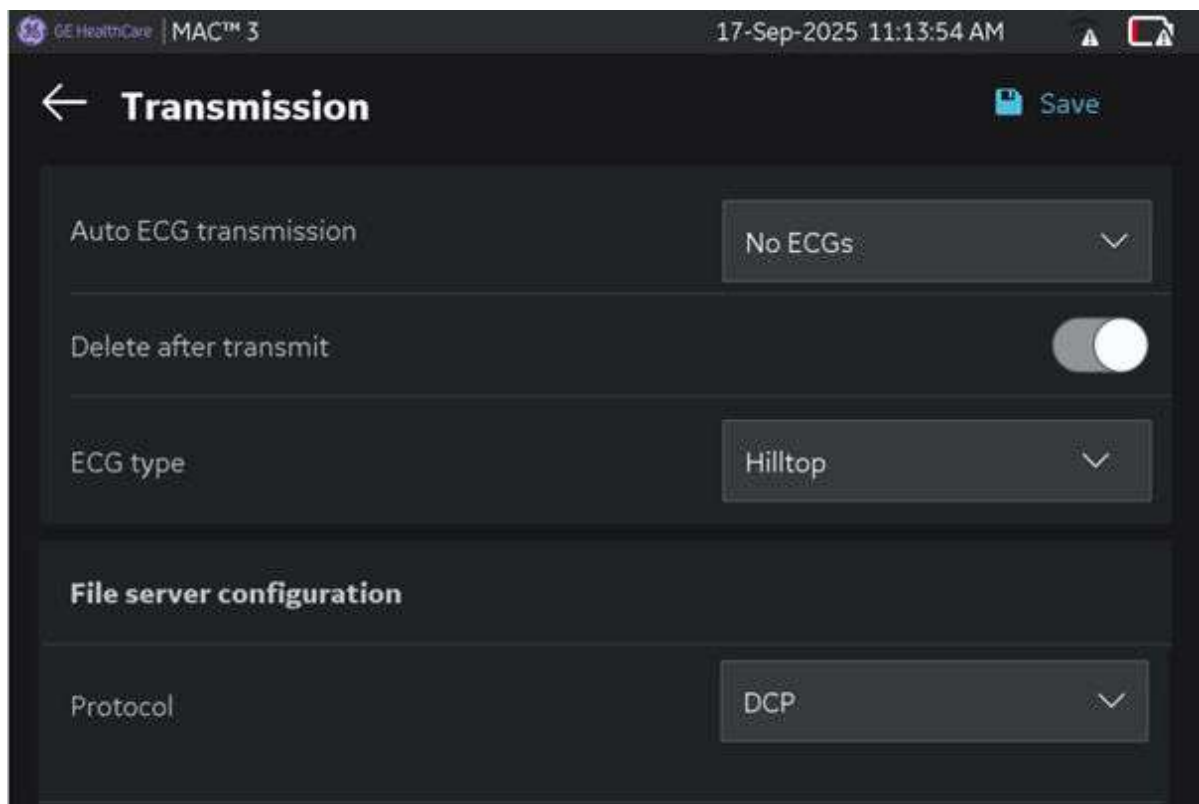
4. Select **Save**.

7.7.2.3 Configure an SFTP server

Make sure that you set the **Ethernet**, **Wi-Fi**, or **GSM** network mode in **Settings > Network** screen to configure the SFTP server. For more information, see [7.8.3 Configure Ethernet network on page 131](#), [7.8.1 Configure Wi-Fi on page 126](#), and [7.8.4 Configure the GSM network on page 133](#).

1. Select **Settings > Workflow > Transmission**.

The **Transmission** setting screen displays.



2. Select the **SFTP** from the **Protocol** drop-down list of **File server configuration**.

The **SFTP** file server configuration screen displays.

The screenshot shows the 'Transmission' settings screen. At the top, there is a back arrow and the title 'Transmission', along with a 'Save' button. The settings are organized into sections:

- Auto ECG transmission:** A dropdown menu currently set to 'No ECGs'.
- Delete after transmit:** A toggle switch that is currently turned on.
- ECG type:** A dropdown menu currently set to 'PDF'.
- PDF report format:** A dropdown menu currently set to '4x2.5s'.
- PDF file name configuration:** A section with four checkboxes, all of which are checked: 'Patient ID', 'Secondary ID', 'Date of birth', and 'Date and Time'.
- File server configuration:** A section with four input fields:
 - Protocol:** A dropdown menu currently set to 'SFTP'.
 - Server name:** A text input field with a red asterisk indicating it is mandatory. Below the field is the placeholder text 'IP address or host name'.
 - Port number:** A text input field with a red asterisk indicating it is mandatory.
 - UserName:** A text input field with a red asterisk indicating it is mandatory.
 - Password:** A text input field with a red asterisk indicating it is mandatory and a toggle icon to show or hide the password.

- Configure the fields as per the information in table.

Table 7-17 SFTP server settings

Field	Action	Description
Server name	Enter the server name. This is a mandatory field.	Enter the server host name or IP address to transmit the files through SFTP protocol.
Port number	Enter the SFTP server port number. This is a mandatory field.	Enter the SFTP port number to transmit the file through SFTP server.
UserName	Enter the username for the SFTP server. This is a mandatory field.	Enter the username to transmit the file through SFTP server.
Password	Enter the password for the SFTP server. This is a mandatory field.	Enter the password to transmit the file through SFTP server.

4. Select the PDF report format from the **ECG type** drop-down list.
5. Select the report format from the **PDF report format** drop-down list.
6. Select the PDF file name from the **PDF file name configuration** list.

The available file name options are:

- Patient ID
- Secondary ID
- Date of birth
- Date and Time

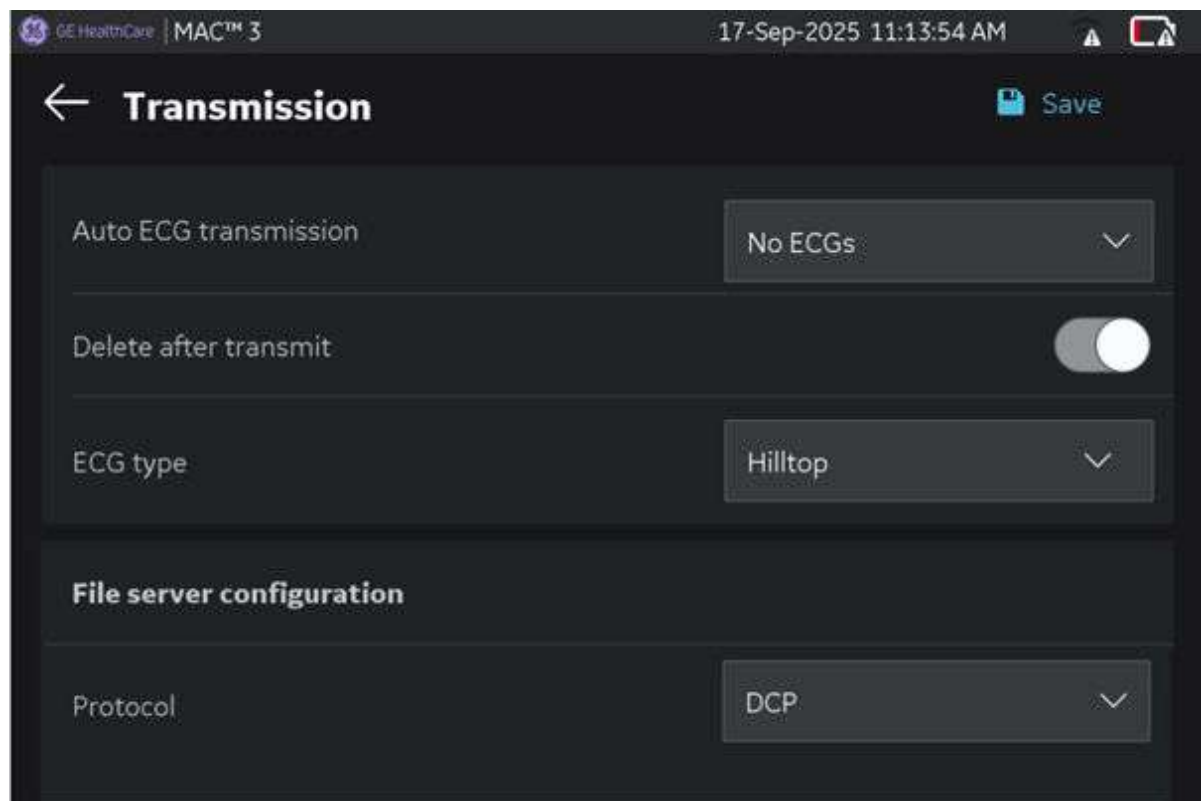
7. Select **Save**.

7.7.2.4 Configure the CareIntellect MUSE server

Make sure that you set the **Ethernet**, **Wi-Fi**, or **GSM** network mode in **Settings > Network** screen to configure the CareIntellect MUSE server. For more information, see [7.8.3 Configure Ethernet network on page 131](#), [7.8.1 Configure Wi-Fi on page 126](#), and [7.8.4 Configure the GSM network on page 133](#).

1. Select **Settings > Workflow > Transmission**.

The **Transmission** setting screen displays.



2. Select the **CareIntellect MUSE** from the **Protocol** drop-down list of **File server configuration**.

The **CareIntellect MUSE** file server configuration screen displays.

GE HealthCare | MAC™ 3 26-May-2025 03:52:54 PM

Transmission

Save

Auto ECG transmission No ECGs

Delete after transmit ☒

ECG type Hilltop

File server configuration

Protocol CareIntellect MUSE

Post URL * <https://stage1.elevarstg-ge>

i Test the connection to save changes. [Test connection](#)

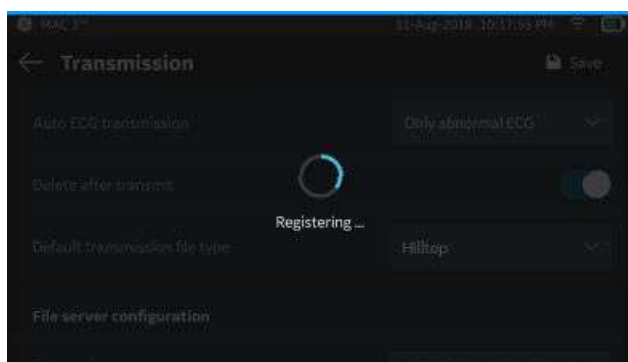
Certificate Server Configuration

Server URL * <https://ge-hc-prod.sac.keys>

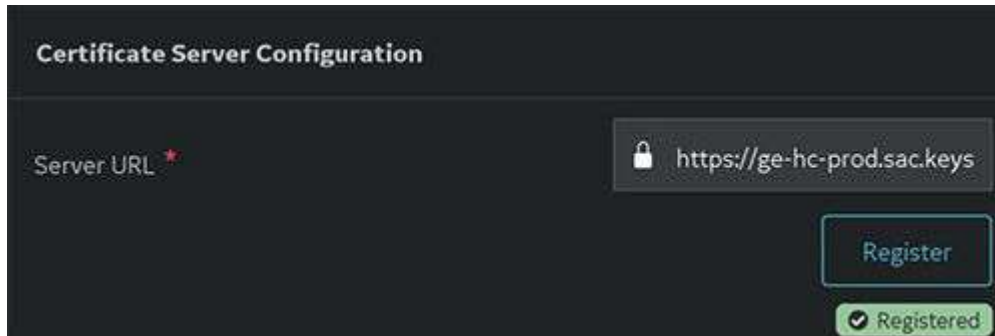
[Register](#)

3. The **KeyScaler** url will be auto filled in the **Server URL** field of the **Certificate Server Configuration** to authenticate the device.
4. Select **Register** to register the device.

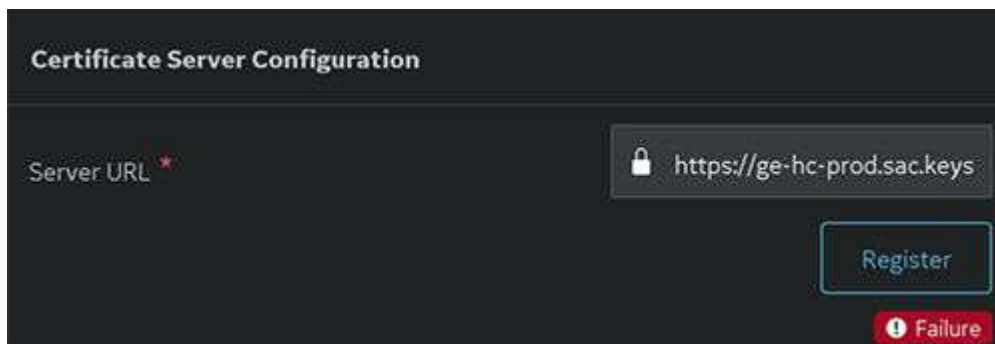
The registration takes a while to complete and displays the status on the screen.



If the registration is complete without any error, the screen displays the status as **Registered**.



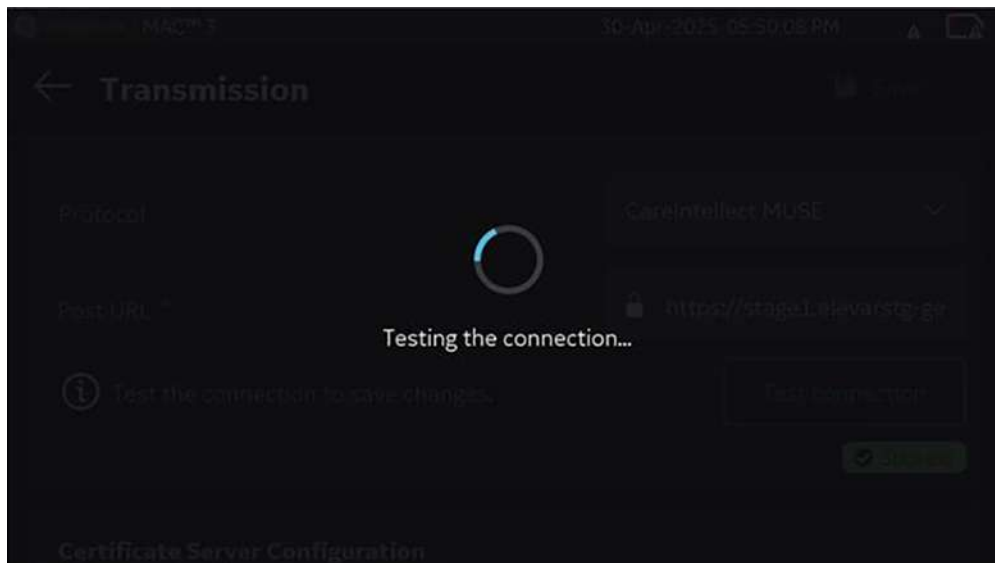
If the registration fails due to error, the screen displays the status as **Failure**.



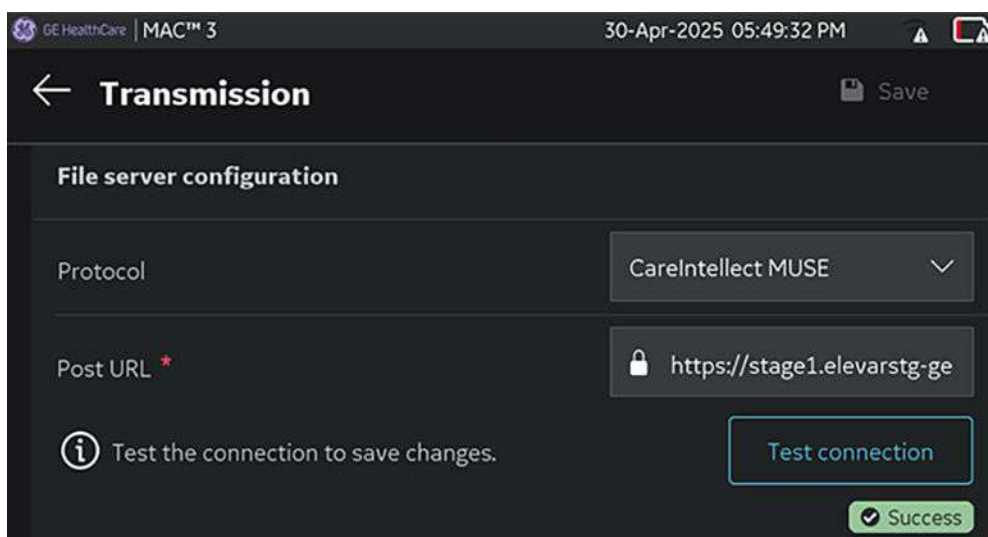
Contact GE HealthCare Service Support representative to troubleshoot the registration errors and complete the registration of the device.

5. The CareIntellect MUSE server url will be auto filled in the **Post URL** field of the **File server configuration** section.
6. Select **Test connection**.

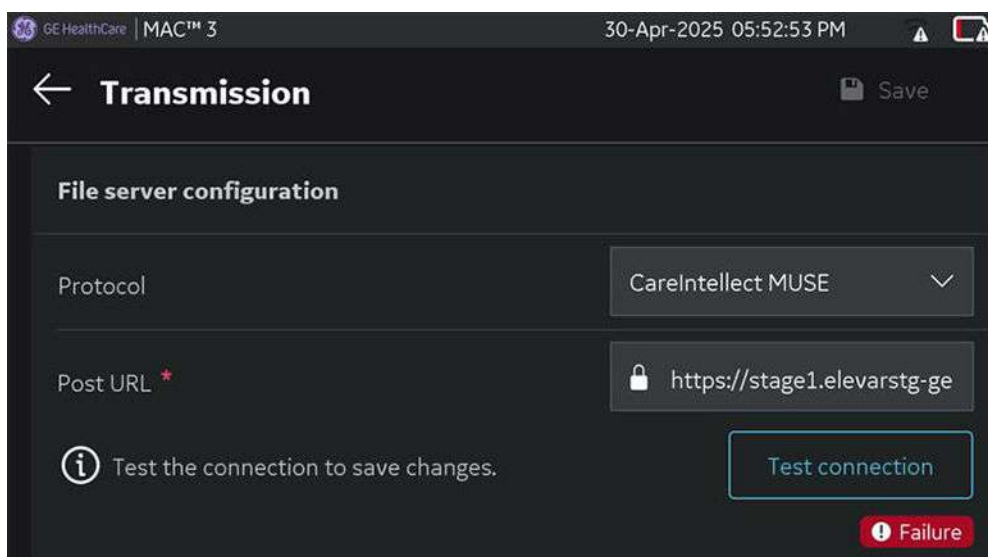
The test connection takes a while to complete and display the status on the screen.



If the test connection is complete without any error, the screen displays the status as **Success**.



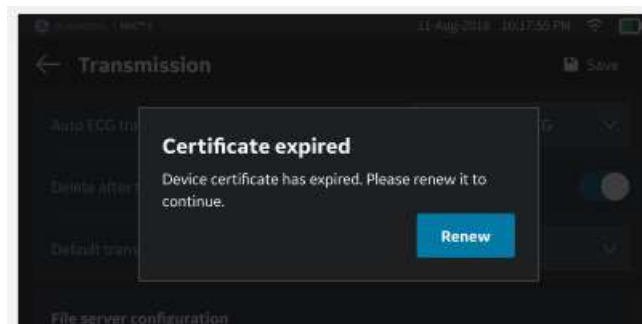
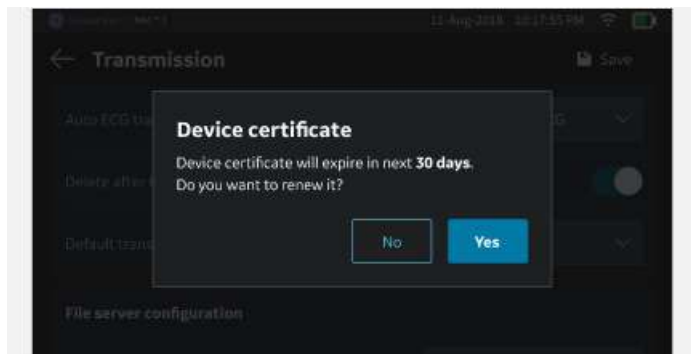
If the registration fails due to error, the screen displays the status as **Failure**.



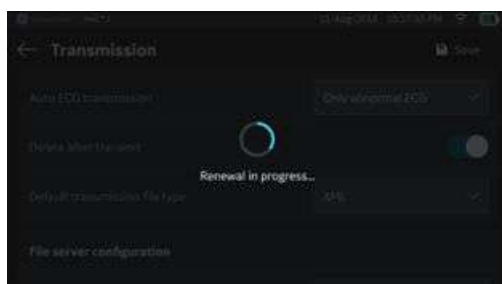
Contact GE HealthCare Service Support representative to troubleshoot the connection errors and complete the **CareIntellect MUSE** server connection to the device.

7. After successful connection, select **Save** to save the **CareIntellect MUSE** server configuration settings.
8.  **NOTE** When you **Power off** the device, the certificate renewal notification displays on the screen 60 days prior to the certificate expiry.

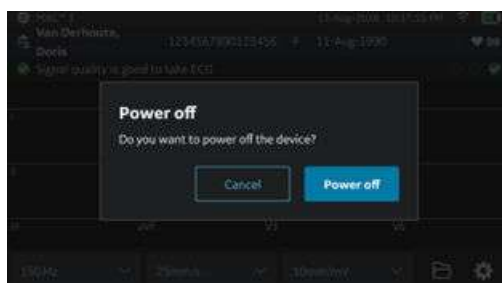
Device certificate about to expire screen displays or certificate expired screen displays.



9. Select **Yes** for the certificate about to expire or select **Renew** for the renewal of expired certificate. The **Renewal in progress** screen displays.

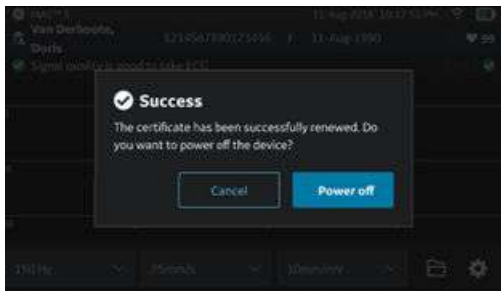


If you select **No** for the certificate about to expire and select **Power off**, to power off the device without renewal of the certificate.



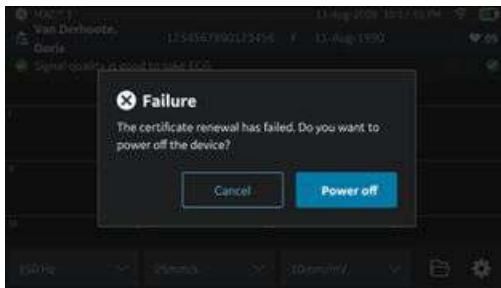
OR

If the renewal of certificate is successful and select **Power off**, to power off the device with renewal of the certificate.



OR

If the renewal of certificate is failure and select **Power off**, to power off the device without renewal of the certificate.



7.8 Configure Network

You can configure and enable the wired (Ethernet), wireless (Wi-Fi), and mobile communication (GSM) network connections on the same device. If you remove the LAN cable, the device uses the wireless or the mobile communication connection.

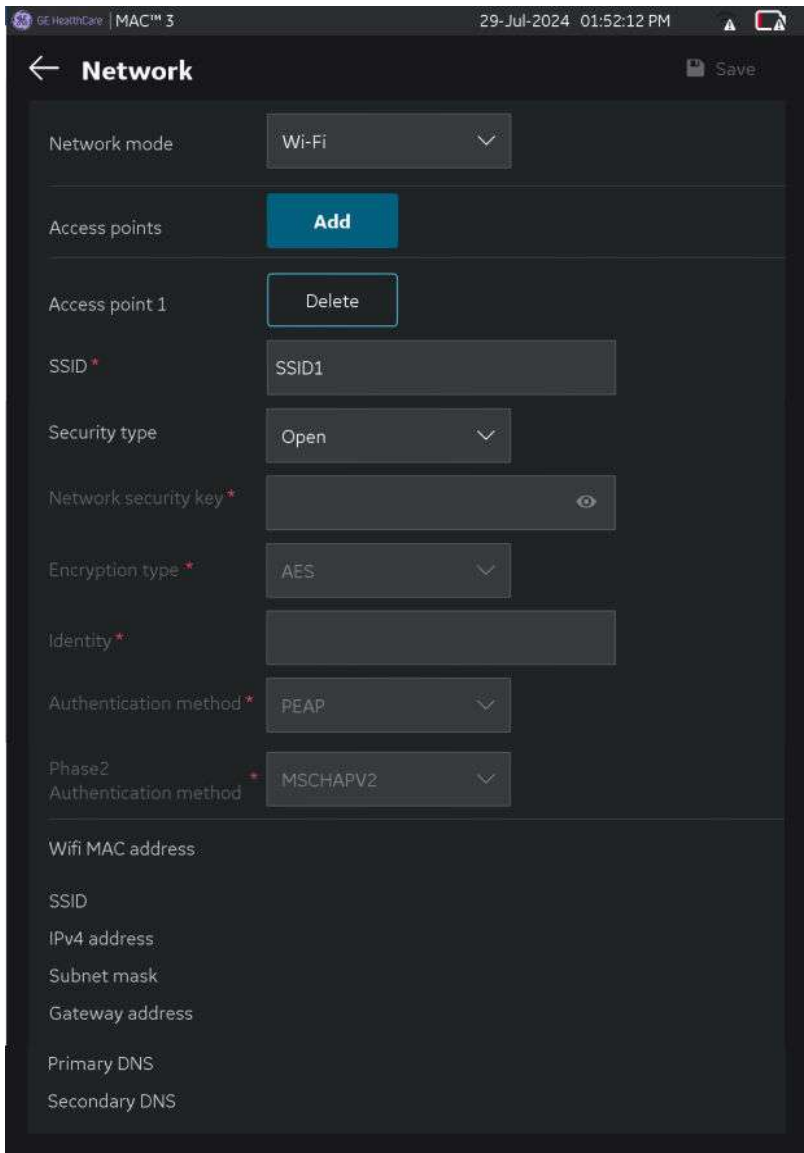
Select **Settings** > **Network** menu to configure:

The screenshot shows the 'Network' configuration screen on a GE HealthCare MAC 3 device. The top status bar displays 'GE HealthCare | MAC™ 3', the date '29-Jul-2024', and the time '01:52:12 PM'. The screen has a dark theme. At the top, there is a back arrow and the title 'Network', followed by a 'Save' button. The main configuration area includes a 'Network mode' dropdown set to 'Wi-Fi'. Below this is an 'Access points' section with an 'Add' button. Under 'Access point 1', there is a 'Delete' button. The configuration fields for the access point include: 'SSID' (text field with 'SSID1'), 'Security type' (dropdown set to 'Open'), 'Network security key' (password field with an eye icon), 'Encryption type' (dropdown set to 'AES'), 'Identity' (text field), 'Authentication method' (dropdown set to 'PEAP'), and 'Phase2 Authentication method' (dropdown set to 'MSCHAPV2'). At the bottom, there is a section for 'Wifi MAC address' with fields for 'SSID', 'IPv4 address', 'Subnet mask', 'Gateway address', 'Primary DNS', and 'Secondary DNS'.

- Wi-Fi - [7.8.1 Configure Wi-Fi on page 126](#)
- Ethernet - [7.8.3 Configure Ethernet network on page 131](#)
- DCP server - [7.7.2.1 Configure a DCP server on page 107](#)
- GSM - [7.8.4 Configure the GSM network on page 133](#)
- Connection Status - [7.8.5 Show network connection status on page 134](#)

7.8.1 Configure Wi-Fi

1. Select **Settings > Network**.
The **Network** setting screen displays.



2. Select **Wi-Fi** from the **Network mode** drop-down list.
3. Configure the fields as per the information in table.

Table 7-18 Wi-Fi network settings

Field	Action	Description
Access points	Add the access point.	Select Add to add the access point to the device for Wi-Fi network connection. You can add only 3 maximum access points.
Access point 1	Delete the access point.	Select Delete to delete the access point from the device Wi-Fi network connection.
SSID	Enter the Service Set Identifier (SSID) for your Wi-Fi network.	Default value: No default value Allowed value: Any value (site-specific)

Continues on the next page

Table 7-18 Wi-Fi network settings (Table continued)

Field	Action	Description
Security type	Select a value from the drop-down list to configure the security type.	Security type of access point. Default value: Open Allowed values: • WPA Personal • WPA Enterprise • Open
Network security key	Enter the password.	Enter the password for the access point (if you enable the Security type to WPA Personal or WPA Enterprise).
Encryption type	Select a value from the drop-down list to configure the encryption type.	Select the encryption type of access point from the drop-down list. Default value: • AES for WPA Personal • TKIP for WPA Enterprise
Identity	Enter the Identity.	Default value: No default value Allowed values: Any value (up to 256 characters).  NOTE The default industrial standard for the Wi-Fi network (WPA Enterprise) is all lower case unless you create a custom Identity. This field is available only when Security type is configured as WPA Enterprise .
Authentication method	Select a value from the drop-down list to configure the authentication method.	The authentication method is the client authentication method used to generate the unique encryption keys for the device. Allowed values: PEAP and TTLS (if you enable Security type only to WPA Enterprise).
Phase2 Authentication method	Select a value from the drop-down list to configure the Phase2 authentication method.	This field is available only when you configure Authentication method to PEAP or TTLS . Allowed values: MSCHAPV2 (if you enable Security type only to WPA Enterprise).

4. Select **Save**.

If no errors and the configuration settings save is successful, the **Wifi MAC address** screen displays.

Wifi MAC address	00:10:2e:e0:08:6b
SSID	Wifi_
IPv4 address	192.168.113.145
Subnet mask	255.255.255.0
Gateway address	192.168.113.2
Primary DNS	192.168.113.231
Secondary DNS	8.8.8.8

7.8.2 Install 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.
- The certificate must be self-contained. It cannot point to another certificate.
- Enable the **USB** and **Allow USB storage** settings in **Settings > System > Hardware** screen.
- Use the USB flash drive with FAT32 file format.

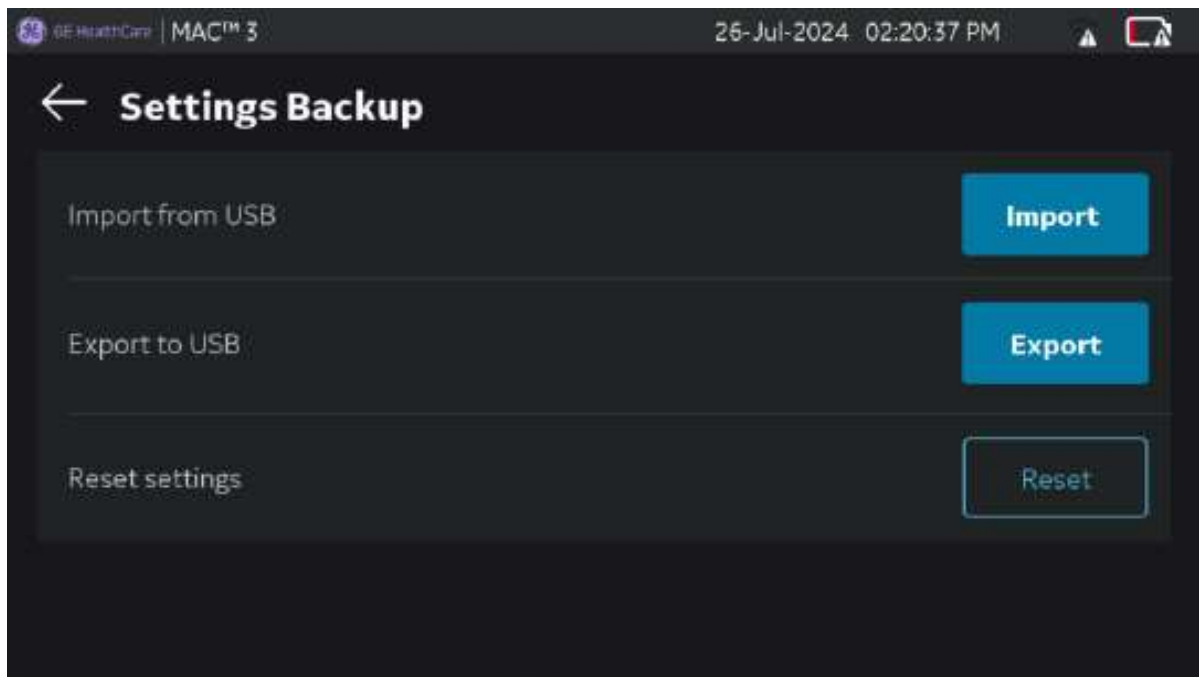


NOTE

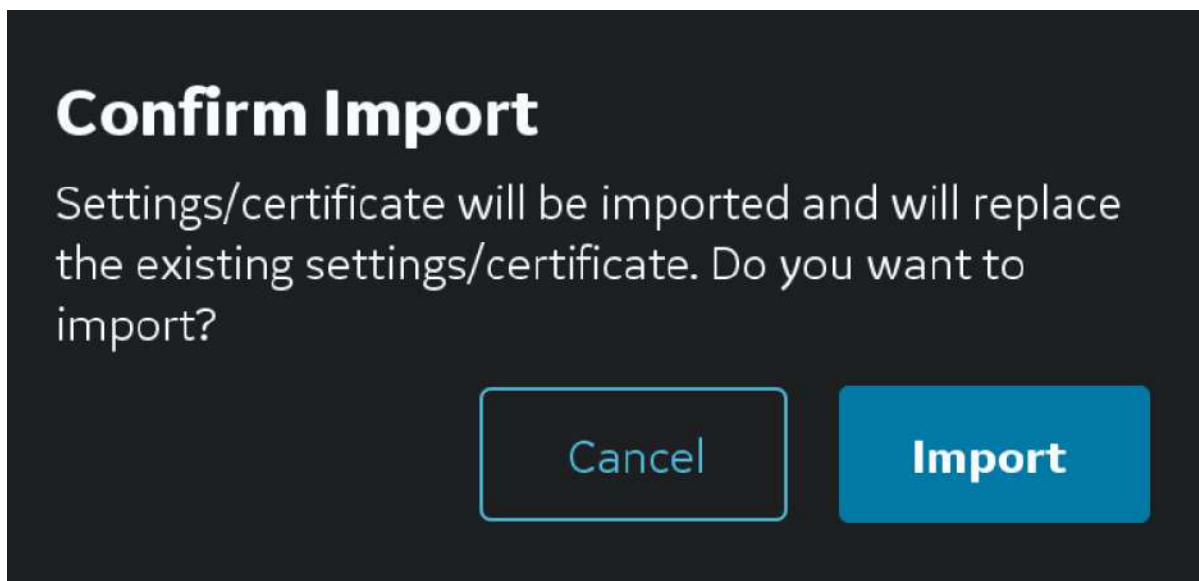
Accept only PEM format certificates. Make sure that you use the correct certificate format, and you import the correct certificate for each protocol.

- For MUSE use **DCPCA.pem** certificate format.
 - For HTTPS use **HTTPSCA.pem** certificate format.
 - For MQTT use **MQTTCA.pem** certificate format.
1. Connect the USB flash drive containing the digitally signed certificate to the device.
 2. Select **Settings > System > Settings Backup**.

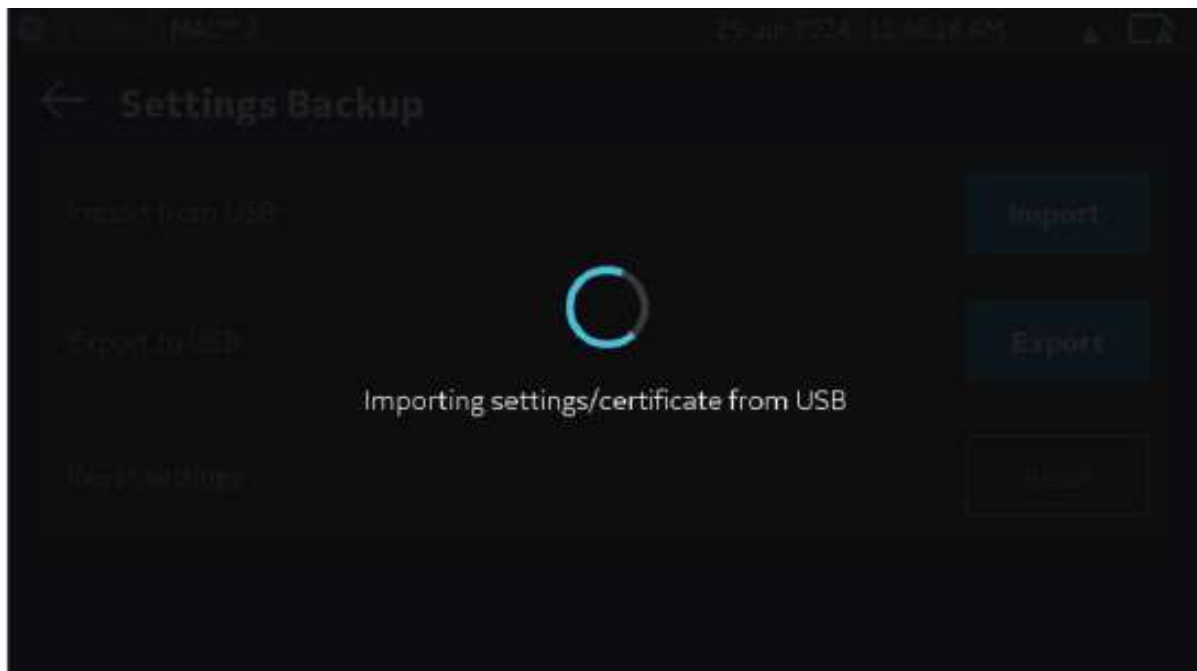
The **Settings Backup** screen display.



3. Select **Import** to import the certificate.
The **Confirm Import** screen display.



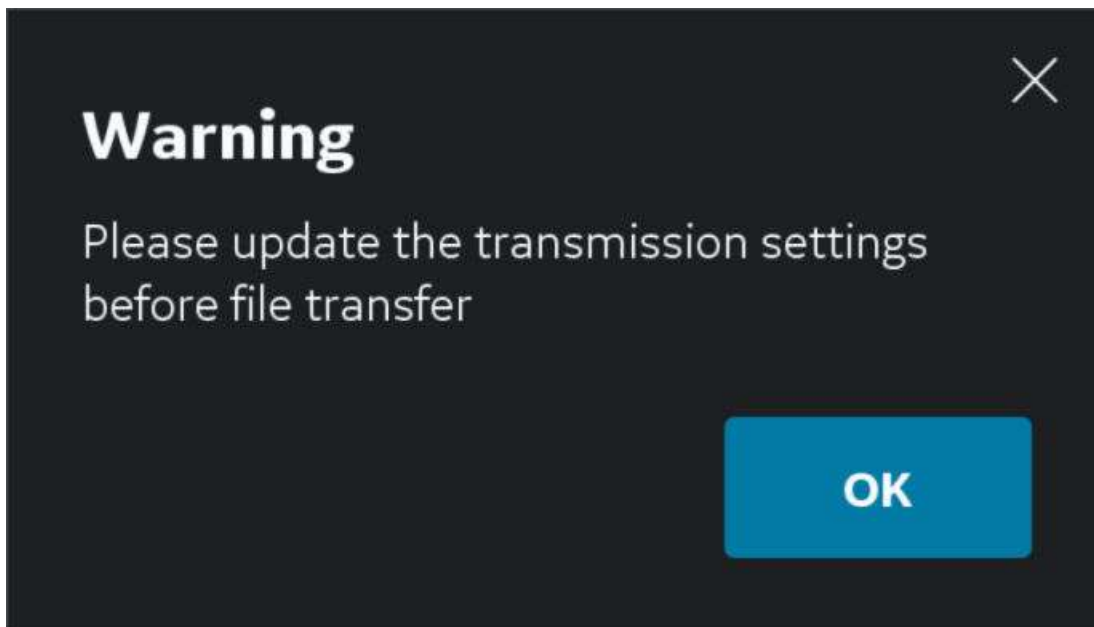
4. Select **Import** to confirm the import of certificate.
The import certificate progress screen displays.



If successful, the **Imported certificate successfully** displays.

7.8.3 Configure Ethernet network

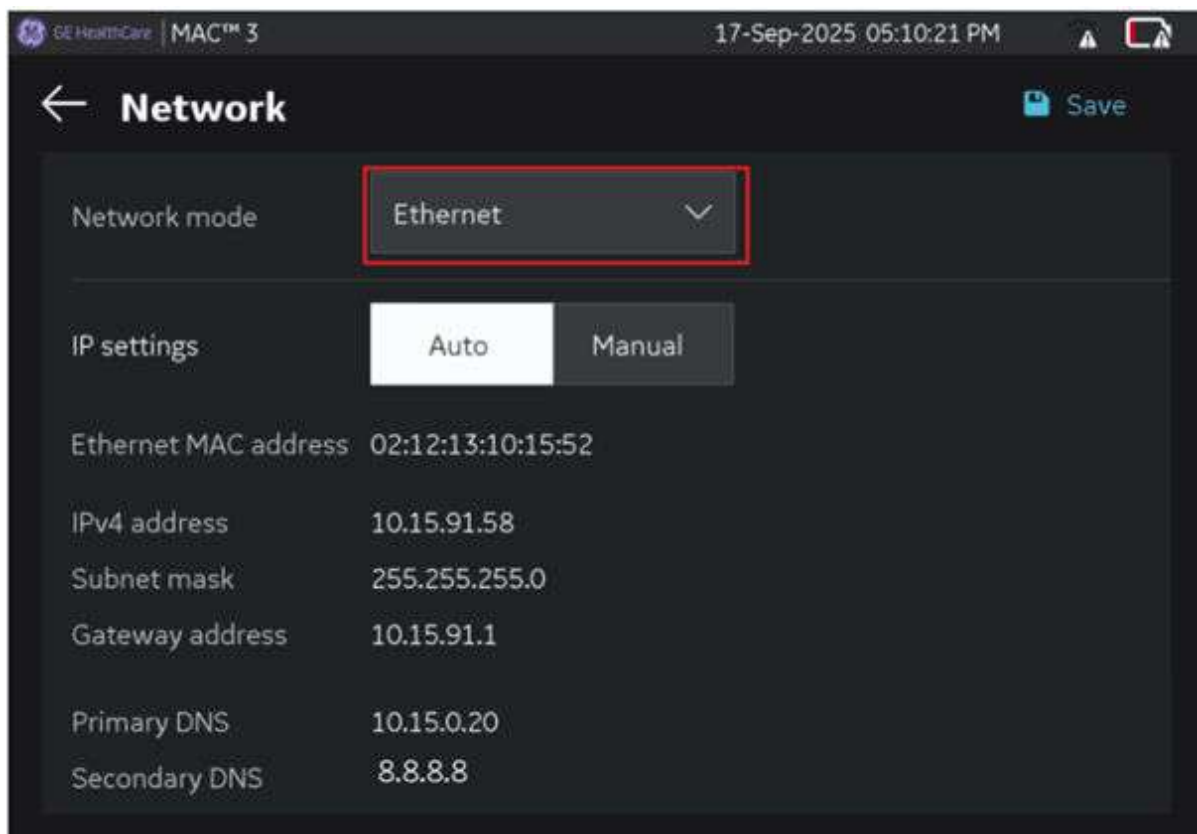
If you change the network mode from Ethernet to another network or from another network to Ethernet, a message displays.



Make sure that you update the transmission settings before you transfer the file when you change the network mode.

1. Select **Settings** > **Network**.
2. Select **Ethernet** from the **Network mode** drop-down list.

The **Ethernet** network setting screen displays.

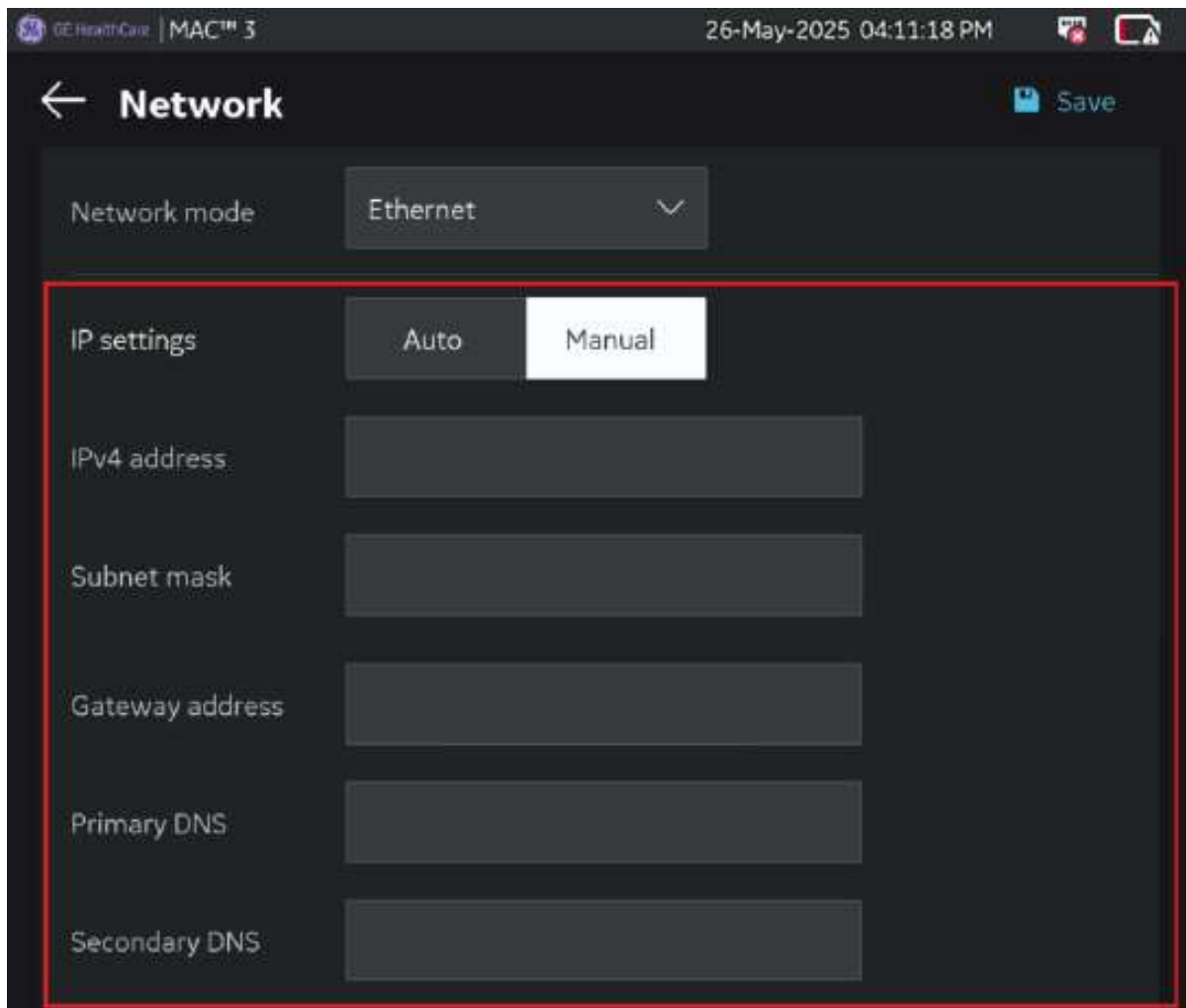


3. Select **Auto** mode for **IP settings**.

The Ethernet IP address is automatically obtained when you connect the LAN cable to the network. The **Ethernet MAC address**, **IPv4 address**, **Subnet mask**, **Gateway address**, **Primary DNS**, and **Secondary DNS** fields are automatically obtained and display on the screen.

4. Select the **Manual** mode for **IP settings**.

The Ethernet IP display to set the address manually.

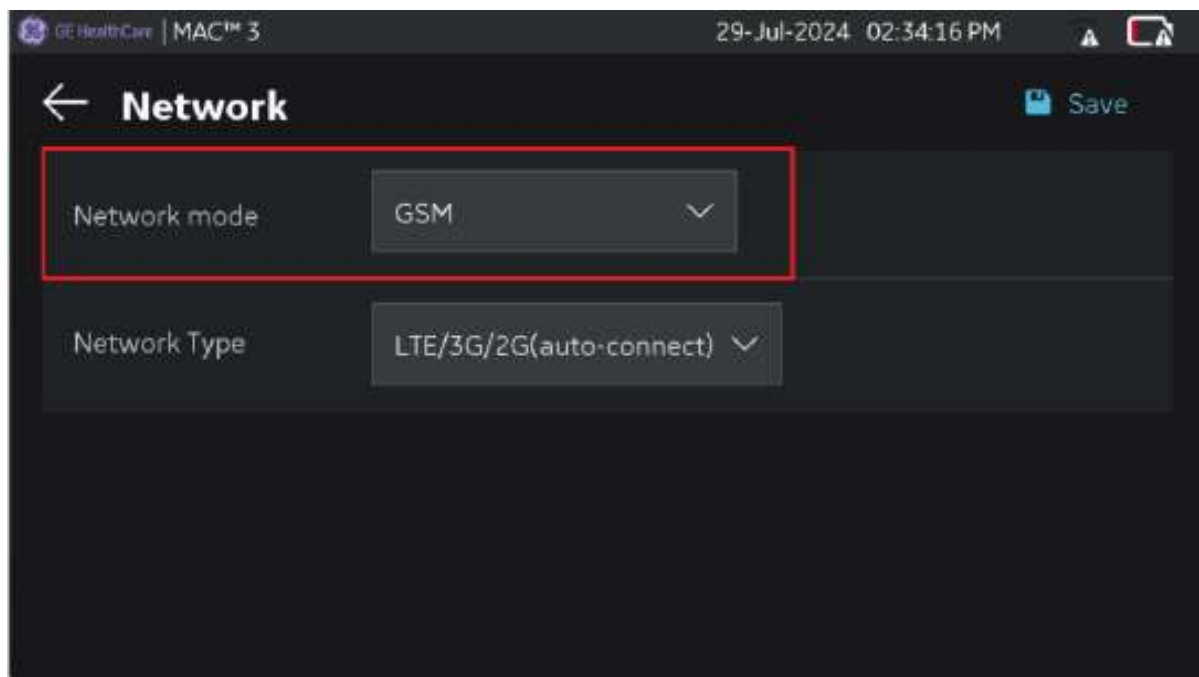


5. Manually enter the values for the below fields:
 - **IPv4 address**
 - **Subnet mask**
 - **Gateway address**
 - **Primary DNS**
 - **Secondary DNS**
6. Select **Save** to save the Ethernet network configuration.

7.8.4 Configure the GSM network

Make sure that you connect the correct SIM for the GSM network type it support. For more information on how to connect the SIM, see [2.1 Connect GSM \(cellular network\) on page 14](#).

1. Select **Settings > Network**.
The **Network** setting screen displays.



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

Table 7-19 GSM network settings

Field	Action	Description
Network mode	Select the mode from the drop-down list to configure the network.	Select the network mode to GSM .
Network Type	Select the type from the drop-down list to configure the network type.	Select the network type. Default value: LTE/3G/2G/(auto-connect) Allowed values: • LTE/3G/2G/(auto-connect) • 2G only • 3G only • LTE only

3. Select **Save**.

7.8.5 Show network connection status

When the wireless, wired, and mobile communication connection is set to **Enable**, the device uses a wired connection when you connect the LAN cable. If you remove the LAN cable, the device uses the wireless or the mobile communication connection.

To view the status of the device connection to the LAN, Wi-Fi, or GSM network, perform the procedure as follows:

1. Select the **Network status** icon on the status bar.

- Review the tables for the description of the network status icon when you connect to the LAN, Wi-Fi, or GSM network.

Table 7-20 LAN network icons

Network status icon	Status	Description
	Connected	The device is connected to a LAN network. The device is connected to a remote server through a LAN while you obtain an IP address.
	Disconnected	The device is not connected to a LAN network. The LAN (Ethernet) cable is not connected to the device.
	No Connection	The device is connected to a LAN without a network connection. The LAN (Ethernet) cable is connected to the device.

Table 7-21 Wi-Fi network icons

Wi-Fi status icon	Status	Description
	Connected	The device is connected to an access point while you obtain an IP address. The icon shows a number of wireless bars to indicate the strength of the wireless signal.
	No connection	The device is not connected to a Wi-Fi network.

For more information about wireless connectivity errors, see [10.7 Network connectivity errors on page 159](#).

Table 7-22 GSM network icons

GSM status icon	Status	Description
	Connected	The device is connected to a mobile communication network while you obtain an IP address. The icon shows a number of GSM bars to indicate the strength of the GSM signal.

Continues on the next page

Table 7-22 GSM network icons (Table continued)

GSM status icon	Status	Description
	No connection	The device is not connected with GSM.

For more information about GSM connectivity errors, see [10.7 Network connectivity errors on page 159](#).

7.9 Configure the clock and language

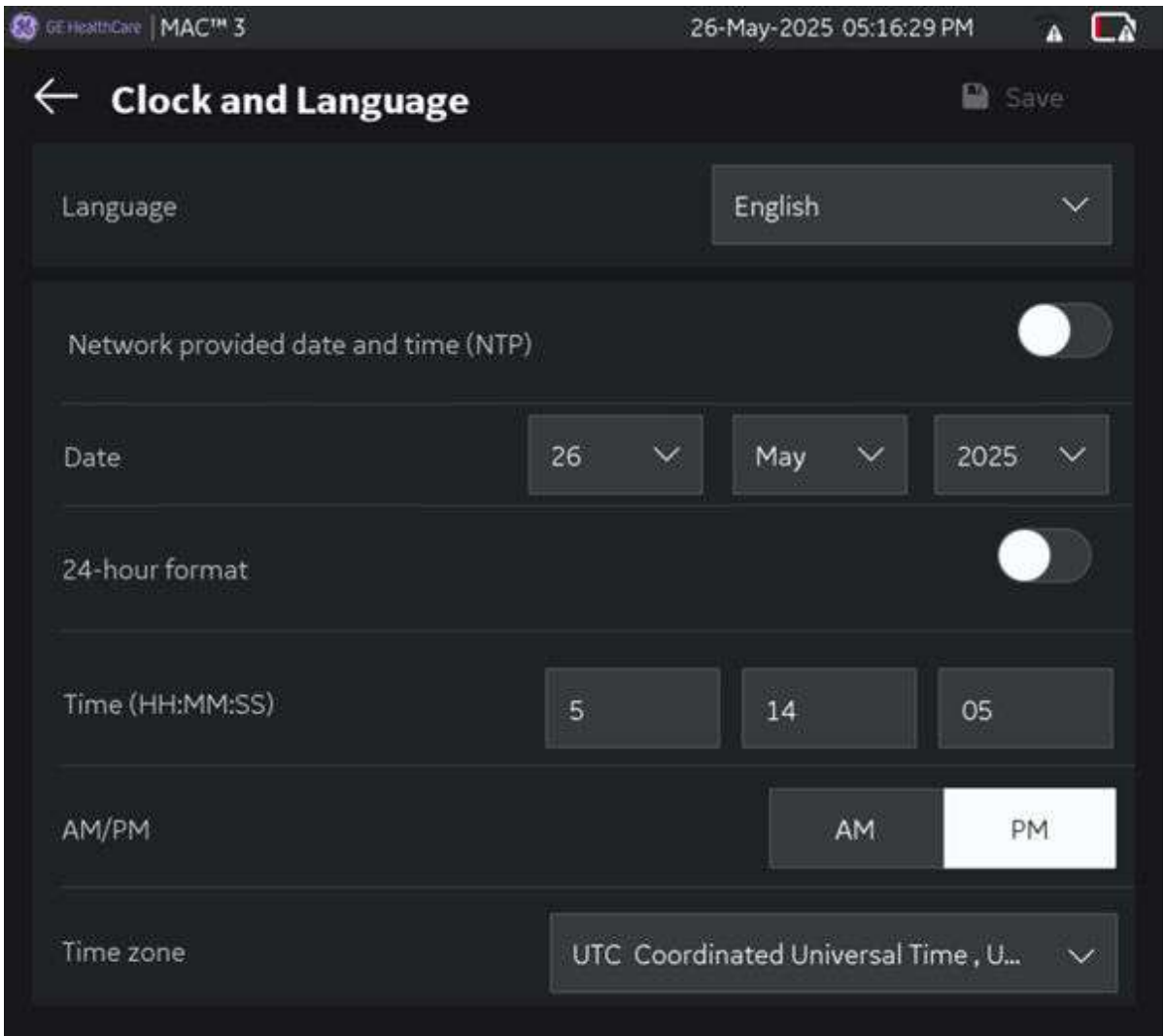
The below items are set by GE HealthCare before the device is shipped.

- 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**.

The **Clock and Language** setting screen displays.



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

Table 7-23 Clock and language settings

Field	Action	Description
Language	Set the default language of the device.	Default value: English Allowed values: List of supported languages
Network provided date and time (NTP)	Enable or disable this setting.	If this setting is enabled, the device receives the NTP server configuration. Default value: Disabled
Date	Set the date for the device.	Select the date from the Day , Month , and Year drop-down.

Continues on the next page

Table 7-23 Clock and language settings (Table continued)

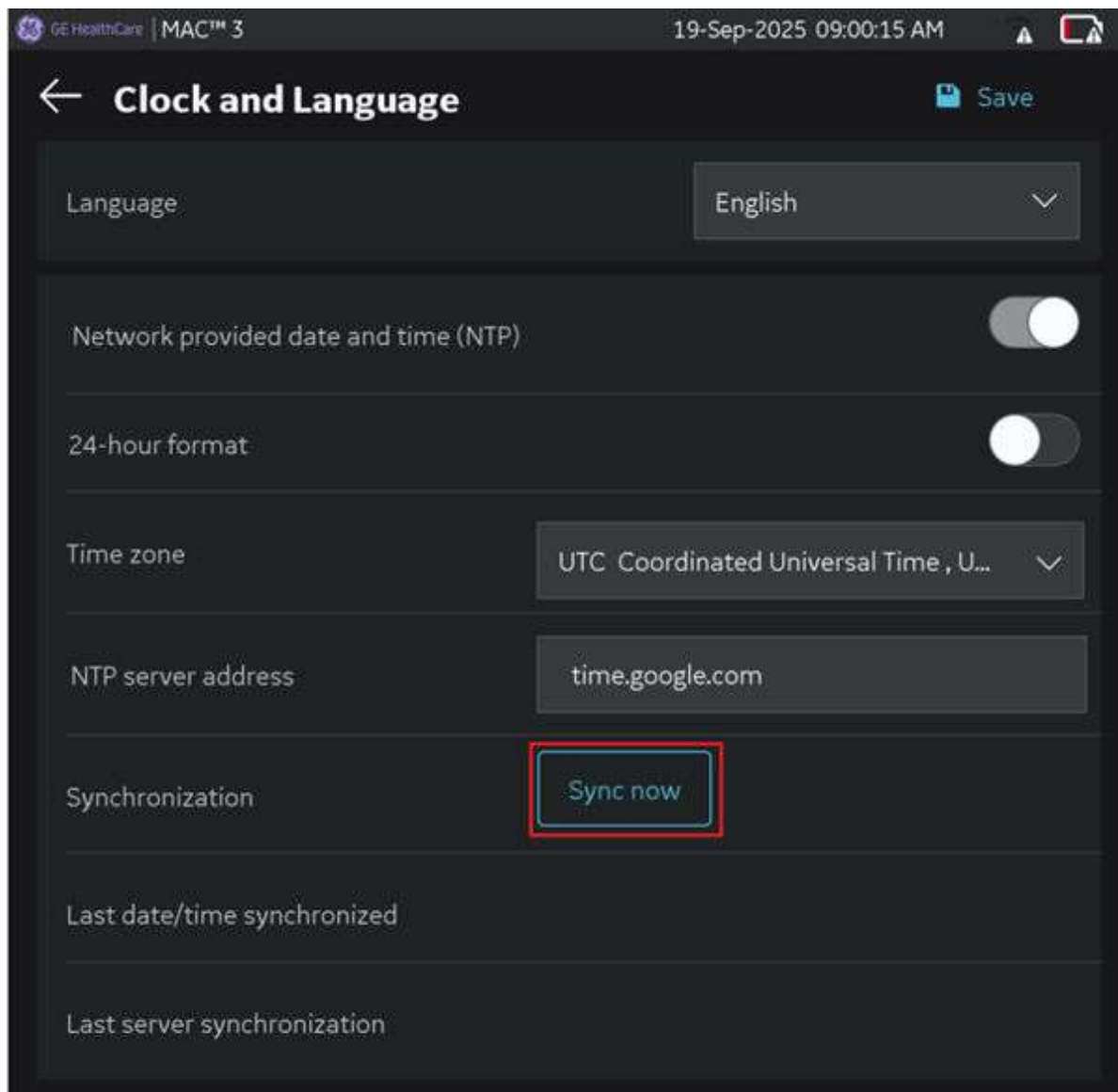
Field	Action	Description
24-hour format	Configure the time format for the device.	- If this setting is disabled, you can configure the hour from 1 to 12 and set AM or PM. - If this setting is enabled, you can configure the hour from 0 to 23 with no selection for AM or PM.
Time (HH:MM:SS)	Enter the current time.	- If the 24-hour format setting is disabled, you can configure the hour from 1 to 12 and set AM or PM. - If the 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/PM	Enable or disable this setting.	If the 24-hour format setting is disabled, select AM or PM. This setting is not available if the 24-hour format is enabled.
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.

3. Enable the NTP server configuration option.

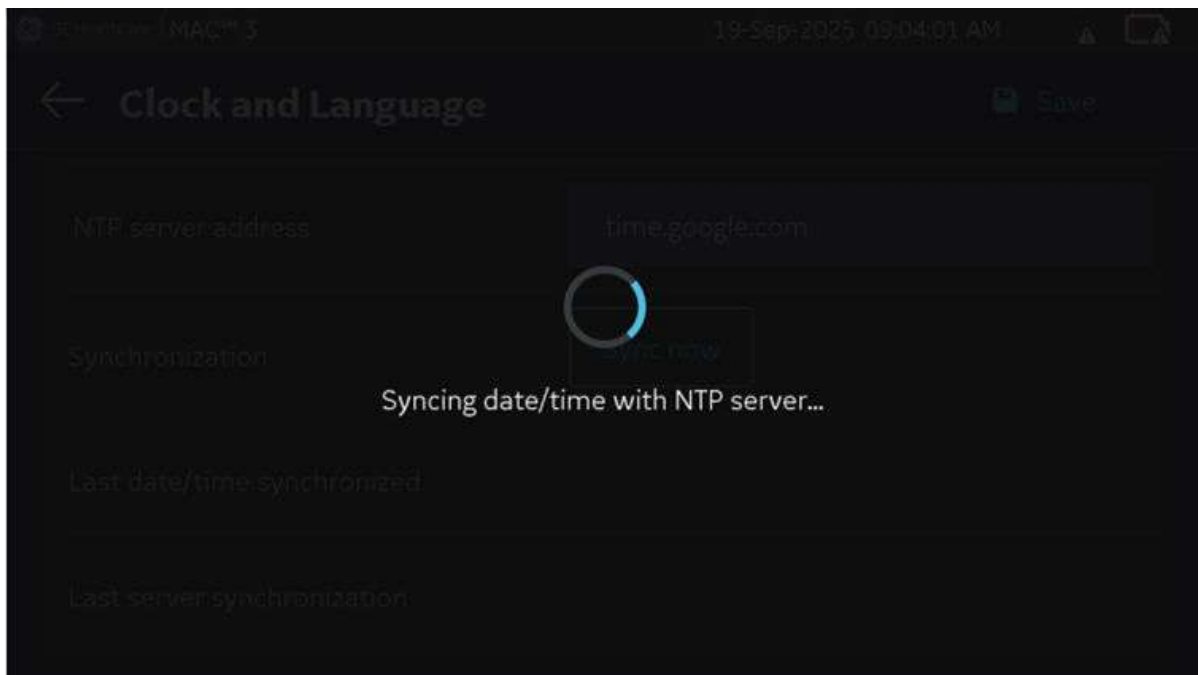
The screenshot displays the 'Clock and Language' configuration interface. At the top, the status bar shows 'GE HealthCare | MAC™ 3' and the date/time '16-Sep-2025 03:01:21 PM'. The title bar includes a back arrow and the text 'Clock and Language', with a 'Save' button on the right. The settings are organized into sections: 'Language' is set to 'English'; 'Network provided date and time (NTP)' is enabled, with the toggle switch highlighted by a red rectangle; '24-hour format' is disabled; 'Time zone' is set to 'UTC Coordinated Universal Time, U...'; 'NTP server address' is an empty text field; 'Synchronization' features a 'Sync now' button; and the bottom section shows 'Last date/time synchronized' and 'Last server synchronization' fields.

4. Enter the valid IP address or host name of the NTP server that synchronizes the current date and time on the device in the **NTP server address** field.

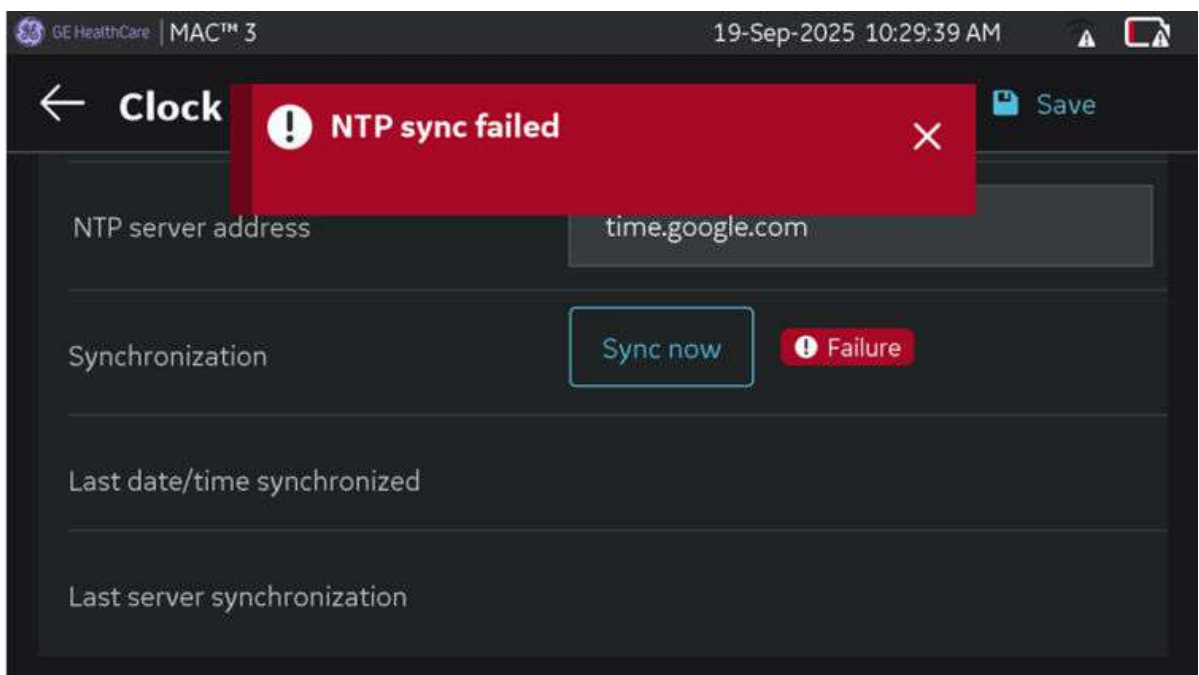
5. Select **Sync now** to synchronize the date and time of the device.



The device synchronizes the date and time with the NTP server.

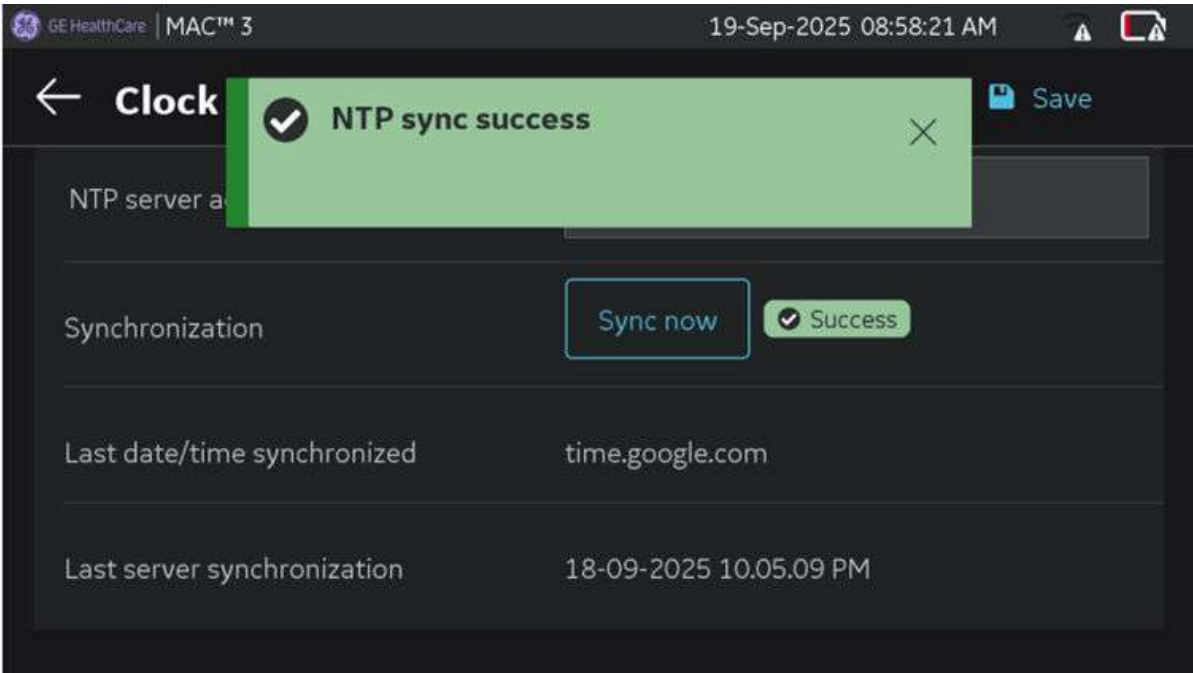


If any errors during syncing the date with NTP server, a failure message displays.



Troubleshoot the errors to synchronize the date with NTP server.

If no errors a success message displays.



Displays the below values:

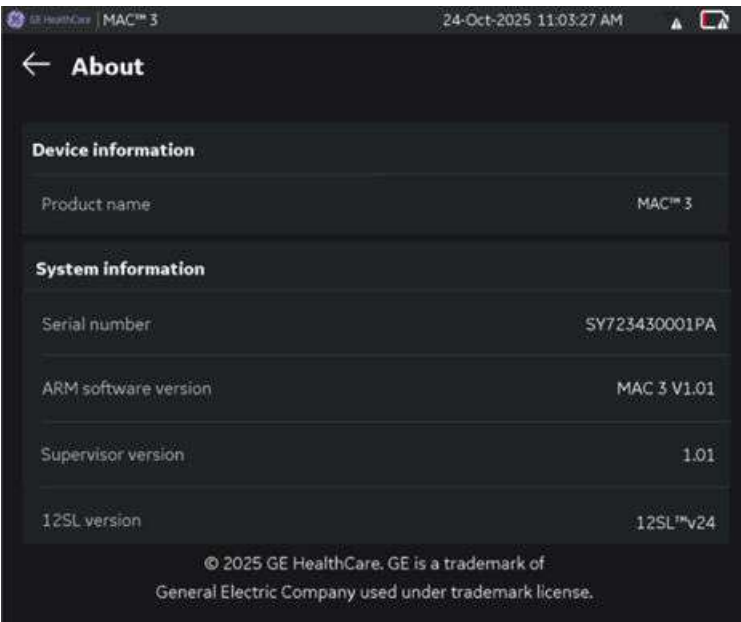
- The date and time when the device was last synchronized with the NTP server.
- The IP address or URL of the NTP server that synchronized the current date and time of the device.

6. Select **Save**.

7.10 About screen

1. Select **Settings > About Device**.

The **About** screen displays.



2. The about screen displays the information as per the table below.

Table 7-24 Information on the About screen

Field	Description
Device information	
Product name	The device information displays the Product name MAC™ 3.
System information	
Serial number	Shows the serial number of the device.
ARM software version	Shows the software version of the device.
Supervisor version	Shows the firmware version of the device.
12SL version	Shows the 12SL version.

8 Maintenance

Regular maintenance, irrespective of usage, is essential to ensure that the equipment functions as required. This section provides basic maintenance information for the following components:

- The device
- Paper
- Battery

8.1 Device maintenance

WARNING



ELECTRICAL HAZARD

Improper handling during inspection or cleaning could result in electrical shock.

To avoid potential shock, observe the following guidelines at all times:

- Before inspecting or cleaning the system, turn it off, unplug it from AC power, and remove the battery.
- Do NOT immerse any part of the equipment in water.

8.2 Clean the printhead

If the printer does not operate, you may need to clean dirt, particles, and unwanted materials from the printhead. To clean the printhead, do the below steps:

1. Dip the cotton swabs in ethyl alcohol and compress to remove out the more solution.
2. Open the printer door.
3. Carefully clean the heating element with the cotton swabs.
- 4.

CAUTION



DAMAGE HEATING ELEMENT

Do not use products that can harm the heating element, such as sandpaper. Avoid unnecessary force when handling the printhead.

CAUTION



RISK OF SKIN BURNS

The printhead gets hot when recording.

Do not to touch the thermal printhead when inserting the paper.

NOTICE**USE OF WRITER PAPER**

Use of other paper may result in recordings of poor quality. The printhead may wear out prematurely, and use of other paper may void the warranty.

Use only original GE HealthCare writer paper. This paper has a special coating that prevents contamination and debris collection on the printhead, and electrostatic buildup.

Close the printer door when it is fully dry.

8.3 Store thermal paper

**NOTE**

To make sure the maximum image life, store thermal paper separately in the manila folders or polyester/polyamide protectors.

To prevent the deterioration or fading, follow these precautions:

1. Store in cool, dark, and dry locations.
Temperature must be below 86°F (30°C). Relative humidity must be less than 65%.
2. Prevent exposure to bright light or ultraviolet sources such as sunlight, fluorescent, and similar lighting which causes yellowing and fading.
3. Do NOT store thermal papers with any of these:
 - Carbon and carbonless forms.
 - Non-thermal papers or any products containing tributyl phosphate, dibutyl phthalate, or other organic solvents. Many medical and industrial writer papers contain these chemicals.
 - Document protectors, envelopes, and sheet separators containing polyvinyl chloride or other vinyl chlorides.
4. Prevent contact with: cleaning fluids and solvents such as alcohols, ketones, esters, ether, and so on.
5. Do NOT use mounting forms, pressure-sensitive tapes, or labels containing solvent-based adhesives.

8.4 Battery maintenance

The system uses a rechargeable battery containing Lithium-Ion cells. The battery contains an integrated safety protection circuit.

The system battery has a shelf life of six months. Recharge the battery once every six months when stored for a long period of time. The system switches off when the battery is completely discharged. Charge battery regularly to maximize battery life.

Because the battery ages, decreases the full capacity of the battery charge and be permanently lost. It decreases the number of the battery charge that you store and will be available for operation. When the capacity is not sufficient for the daily operation of the system, you need to replace the battery.

To print an ECG after the low battery shutdown, perform the below steps:

1. Connect the system to an AC power supply.

2. Recharge the battery for 20 minutes.
The system is ready to print an ECG.

To print an ECG after a battery is fully discharged, perform the blow steps:

1. Connect the system to an AC power supply.
2. Recharge the battery for 90 minutes.
The system is ready to print an ECG.

**NOTE**

The system does not print an ECG without a working battery.

8.5 Regular maintenance

Also, to normal system use, make sure that you do regular cycles of deep discharge of the battery for stable performance. A deep discharge cycle occurs when the battery is discharged until the system shutdown. The battery is charged until it is full.

**NOTE**

For optimal battery life, GE HealthCare recommends one deep discharge cycle every three months, but does not recommend over-exercising the battery with multiple deep discharge cycles.

8.6 Battery safety

See the below warnings when you operate the system battery.

CAUTION**EXPLOSION OR FIRE**

If, you do not use the GE HealthCare recommended batteries, can cause injury/burns to patients or users. It may void the warranty.

WARNING**PHYSICAL INJURY**

The leak from battery cells can occur in extreme conditions. The liquid is caustic to eyes and skin.

If the liquid comes in contact with eyes, skin, or clothing, flush with clean water and get medical aid.

8.7 Replace the battery

When, you charge the battery to the full capacity and cannot operate the device in battery mode:

- For minimum of 360 minutes without print.
- To perform 12-lead resting ECG and print each ECG report every fifteen minutes for a minimum of 3 hours.

Use the below instructions to replace the battery.

1. Carefully lift the notch and move the battery cover in the direction shown on the cover to release from the battery compartment.
2. Remove the old battery.
3. Put the new battery in the battery compartment and move it to align to the battery pins.



4. Move the battery cover to engage the notch.



8.8 Charge the battery

To fully charge the system battery.

1. Connect the system to an AC wall outlet.

2. **NOTE**

If the battery discharged deeply, you must charge the battery for 6 to 7 hours.

Charge the system battery 2 to 3 hours or until the battery LED switch to off.

8.9 Is the battery charging?

Make sure that you verify the below indications that show the device battery charges:

- The amber battery indicator is on.
- The battery gage icon shows the battery charge.

**NOTE**

If the battery is fully charged or exceeds safe charging temperature, the system will not charge the battery.

8.10 When should you charge the battery?

- **Before initial use**
To make sure a fully charged battery, charge the system before you use it for the first time.
- **Between Acquisitions**
To make sure a fully charged battery, power off the system. Connect it to an AC wall outlet until you use the system again. This extends the battery runtime.
- **When the battery is low**
The amber light on the keypad flashes intermittently.
- **When the battery fully discharges**
When, the battery fully discharges the system powers off. To operate the system, you must connect the system to an AC wall outlet.

8.11 Preventive maintenance

GE HealthCare does not recommend any preventive maintenance for this system. But, you may perform the preventive maintenance. For more information on how to perform preventive maintenance, refer to *MAC 3 Service Manual*. If you require more technical support, contact the nearest GE HealthCare Service Center.

9 Cleaning and disinfection

- Do not disassemble and reassemble the device during the cleaning and disinfection process.
- No special accessories are required.

9.1 Inspect the device

Carefully inspect the devices between operation to verify the correct function. The damage and wear on a device may include but is not limited to color change, more scratches, wear, and cracks. Do not use the incorrect operations, damaged, and more worn out devices.

9.2 Care at the point of use

Clean the devices immediately after you use. Keep the dirty devices away from the clean devices to prevent the contamination of personnel or near area.

9.3 Preparation for cleaning

For multi-piece or complex instruments, refer to their disassembly instructions. The disassembly instructions are available in the *MAC™ 3 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.

9.4 Clean and disinfect guidelines

Make sure that you follow the below guidelines while you clean and disinfect the device.

- Follow the instructions to clean and hazards correctly issued by GE HealthCare or other suppliers listed.
- Prevent exposure to hypochlorite solutions and solutions containing iodine or high chlorine content, as these will promote corrosion.
- Prevent exposure to highly alkaline conditions (pH > 11), as this can damage products (for example, aluminum parts).
- Do not use the 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 the fluid to pool around connection pins. If this occurs, dry with a soft, lint-free cloth.
- Prevent contact with open vents, plugs, or connectors when you clean and disinfect the device.
- Do not autoclave or steam-clean the device.
- Do not use the device until you dry fully.

- Do not use any of below materials to clean the device, because their use may damage the equipment surfaces.
 - Organic solvents
 - Abrasive cleaners or solvents of any type
 - Acetone
 - Ketone
 - Betadine
 - Sodium salts
- Do not clean and disinfect the power cord and power adapter.

9.5 Visual inspection, cleaning and disinfection frequency

The table indicates the frequency of visual inspection, cleaning, and disinfection procedures.

Component	Visual Inspection	Cleaning	Disinfection
Device	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.		

9.6 Clean and disinfect the device

The device is 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 can result in electrical shock.

To prevent potential shock, follow the guidelines at all times:

Before you inspect or clean the device, turn it off, unplug it from AC power, and remove the battery.

Do not immerse any part of the equipment in water.

9.6.1 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 correctly.

If you see any items that need the repair, call a GE HealthCare qualified service representative to make the repairs. Stop to use the device until you make the applicable repair.

9.6.2 Clean the device



NOTE

The automated washer-disinfector is not applicable for MAC 3 medical devices.

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 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.

9.6.3 Post-clean inspection

GE HealthCare devices must be visually inspected and test operations after you clean and before the disinfection for below items:

- Cleanliness
- Damage, including but not limited to corrosion (rust, pitting), color change, more 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 correctly, that have unrecognizable markings, that have missing or worn part numbers, or that are damaged. Disassembled devices must be reassembled before you disinfect unless otherwise instructed.

9.6.4 Disinfect the device



NOTE

The automated washer-disinfector is not applicable for MAC 3 medical devices.

Make sure that you clean and remove all the soil and organic matter that you see on the device. See [9.6.2 Clean the device on page 151](#).

1. Dispense fresh Super Sani-Cloth® Wipe(s) from the canister.

2. Apply disinfectant to all the surface and use new wipes.
Treated surfaces must remain visibly wet for a minimum of three minutes. Use more new 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.

9.7 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 the instruments between operation to verify if the device function correctly.

Refer to the supplier's instructions for leadwire cleaning and disinfection.

Refer to the supplier's instructions for reusable electrode cleaning, disinfection, and sterilization.

See the *Diagnostic Cardiology Supplies and Accessories Guide, 2102946-001*.

9.8 Storage

Store the device in a clean and dry, well-ventilated area protected from dust, moisture, insects, vermin, and extremes of temperature and humidity.

9.9 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.

- Caviwipes
- Cleanisept Wipes
- Clinell Sporicidal Wipes
- Clinell Universal Range
- Clorox Healthcare® Hydrogen Peroxide Cleaner Disinfectant Wipes
- Ethanol (ethyl alcohol) 96% (v/v)
- Mikrozid Sensitive Wipes
- Oxivir® Tb Wipes or Oxivir® Tb

- PDI Easy Screen Cleaning® and Isopropyl alcohol 70% (m/m)
- PDI Super Sani-Cloth®
- PDI Sani-Cloth® Bleach
- PDI Sani-Cloth® AF3
- PDI Sani-Cloth® Plus
- Sodium Hypochlorite (NaClO) 5% solution)
- Water and soap solution

9.10 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™ 3 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.

10 Troubleshooting

10.1 System errors

The table list messages that you can find while you use the device.

Table 10-1 Error messages while you use the device

Error message	Error condition	How to troubleshoot:
Device memory is 70 percent full.	Storage 70% full.	Delete some previous files to increase the storage space.
Device memory is 80 percent full.	Storage 80% full.	Delete some previous files to increase the storage space.
Device memory is 90 to 99 percent full.	Storage 90 to 99% full.	Delete some previous files to increase the storage space.
Device memory is full.	Device storage is full.	Delete some previous files to increase the storage space.
25% remaining	Low battery.	Make sure that you connect the device to AC/DC power adapter to the mains.
5% remaining. The device will soon shutdown unless connected to a power socket.	Critical low battery.	Make sure that you connect the device to AC/DC power adapter to the mains.

10.2 ECG acquisition errors

The table list messages that you can find while you acquire the ECG.

Table 10-2 Error messages while you acquire ECG

Error message	Cause	How to troubleshoot:
Baseline wander warning	Movement of ECG leads.	Make sure that you decrease the movement of leads and patient.
Muscle tremor warning	Irregular ECG.	Make sure that you decrease the muscle tremor and acquire the ECG.
AC noise level warning	Noise in leads.	Connect the leads correctly to decrease the noise and try again.
Limb lead disconnected	RA/R disconnected.	Connect RA/R lead correctly.
	Overload or saturation	Avoid overload or saturation.
L disconnected	LA/L disconnected.	Connect LA/L.
Poor data quality in leads	RL/N disconnected.	Connect RL/N.
F disconnected	LL/F disconnected.	Connect LL/F.
C1 disconnected	V1 disconnected.	Connect V1.
C2 disconnected	V2 disconnected.	Connect V2.

Continues on the next page

Table 10-2 Error messages while you acquire ECG (Table continued)

Error message	Cause	How to troubleshoot:
C3 disconnected	V3 disconnected.	Connect V3.
C4 disconnected	V4 disconnected.	Connect V4.
C5 disconnected	V5 disconnected.	Connect V5.
C6 disconnected	V6 disconnected.	Connect V6.
Limb lead disconnected	All leads disconnected.	Connect all leads.
Cable disconnected	Patient cable disconnected.	Connect patient cable.

10.3 Printer errors

Table 10-3 Printer errors encountered during ECG patient report printing

Error message	Error condition	How to troubleshoot:
Reload paper or check paper type and press 'ECG' to continue or Press 'STOP' key to cancel printing.	Paper is jammed or empty and/or paper tray is empty.	Carefully remove the stuck paper from the rollers inside the printer and verify that you load the remaining papers correctly in the paper tray or make sure that the sufficient paper in the paper tray. The print will restart automatically.
Writer Operation requires a battery. Please install battery.	No battery inserted.	Insert the battery to the device and restart the print.
Close door or check door status and press ECG to continue or Press STOP key to cancel printing.	The printer door is open.	Close the printer door. The print will restart automatically.

Table 10-4 Printer errors encountered during rhythm printing

Error message	Error condition	How to troubleshoot:
Reload paper or check paper type and press 'ECG' to continue or Press 'STOP' key to cancel printing.	Paper is jammed or empty and/or paper tray is empty.	1. Carefully remove the stuck paper from the rollers inside the printer and verify that you load the remaining papers correctly in the paper tray. 2. Make sure that the sufficient paper in the paper tray. 3. Select Start Rhythm key  in the key-sheet of the device to restart rhythm print.

Continues on the next page

Table 10-4 Printer errors encountered during rhythm printing (Table continued)

Error message	Error condition	How to troubleshoot:
Writer Operation requires a battery. Please install battery.	No battery inserted.	1. Insert the battery to the device. 2. Select Start Rhythm key  in the key-sheet of the device to restart rhythm print.
Close door or check door status and press ECG to continue or Press STOP key to cancel printing.	The printer door is open.	1. Close the printer door. 2. Select Start Rhythm key  in the key-sheet of the device to restart rhythm print.

Table 10-5 Printer errors encountered during printing of the list of stored records

Error message	Error condition	How to troubleshoot:
Reload paper or check paper type and press 'ECG' to continue or Press 'STOP' key to cancel printing.	Paper is jammed or empty and/or paper tray is empty.	Carefully remove the stuck paper from the rollers inside the printer and verify that you load the remaining papers correctly in the paper tray.
Writer Operation requires a battery. Please install battery.	No battery inserted.	1. Insert the battery to the device. 2. Select Print icon  from the file manager to restart print of the stored records list.
Close door or check door status and press ECG to continue or Press STOP key to cancel printing.	The printer door is open.	1. Close the printer door. 2. Select Print icon  from the file manager to restart print of the stored records list.

Table 10-6 Common printer errors

Error message	Error condition	How to troubleshoot:
5% remaining. The device will soon shutdown unless connected to a power socket.	Critical low battery.	Connect the AC/DC power adapter to the mains.
Print head Temperature is high, Please stop the device!	High printer temperature.	Restart the system to check if the error is resolved. If the error continues, contact your GE HealthCare Service Support representative.

Continues on the next page

Table 10-6 Common printer errors (Table continued)

Error message	Error condition	How to troubleshoot:
Reload paper or check paper type and press 'ECG' to continue or Press 'STOP' key to cancel printing.	Paper is jammed or empty and/or paper tray is empty.	Carefully remove the stuck paper from the rollers inside the printer and verify that you load the remaining papers correctly in the paper tray or make sure that the sufficient paper in the paper tray. The print will restart automatically.
Writer Operation requires a battery. Please install battery.	No battery inserted.	Insert the battery to the device and retry the print.
Close door or check door status and press ECG to continue or Press STOP key to cancel printing.	The printer door is open.	Close the printer door. The print will restart automatically.

10.4 Configuration file errors

Table 10-7 Errors encountered during file configuration

Error message	Cause	How to troubleshoot
Import certificate failed	Configuration import success and certificate import failed.	If the error continues, contact your GE HealthCare Service Support representative.
Import settings failed	Import certificate success and import configuration failed.	Verify the configuration file. If the error continues, contact your GE HealthCare Service Support representative.
USB initialization failed	The USB flash drive is not connected correctly in the USB port.	Make sure that the USB flash drive is connected tightly into the USB port.
USB file system is invalid	File system is not compatible.	Change the USB file system to supported file system.
USB storage memory is full. Insert a new USB.	The USB storage is full you cannot save more files.	Make sure that the connected USB contains the sufficient free space to store more files.
USB is write protected.	The USB flash drive is read only.	Remove write protection of the USB flash drive.

10.5 Configuration file errors

Table 10-8 Errors encountered during patient report transmission

Error message	Cause	How to troubleshoot
Operation failed	No network connection, incorrect network settings or auto delete failed.	Verify the network connection and try again. If the error continues, contact your GE HealthCare Service Support representative.
User cancelled operation	The transmission aborted by user.	Try to transmit again and make sure that you do not press the STOP button accidentally.

Continues on the next page

Table 10-8 Errors encountered during patient report transmission (Table continued)

Error message	Cause	How to troubleshoot
Device memory is 70 percent full.	Storage is 70% full.	Delete some previous files to increase the storage space.
Device memory is 80 percent full.	Storage is 80% full.	Delete some previous files to increase the storage space.
Device memory is 90–99 percent full.	Storage is 90 to 99% full.	Delete some previous files to increase the storage space.
Device memory is full.	Device storage is full.	Delete some previous files to increase the storage space.
No USB connected	The USB flash drive is not detected.	Verify that the USB flash drive is tightly connected into the USB port. If the error continues, use the another USB flash drive.
USB initialization failed	The USB flash drive is not connected correctly in the USB port.	Make sure that you connect the USB flash drive tightly into the USB port.
USB file system is invalid	The file system is not compatible.	Change the USB file system to supported file system.
USB storage memory is full. Insert a new USB.	The USB storage is full and you cannot save more files.	Make sure that the connected USB contains the sufficient free space to store more files.
USB is write protected.	The USB flash drive is read only.	Remove write protection of the USB flash drive.
Unknown error	Unknown error	If the error continues, contact your GE HealthCare Service Support representative.

10.6 USB Flash Drive Errors

Table 10-9 USB device errors

Error message	Error condition	How to troubleshoot
USB initialization failed	The USB flash drive is not connected correctly in the USB port.	Make sure that the USB flash drive is connected tightly into the USB port.
USB storage memory is full. Insert a new USB.	The USB storage is full you cannot save more files.	Make sure that the connected USB contains the sufficient free space to store more files.
USB file system is invalid	The file system is not compatible.	Change the USB file system to supported file system.
USB is write protected	The USB flash drive is read only.	Remove write protection of the USB flash drive.
Unknown errors	The USB flash drive has an unknown error.	Remove this USB flash drive, connect the another USB flash drive that have the permission to write.

10.7 Network connectivity errors

Table 10-10 Errors during wireless network connection

Error message	Cause	How to troubleshoot
- Access point 1, details not valid - Access point 2, details not valid - Access point 3, details not valid	Access point fields are either empty and/or does not meet the minimum requirements.	Enter correct details.

Table 10-11 Errors during LAN network connection

Error message	Cause	How to troubleshoot
Not a valid IP address	The user entered an invalid IP address.	Enter the correct IP address.
Not a valid subnet mask	The user entered an invalid subnet mask.	Enter the correct subnet mask.
Not a valid gateway	The user entered an invalid default gateway.	Enter the correct default gateway.
DCP discovery failed	The automatic DCP settings failed.	Try again. If the problem continues, enter the DCP settings manually.
DCP connection test failed	The connection settings is invalid.	Enter the correct settings and try again. If the error continues, contact your GE HealthCare Service Support representative.

Table 10-12 Errors during GSM network connection

Error message	Cause	How to troubleshoot
Network Ping Fail.	Unknown error.	If the error continues, restart the device and try again.

A 12SL statements

The 12SL statements list in the below table do not show on the ECG reports when you enable the **Screening criteria** setting in 12SL screen.

Table A-1 12SL screening criteria statement list

Statement
Aberrant conduction
Abnormal QRS-T angel, consider primary T wave abnormality
Cannot rule out
Deep Q wave in lead V6
Early repolarization
Incomplete right bundle branch block
Junctional ST depression, probably abnormal
Junctional ST depression, probably normal
(masked by fascicular black?)
Minimal voltage criteria for LVH, may be normal variant
Moderate voltage criteria for LVH, may be normal variant
Nonspecific intraventricular conduction delay
Northwest axis
, plus right ventricular enlargement
Possible
Prominent mid-precordial voltage.
Pulmonary disease pattern
Right axis deviation
Right superior axis deviation
Rightward axis
RST' or QR pattern in V1 suggests right ventricular conduction delay
S1-S2-S3 pattern, consider pulmonary disease, RVH, or normal variant
ST elevation, consider early repolarization, pericarditis, or injury
ST elevation, probably due to early repolarization
with 2:1 AV conduction
with 3:1 AV conduction
with 4:1 AV conduction
with 5:1 AV conduction
with a competing junctional pacemaker

Continues on the next page

Table A-1 12SL screening criteria statement list (Table continued)

Statement
with rapid ventricular response
with retrograde conduction
with slow ventricular response
with undetermined rhythm irregularity

B Report formats

B.1 ECG report formats

The **Normal ECG** report is for those patients with less than 200 BPM.

Table B-1 Normal ECG report formats

Report format	Description
4 by 2.5s	Shows four columns of three rows of waveforms. Each column is 2.5 seconds wide.
4 by 2.5s + 1 rhythm Id	Shows two parts: - The upper part shows four columns of three rows of waveforms. Each column is 2.5 seconds wide. - The lower part shows one row of 10 seconds of one lead. You can configure the rhythm lead in Lead Groups setting.
4 by 3s simult	Shows four columns of three rows of waveforms. Each column is 3 seconds wide.
4 by 10s	Shows four columns of 3 rows of waveforms. Each column is 10 seconds wide. Three leads are printed on each page. This results in four page report.
Authorhythm	Shows one column of 3 rows of waveforms. You can configure the rhythm lead in Lead Groups setting. Each column is 10 seconds wide. When you print 3 rows, this report contains more data, such as measurements or interpretation.

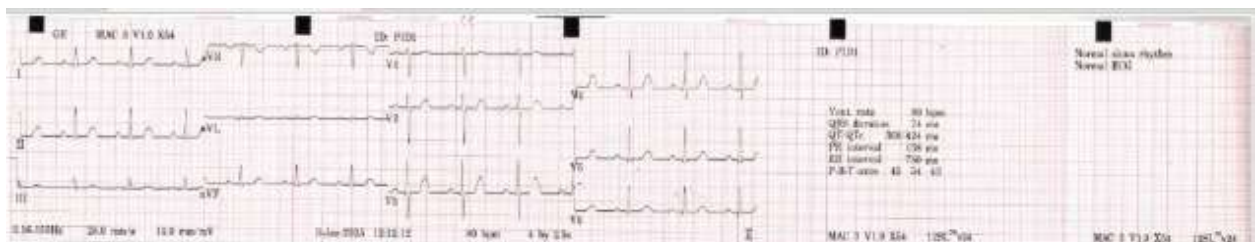
The **Abnormal ECG** report is for those patients with more than 200 BPM.

Table B-2 Normal ECG report formats

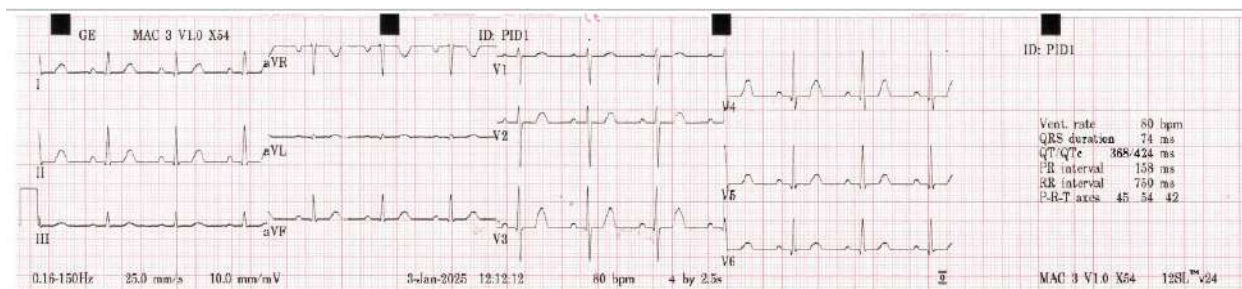
Report format	Description
4 by 10s	Shows four columns of 3 rows of waveforms. Each column is 10 seconds wide. Three leads are printed on each page. This results in four page report.

The below screens show the samples of each ECG report formats.

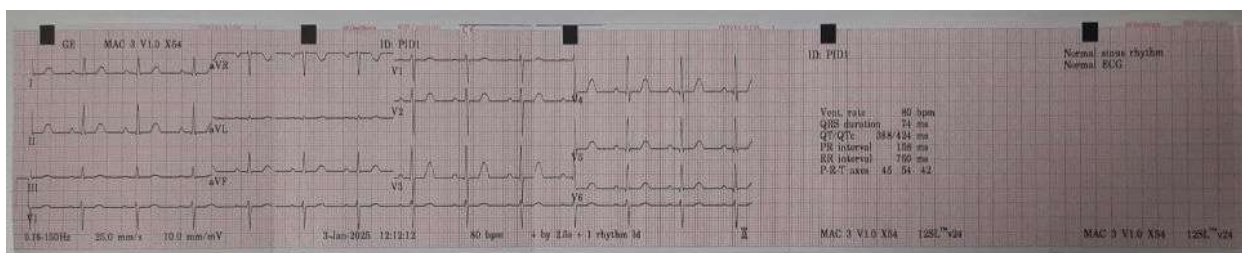
4 by 2.5s - with interpretation



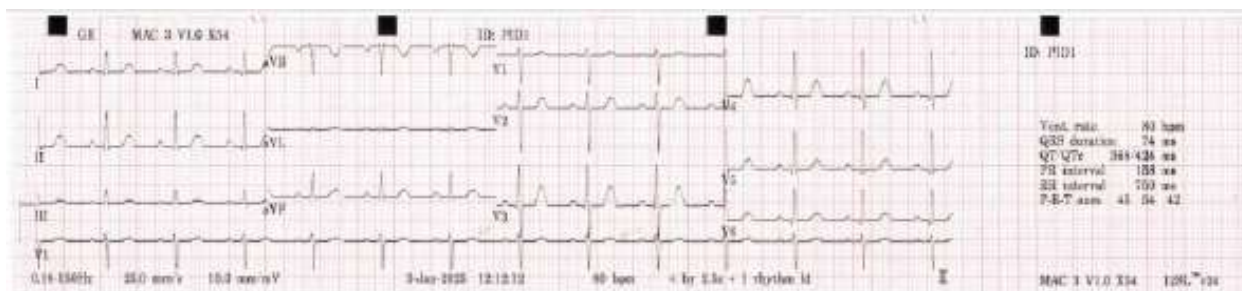
4 by 2.5s - without interpretation



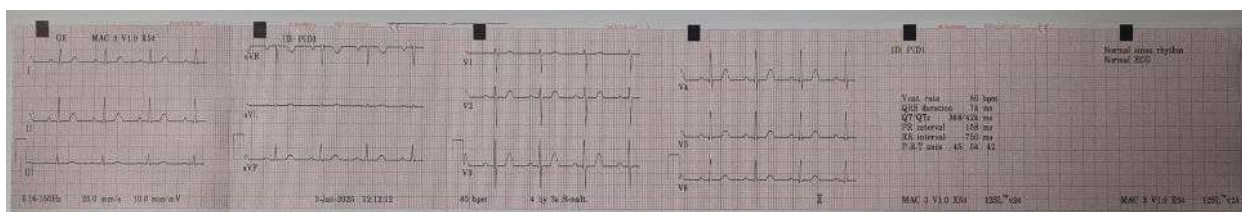
4 by 2.5s + 1 rhythm Id - with interpretation



4 by 2.5s + 1 rhythm Id - without interpretation



4 by 3s simult - with interpretation



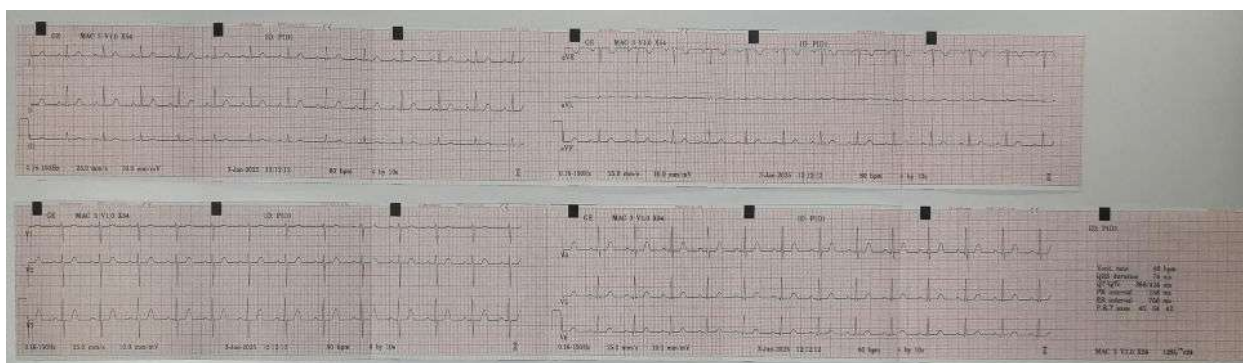
4 by 3s simult - without interpretation



4 by 10s - with interpretation



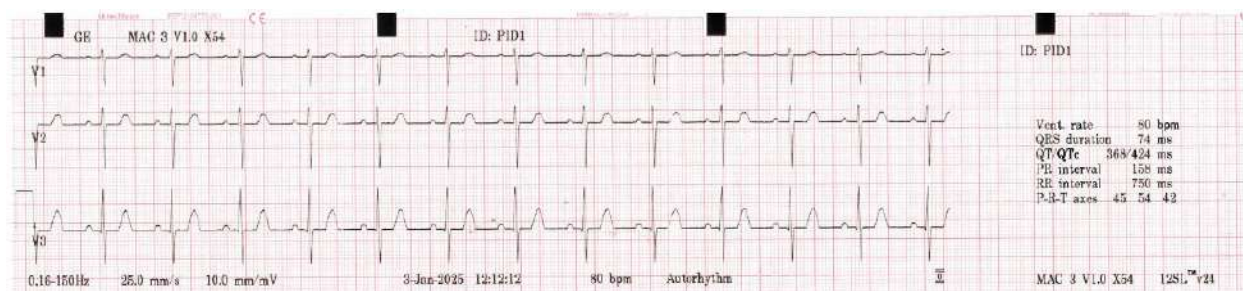
4 by 10s - without interpretation



Autorhythm - with interpretation



Autorhythm - without interpretation



B.2 PDF report formats

You can select the report format for the PDF report print.

Table B-3 PDF report formats

Report format	Description
4 by 2.5s	Shows four columns of three rows of waveforms. Each column is 2.5 seconds wide.
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. - The lower part shows one row of 10 seconds of one lead. You can configure the rhythm lead in Lead Groups setting.
2 by 5s	Shows two columns of six rows of waveforms. Each column is 5 seconds wide.
2 by 5s + 1 rhythm ld	Shows two parts: - The upper part contains two columns of six rows of waveforms. Each column is 5 seconds wide. - The lower part contains a row of 10 seconds of one lead. You can configure the rhythm lead that print in the report.
2 by 5s @ 50mm/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.
4 by 10s	Shows four columns of 3 rows of waveforms. Each column is 10 seconds wide. Three leads are printed on each page. This results in four page report.
Autorhythm (12 lead)	Shows one column of 12 rows of waveforms. You can configure the rhythm lead in Lead Groups setting. Each column is 10 seconds wide.

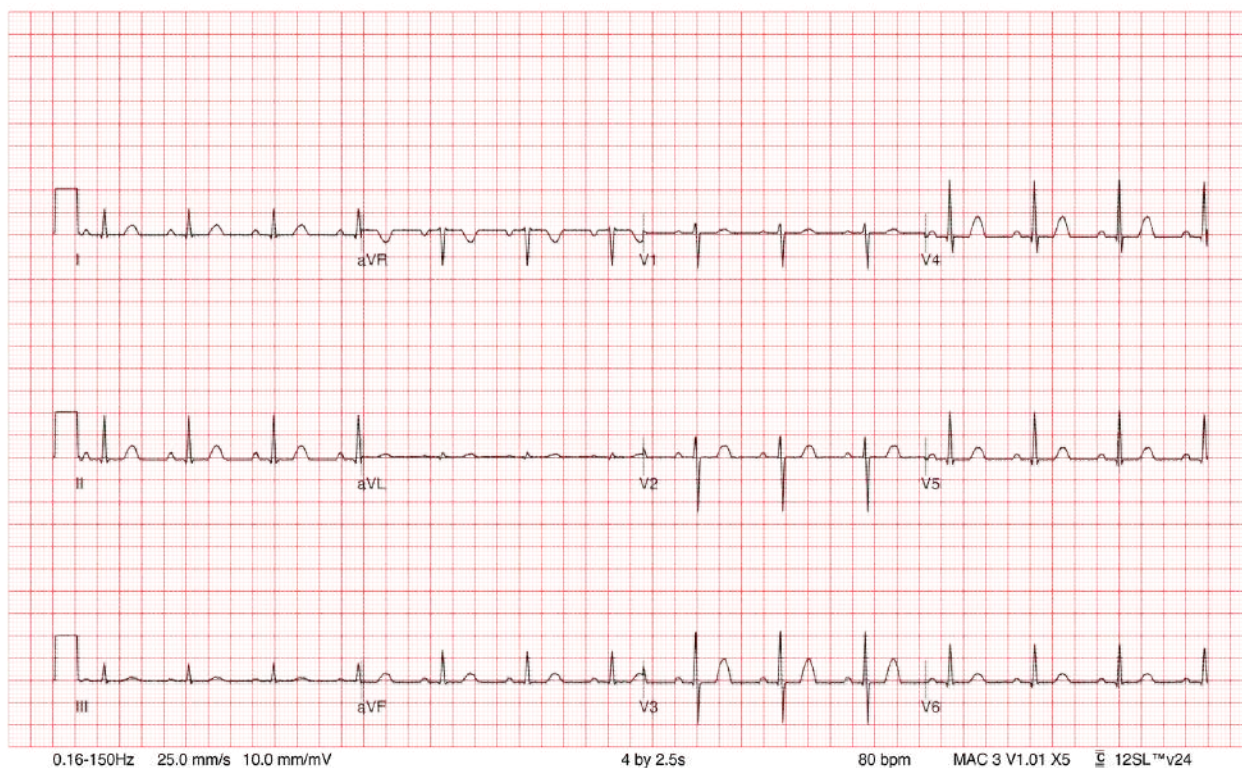
The below screens show the samples of each PDF report formats.

4 by 2.5s

JANE,DOE
ID: PID 1
3-Jan-2000
Female

Vent. rate 80 bpm
PR interval 160 ms
QRS duration 72 ms
QT/QTc 366/422 ms
RR interval 750 ms
P-R-T axes 46 55 47

28-Oct-2025 11:21:16
Normal sinus rhythm
Normal ECG

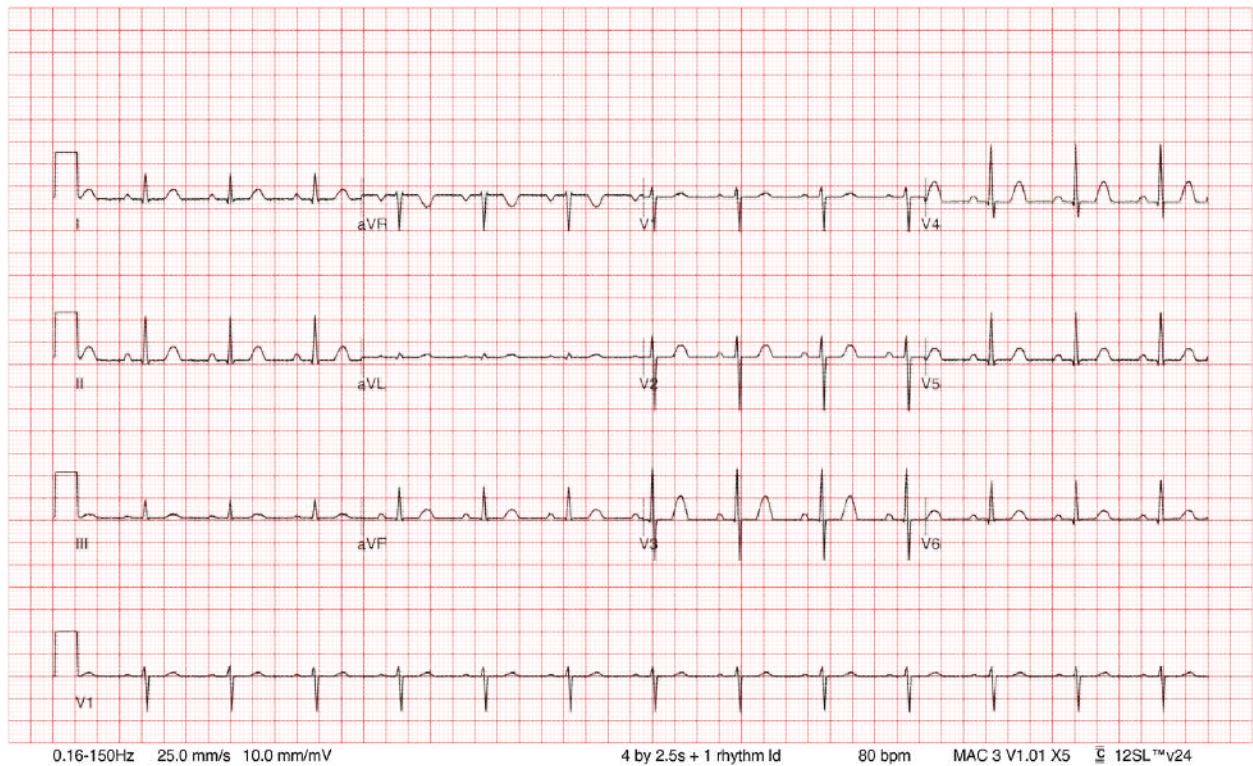


4 by 2.5s + 1 rhythm Id

JOHN,DOE
ID: PID 1
27-Dec-1999
Male

Vent. rate 80 bpm
PR interval 158 ms
QRS duration 74 ms
QT/QTc 368/424 ms
RR interval 750 ms
P-R-T axes 45 56 50

28-Oct-2025 11:24:17
Normal sinus rhythm
Normal ECG

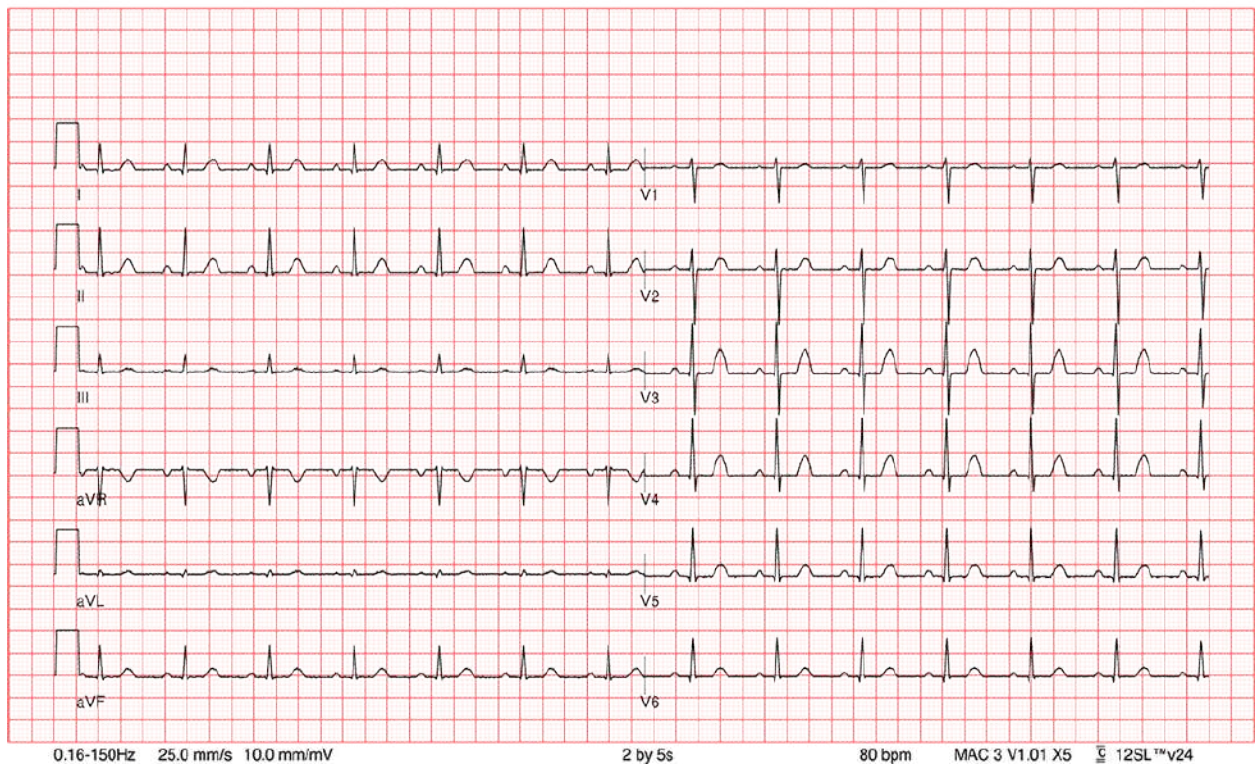


2 by 5s

JANE,DOE
ID: PID 1
3-Jan-2000
Female

Vent. rate 80 bpm
PR interval 158 ms
QRS duration 72 ms
QT/QTc 366/422 ms
RR interval 750 ms
P-R-T axes 46 56 48

28-Oct-2025 11:25:50
Normal sinus rhythm
Normal ECG

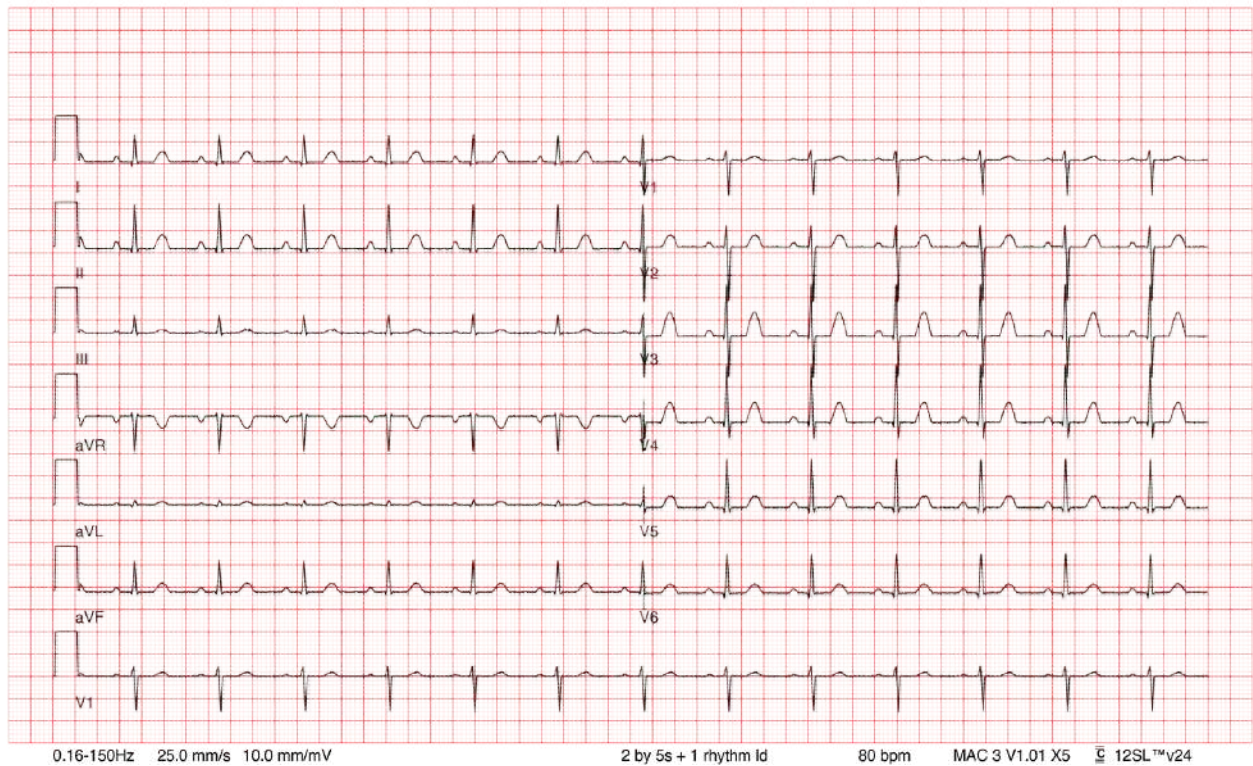


2 by 5s + 1 rhythm ld

Lname,Fname
ID: PID 1
3-Jan-2000
Female

Vent. rate 80 bpm
PR interval 160 ms
QRS duration 74 ms
QT/QTc 366/422 ms
RR interval 750 ms
P-R-T axes 49 55 48

28-Oct-2025 11:27:19
Normal sinus rhythm
Normal ECG

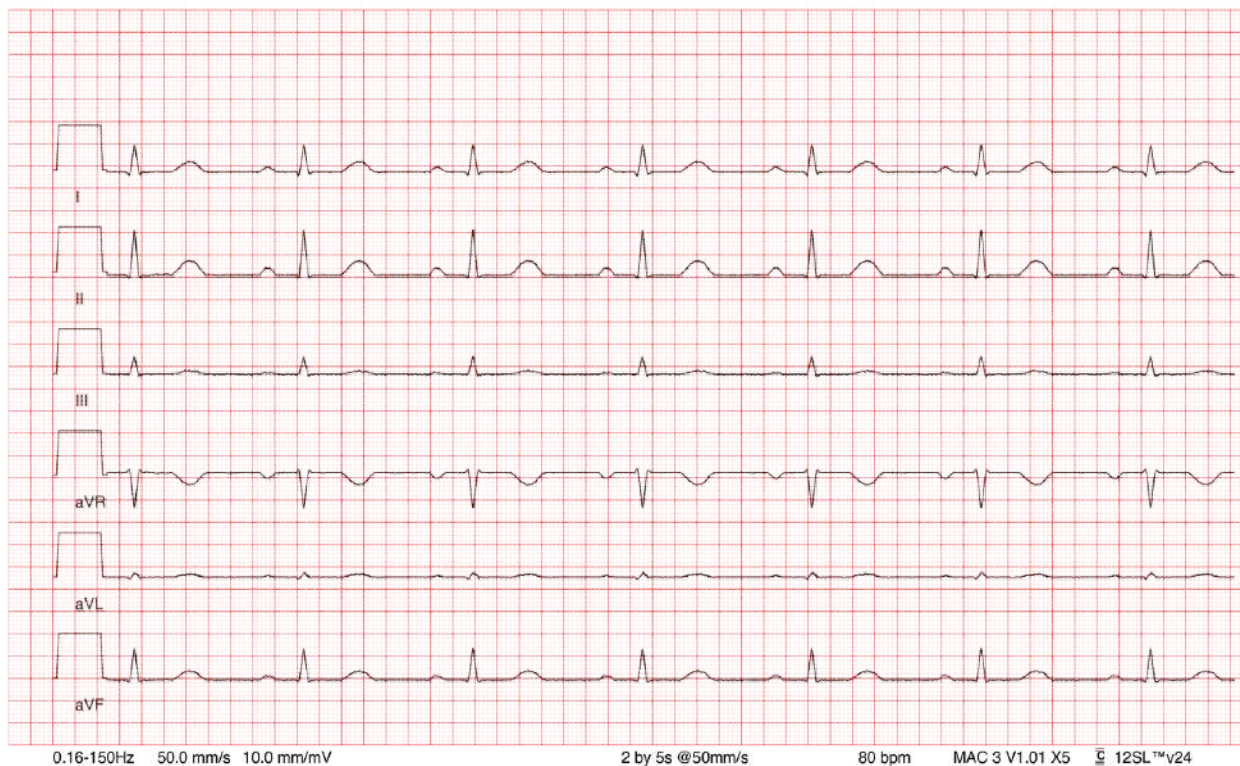


2 by 5s @ 50mm/s

JANE, DOE
ID: PID 1
3-Jan-2000
Female

Vent. rate 80 bpm
PR interval 158 ms
QRS duration 74 ms
QT/QTc 370/426 ms
RR interval 750 ms
P-R-T axes 47 55 47

28-Oct-2025 11:29:13
Normal sinus rhythm
Normal ECG

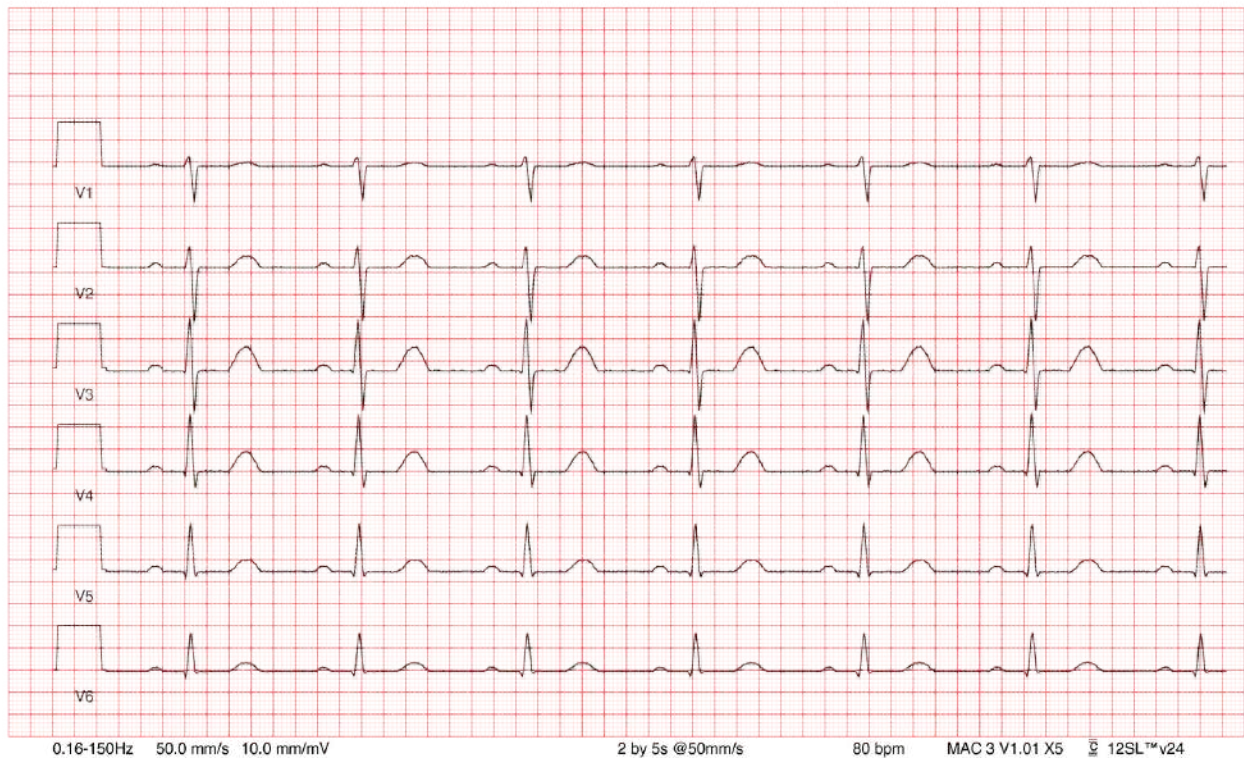


2 by 5s @ 50mm/s Page 2JANE,DOE
ID: PID 1

28-Oct-2025 11:29:13

Continuation Page 2

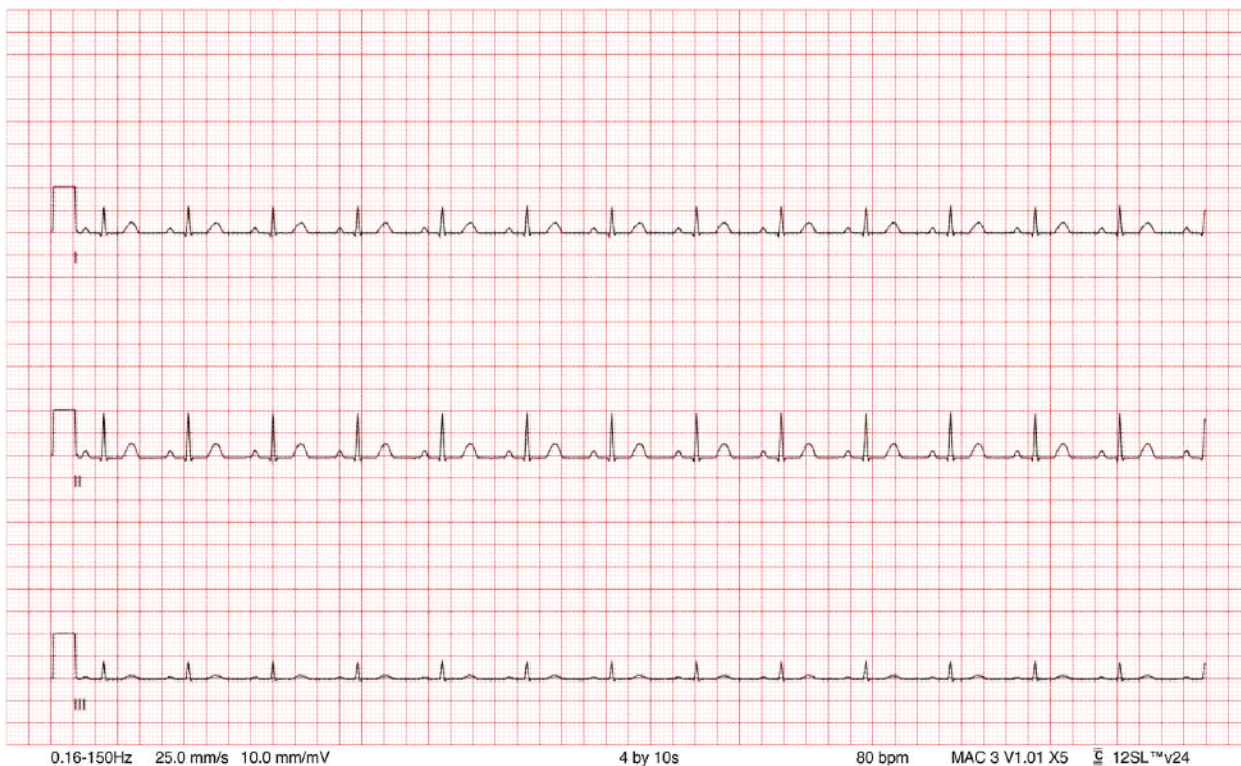
Vent. rate	80 bpm
PR interval	158 ms
QRS duration	74 ms
QT/QTc	370/426 ms
RR interval	750 ms
P-R-T axes	47 55 47

**4 by 10s**

JOHN,DOE
ID: PID 1
27-Dec-1999
Male

Vent. rate 80 bpm
PR interval 160 ms
QRS duration 72 ms
QT/QTc 366/422 ms
RR interval 750 ms
P-R-T axes 47 55 48

28-Oct-2025 11:30:41
Normal sinus rhythm
Normal ECG



4 by 10s Page 2JOHN,DOE
ID: PID 1

28-Oct-2025 11:30:41

Continuation Page 2

Vent. rate	80 bpm
PR interval	160 ms
QRS duration	72 ms
QT/QTc	366/422 ms
RR interval	750 ms
P-R-T axes	47 55 48

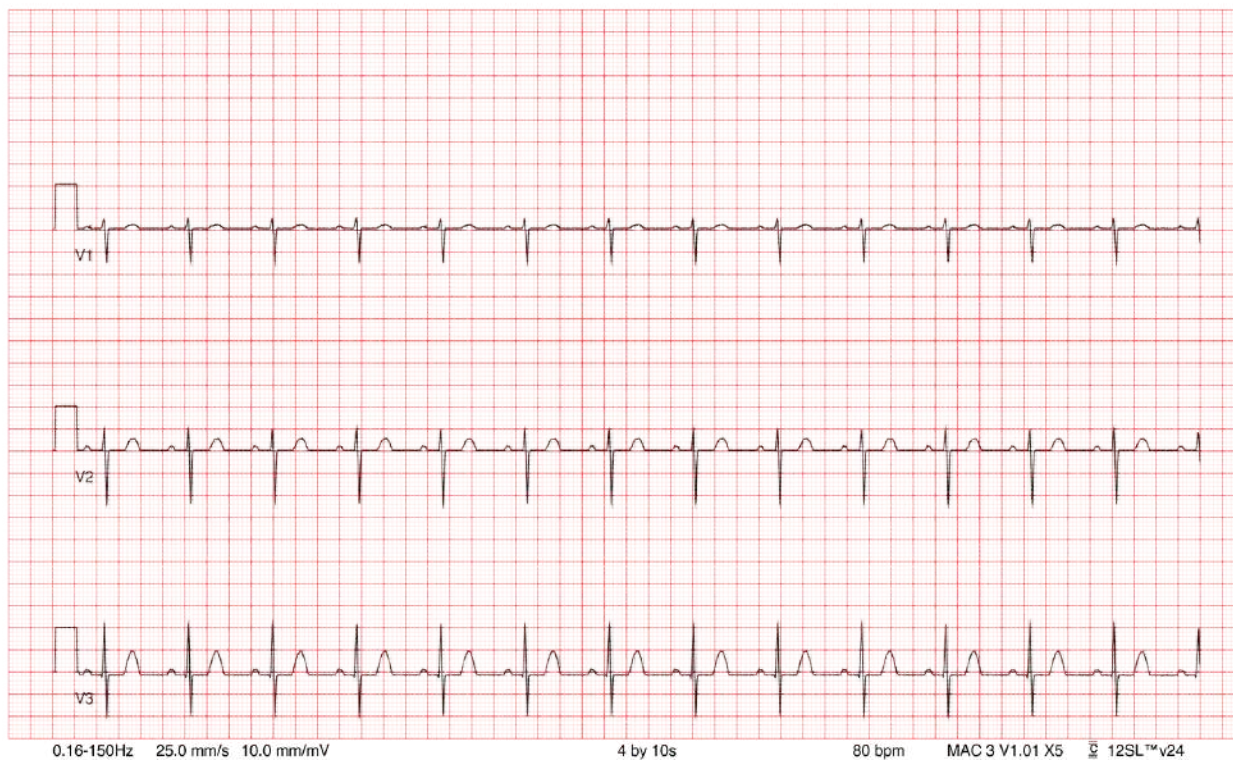


4 by 10s Page 3JOHN,DOE
ID: PID 1

28-Oct-2025 11:30:41

Continuation Page 3

Vent. rate	80 bpm
PR interval	160 ms
QRS duration	72 ms
QT/QTc	366/422 ms
RR interval	750 ms
P-R-T axes	47 55 48

**4 by 10s Page 4**

JOHN,DOE
ID: PID 1

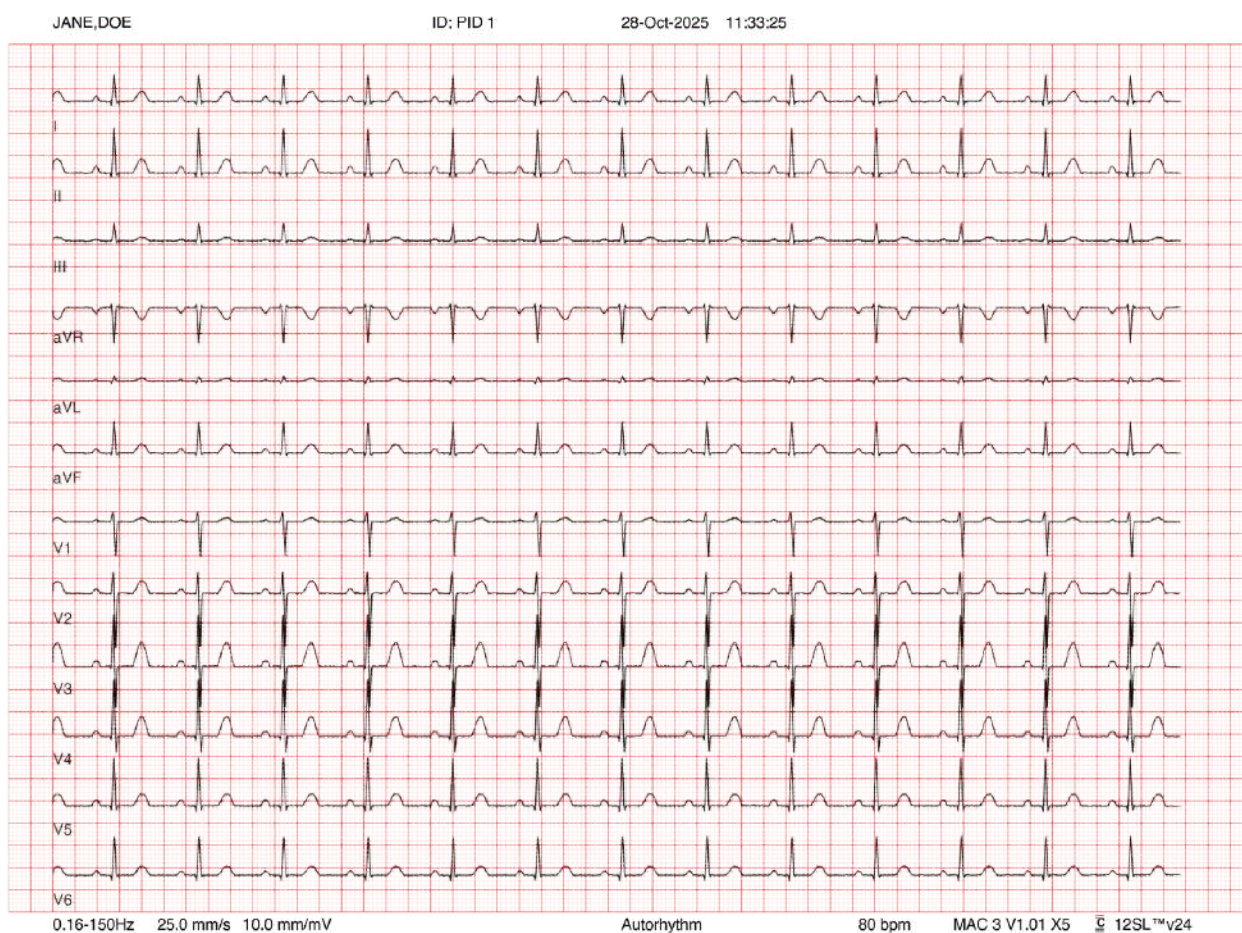
28-Oct-2025 11:30:41

Continuation Page 4

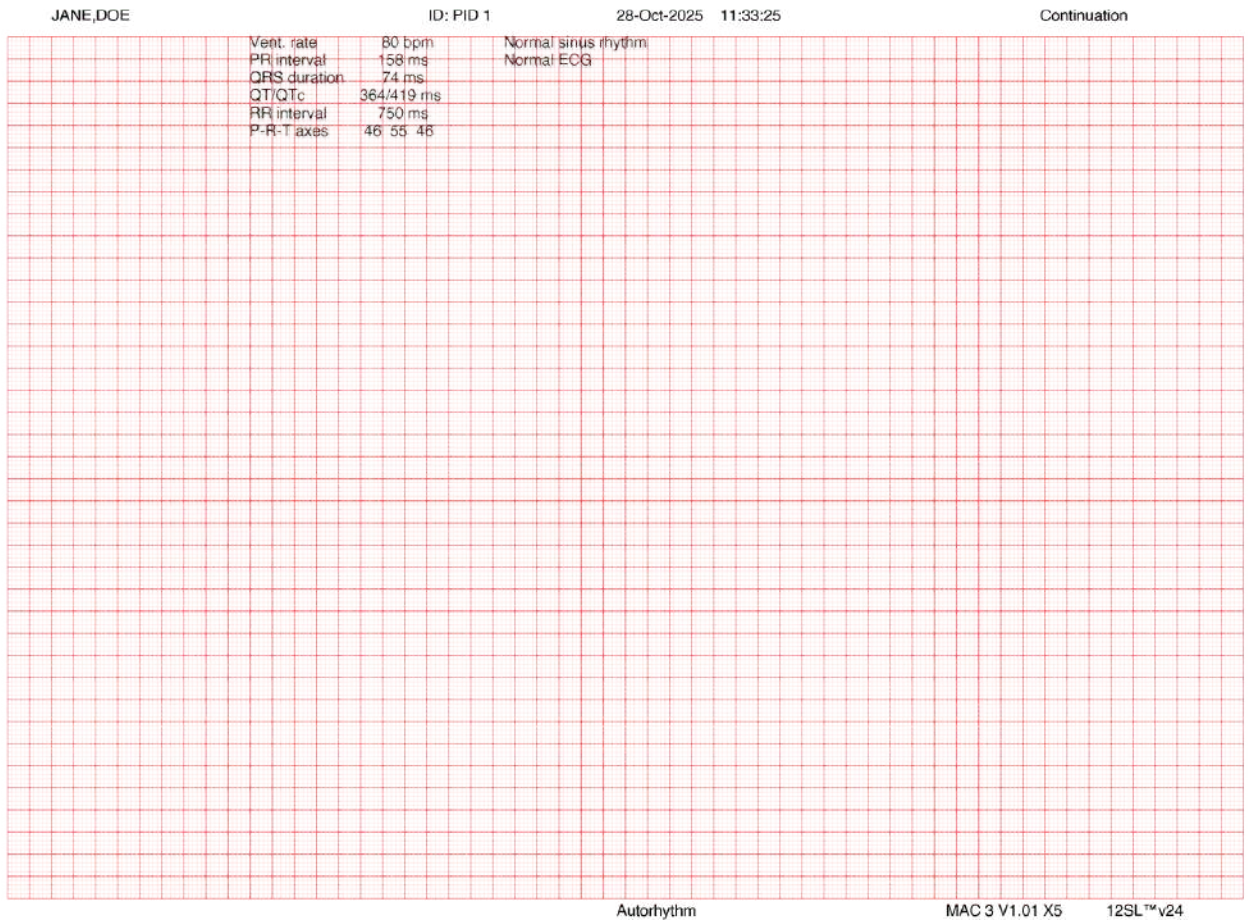
Vent. rate	80 bpm
PR interval	160 ms
QRS duration	72 ms
QT/QTc	366/422 ms
RR interval	750 ms
P-R-T axes	47 55 48



Authorhythm (12 lead)



Autorhythm (12 lead) Continuation



C Patient preparation

C.1 Prepare the patient skin

Below steps are necessary to correctly prepare a patient skin before you acquire an ECG. Prepare the skin carefully for the interference free ECG. The signal quality shows 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 you apply the RA/R electrode. If RA/R electrode disconnect, the system reports that all electrodes are off the patient.

C.2 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 that 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.

C.3 Standard 12-lead electrode placement

To acquire a standard 12-lead ECG, use the electrode placement shown in the diagram below.

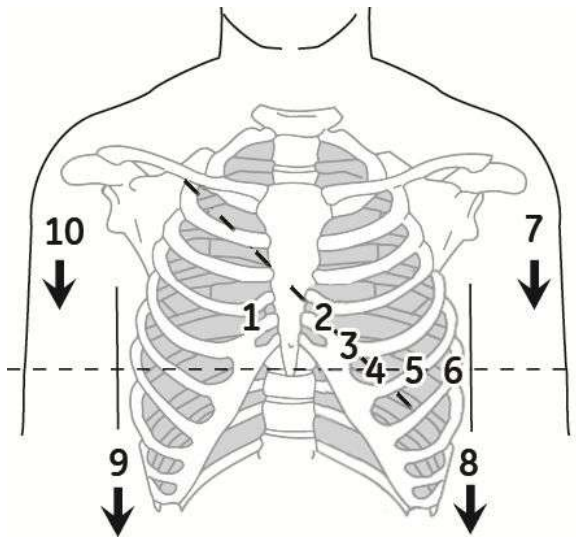


Table C-1 Standard 12-lead electrode placement

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 (alternate placement— left inner wrist).
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 (alternate placement— right inner wrist).

D Patient data fields

When you perform a patient test, all the **Patient Data** fields are read-only.

Table D-1 Patient data fields

Field	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: 3 to 16 characters	• A to Z • a to z • 0 to 9 • All characters are supported.
		Swedish Patient ID: 10 (Short) to 12 (Long) characters	Valid values: '0 to 9' and '-' or '+'. The PID must be in one of the below short formats: • <i>yyymmdd+xxgc</i> • <i>yyymmdd-xxgc</i> • <i>yyymmddxxgc</i> or in the long formats as follows: • <i>yyyymmdd+xxgc</i> • <i>yyyymmdd-xxgc</i> • <i>yyyymmddxxgc</i> • <i>yy</i> and <i>yyyy</i> = patient year of birth • <i>dd</i> = patient day of birth • <i>mm</i> = patient month of birth • + or - = patient age  NOTE If + or - is not before the patient age, the age is less than 100 years. • <i>xx</i> = patient place of birth • <i>g</i> = patient gender ◦ male = odd number ◦ female = even number • <i>c</i> = checksum digit
Visit Number	Visit number given to this patient.	Maximum 19 characters	• A to Z • a to z • 0 to 9 • All characters are supported.

Continues on the next page

Table D-1 Patient data fields (Table continued)

Field	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.
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 that your administrator configure. - 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.
Age	Patient age	Not Applicable	If you select the Age text box on the Patient Data screen, the Date of Birth text box is not available for you to select 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 show on the Patient Information bar.
Secondary ID	An alternative identification method.	1 to 17 characters	- A to Z - a to z 0 to 9 - All characters are supported.
Location ID	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 Settings > System > Device . You can edit the location.	Maximum 4 characters	0 to 9999
Technician ID	Technician doing the ECG.	Maximum 20 characters	- A to Z - a to z 0 to 9 - All characters are supported.

Continues on the next page

Table D-1 Patient data fields (Table continued)

Field	Description	Length	Accepted values
Acquiring Tech User	Acquiring technician username.	Maximum 64 characters	• A to Z • a to z • 0 to 9 • All characters are supported.

E Configure the MUSE system for network communication

E.1 MUSE installation

For instructions to install MUSEAPI3 on MUSE V9 servers, refer to *MUSE v9 Devices and Interfaces Instruction Manual*.

For instructions to install WebAPI on MUSE NX servers, refer to *MUSE NX R2 Installation and Upgrade Manual*.

E.2 Set up DCP inbound communication for MUSE v9.x or NX

For instructions to set up a MUSE v9 server for DCP communication, refer to *MUSE v9 Devices and Interfaces Instruction Manual*.

For instructions to set up a MUSE NX server for DCP communication, refer to *MUSE NX R2 Administrator Manual*.

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.

F.1 DCP transmission to the MUSE system

1. Transmit an ECG test from the MAC 3 device to the MUSE system through the DCP protocol.
2. Verify the test if the acquisition to the MUSE system is successful.

F.2 DCP transmission to the CardioSoft System

1. Transmit an ECG test from the MAC 3 device to the CardioSoft system through the DCP protocol.
2. Verify the test if the acquisition to the CardioSoft system is successful.

G Technical specifications

G.1 System specifications

Table G-1 Device physical specifications

Item	Description
Device type	Microprocessor augmented automatic electrocardiograph; 12-leadwire acquisition with programmable lead configuration.
Height	64 mm
Width	171 mm
Depth	294 mm
Weight	1.5 kg with battery installed but without paper.
USB Port	1 USB 2.0 port supplying 0.5 Amps of Current.
Mechanical design	Housing with fixed angle graphics display. Software on mainboard.

Table G-2 Display specifications

Item	Description
Display	5.0 inch (12.7 cm) diagonal graphics LED backlit.
Touchscreen	Projected Capacitive (PCAP) multipoint touch input that works while wearing medical exam gloves.
Resolution	720 X 1280 pixels with scrolling waveform.
Data	Heart rate, patient ID, date and time, battery power indicator, scrolling waveforms, lead labels, speed, gain and filter settings, warning messages, information messages, prompts. 12-leads standard display.

Table G-3 Printer specifications

Item	Description
Technology	Integrated thermal dot array
Writer speed	5, 12.5, 25, and 50 mm/s
Number of traces	3 leads + 1 rhythm or 3 leads; user selectable
Sensitivity/gain	2.5, 5, 10, 20 mm/mV, and 10/5 mm/mV split gain
Speed accuracy	±5%
Amplitude accuracy	±5%
Horizontal resolution	40 dots/mm at 25 mm/s
Vertical resolution	8 dots/mm
Paper type	Thermal. Z-fold perforated, 80 mm width, 280 sheets/pack.

Table G-4 Electrical specifications

Item	Description
Power supply	AC mains or battery operation
Input voltage	100–240 VAC $\pm 10\%$
Input current range	Maximum 0.6A @ 90 VAC, 0.3A @ 240 VAC
Input frequency	50/60 Hz ± 3 Hz
Output voltage	12 V $\pm 5\%$
Output current	1.5 A
Output power	18 W
Model	ME20B1203F02, SL Power Electronics

Table G-5 Battery specifications

Item	Description
Type	Rechargeable Lithium-Ion battery.
Model	U80195-2 (2073265-001), TOTEX
Nominal voltage	7.2 VDC
Rated capacity	3350 mAh $\pm 10\%$
Charge time	Approximately 300 minutes from total discharge when device is off (standby).
Battery capacity	120 resting ECG recordings for 5 hours (typical) of continuous monitoring without printing, at a minimum.

Table G-6 Keypad specifications

Item	Description
Type	Membrane keyboard with tactile feedback

Table G-7 Other input device specifications

Item	Description
External USB barcode reader	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.

G.2 ECG specifications

Table G-8 Report formats

Item	Description
Thermal printer report formats	4 by 2.5s 4 by 2.5s + 1 rhythm lead 4 by 3s 4 by 10s Autorhythm (10-second ECG data for 3 leads) Printing of 4 by 10s or Autorhythm for abnormal ECG Continuous 3-channel rhythm
PDF report format (A4 format)	4 by 2.5s 4 by 2.5s + 1 rhythm lead 2 by 5s 2 by 5s + 1 rhythm lead 2 by 5s @ 50mm/s 4 by 10s Autorhythm (12-lead)

Table G-9 Patient information

Item	Description
Supported patient information	Patient ID, Visit number, Last name, First name, Date of birth, Gender, Technician ID, Acquiring Tech User, Location ID, and Secondary ID.

Table G-10 ECG data processing specifications

Item	Description
Storage	200 records consisting of 10 seconds Resting ECG records on the device internal memory.
External storage	USB-compliant flash drive supporting the FAT32 file system.
Signal input	Defibrillation-proof type CF applied part. Defibrillation protection: Per IEC 60601-2-25:2011.
ECG interpretation	12SL ECG Analysis Program for Adults and Pediatrics.
Computerized measurements	12-lead analysis
ECG analysis frequency	500 samples/second (sps)
Digital sampling rate	2,000 samples/second/channel
ECG on-screen preview	On-screen preview of acquired 10-second ECG waveform with 12SL measurement and optional 12SL interpretation.
Acquisition mode	Pre-acquisition or post-acquisition, provide 10 seconds of instantaneous ECG acquisition.
Dynamic range	AC Differential ± 5 mV, DC offset ± 300 mV
Resolution	4.88 μ V/LSB @ 500 sps

Continues on the next page

Table G-10 ECG data processing specifications (Table continued)

Item	Description
Skew between channels	<100 μ S
Frequency response	-3 dB @ 0.01 to 150 Hz
Low cut-off frequency	0.01 Hz, 0.02 Hz, 0.16 Hz or 0.32 Hz (-3 dB limits)
High cut-off frequency	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
Adaptive AC filter	47 Hz to 53 Hz when set to 50Hz, 57 Hz to 63 Hz when set to 60 Hz
Common mode rejection	>100 dB (with AC filter switched on)
Input impedance	>10M Ω @ 10 Hz, defibrillator protected
Patient leakage	<10 μ A
Special acquisition functions	Disconnected lead detection except RL, excessive AC noise, baseline wander and muscle tremor messages. Limb lead and chest lead reversal detection.
Heart rate meter	30 to 300 BPM $\pm$ 10% or $\pm$ 5 BPM, whichever is greater. Heart rates outside this range will not be displayed.
Start-up time	Less than 15 seconds

Table G-11 Stored/transmitted ECG waveform

Item	Description
Bandwidth	0.01 to 150 Hz
Sample rate	500 sps
Resolution	4.88 μ V

G.3 Environmental specifications

Table G-12 Environmental specifications

Item	Description
Operating conditions	
Temperature	5°C to 40°C (41°F to 104°F)
Relative humidity (RH)	25% to 95% (non-condensing)
Atmospheric pressure	70 to 106kPa
Transport/Storage conditions	
Temperature	-15°C to 50°C (59°F to 122°F)
Relative humidity (RH)	25% to 95% (non-condensing)
Atmospheric pressure	50kPa to 106kPa

G.4 Safety specifications

Table G-13 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.
Type of protection against electrical shock	Class 1, internally powered
Degree of protection against ingress of liquids	IP20
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	Defibrillation-proof type CF applied part

G.5 Network specifications

Table G-14 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
Wireless specifications	
Wireless standards	802.11a/b/g/n WLAN interfaces Configured manually or via DHCP
Authentication protocols	• Open • WPA • WPA2
Authentication methods	• PSK • PEAP-MSCHAPV2 • TTLS-MSCHAPV2
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
GSM network specifications	
GSM	Support 2G/3G/4G

Continues on the next page

Table G-14 Network specifications (Table continued)

Item	Description
GSM bands	Support • LTE-FDD: B1/B2/B3/B4/B5/B7/B8/B12/B13/B18/B19/B20/B25/B26/B28 • LTE-TDD: B38/B39/B40/B41 • WCDMA: B1/B2/B4/B5/B6/B8/B19 • GSM: B2/B3/B5/B8

H Regulatory and safety information

This section provides information about the safe use and regulatory compliance of the MAC 3 system. The system software is considered medical software. As such it was designed and manufactured to the appropriate medical regulations and controls.

H.1 Intended use

The MAC 3 Resting ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information for adult and pediatric populations.

Basic system delivers 3, 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 3 is intended to be used by trained operators in a hospital or medical professional's facility environment as well as used in clinics, physician offices, outreach centers or wherever ECG testing is performed to record ECG signals from surface electrodes.

H.2 Indications for use

The MAC 3 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 by trained operators in hospital or medical professional's facility environment as well as used in clinics, physician offices, outreach centers, or wherever ECG testing is performed. 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.

H.3 Contraindications

This system is not intended for use in the following manner:

- With high-frequency surgical units
- As an intra-cardiac application
- As a vital signs physiological monitor
- During patient transport
- As a sole means of diagnosis

H.4 Clinical benefits

The clinical benefits of the MAC 3 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.

H.5 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 H-1 Definitions of safety conventions

Safety conventions	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.
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data.

H.6 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.

WARNING



EXPLOSION HAZARD

The system is not designed for use in areas where an explosion hazard may occur. An explosion hazard may result from the use in oxygen-rich environments or in the presence of flammable anesthetics, skin cleansing agents, and disinfectants.

Do not use the system in oxygen-rich environments or in the presence of flammable anesthetics, skin cleansing agents, and disinfectants.

WARNING



BATTERY OPERATION

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

**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.

**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 mains with protective earth.

**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 3 should comply with IEC 60950/IEC60601 or equivalent safety standard.

**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, unplug the power cord, remove the battery and inform your service technician. Do not use the device until it is checked by a service technician.

**WARNING****ELECTRODE CABLES**

Electrode cables should not be connected to an AC power outlet.

**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.

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.

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**LOW BATTERY SHUT DOWN**

If the battery is not charged for a long enough period of time, or after multiple attempts to power on following a low-battery shut down, charge the battery for a minimum of half an hour before using the device. It is recommended that you keep the unit charged to avoid a low-battery shut down.

The battery supplied with the system has a shelf life of six months.

WARNING**OPERATOR**

Medical technical equipment such as this electrocardiograph system must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.

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.

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**POWER REQUIREMENTS**

Before connecting 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's label.

CAUTION**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 (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.

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**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 HealthCare or its representatives.

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.

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.

CAUTION**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.

CAUTION**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.

CAUTION**EXPLOSION HAZARD**

Do NOT use in the presence of flammable anesthetics vapors or liquids.

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 HealthCare 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.

CAUTION**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.

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.

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.

H.7 Classification of medical device

The MAC 3 device is classified as follows according to IEC 60601-1.

Table H-2 Medical device classifications

Category	Classification
Type of protection against electrical shock.	Class I, internally powered.
Degree of protection against electrical shock.	Defibrillation-proof type CF applied part.
Degree of protection against harmful ingress of solids and liquids.	The Ingress Protection (IP) code for this device is IP20.
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

H.8 Certification information

Table H-3 Certification information

	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.

H.9 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.

H.10 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.

H.11 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)
 - High-frequency surgical units, such as diathermy, electrocautery, argon beam coagulators, etc.
 - X-ray, CT, or MRI devices
- These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

CAUTION**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.

CAUTION**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.

CAUTION**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.

H.11.1 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 H-4 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

H.11.2 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 H-5 EMC immunity test

Immunity test	EN60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	$\pm 2, \pm 4, \pm 8$ kV contact $\pm 2, \pm 4, \pm 8, \pm 15$ kV air	$\pm 2, \pm 4, \pm 8$ kV contact $\pm 2, \pm 4, \pm 8, \pm 15$ kV air
Electrical Fast Transient/burst (EFT) IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply 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
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	voltage dips for 0% of U_n for 0.5 cycles and phase angles of $0^\circ, 45^\circ, 90^\circ, 135^\circ, 180^\circ, 225^\circ, 270^\circ$ and 315° . voltage dips for 0% of U_n for 1 cycle and phase angles of 0° voltage dips for 70% of U_n for 25 / 30 cycles and phase angles of 0° voltage dips for 70% of U_n for 25 / 30 cycles and phase angles of 0° Voltage interruptions for 0% of U_n for 250 / 300 cycles	voltage dips for 0% of U_n for 0.5 cycles and phase angles of $0^\circ, 45^\circ, 90^\circ, 135^\circ, 180^\circ, 225^\circ, 270^\circ$ and 315° . voltage dips for 0% of U_n for 1 cycle and phase angles of 0° voltage dips for 70% of U_n for 25 / 30 cycles and phase angles of 0° voltage dips for 70% of U_n for 25 / 30 cycles and phase angles of 0° Voltage interruptions for 0% of U_n for 250 / 300 cycles
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 6 Vrms in Amateur radio bands between 0.15-80 MHz	3 Vrms 0.15 MHz to 80 MHz 6 Vrms in ISM bands between 0.15 MHz and 80 MHz 6 Vrms in Amateur radio bands between 0.15-80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - to 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz - to 2.7 GHz 80 % AM at 1 kHz

Continues on the next page

Table H-5 EMC immunity test (Table continued)

Immunity test	EN60601 test level	Compliance level
 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.		

Table H-6 Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
134.2 kHz	Pulse modulation ^{*1} 2.1 kHz	65 ^{*2}
13.56 MHz	Pulse modulation ^{*3} 50 kHz	7.5 ^{*4}
^{*1} The carrier shall be modulated using a 50% duty cycle square wave signal. ^{*2} r.m.s., before modulation is applied. ^{*3} The carrier shall be modulated using a 50% duty cycle square wave signal. ^{*4} r.m.s., before modulation is applied.		

Table H-7 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band ^{*1} (MHz)	Service ^{*2} (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)
385	380 to 390	TETRA 400	Pulse modulation ^{*3} 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ^{*4} ± 5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation ^{*5} 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ^{*6} 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900;	Pulse modulation ^{*7} 217 Hz	28
1845				

Continues on the next page

Table H-7 Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment (Table continued)

Test frequency (MHz)	Band ^{*1} (MHz)	Service ^{*2} (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)
1970		DECT; LTE Band 1, 3, 4, 25; UMTS		
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ^{*8} 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation ^{*9} 217 Hz	9
5500				
5785				
 NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.				
^{*1} For some services, only the uplink frequencies are included. ^{*2} For some services, only the uplink frequencies are included. ^{*3} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{*4} As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case. ^{*5} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{*6} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{*7} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{*8} The carrier shall be modulated using a 50 % duty cycle square wave signal. ^{*9} The carrier shall be modulated using a 50 % duty cycle square wave signal.				

H.11.3 Essential performance (EMC)

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 maintenance in the case of electromagnetic disturbances, see the below table:

Table H-8 Basic safety and essential performance maintenance

Essential performance	Expected degradations (acceptance criteria)	Maintainance of essential performance after the disturbance has been removed
Defibrillation protection	- Temporary function loss during defibrillation. - EMC disturbance during defibrillation is not considered.	- The device resumes normal operation in the previous operating mode within 5 seconds after the defibrillation is completed. - Not applicable since any one disturbance at a time is considered (single-fault).

Continues on the next page

Table H-8 Basic safety and essential performance maintenance (Table continued)

Essential performance	Expected degradations (acceptance criteria)	Maintainance of essential performance after the disturbance has been removed
ECG measurements ^{*1}	Temporary function loss during: - Electrostatic Discharge (ESD) - Electrical Fast Transients (EFT) - Conducted RF (CRF)	The device resumes normal operation in the previous operating mode 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 - The display and to print may require manual intervention (for example, system restart) to start/continue operation.
Filters (including line frequency filters)	No degradation in the absence of EMC/Defibrillation.	The device will maintain the essential performance when the Filters are enabled.
Electrosurgery (ESU) interference	This system is NOT intended to be used along with ESU devices.	Not applicable.
^{*1} 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 $\pm 50 \mu\text{V}$ for reference values $\leq 500 \mu\text{V}$, or by more than 5 % or $\pm 100 \mu\text{V}$ (whichever is greater) for reference values $> 500 \mu\text{V}$.		

H.12 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.

H.13 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.

H.14 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.

H.15 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, 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.

H.16 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.

H.17 Notification to member states

Any serious incident related to the use of this GE HealthCare device, should be reported to both the manufacturer and the health authority/competent authority where the device is installed.

To report to GE HealthCare, either contact your local service representative or report to, in-box.complaints@gehealthcare.com.

Please provide the following information:

- The catalogue number or the model designation of the device as stated on its identification plate affixed on the device.
- The System ID/Serial Number/Lot Number of the device.
- Date of incident.
- Description of incident, including any patient, or user impact/injury.
- Your contact information (facility, address, contact name, title, and telephone number).

H.18 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.

H.19 Product and packaging information

This section contains information on the labels and symbols used on the device and package box.

H.19.1 Hardware label locations

The illustrations and table in this section describe the labels and their location on your device and its packaging.

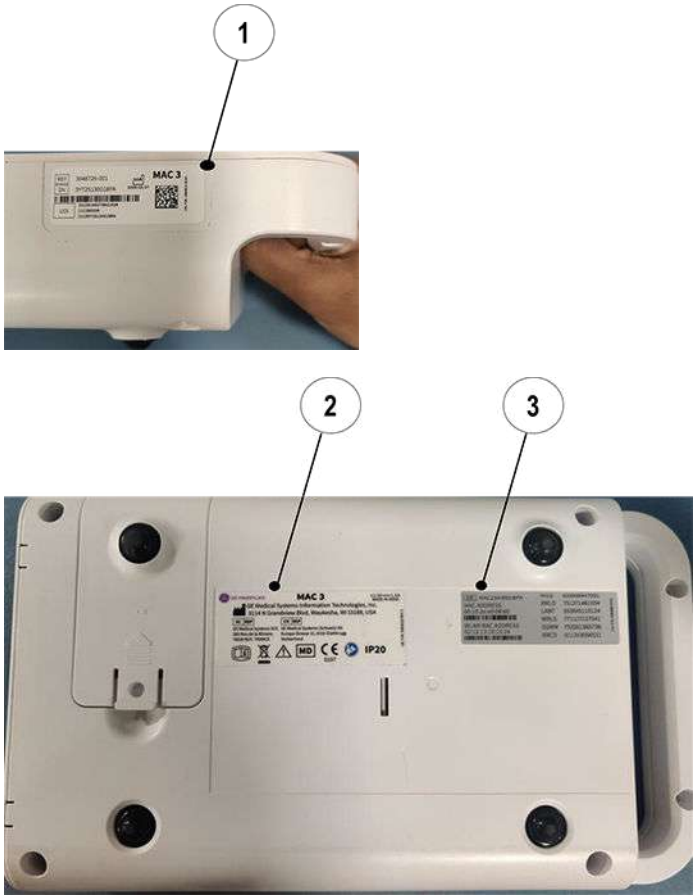


Table H-9 Label descriptions on the device and packaging

Item	Label	Location	Description																								
1	Serial number and UDI label	Back of the device	Identifies this device. See H.20 Serial number label on page 207 and H.24 Unique device identifier on page 212 for the description of the label contents.																								
2	MAC 3 system product label	Bottom of the device	Provides regulatory and cautionary information. See H.21 Product label on page 208 for an explanation of the label.																								
3	Option code and MAC address label	Bottom of the device	The MAC address of the wired network card. Use the option codes to set up the purchased options in your system. <table><tr><td>SN</td><td><SERIAL NUMBER></td><td>MI12</td><td><OPTION CODE></td></tr><tr><td>MAC ADDRESS</td><td><MAC ADDRESS></td><td>XMLO</td><td><OPTION CODE></td></tr><tr><td><MAC ADDRESS BRCD></td><td></td><td>LANT</td><td><OPTION CODE></td></tr><tr><td>WLAN MAC ADDRESS</td><td><WLAN MAC ADDRESS></td><td>WRLS</td><td><OPTION CODE></td></tr><tr><td><WLAN MAC ADDRESS BRCD></td><td></td><td>GSMM</td><td><OPTION CODE></td></tr><tr><td></td><td></td><td>BRCD</td><td><OPTION CODE></td></tr></table>	SN	<SERIAL NUMBER>	MI12	<OPTION CODE>	MAC ADDRESS	<MAC ADDRESS>	XMLO	<OPTION CODE>	<MAC ADDRESS BRCD>		LANT	<OPTION CODE>	WLAN MAC ADDRESS	<WLAN MAC ADDRESS>	WRLS	<OPTION CODE>	<WLAN MAC ADDRESS BRCD>		GSMM	<OPTION CODE>			BRCD	<OPTION CODE>
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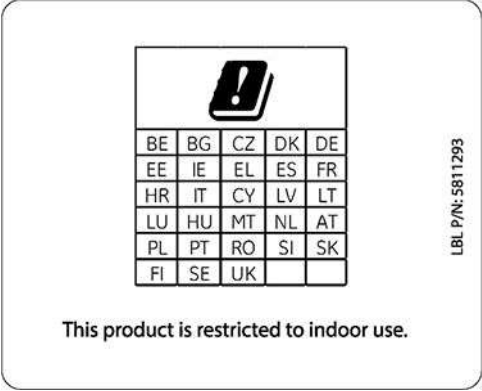


Table H-10 Label descriptions on the shipping package of the device

Item	Label	Description
4	Shipping label	Regulatory and safety shipping information of MAC 3 system. 
5	Battery shipping label	

Continues on the next page

Table H-10 Label descriptions on the shipping package of the device (Table continued)

Item	Label	Description
6	Radio Equipment Directive (RED) Label	The Radio Equipment Directive registration information. 
7	Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance.	The Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance.
8	Environmental symbols	Safety indicators required for shipping. For a full description of symbols, see H.22 Symbol descriptions on page 208 .
9	Extended Produce Responsibility (EPR) compliance in India.	Compliance to take responsibility for the environmental impact of the batteries. 

H.20 Serial number label

The serial number label is in the below format.

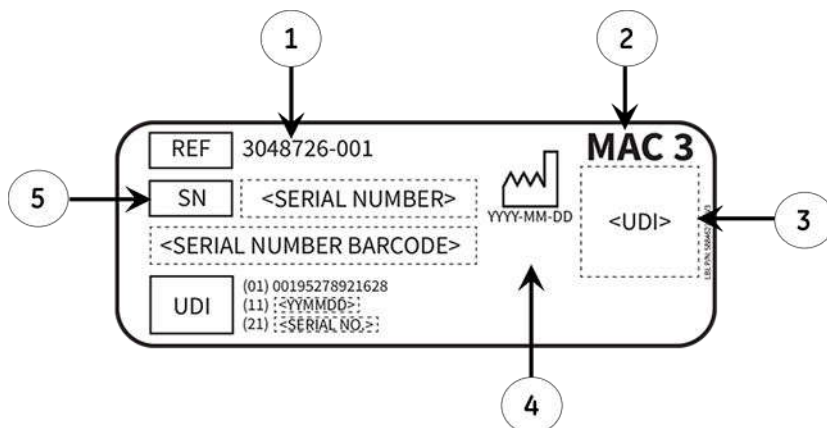
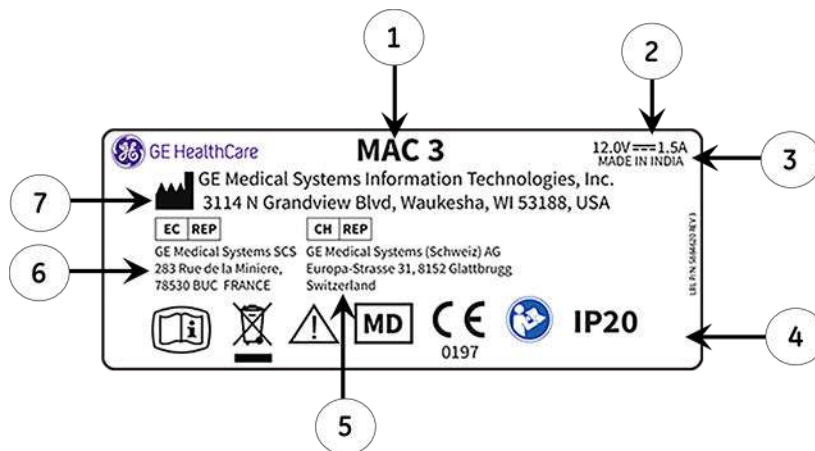


Table H-11 Serial number label format

Item	Description
1	Product part number
2	Product mode (MAC 3)
3	UDI barcode
4	Date of manufacture in YYYY-MM-DD format
5	Device serial number

H.21 Product label

The product label is in the below format.

**Table H-12 Product label format**

Item	Description
1	Product name
2	Electrical rating of the device
3	Country of origin
4	Symbols. See H.22 Symbol descriptions on page 208 for a description of the symbols used on this label.
5	Authorized representative in Switzerland. See H.22 Symbol descriptions on page 208 for the description of the CH REP symbol.
6	Authorized representative in the European Community. See H.22 Symbol descriptions on page 208 for the EC REP symbol.
7	Manufacturer name and address

H.22 Symbol descriptions

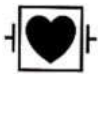
For equipment symbols not shown, refer to the original equipment manufacturer (OEM) manuals.

Table H-13 Symbols, icons, and descriptions on the device or packaging

Symbol	Description
	Catalog or Orderable Part Number The manufacturer's catalog or part number.
	Serial Number The manufacturer's serial number.
	Batch Code or Lot Number The manufacturer's batch code or lot number.
	Medical Device The device is used for medical purpose.
	Date of Manufacture (Year-Month-Date) 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.
	Authorized Representative in the European Community The name and address of the authorized representative in the European Community for this device.
	12SL The device uses the Marquette™ 12SL ECG Analysis Program to analyze and interpret ECG readings.
IP20	IP Code (Ingress Protection Rating) Protects the equipment inside the enclosure against ingress of solid foreign objects having a diameter of 12.5 mm and greater.
	CE Mark The device or product conforms with applicable EU (European Union) directives.
	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.

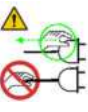
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Table H-13 Symbols, icons, and descriptions on the device or packaging (Table continued)

Symbol	Description
	Follow Instructions For Use Read and understand the operator's manual before using the device or product. <i>As a mandatory action sign, this symbol is identified by a blue background and white symbol.</i>
	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 HealthCare 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.
	Can Be Recycled You may recycle this material or device. Recycle or dispose of in accordance with local, state, or country laws.
	Temperature Limits 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.
	Humidity Limits 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.
	Atmospheric Limits 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.
	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.

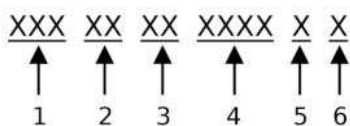
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Table H-13 Symbols, icons, and descriptions on the device or packaging (Table continued)

Symbol	Description
	Do Not Stack You should not stack the container or place a load on the container.
	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.
	Unique Device Identification Indicates a unique marking for identification of the medical device.
	Authorised Representative in Switzerland The name and address of the authorised representative in Switzerland for this device.

H.23 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 H-14 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.

Continues on the next page

Table H-14 Serial number format (Table continued)

Item	Name	Description
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.

H.24 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 serial number label on the back of the device.

H.25 Wireless regulations

The wireless and wired LAN functionality of the MAC 3 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 3 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 3 functionality and are not specified.

H.25.1 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.

"Harmful interference" is defined in 47 CFR §2.1 by the FCC as follows: Interference which endangers the functioning of a radionavigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the [ITU] Radio Regulations.

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.

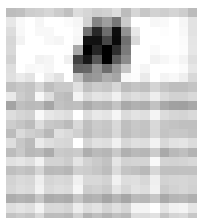
Limited by local law regulations, version for North America does not have region selection option.

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.

H.25.2 RED information

The MAC 3 embedded wireless module complies with CE RED 2014/53/EU.

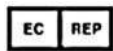


This product is restricted to indoor use.

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



GE Medical Systems
Information Technologies, Inc.
3114 N Grandview Blvd
Waukesha, WI 53188 USA



GE Medical Systems S.C.S.
283 rue de la Minière
Buc 78530 France

GE Medical Systems Information Technologies, Inc., doing business as GE HealthCare.



GE HealthCare

www.gehealthcare.com

GE Healthcare

Marquette™ 12SL™ ECG Analysis Program

Physician Guide

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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.

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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

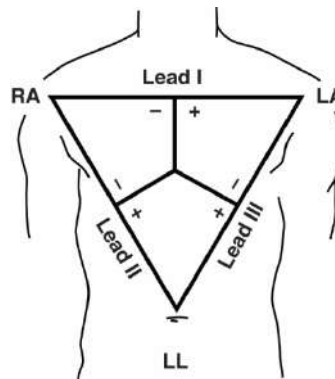
SIMULTANEOUS 12-LEAD ACQUISITION

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):

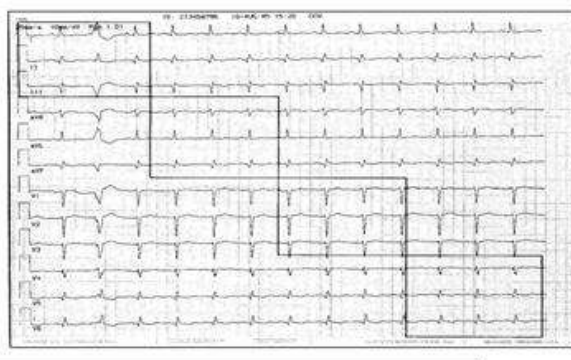
- $III = II - I$
- $aVR = -(I + II)/2$
- $aVL = I - II/2$
- $aVF = II - I/2$



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 displayed. 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

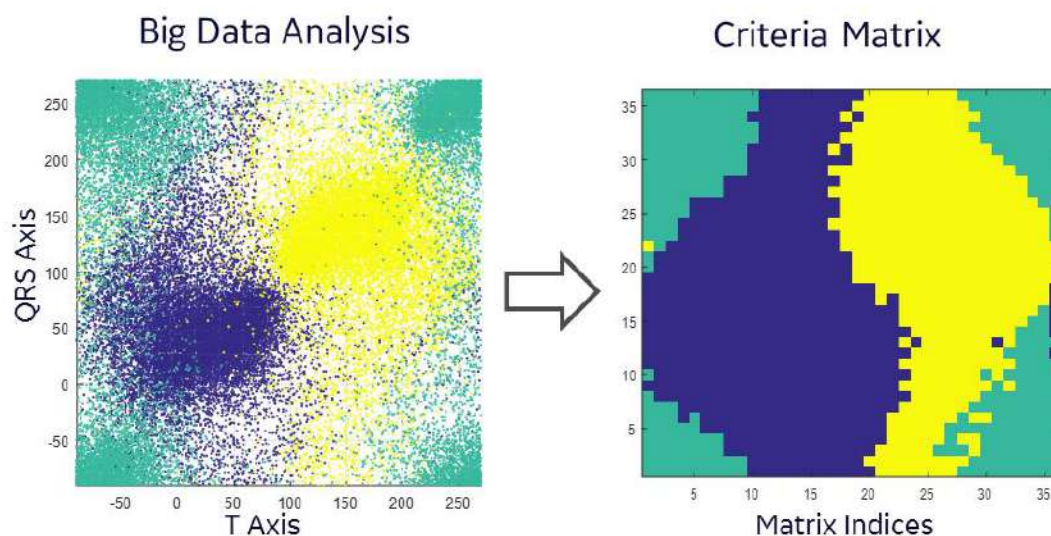
Even when the skin is marked as to where to place chest electrodes for repeat ECGs for serial analysis, normal day-to-day variation is considerable, especially with respect to QRS voltage measurement in the precordial leads.[70-72] An undisciplined approach to recording ECGs increases the variability 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

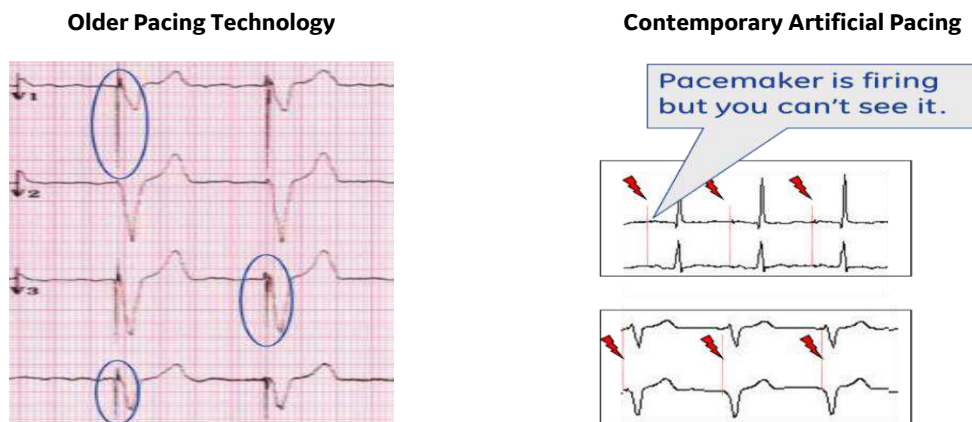
Over the last decade, there has been a significant increase in permanent pacemaker implantation as well as advancements in pacemaker technology.

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]

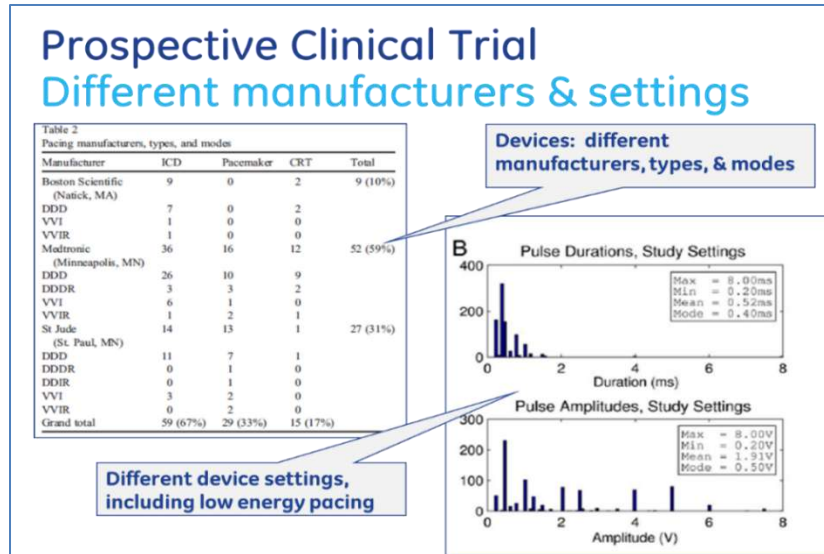
Examples of Artificial Pacing, Then and Now



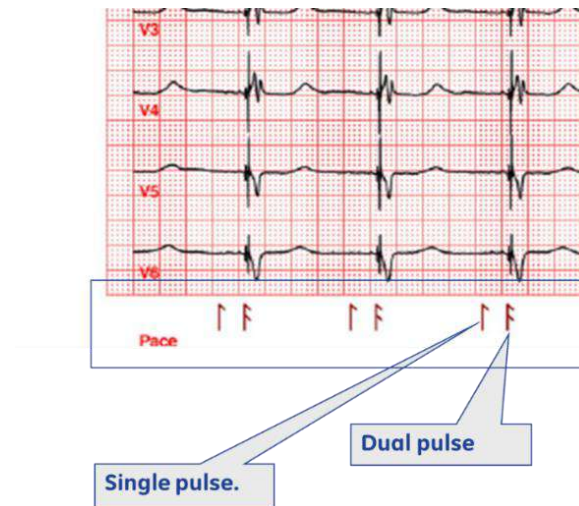
All of this makes the interpretation of the paced ECG difficult and given it has been reported that roughly 10% of in-hospital ECGs are paced,[88] it has become a significant challenge for both the computer[89] and human reader.[85, 90] To combat this, GE Healthcare (Milwaukee, WI) developed a new high-bandwidth 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.

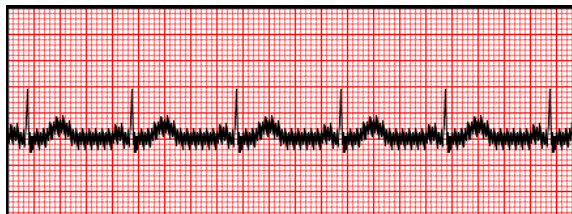
Fortunately, the characteristics of the P-QRS-T have been well studied and there is plenty of documentation as to the limitation of which frequencies can be generated by the heart.[1, 52, 86, 92, 93] Frequencies below 0.67Hz cannot be generated by the heart. If the recorded signal exhibits a waveform 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.

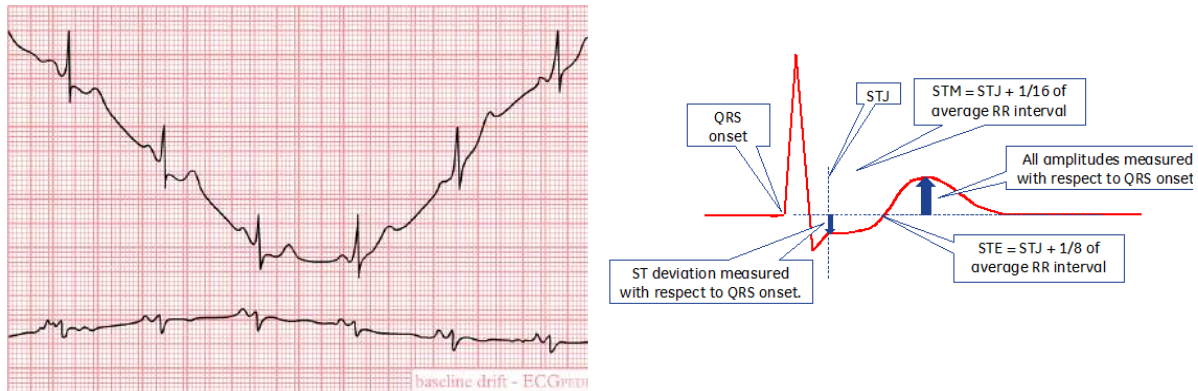
A filter that attempts to eliminate a single frequency from the spectrum of frequencies is often referred to as a “notch filter”. The “notch filter” used in GE Healthcare’s electrocardiographs does more than simply attenuate either 50 or 60 Hz. It locks onto the artifact and measures its amplitude as 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.

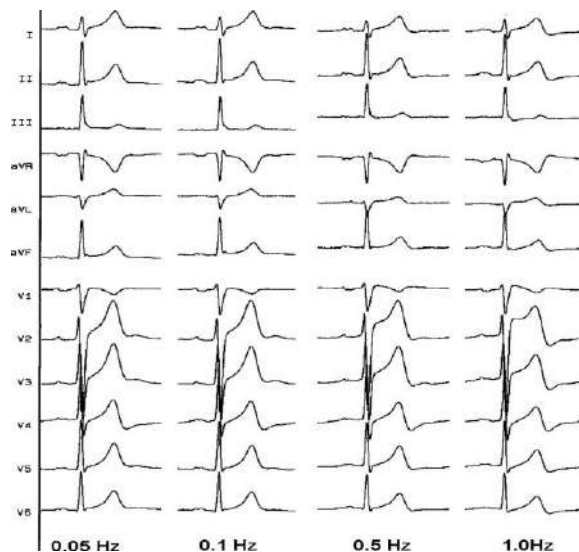


Baseline wander is a low frequency signal. Filters that remove low frequencies are referred to as high-pass filters since they pass along higher frequencies yet leave behind lower frequencies.

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 ($\leq 0.05\text{Hz}$). 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]

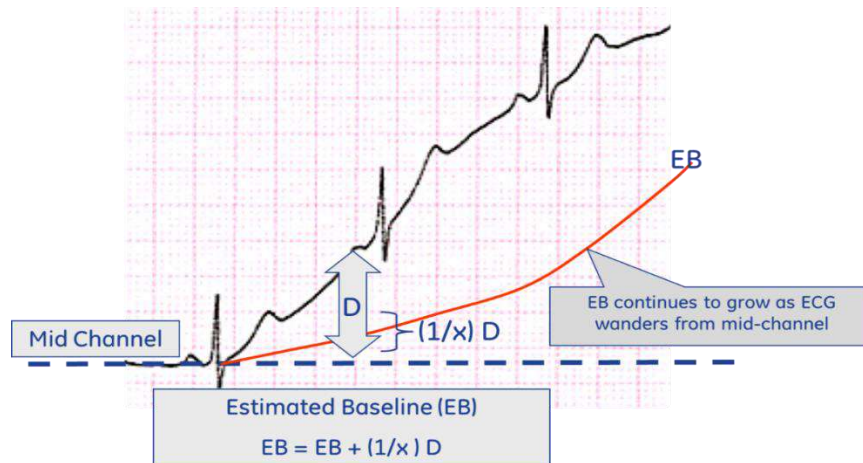
Since the introduction of the 12SL program, a ZPD high pass-filter (≤ 0.32 Hz) has been used to remove baseline sway. Baseline wander is aggressively removed from the 12-lead report without ST-segment distortion. The representative complex generated by 12SL reveals a ST-segment not contaminated by baseline 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.

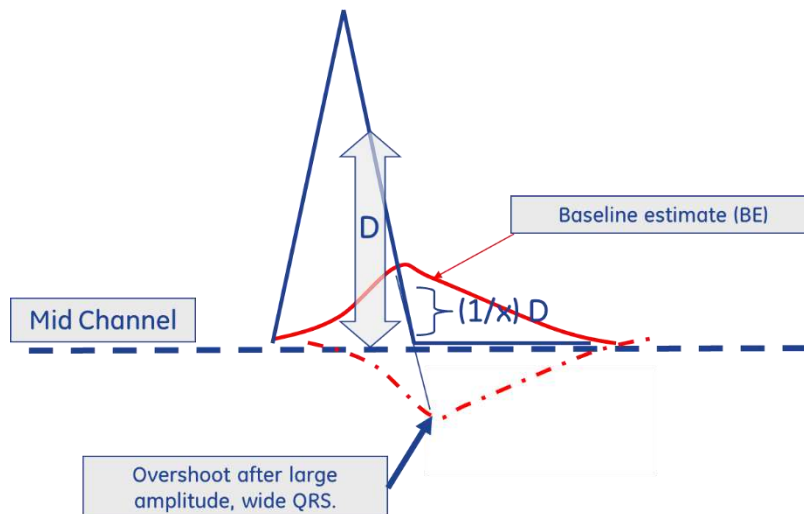
ZPD is an important advancement now available when printing a rhythm strip. Consider that a study conducted in an emergency department found, that as opposed to the 12-lead ECG reports, 93% of rhythm tracings had clinically significant alterations that could be construed as an acute coronary syndrome (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.

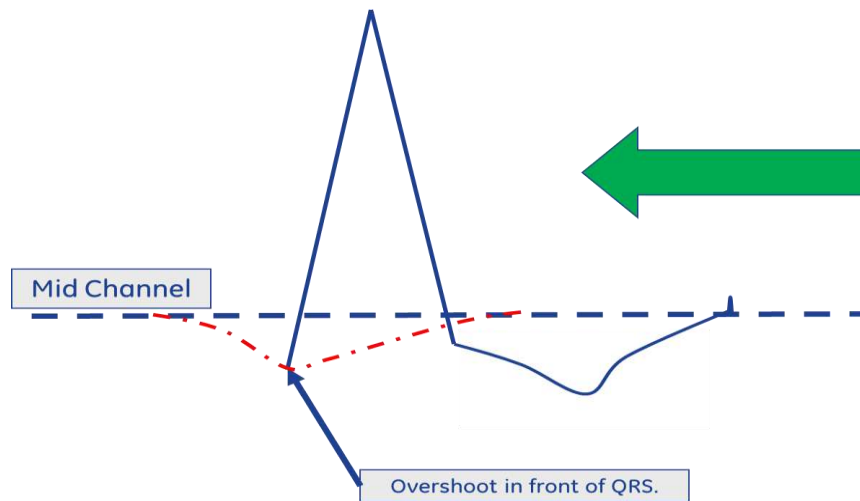
More precisely, the first diagram shows the computer estimating the baseline sway and then subtracting it from the incoming signal. In real-time, the amplitude of each sample is measured relative to the middle of the channel. The estimate of the baseline sway is determined by having a running tally of a fraction of these amplitudes. That fraction becomes larger as the high-pass filter setting increases.



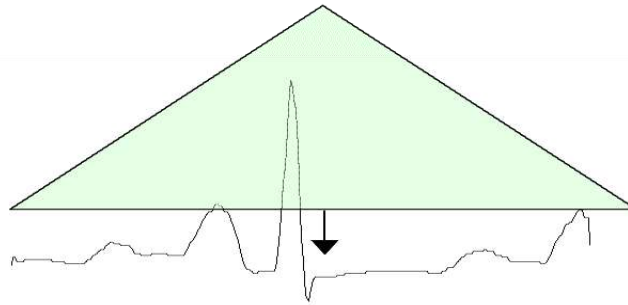
Unfortunately, this filter cannot discriminate between a large or wide QRS complex versus baseline sway. See figure below. The filter can be unduly influenced by the QRS, resulting in an overshoot immediately after the QRS. This effect is apparent in the ECG presented above. Those leads with the largest 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 μ V; 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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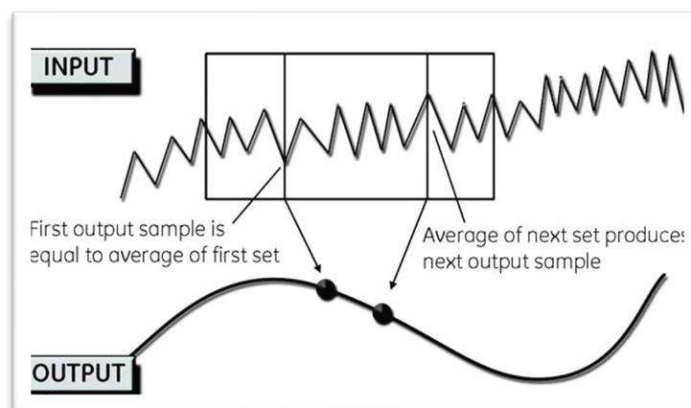
QRS DETECTION

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.

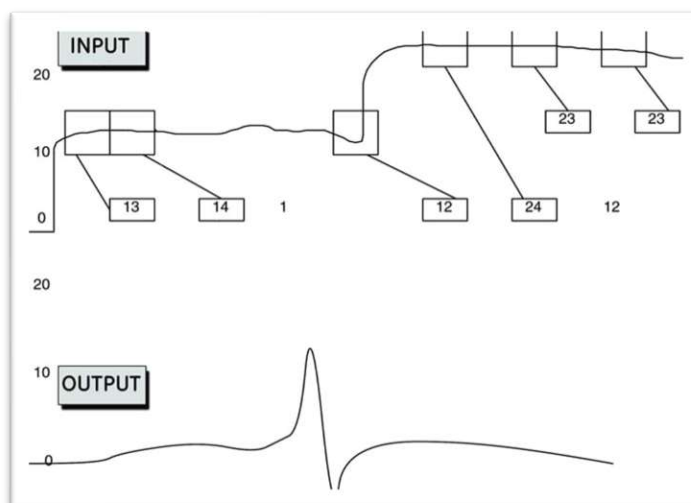
Before the QRS detector can scan the signal data for something that resembles a QRS, it must first remove any pacemaker artifact. This is because pacemaker signals can be large in amplitude and they could fool the detector. The program identifies pacemaker artifact through two independent methods. Separately, 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.

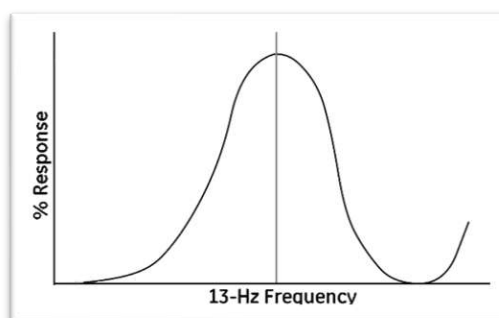
Reduce High Frequencies by Adding



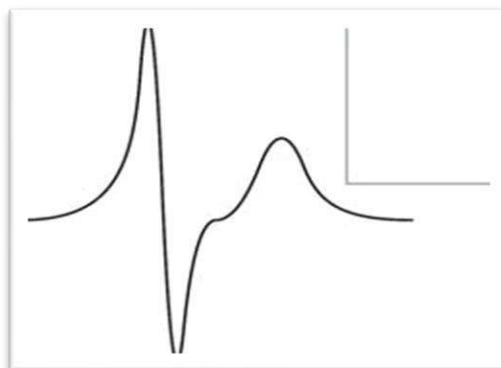
Eliminate Low Frequencies by Subtracting



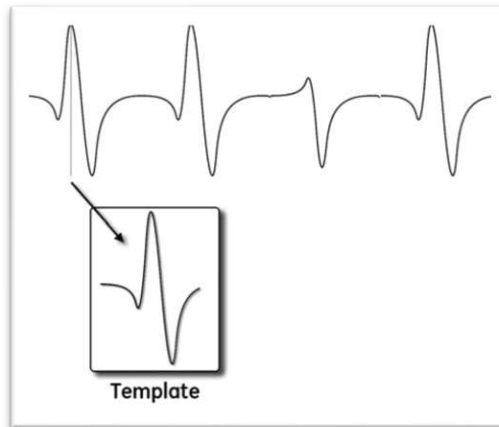
This filter makes the QRS detector more resilient in the presence of noise. It also decreases the probability of a false detection due to T waves. Following is a diagram of the frequency response of the QRS detector.



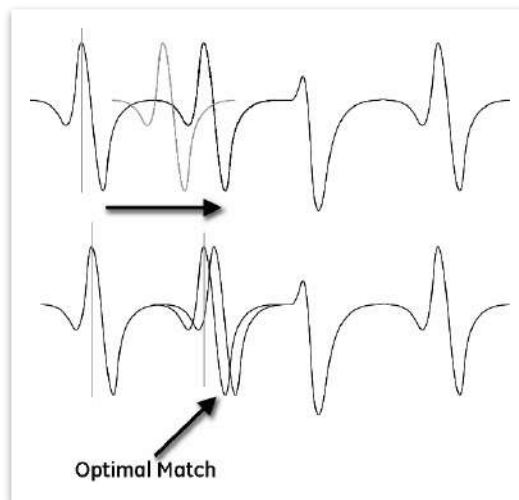
The output of this filter is summed across all 12 leads. Once the summed output crosses a specific threshold, a QRS is detected. To avoid the following T wave, the threshold is increased for a short period of time (200 ms).



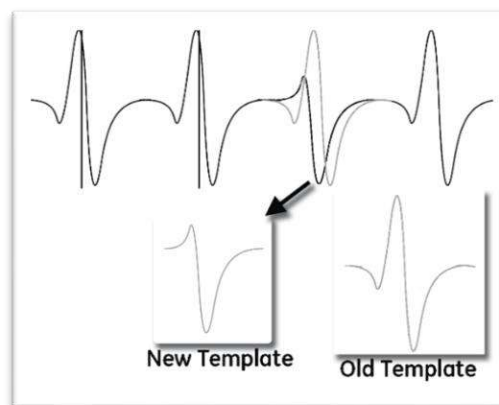
Once a QRS is detected, the 12SL analysis program makes a template of it for each lead.



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.



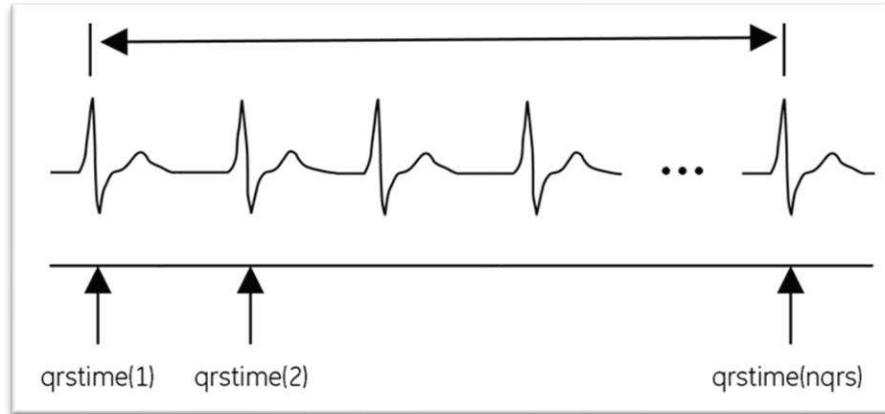
If the filter output exceeds thresholds, but there is no match, it is assumed that a different beat type has been detected and an additional set of lead templates is made for further matching tests.



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.



$$rate = \frac{(\text{number of QRSs} - 1) \text{ beats}}{(\text{time difference between first and last QRS}) \text{ msec}} * 60000 \text{ msec/min}$$

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.

$$rate = \frac{60000 \text{ msec/min}}{(\text{average RR}) \text{ msec/beat}}$$

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.

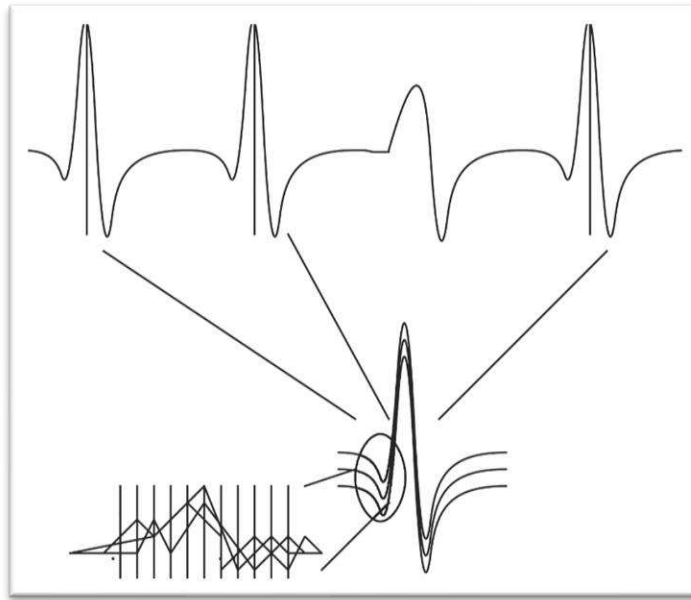
MEDIAN FORMATION

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	<u>10</u>	15	100	Median is 10

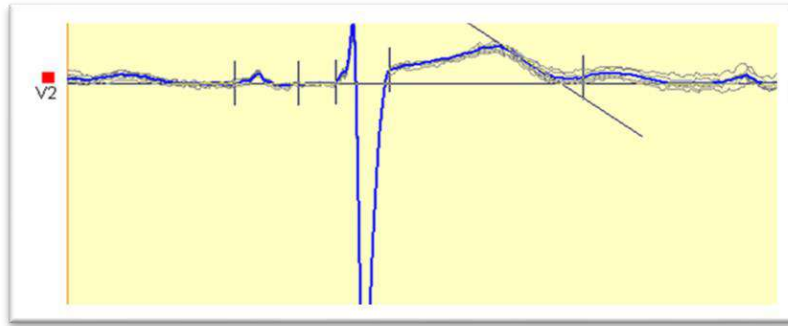
Average

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.

$$QTc \text{ (Bazett)} = \frac{QT}{\sqrt{RR}}$$

$$QTc \text{ (Fridericia)} = \frac{QT}{\sqrt[3]{RR}}$$

$$QTc \text{ (Framingham)} = QT + 0.154 (1 - RR)$$

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).

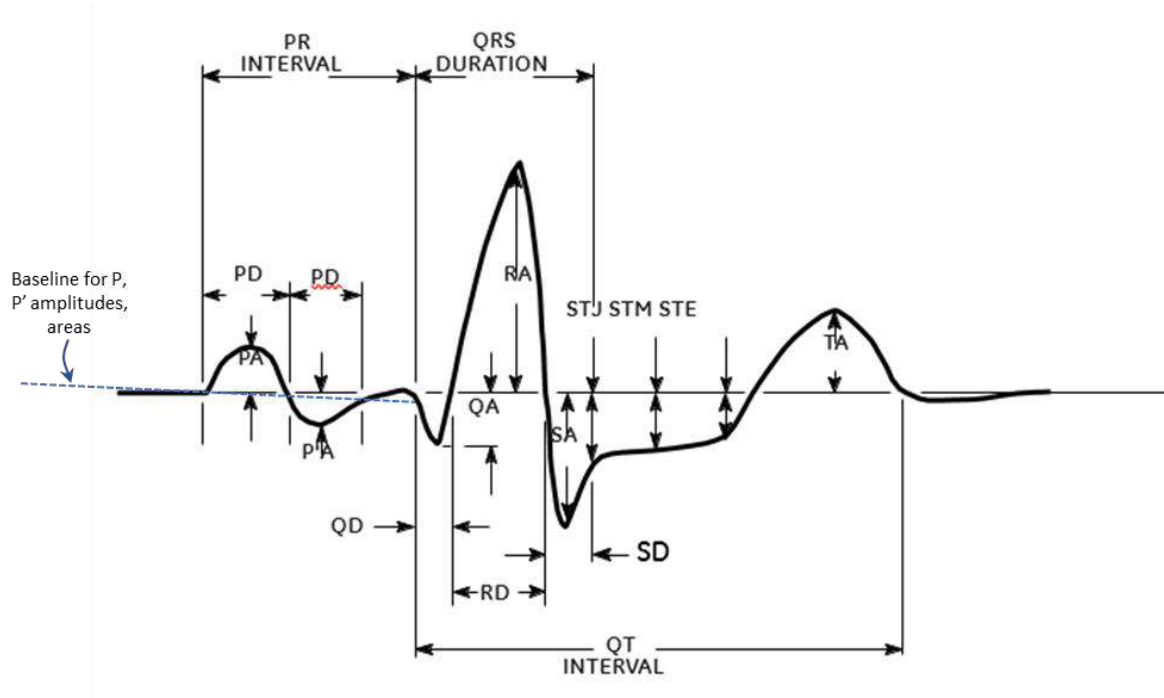
NOTE:

- Not all products will display Fridericia or Framingham QTc.
- Unless otherwise denoted on the ECG report, the reported QTc is the Bazett-corrected value.

WAVE MEASUREMENT – 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 160 μ V-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 μ V.

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.

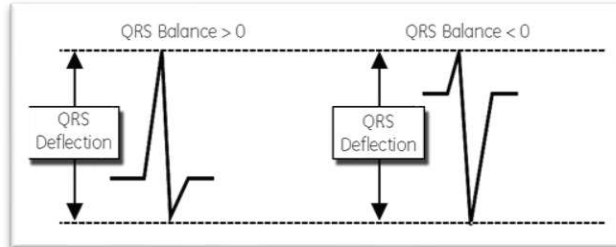
Areas of the waves are the integral with respect to the interpolated P baseline for P and P', or with respect to the 0 μ V baseline for all other waves. The measurements are provided as the sum of samples in waveform data units (4.88 μ V per data unit), normalized to 250 samples per second. To put this 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 μ V * 40 ms, or 4000 μ V*ms (4 μ V*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 μ V*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.

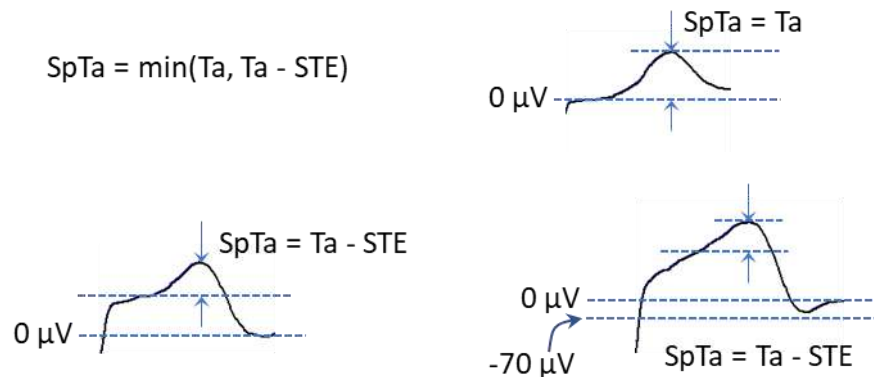
In addition to the individual wave durations and amplitudes defined above, the following measurements are also defined for each lead:

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.



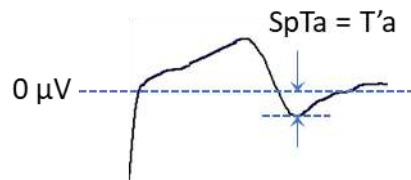
Maximum ST amplitude	Maximum of STJ, STM, and STE
Minimum ST amplitude	Minimum of STJ or STM
Special T amplitude	This value reflects the T amplitude without ST segment effects. The value of the special T amplitude depends on the pattern of the overall T wave. For example, monophasic vs biphasic and the 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 $> -70\ \mu V$ 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.



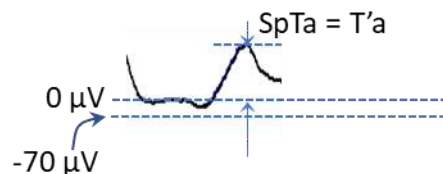
Case 2: Biphasic T wave with positive T and small negative T', where the T' is larger than the small negative T' of case 1.

In this case, the special T amplitude is equal to the T' amplitude.



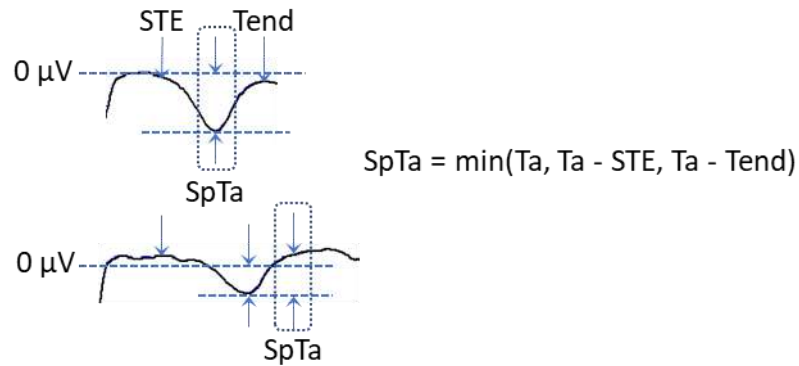
Case 3: Biphasic T wave with small negative T and positive T', where the T amplitude is $> -70 \mu V$ and the T' amplitude > 4 times the absolute value of the absolute value of the T amplitude.

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).

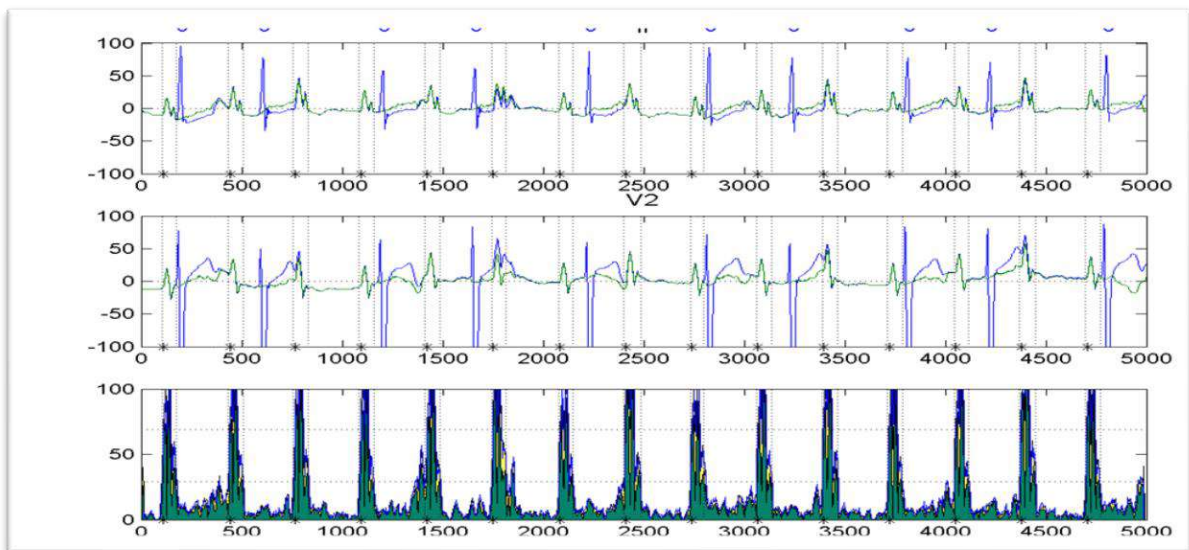
In this case, the special T amplitude is the minimum of T amplitude, T amplitude minus STE, or T amplitude minus amplitude at T offset (T_{end}). Note that in this case, a negative STE and T_{end} makes the SpTa equal to the T amplitude, while a positive STE or T_{end} makes the SpTa more negative than the T amplitude.



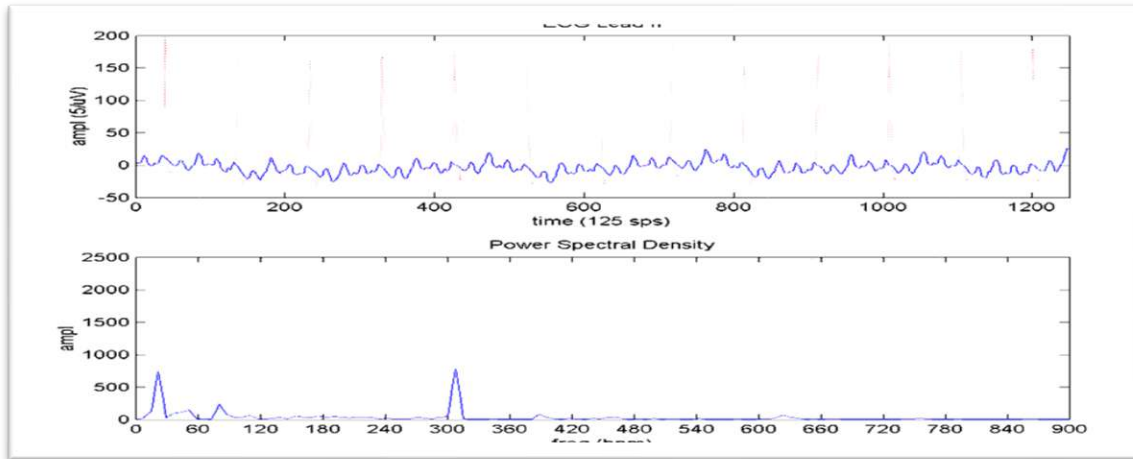
P WAVE DETECTION

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.

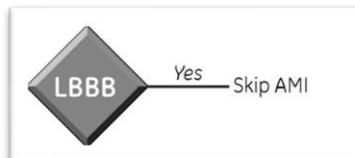
Rules for interpreting the ECG can be quite complex. This manual presents an overview of each unit before delving into the details. The hyperlinks below will allow you to skip to the section you are interested in finding.

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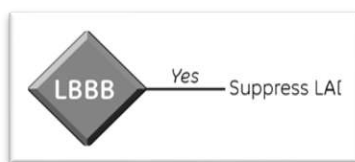
The following figures and flow-chart symbols are intended to facilitate the use of this guide:

- 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:

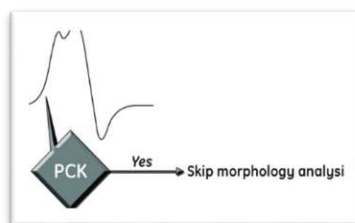


Suppress statement:



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.



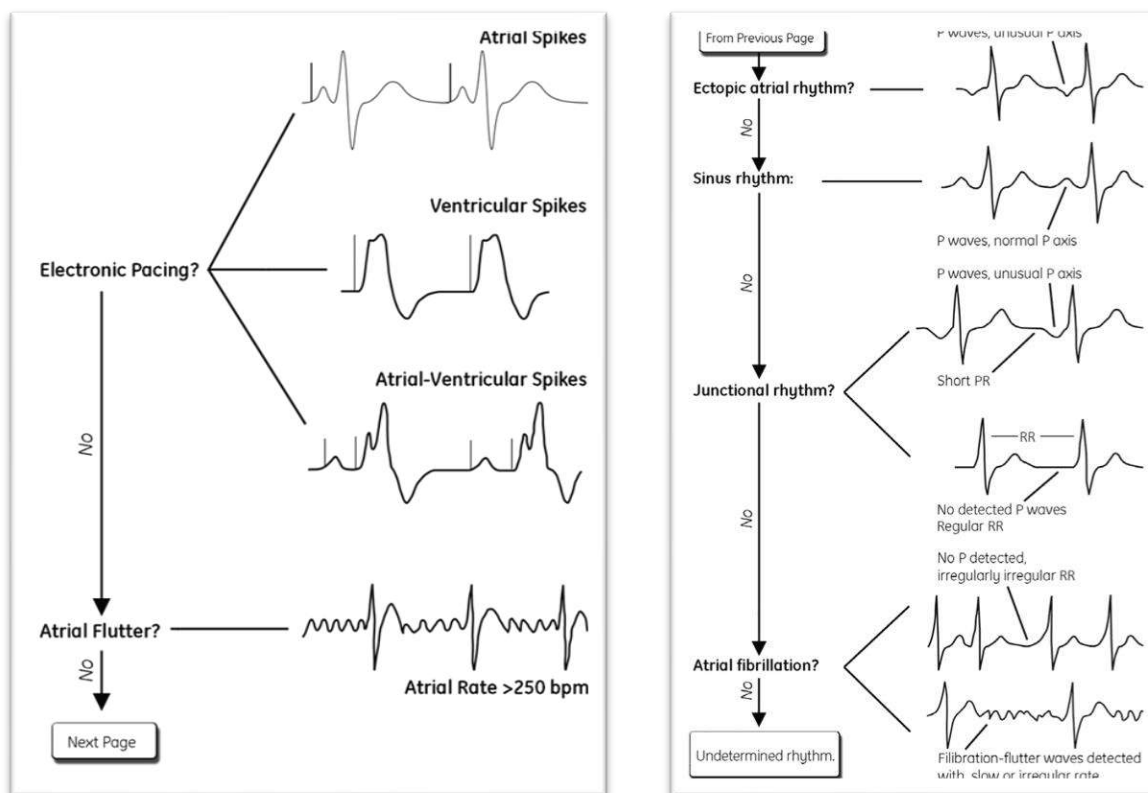
RHYTHM CRITERIA

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
<i>Atrial-paced rhythm</i>	APR	Pace spikes in front of P waves, where P waves are synchronous with QRS complexes.
<i>Ventricular-paced rhythm</i>	VPR	Pace spikes in front of QRS complexes and either no organized atrial activity or atrial activity asynchronous to the QRS complex.
<i>Atrial-sensed ventricular-paced rhythm</i>	ASVPR	Pace spikes in front of QRS complexes which follow non-paced, organized atrial activity (for example, sinus or ectopic atrial rhythm)
<i>AV dual-paced rhythm</i>	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
<i>*** Suspect unspecified pacemaker failure</i>	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.
<i>Bi-ventricular pacemaker detected</i>	BIVPCK	Requires at least 50% more ventricular spikes detected than ventricular- paced beats.

ATRIAL FLUTTER

<i>Rhythm Statement</i>	<i>Acronym</i>	<i>Description</i>
<i>Atrial Flutter</i>	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.

<i>Rhythm Statement</i>	<i>Acronym</i>	<i>Description</i>
<i>Unusual P axis, possible ectopic atrial bradycardia</i>	EABRAD	Requires atrial rate less than 60 bpm.
<i>Unusual P axis, possible ectopic atrial rhythm</i>	EAR	Requires atrial rate from 60 to 100 bpm
<i>Unusual P axis, possible ectopic atrial tachycardia</i>	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
<i>Sinus bradycardia</i>	SBRAD	Requires atrial rate from 45 to 59 bpm.
<i>Normal sinus rhythm</i>	NSR	Requires atrial rate from 60 to 100 bpm and no rhythm modifiers appended or only with sinus arrhythmia appended.
<i>Sinus rhythm</i>	SRTH	Requires atrial rate from 60 to 100 bpm and any rhythm modifiers appended beyond with sinus arrhythmia.
<i>Sinus tachycardia</i>	STACH	Requires atrial rate over 100 bpm.
<i>Marked sinus bradycardia</i>	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
<i>Unusual P axis and short PR, probable junctional bradycardia</i>	JBRAD	Requires ventricular rate less than 50 bpm.
<i>Unusual P axis and short PR, probable junctional rhythm</i>	JR	Requires ventricular rate from 50 to 75 bpm.
<i>Unusual P axis and short PR, probable junctional tachycardia</i>	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 <i>Undetermined rhythm</i> .

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 <i>complete heart block</i> or <i>with AV dissociation</i> 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: <i>Junctional rhythm</i>, <i>Junctional bradycardia</i>, <i>Idioventricular rhythm</i>, <i>Wide QRS rhythm</i>, or <i>Wide QRS tachycardia</i>.

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
<i>with rapid ventricular response</i> *	RVR	Requires ventricular rate higher than 100 bpm.
<i>with slow ventricular response</i> *	SVR	Requires ventricular rate lower than 60 bpm.
<i>with a competing junctional pacemaker</i> *	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
<i>with variable AV block</i>	VAVB	Requires range of RR intervals is 10% or more of the average RR interval.
<i>with 2:1 AV conduction</i> *	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.
<i>with 3:1 AV conduction</i> *	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.
<i>with 4:1 AV conduction</i> *	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.
<i>with 5:1 AV conduction</i> *	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
<i>with occasional</i>	OCC	Requires 1 or 2 beats.
<i>with frequent</i>	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.
<i>and consecutive</i>	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
<i>premature supraventricular complexes</i>	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.
<i>premature atrial complexes</i>	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
<i>premature ventricular complexes</i>	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.
<i>in a pattern of bigeminy</i>	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
<i>fusion complexes</i>	\$SFUS	Requires QRS complex that is different from dominant beat type and is not premature and not late.
<i>with junctional escape complexes</i>	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
<i>premature ventricular complexes</i>	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
<i>with ventricular escape complexes</i>	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
<i>ventricular-paced complexes</i>	VPCX	Requires ventricular-paced complexes that are of a different morphology than the dominant beat and the predominant rhythm is not Ventricular- paced rhythm.
<i>AV dual-paced complexes</i>	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.
<i>atrial-sensed ventricular-paced complexes</i>	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.
<i>sinus complexes</i>	SCX	Requires predominant rhythm of paced and QRS complexes of a normal morphology with normal P waves.
<i>supraventricular complexes</i>	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.
<i>with intrinsic complexes</i>	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	NT: Nonspecific T wave abnormality
	QRS-T Angle	AQRST: Abnormal QRS-T angle, consider primary T wave abnormality
QT Interval		LNGQT: Prolonged QT QTcB/QTcFrid/QTcFram $\geq$ 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.

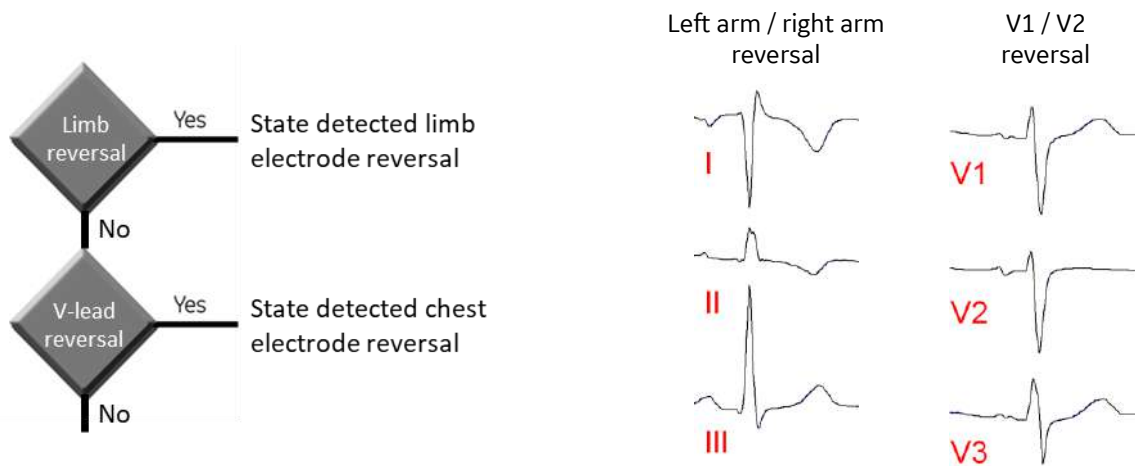
The following four limb electrode reversals and twelve precordial electrode reversals are detected:

- 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:

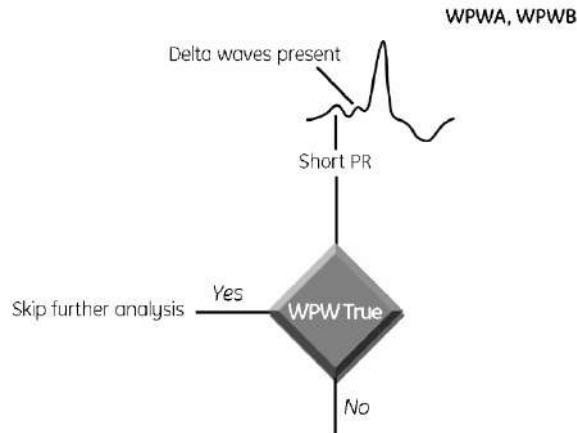
- V4/V5, V4/V6
- V5/V6

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.

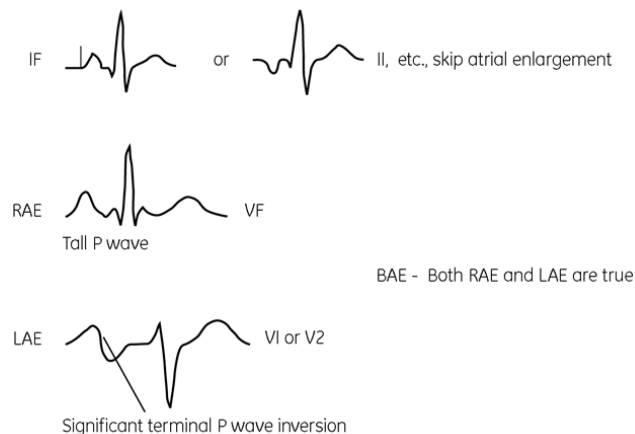
Ventricular pre-excitation, WPW pattern type B requires WPW test and predominantly negative QRS in V1 or V2.

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 μ V 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 **Batrial enlargement** is instead stated.

QRS Axis

Acronyms: RAD, RAD4, RAD5, LAD3, INDAX

Tests are skipped if WPW is stated.

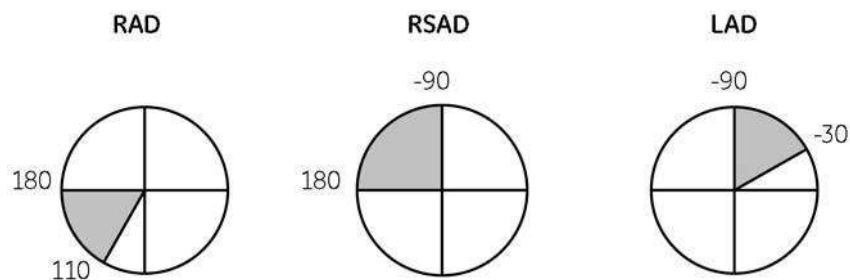
Rightward axis requires QRS axis between 90 and 109 degrees.

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 $< 50 \mu\text{V}$ 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)

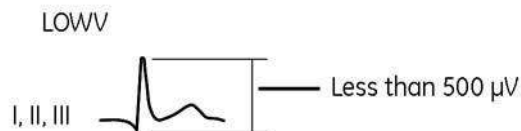


Low Voltage QRS

Acronym: LOWV

Test is skipped if WPW is stated or QRS duration > 120 ms.

Low voltage QRS requires QRS deflection of all limb leads $< 500 \mu\text{V}$ or QRS deflection $< 1000 \mu\text{V}$ in all 12 leads.

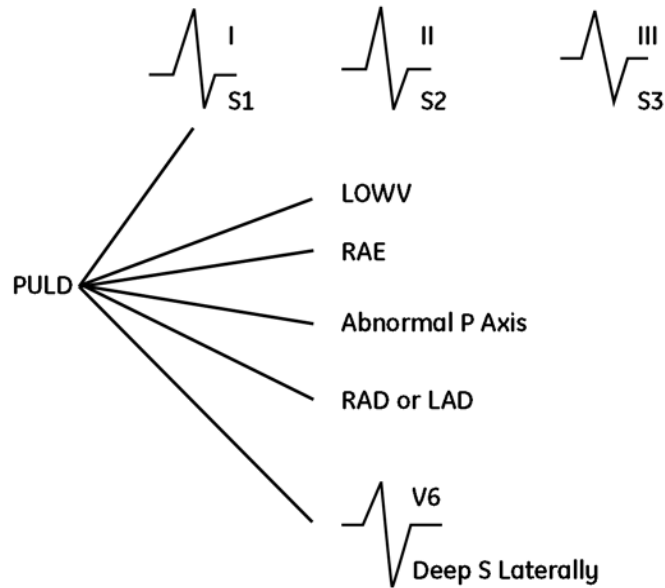


Pulmonary Disease Pattern

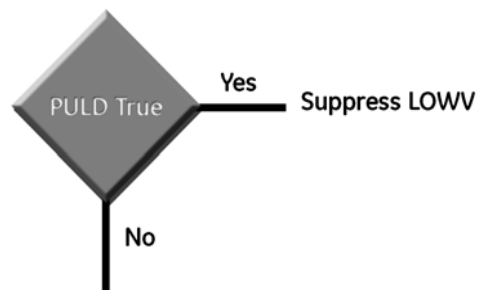
Acronym: PULD

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*.



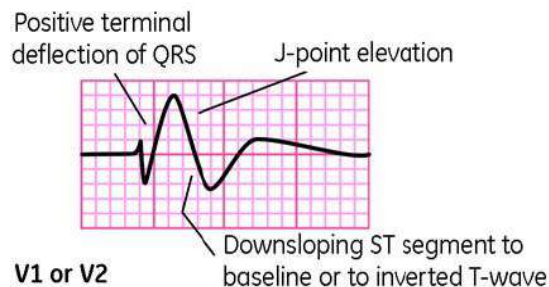
Brugada

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 $\geq 200 \mu\text{V}$ 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

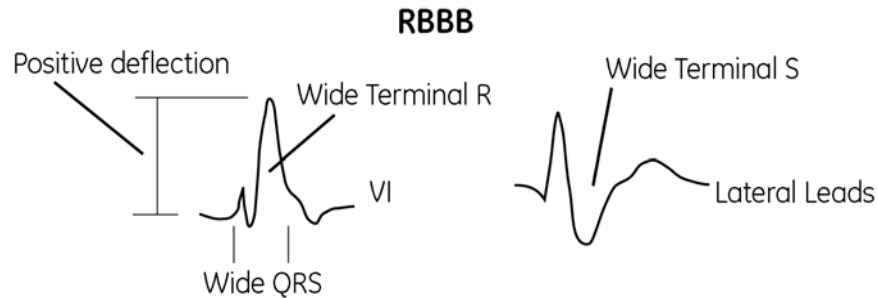
All tests for conduction abnormalities are skipped if WPW is stated.

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+

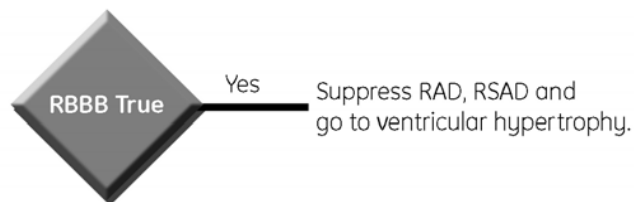


Tests for **Right bundle branch block** examine for a wide QRS, predominantly upright QRS with terminal R or R' in leads V1 or V2, and wide terminal S waves in the lateral leads.

If RBBB is true and R or R' amplitude $> 1500 \mu\text{V}$ 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*.

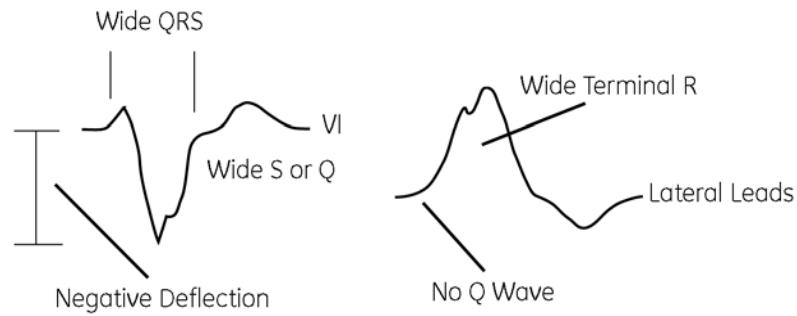
If RBBB is true, skip further conduction tests and go to ventricular hypertrophy tests.



Left Bundle Branch Block

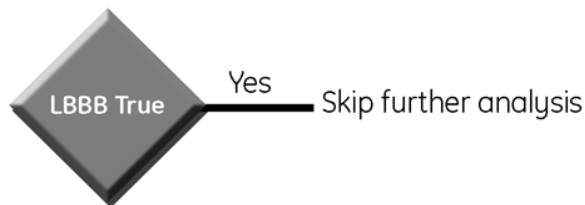
Acronym: LBBB

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.

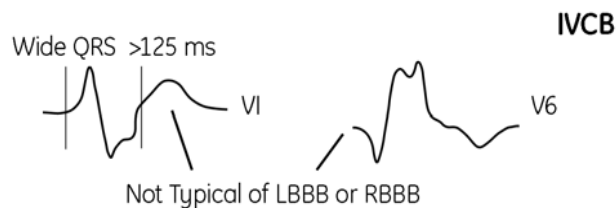
If LBBB is true, skip all further analysis.



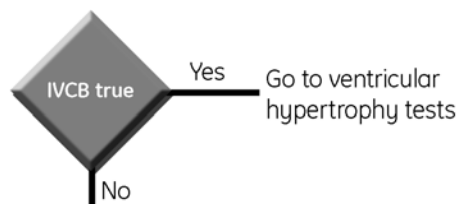
Nonspecific Block

Acronym: IVCB

If the QRS duration is > 125 ms and neither RBBB nor LBBB are stated, then **Nonspecific intraventricular conduction block** is stated.

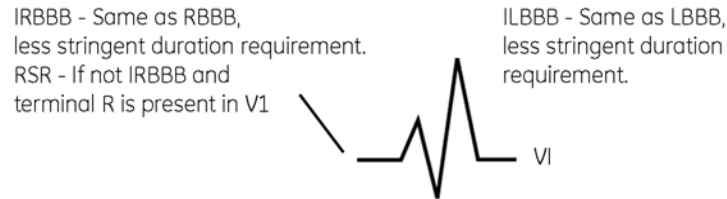


If IVCB is true, go to ventricular hypertrophy tests. If not true, test for incomplete blocks.



INCOMPLETE BLOCKS

Acronyms: IRBBB, RSR, ILBBB



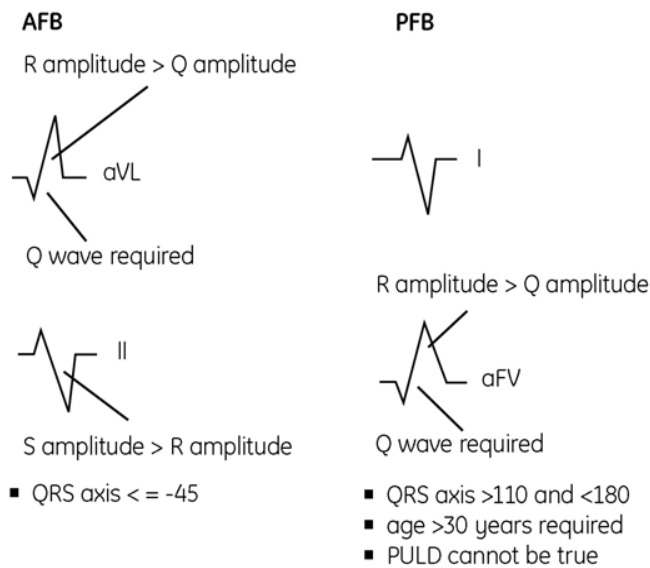
Incomplete right bundle branch block criteria are similar to RBBB, but less stringent. QRS duration is greater than 90 ms and less than 120 ms.

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, PFB



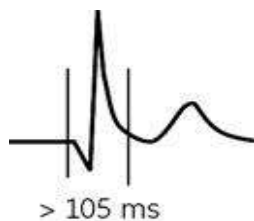
Left anterior fascicular block requires QRS axis ≤ -45 degrees, R amplitude > Q amplitude in leads I and aVL, any Q wave in lead I, and maximum of S and S' is greater than R and R' in lead II.

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**.



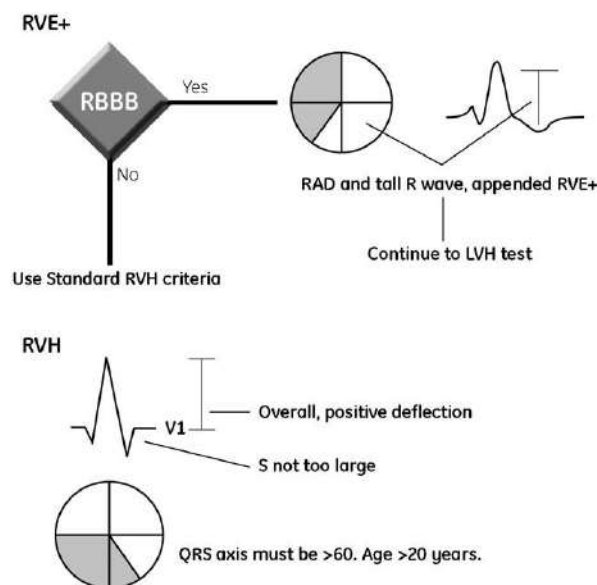
If no conduction abnormality is stated and QRS duration is greater than 105 ms, then state **Nonspecific intraventricular conduction delay**.

Ventricular Hypertrophies

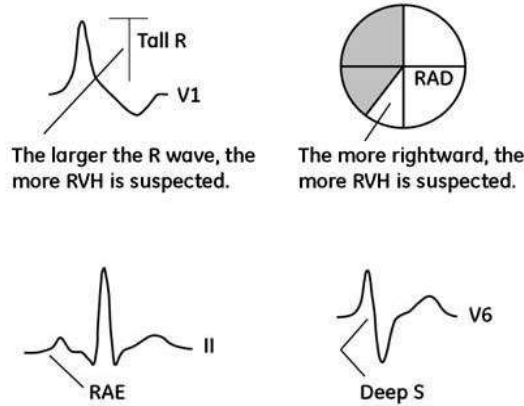
All tests for ventricular hypertrophy are skipped if WPW is stated.

RIGHT VENTRICULAR HYPERTROPHY

Acronyms: RVH, RVE+, 2ST



If RBBB is true and R or R' amplitude > 1500 μ V in lead V1 and QRS axis > 110 degrees, then state **Right bundle branch block, plus right ventricular hypertrophy**.

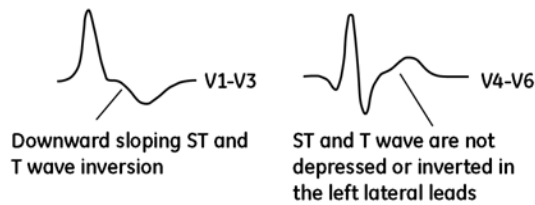


In the absence of RBBB, more standard criteria are used for RVH. In this case, the test is skipped if WPW or Brugada are detected, the QRS amplitude is negative or the S amplitude $> 100 \mu\text{V}$ in V1, or the QRS axis is < 60 degrees.

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.

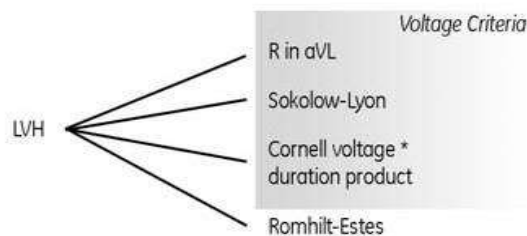
If the program finds a repolarization abnormality that is also indicative of RVH, it will upgrade any RVH call to **Right ventricular hypertrophy with repolarization abnormality**.



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 $> 1100 \mu\text{V}$.

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 $> 3500 \mu\text{V}$ 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, $600 \mu\text{V}$ is added to the Cornell voltage. This test requires a Cornell product $> 244 \mu\text{V} \cdot \text{sec}$, 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:

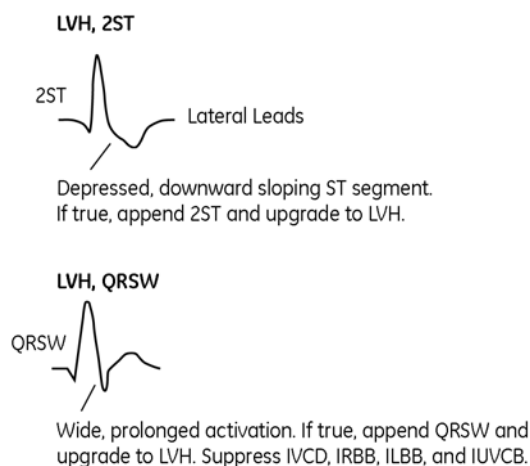
- **Minimal voltage criteria for LVH, may be normal variant** (QRSV)
- **Moderate voltage criteria for LVH, may be normal variant** (LVH3)
- **Voltage criteria for left ventricular hypertrophy** (LVH)
- **Left ventricular hypertrophy** (LVH2)

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**.

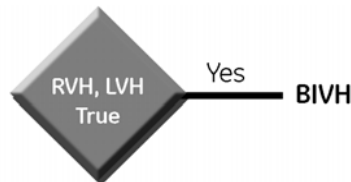
If *with QRS widening* is stated, suppress IRBBB, IVCD, IVDB, and ILBBB.

BIVENTRICULAR HYPERTROPHY

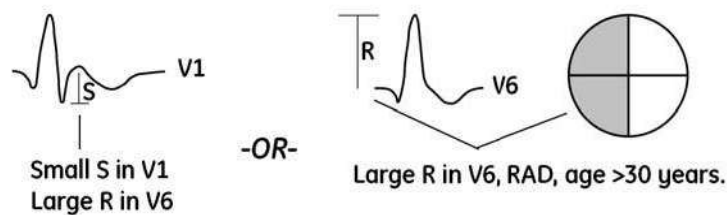
Acronyms: BIVH, 2ST, QRSW

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***.

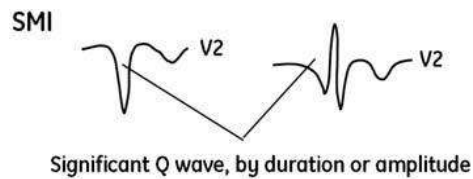
If both of the above conditions are true, then append ***with QRS widening and repolarization abnormality***.

Infarction / Poor R-wave progression

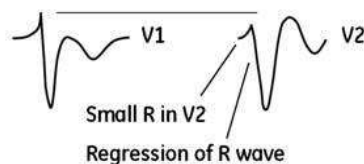
All tests for infarction are skipped if WPW or LBBB is stated.

SEPTAL MYOCARDIAL INFARCTION

Acronym: SMI



-OR-

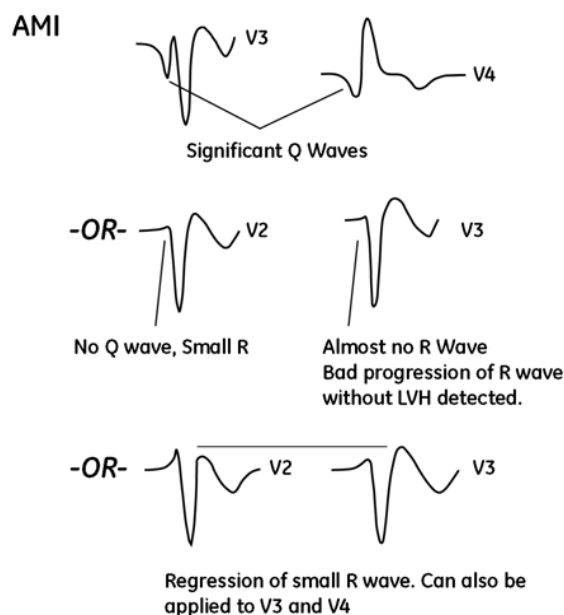


Degree of confidence is based on repolarization. If the ST is elevated, with terminal or complete T wave in version, **Septal infarct** is stated without qualification, otherwise it is preceded by **Cannot rule out**.

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:

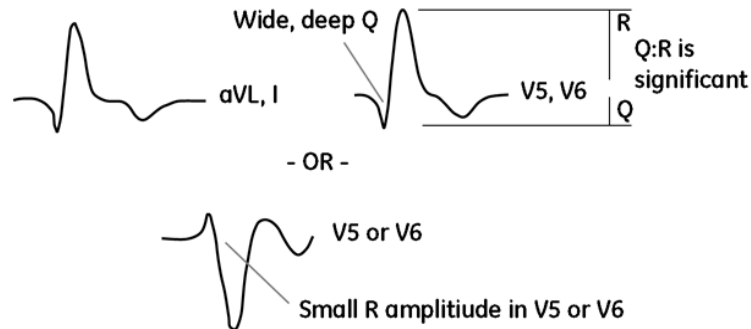
- **Cannot rule out anterior infarct**
- **Possible anterior infarct**
- **Anterior infarct**

If anterior injury is present, then append: , **possibly acute**, otherwise, append: , **age undetermined**.

LATERAL MYOCARDIAL INFARCTION

Acronym: LMI

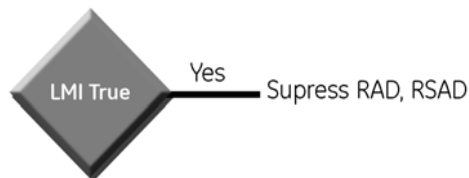
The program looks for R wave regression or poor R wave progression in V5 and V6 and also considers if at least two of the four lateral leads have wide and deep Q waves that have significant Q:R ratios.



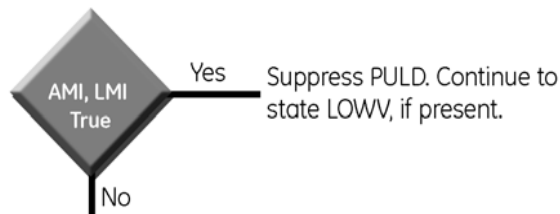
If the criteria detected significant Q waves, it states an unqualified **Lateral infarct**; otherwise it will prepend **Possible**.

If inferior injury is present, then append: , **possibly acute**, otherwise, append: , **age undetermined**.

If *LMI* is true, suppress all statements concerning right axis deviation.



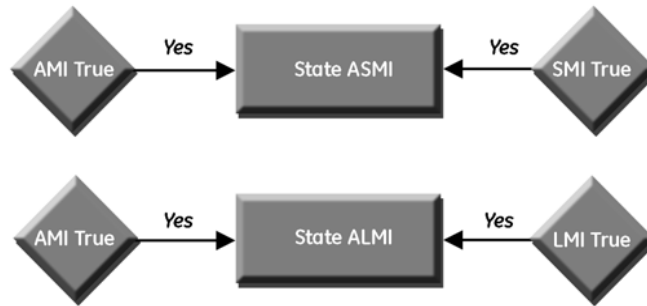
If *AMI* or *LMI* is true, suppress *PULD*.



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**.

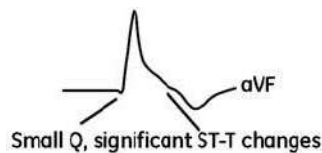
The first statement above requires the detection of *left anterior fascicular block* but will be overridden if criteria for one of the stronger statements is met.

Significant Q:R ratio is the main component of the IMI tests.

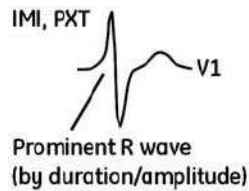


The significance of the Q:R ratio is evaluated in conjunction with other parameters, namely: Q amplitude, Q duration, QRS axis, and presence of Q in lead II.

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**.

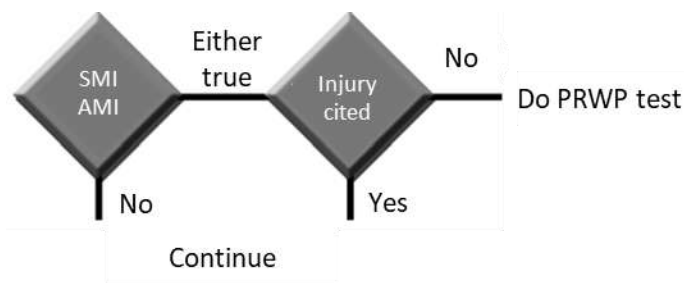
If the max ST elevation in V2 < -150 μV , then append: ", **possibly acute**, otherwise, append: ", **age undetermined**".

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

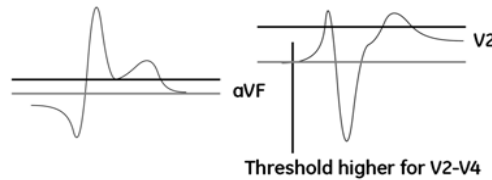
Skip all tests for ST elevation abnormalities if WPW, LBBB, or ventricular rate > 120 bpm and RBBB.

EPICARDIAL INJURY

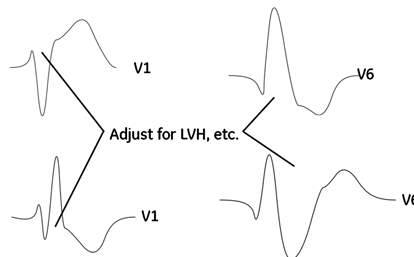
Acronyms: AC, INJ, AINJ, LINJ, IINJ, ALINJ, ILINJ, AIOHAI, LIOHAI, IIOHAI, ALIHAI, ILIHAI

Three items are used for stating injury: degree of ST elevation, ST:T ratio, and reciprocal changes.

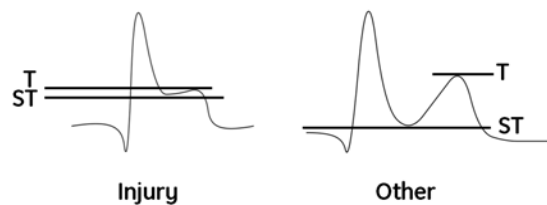
All leads are inspected for ST elevation. Anteroseptal leads are tested with a higher threshold than the other leads.



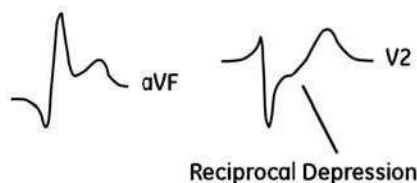
The thresholds are also adjusted for repolarization abnormalities that can occur with LVH and/or conduction abnormalities.



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.

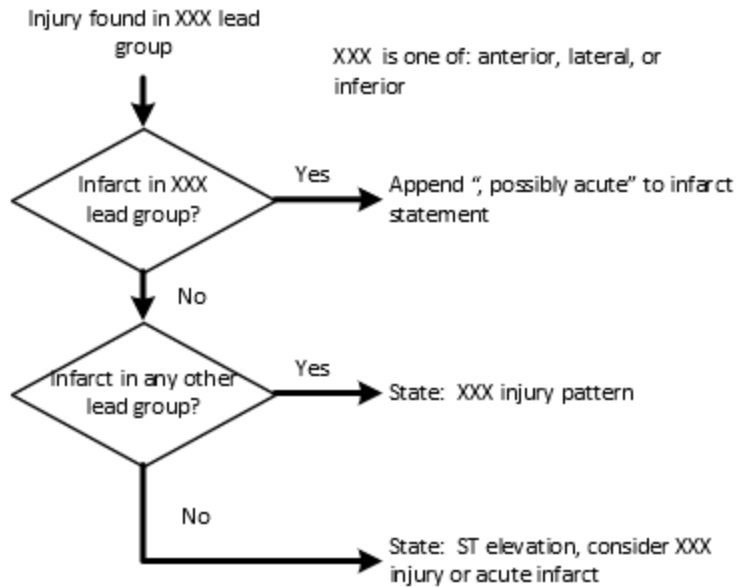


All leads on the opposite side of the ST vector are analyzed for reciprocal depression. If present, the ST elevation is considered more like injury.



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.

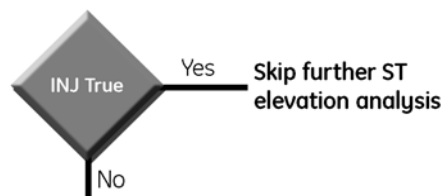
If an infarct has been cited for a different lead group (with or without injury) but not for the lead group with the injury pattern, the program will state **XXX injury pattern**, where XXX is anterior, lateral, or inferior.

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.

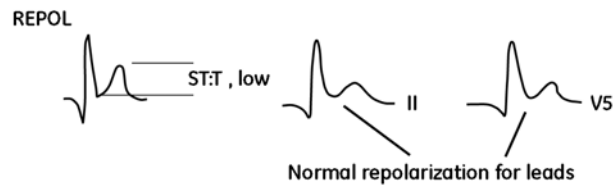
EARLY REPOLARIZATION

Acronyms: SERYP2, 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:

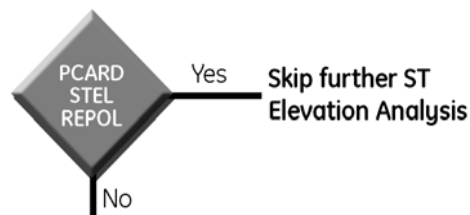
- **Possible acute pericarditis**
- **Acute Pericarditis**

ST ELEVATION, MECHANISM UNKNOWN

Acronym: SERYP1

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.



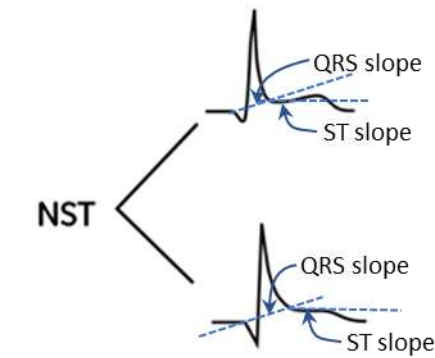
NONSPECIFIC ST (ELEVATION) ABNORMALITY

Acronym: NST

This test is skipped if RBBB, Brugada, or any MI stated, or the QRS duration > 120 ms.

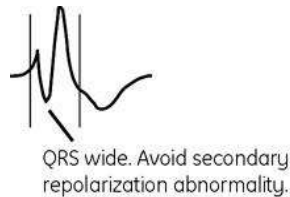
Nonspecific ST elevation abnormality requires that no other ST elevation abnormalities stated and ST elevation > 50 μ V, slope from QRS onset to J-point greater than slope of ST segment, and T wave not tall in any 2 of leads I, II, III, aVF, and V3 through V6.

If true, state **Nonspecific ST abnormality**.

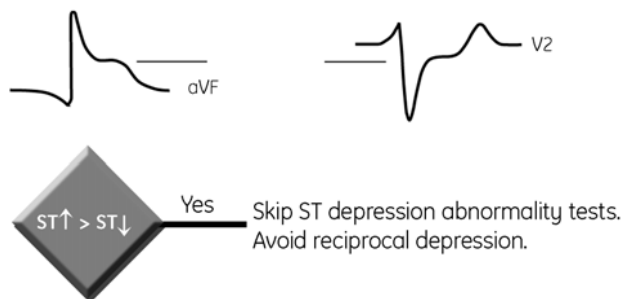


ST Depression Abnormalities

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.

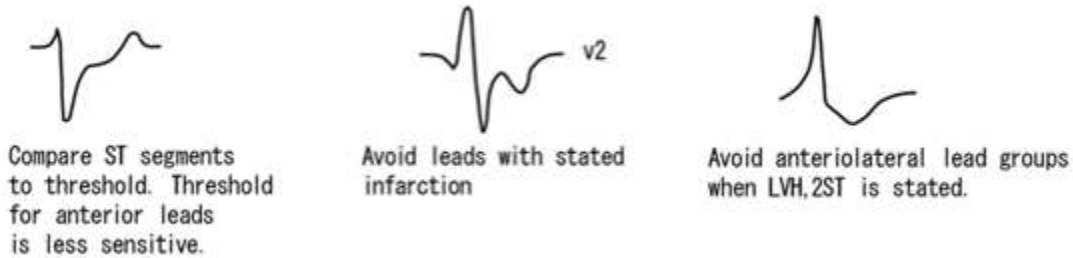


SUBENDOCARDIAL INJURY

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 $-100 \mu\text{V}$ for frontal plane leads and $-200 \mu\text{V}$ for precordial leads.



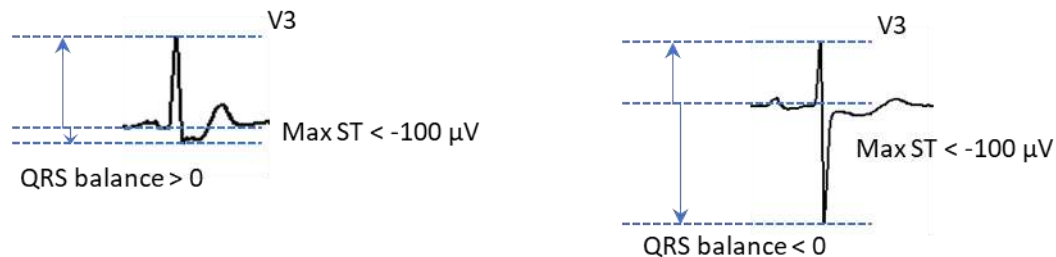
Septal subendocardial injury requires no septal MI, no posterior MI, and the maximum ST of either V1 or V2 below the threshold.

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 $< -100 \mu\text{V}$. If the QRS balance is positive, the test also requires a positive T wave amplitude.

Test for anterior subendocardial injury in presence of LVH with repolarization abnormality



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.

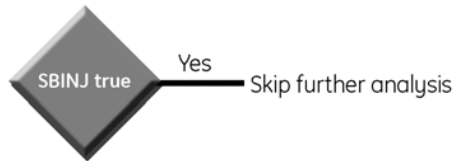
Inferior subendocardial injury requires no inferior MI, no LVH with repolarization abnormality, and the maximum ST of either II or aVF below the threshold.

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.



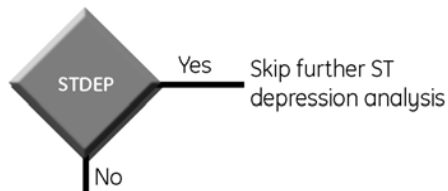
If any repolarization abnormality has been stated in association with ventricular hypertrophy, skip all further tests for ST depression abnormalities.



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 μ V.

If true, state **ST depression, consider subendocardial injury (STDEP)**.

If STDEP is true, skip all further tests for ST depression abnormalities.



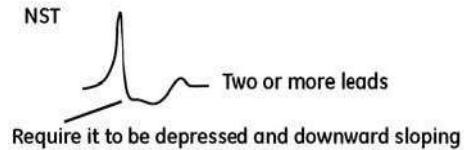
If RBBB or Brugada are true, or nonspecific ST elevation abnormality has already been found from the ST elevation tests, skip all further tests for ST depression abnormalities.



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

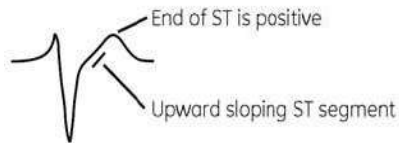
Acronyms: JST, JSTN

Skip tests for junctional ST depression if any infarct is cited.

Junctional ST depression requires the ST level at the J-point (STJ) < -100 μ V 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**.

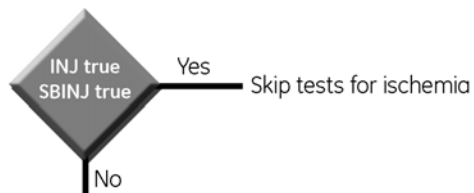
T Wave Abnormalities

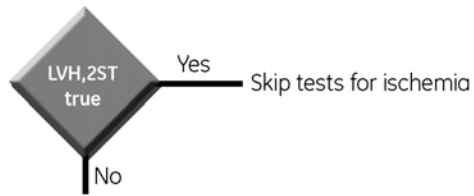
ISCHEMIA

Acronyms: AT, LT, IT, ALT, ILT, MAT, MLT, MIT, MALT, MILT

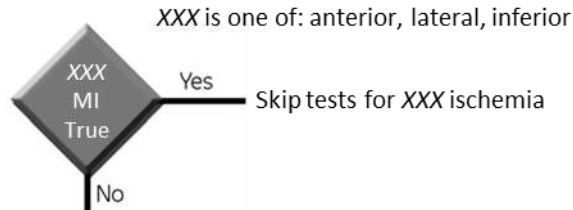
Tests for ischemia look at inverted T waves, after ruling out other causes or confounders.

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.

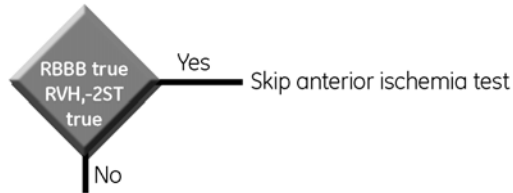




T wave abnormalities are also not tested in lead groups where infarction is stated.



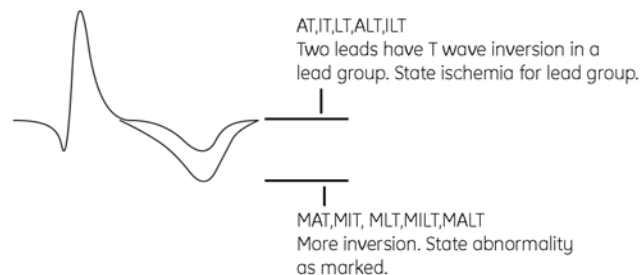
Additional restrictions are applied to anterior leads in order to avoid calling anterior ischemia in the presence of posterior infarct (PMI), Brugada, RBBB or right ventricular hypertrophy with repolarization abnormality (RVH, -2ST).



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 μ V for the less severe statement, or two or more leads with special T amplitude < -500 μ V for the more severe (Marked) statement



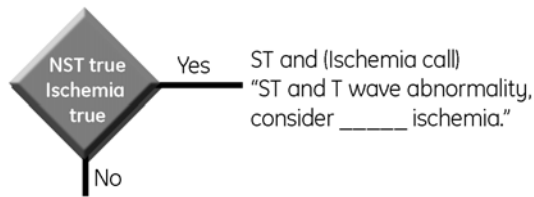
If anatomically contiguous lead groups are true for ischemia, combine as applicable:

- 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".

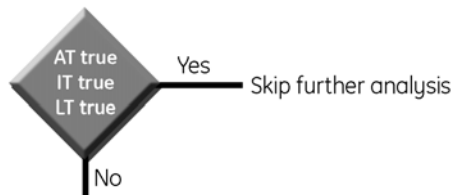
If ischemia is stated and a nonspecific ST abnormality was previously detected, make one statement as opposed to two:

ST & (Marked) T wave abnormality, consider XXX ischemia

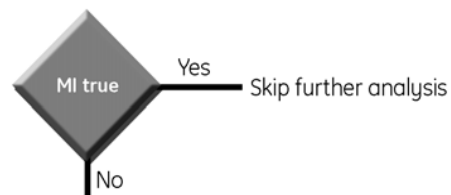


If any ischemia is stated, suppress *Early Repolarization* and *ST elevation, probably due to early repolarization*.

If ischemia is called, skip further analysis of T waves.



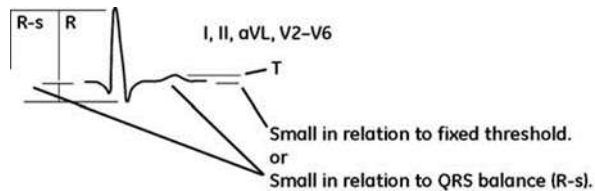
If any infarction is present, skip further analysis of T waves.



NONSPECIFIC T WAVE ABNORMALITY

Acronym: NT

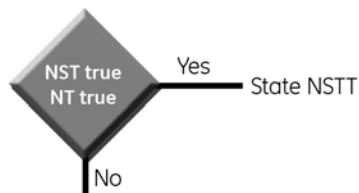
Small T waves or shallow T wave inversion are found in at least two leads.



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:

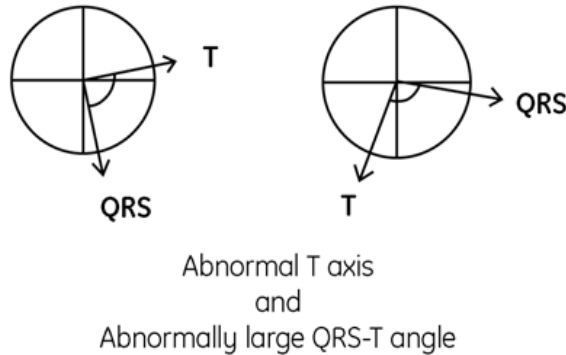
Nonspecific ST and T wave abnormality



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.



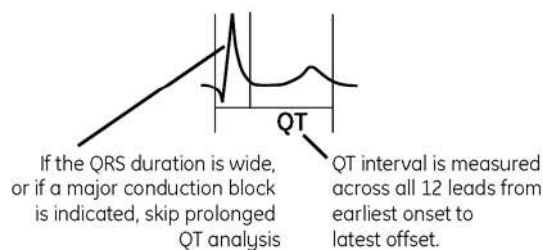
The test requires a difference between the QRS and T axes ≥ 60 degrees and T axis less than 0 degrees or more than 90 degrees.

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 $QT_c \geq 500$ ms, then say **Prolonged QT**.

If the $QT_c \geq 480$ ms but less than 500 ms, then say **$QT_cX \geq 480$ msec**, where QT_cX is one of **QT_cB** , **QT_cFrid** , or **QT_cFram** , 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

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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

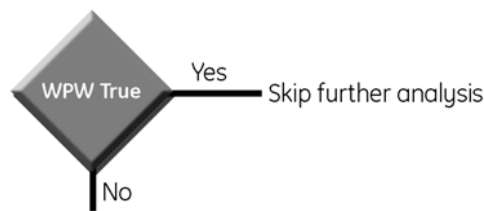
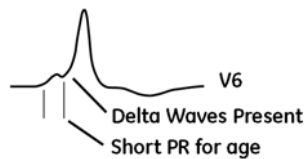
Test is skipped if rhythm is atrial fibrillation, atrial flutter, or no P wave is present.

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.

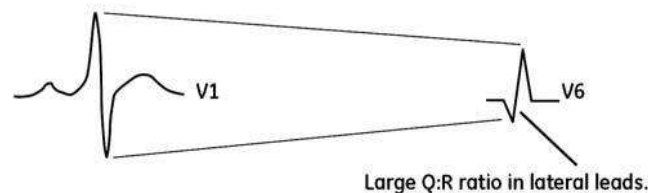
WPW



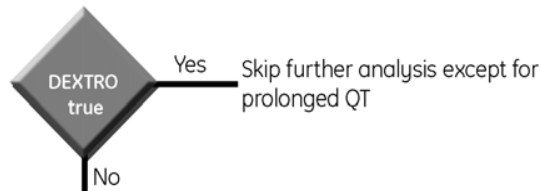
Dextrocardia

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

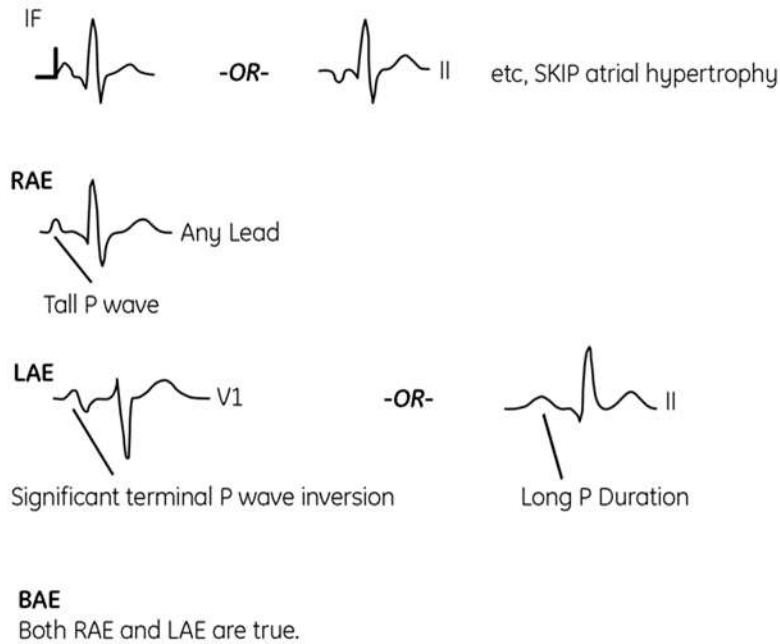
Acronyms: RAE, LAE, BAE

Tests are skipped if WPW, DEXTRO, rhythm is not sinus, or abnormal P axis.

Right atrial enlargement requires P wave amplitude $> 250 \mu\text{V}$ 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.

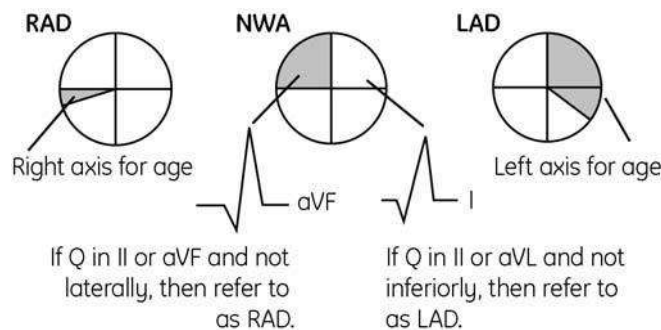
If tests pass for both RAE and LAE, then **Biatrial enlargement** is instead stated.



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 $\geq$ right axis limit for age.

Northwest axis requires age $\geq$ 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.

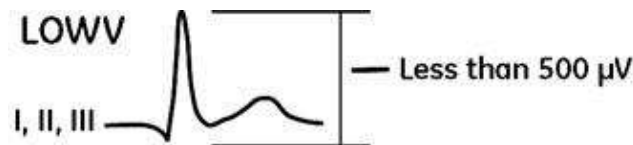
Left axis deviation requires (a) QRS axis between left axis limit for age and -89 degrees, or (b) QRS axis in northwest quadrant, age $\geq$ 1 month, and at least one Q wave is present in either a lateral lead or an inferior lead, but not in both lead groups.

Indeterminate axis requires absolute value of R amplitude minus S amplitude is $< 50 \mu\text{V}$ 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 $< 500 \mu\text{V}$ or (b) QRS deflection $< 1000 \mu\text{V}$ in all limb leads and $< 1500 \mu\text{V}$ in all precordial leads.

Pulmonary Disease Pattern

Not diagnosed by pediatric program.

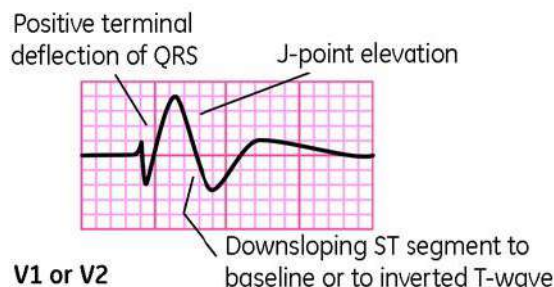
Brugada

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 $\geq 200 \mu\text{V}$ 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.

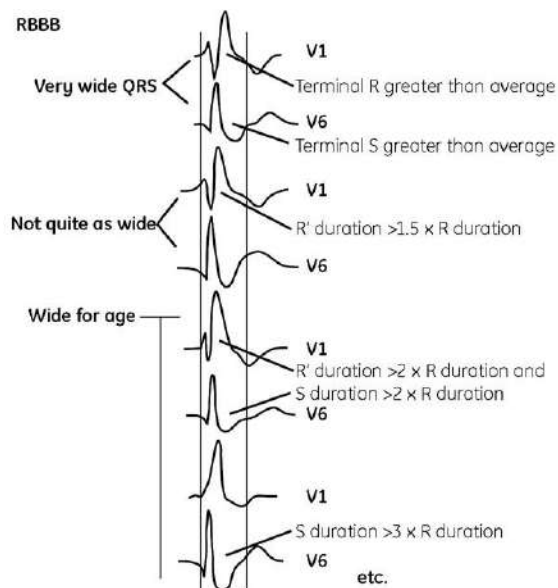
RIGHT BUNDLE BRANCH BLOCK

Acronyms: RBBB, RBBRVH, IRBBB, RVE+

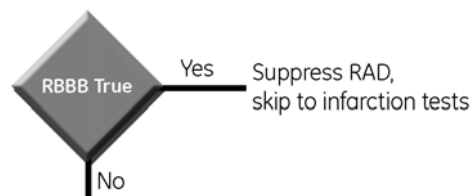
Test is skipped if BRUG is stated.

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.

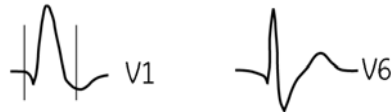
If the QRS is very wide, the program tests for terminal slowing on the right. As the QRS gets narrower, the tests for terminal slowing on the right become increasingly more difficult to pass.



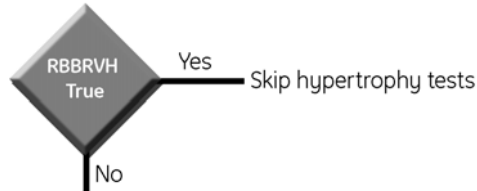
If *RBBB* is true, state **Right bundle branch block** and suppress all statements concerning right axis deviation and do not test for hypertrophy.



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**.

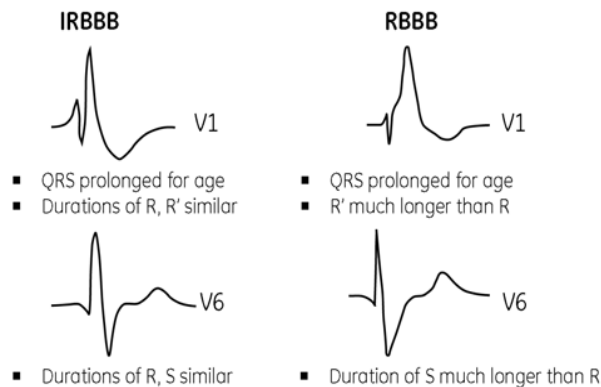


If RBBRVH is called, bypass hypertrophy tests.



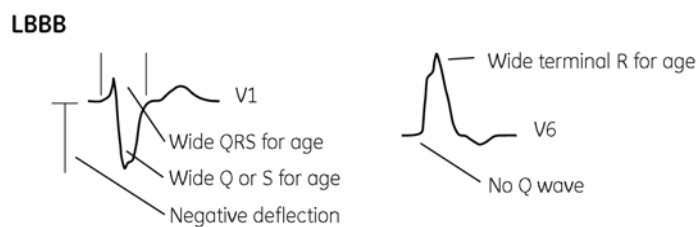
If the QRS has some of the attributes of RBBB, but the rightward terminal slowing is not evident enough for the criteria to state a complete block, the program will state **Incomplete right bundle branch block**.

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.

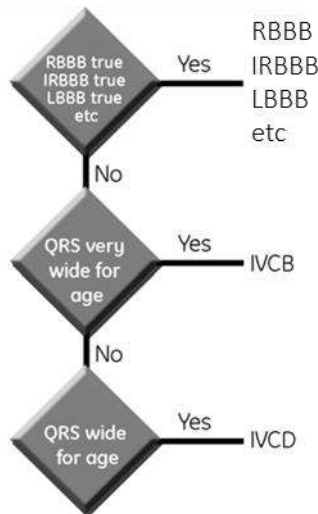
If LBBB is true, skip all further analysis.

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

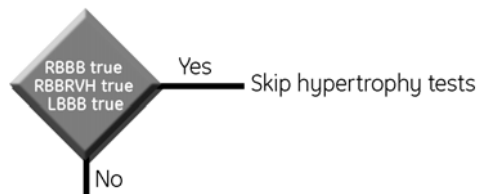
Acronyms: IVCD, IVCB

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

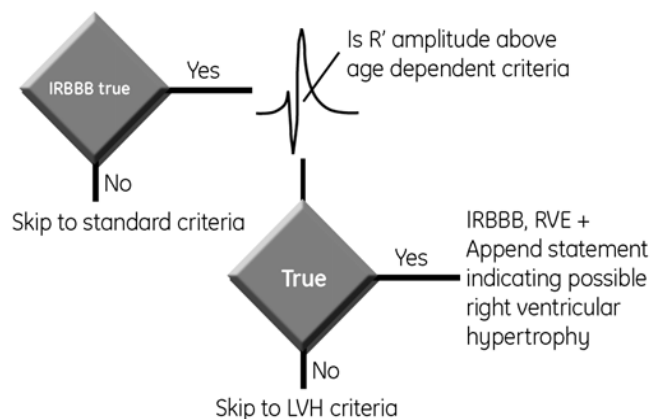
If WPW, DEXTRO, or any complete block has been stated, do not test for ventricular hypertrophy, and continue to test for infarction.



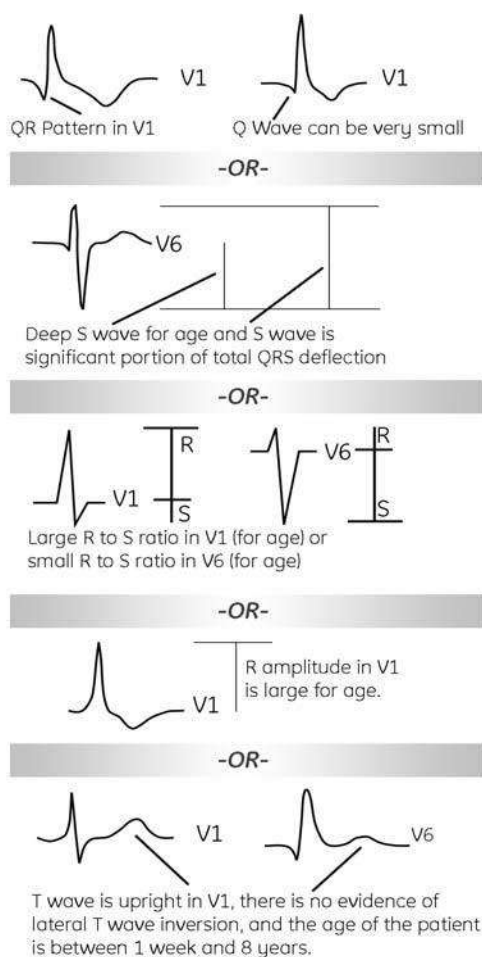
RIGHT VENTRICULAR HYPERTROPHY

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.

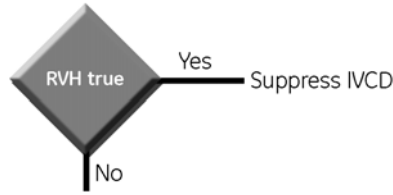


There are several ways in which *RVH* can be diagnosed via the standard criteria. **Possible right ventricular hypertrophy** is stated if any of these tests are true.

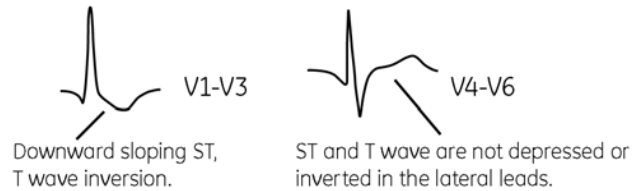


If the R amplitude in V1 is large for age, or there is a QR pattern in V1, the program states **Right ventricular hypertrophy** without the prefix *possible*.

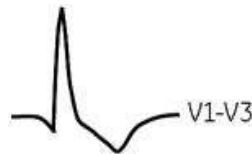
If *RVH* is stated (with or without the prefix *possible*), *IVCD* and *LOWV* are suppressed.



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**.

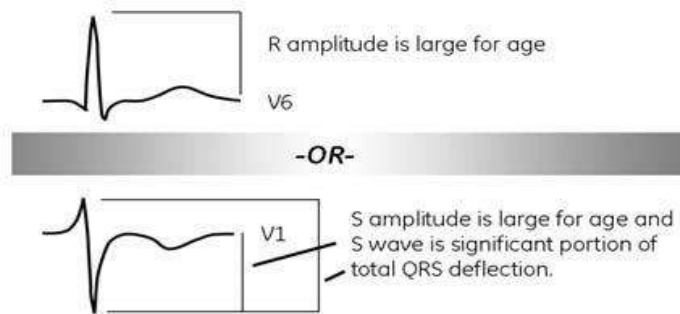


If the ST-T meets the criteria for *RVH* with repolarization abnormality and also meets more rigid criteria for strictly downward sloping ($STM > STE > T$ amplitude and T amplitude $< -200 \mu V$ in at least two of V1-V3), the program will append **with strain pattern**.

LEFT VENTRICULAR HYPERTROPHY

Acronym: LVH

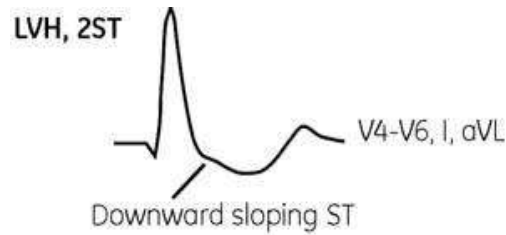
The criteria first examine the voltage in leads V1 and V6.



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.

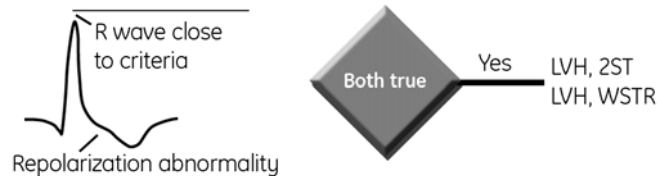
If this repolarization abnormality is found in conjunction with voltage criteria for *LVH*, the program will state: **Left ventricular hypertrophy with repolarization abnormality**.



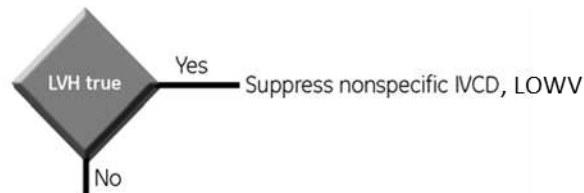
If the ST-T meets the criteria for *LVH with repolarization abnormality* and also meets more rigid criteria for strictly downward sloping (STM > STE > T amplitude and T amplitude < -200 μ V in at least two of V4-V6, I, or aVL), the program will state **Left ventricular hypertrophy with strain pattern**.



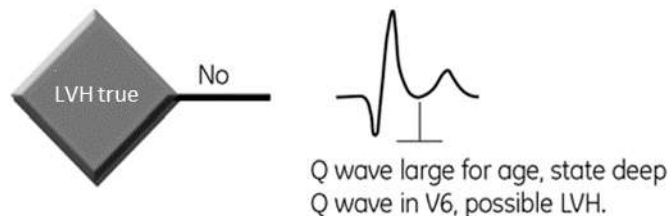
T wave inversion in the lateral leads is abnormal for all ages. If a repolarization abnormality is detected in the lateral leads and the ECG exhibited voltage that was close to the aforementioned criteria, the program would upgrade the diagnosis to *LVH*.



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*.

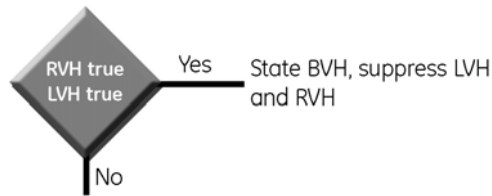


BIVENTRICULAR HYPERTROPHY

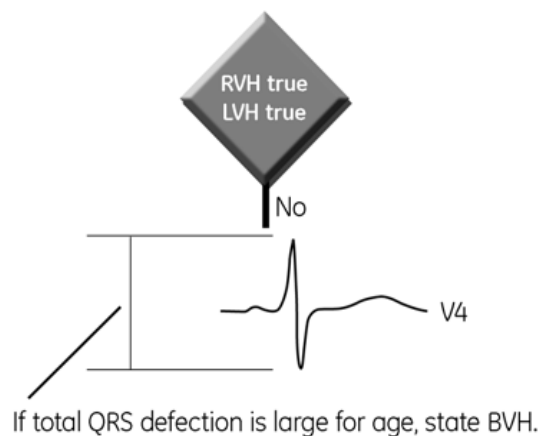
Acronyms: BVH, PMDPV

The way in which the program detects *BVH* is dependent upon what hypertrophy has already been detected by the program.

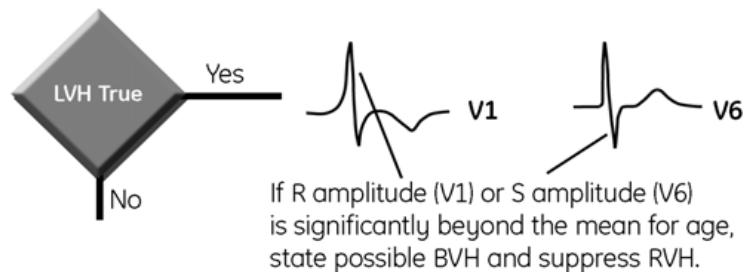
If both *RVH* and *LVH* have already been detected by the program, the program will state ***Biventricular hypertrophy***.



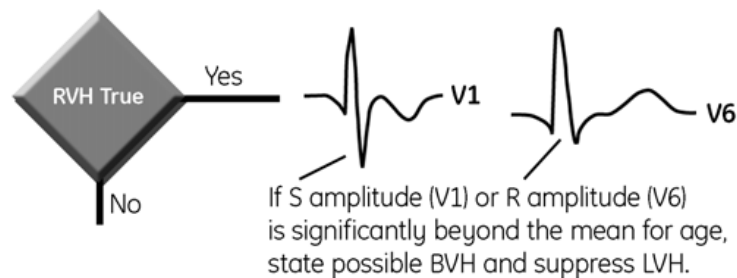
If neither *LVH* nor *RVH* have been detected, then inspect mid-precordial leads. If the total QRS deflection in V4 is large for age and the QRS is balanced (neither predominantly positive nor negative), then state ***Prominent mid-precordial voltage, possible biventricular hypertrophy***.



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.

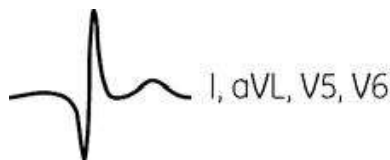
ANTERIOR MYOCARDIAL INFARCT

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, V5, V6 are required for diagnosis. These criteria are used to avoid the deep Q waves that occur normally in the pediatric ages.

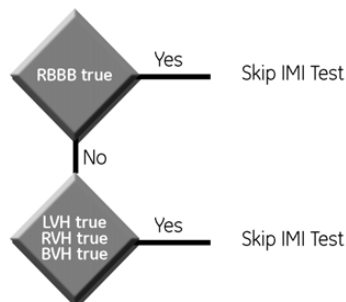


If the criteria are met, state **Possible lateral infarct** and suppress *Deep Q wave in lead V6, possible left ventricular hypertrophy*.

INFERIOR MYOCARDIAL INFARCT

Acronym: IMI

Do not test if RBBB or any hypertrophy is detected.



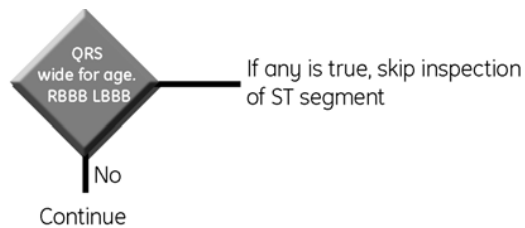
Criteria for inferior MI is very specific. A deep, wide Q wave with a large Q:R ratio in lead aVF is required for diagnosis. These criteria are used in order to avoid the large Q waves that occur normally in the pediatric ages.



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.

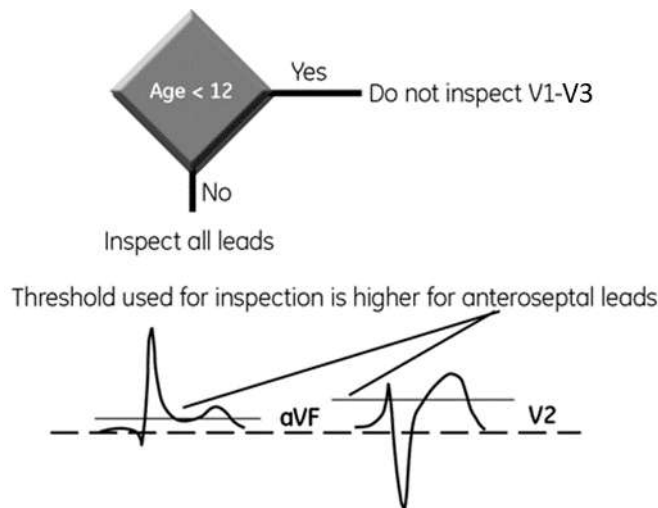


MARKED ST ELEVATION

Acronym: STELIN

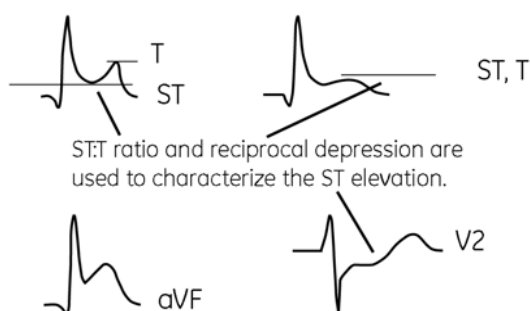
The program examines lead groups for ST elevation characteristic of an injury pattern. However, the program will merely state these descriptively rather than mentioning injury, e.g., *ST elevation in anterior leads*.

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.

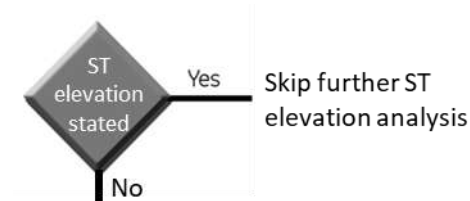
An injury pattern is suspected the larger the ST elevation and ST:T ratio. Reciprocal depression is also considered to be an indicator of injury.



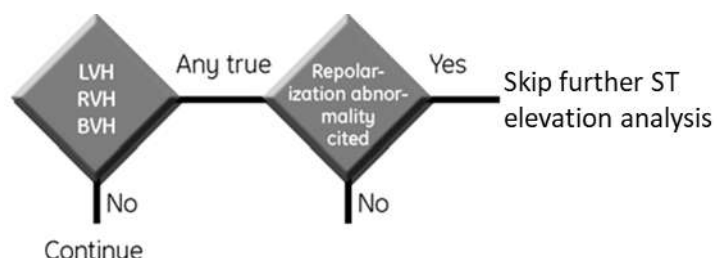
ST elevation that has these injury-like characteristics is stated descriptively by lead group. The following may be stated:

- **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.



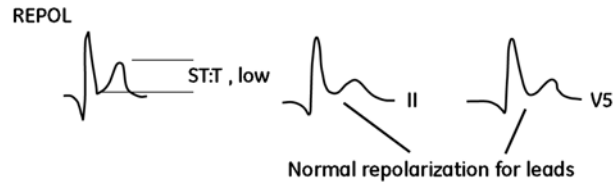
EARLY REPOLARIZATION

Acronyms: SERYP2, 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: SERYP1

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

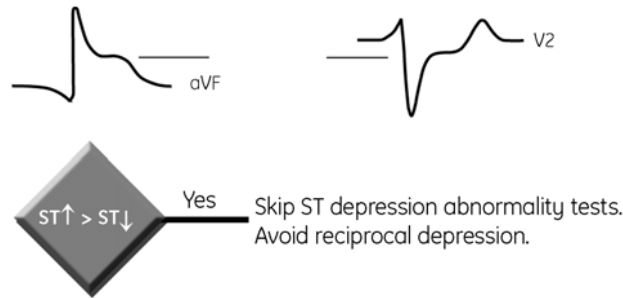
This test, with its associated statement *Nonspecific ST abnormality*, is not done in the pediatric analysis. Note, however, that this same statement may still be made for nonspecific ST depression abnormalities.

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.



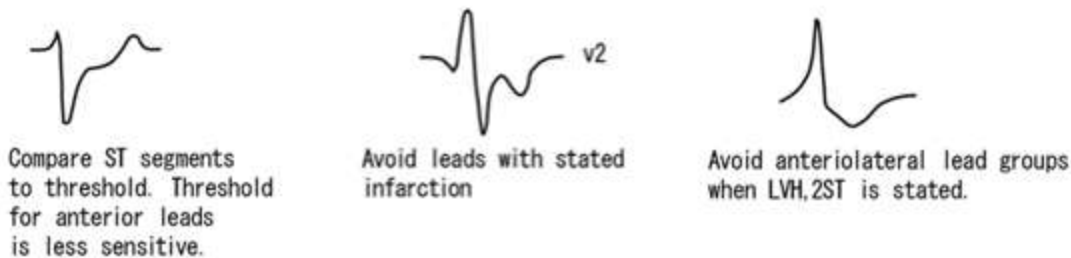
MARKED ST DEPRESSION

Acronym: STDPIN

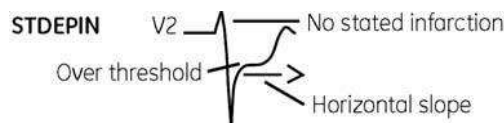
Do not test for significant ST depression if ST elevation injury already stated.

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 $-100\ \mu\text{V}$ for frontal plane leads and $-200\ \mu\text{V}$ 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.

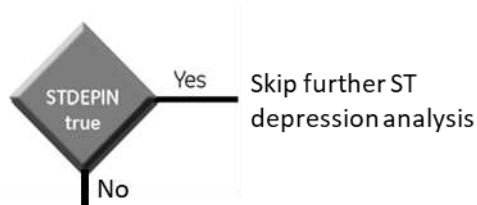
ST depression in inferior leads requires no inferior MI, no LVH with repolarization abnormality, and the maximum ST of either II or aVF below the threshold.

If anatomically contiguous lead groups have ST depression, combine as applicable:

- ST depression in septal leads + ST depression in anterior leads = ST depression in anterosseptal 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

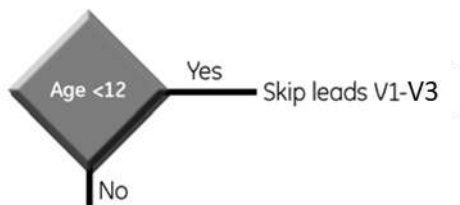
If any significant localized ST depression statements are made, skip all further tests for ST depression abnormalities.



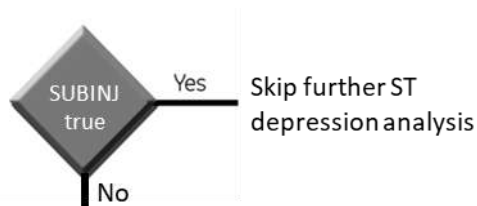
If any repolarization abnormality has been stated in association with ventricular hypertrophy, skip all further tests for ST depression abnormalities.



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.

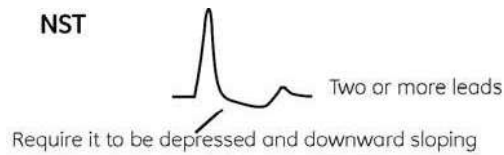


NONSPECIFIC ST ABNORMALITY

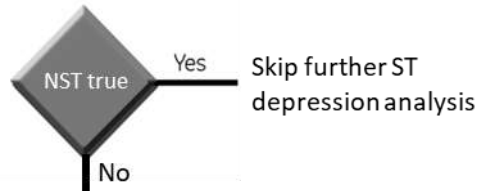
Acronym: NST

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



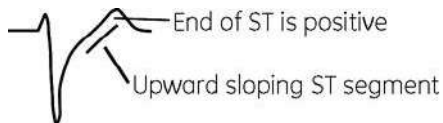
JUNCTIONAL ST DEPRESSION

Acronyms: JSTN, JST

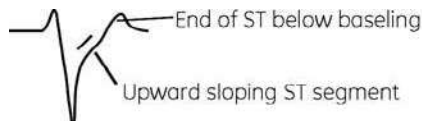
Skip this test if any ventricular hypertrophy with repolarization abnormality, RBBB, BRUG, or any infarct.

Examine leads for upsloping ST segment, where ST at the J-point is less than $-100 \mu\text{V}$. Skip lead aVR. For age less than 12 years, also skip V1-V3.

If, in at least two leads, the STJ is less than $-100 \mu\text{V}$ and STE is positive, state: **Junctional ST depression, probably normal.**

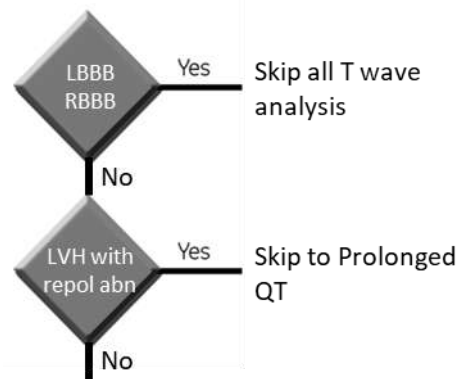


If, in at least two leads, the STJ is less than $-100 \mu\text{V}$ and STE is greater than one half of STJ, state: **Junctional ST depression, probably abnormal.**



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.



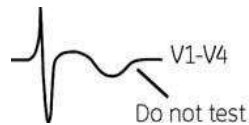
T Wave INVERSION

Acronym: TINVIN

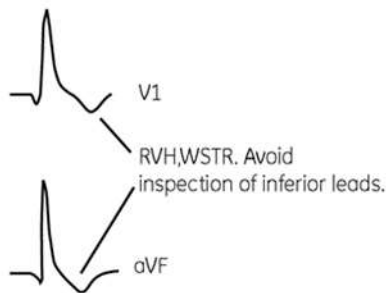
Examine leads for inverted T waves. If T waves are inverted, then state descriptively as opposed to stating ischemia.

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.

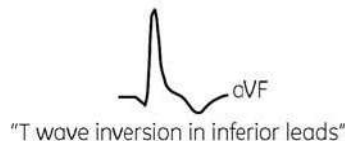


If *RVH with strain pattern* was noted, do not inspect inferior leads.



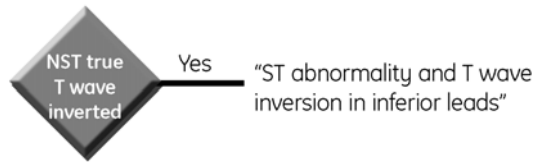
If two or more lateral leads (V5, V6, I, aVL) have inverted T waves, state ***T wave inversion in lateral leads.***

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.***



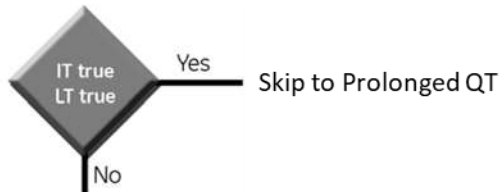
If T wave inversion noted in both lateral and inferior lead groups, instead state ***T wave inversion in inferolateral leads.***

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.

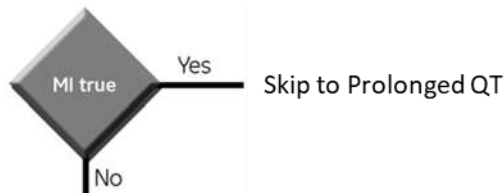


If any T wave inversion is stated, suppress *Early Repolarization* and *ST elevation, probably due to early repolarization*.

If *T wave inversion* is stated, skip to Prolonged QT.



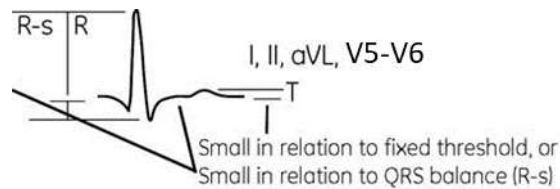
If *infarction* is present, skip to Prolonged QT.



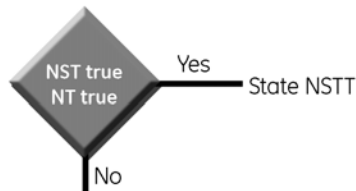
NONSPECIFIC T WAVE ABNORMALITY

Acronyms: NT, NSTT

If small T waves or shallow T wave inversion are found in at least two leads, state **Nonspecific T wave abnormality**.



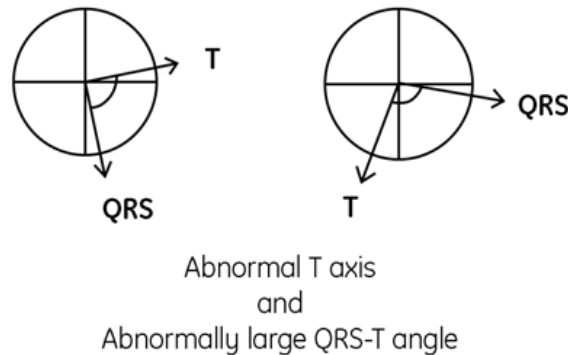
If a nonspecific ST abnormality is found in conjunction with NT, then make one statement as opposed to two and instead state **Nonspecific ST and T wave abnormality**.



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.



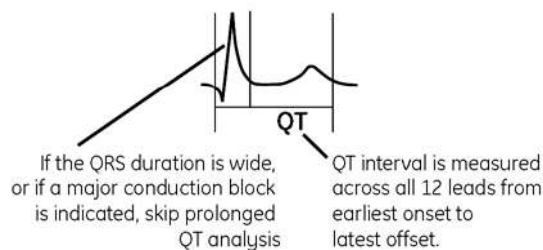
The test requires a difference between the QRS and T axes ≥ 60 degrees and T axis less than 0 degrees or more than 90 degrees.

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 $QTc \geq 460$ ms and < 480 ms, then say **Borderline Prolonged QT.**

If $QTc \geq 480$ 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)

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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
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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 ($\approx 15\%$) in Symptomatic Population

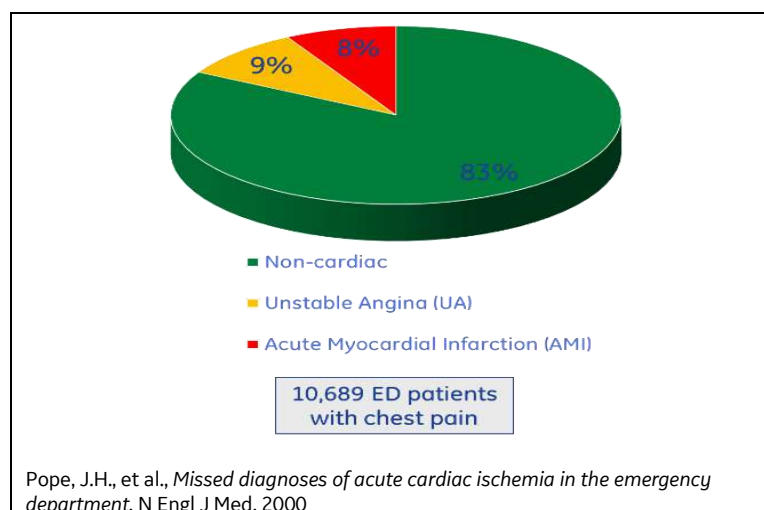
Even in the presence of chest pain, the prevalence of ACS has been found to be roughly 15%.

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).



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 $\approx 80\%$.

Inability to Differentiate Based on Symptoms

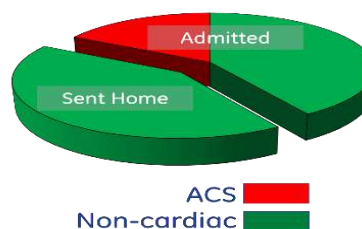
Signs and symptoms of ACS usually begin abruptly and include any of the following: chest pain (often described as aching, pressure, tightness or burning) which may radiate to the shoulders or arms; pain in the upper abdomen, back, neck or jaw; shortness of breath; nausea or vomiting; etc.[107] These 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]

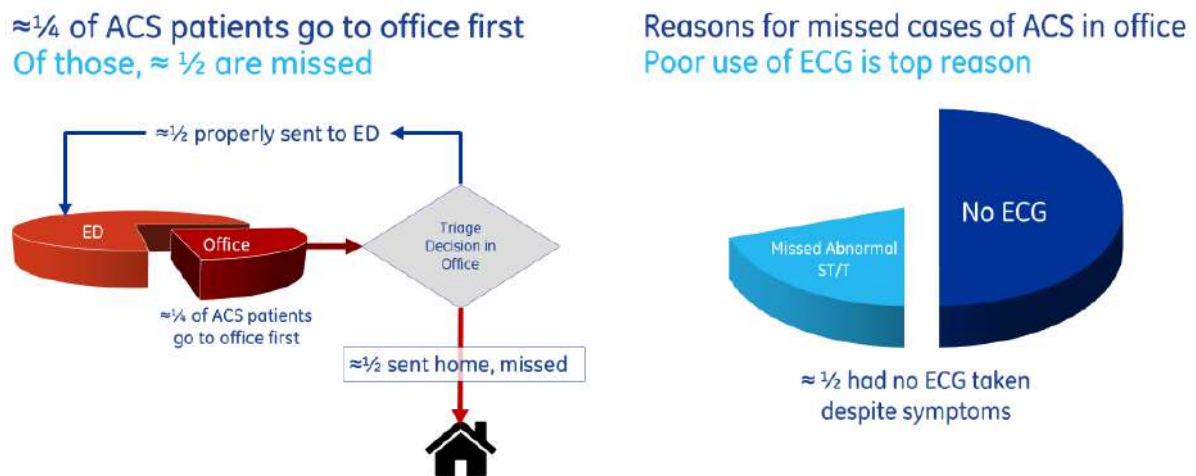
Higher False Negative (FN) Rate in Office

“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]

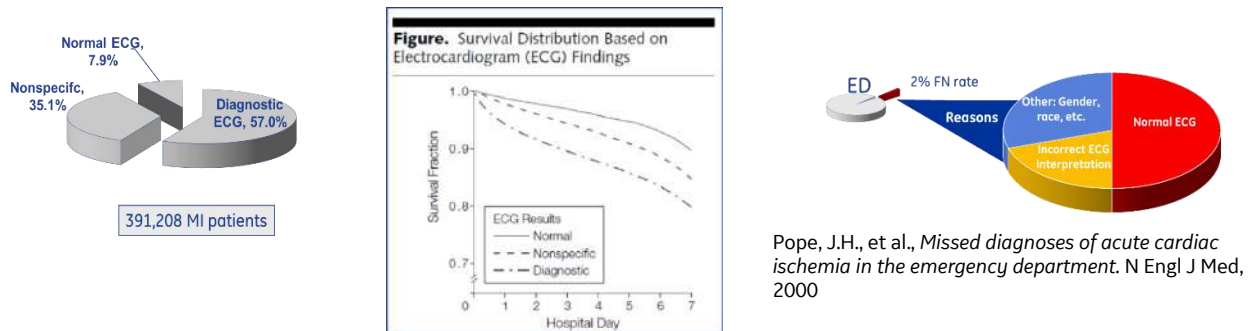
Top Reasons for Misdiagnosis

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.

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 obtaining a prior “ECG for comparison or the time to observe evolutionary ST-segment changes.”[111]

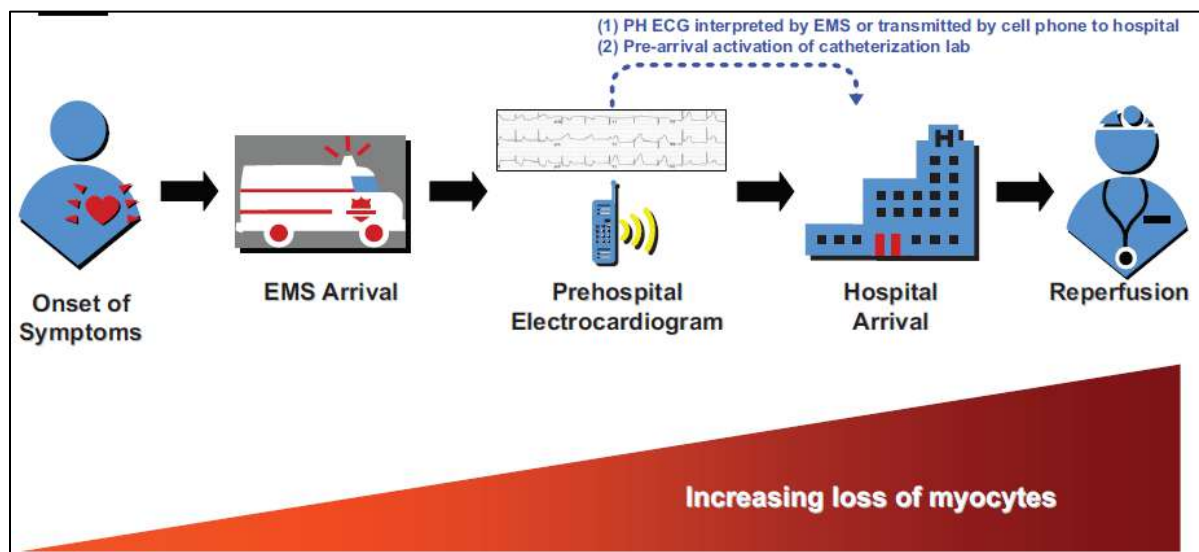
When the current ECG is negative, a significant change from a prior is predictive of poor outcome and a 2.1 times greater likelihood of intervention. This result was obtained via a year-long study at a single hospital, where 258 out of the 498 patients admitted for a heart attack had a prior ECG on file.[164] 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 manufactures 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]

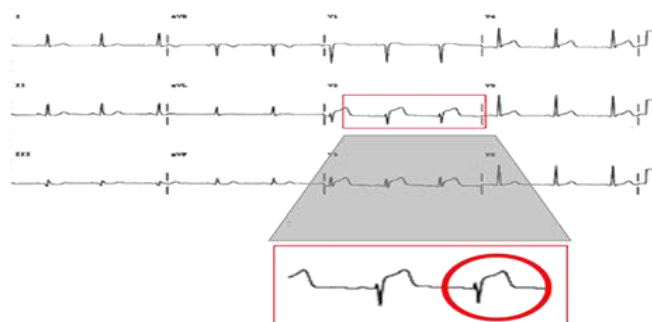
Expert electrocardiographers can identify STEMI with a high level of specificity whether they use the “conventional ST elevation criteria of 1 mm in any 2 contiguous leads”[175] or the more stringent ACC/ESC criteria which requires a 2 mm (200µV) ST deviation in leads V1-V4.[176] Specificity is unacceptably low when strictly applying these ST elevation (STE) thresholds.

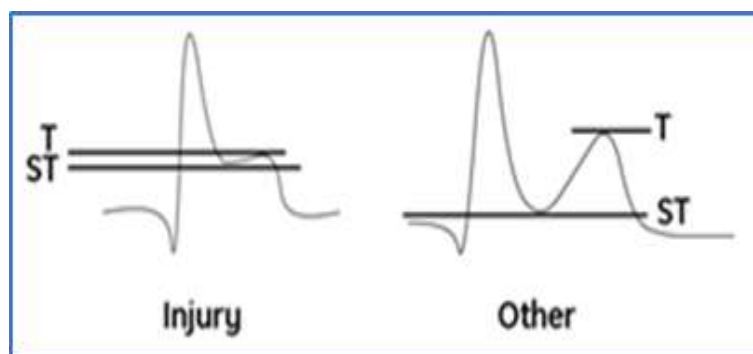
For instance, in an assessment of 6,014 healthy men enrolled in the U.S. Air Force (ages 16 to 58) it was found that “91 percent had ST segment elevation of 1 to 3 mm in one or more precordial leads.”[177] In yet another, much larger prospective study, STE >0.1 mV (100µV) in at least 2 inferior or lateral 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.

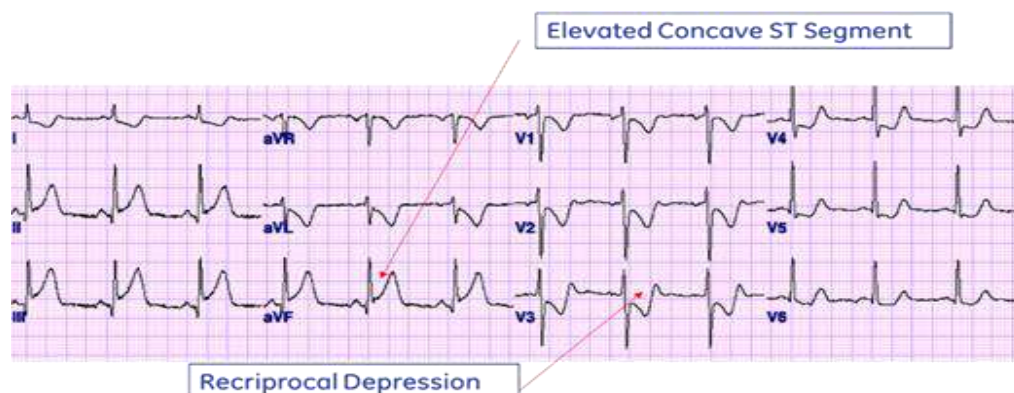




Discrimination of a STEMI based on whether the ST-segment is convex versus concave helps, but not that much. Indeed, in the first of a series of studies where PHECGs were obtained by paramedics and correlated against clinical outcomes, only half of STEMI's had convex ST segments.[17] Subsequent studies 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

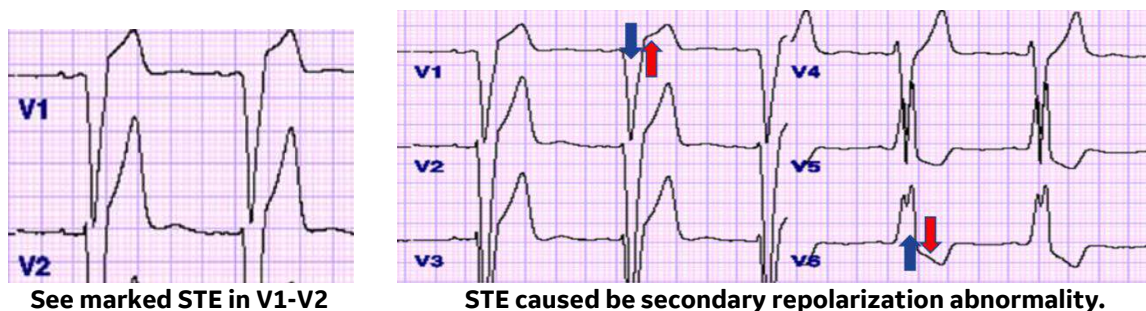
resolution adds additional important prognostic insight and deserves consideration in the management of these patients and future STEMI guidelines.”[185]

APPROPRIATE USE OF RECIPROCAL DEPRESSION

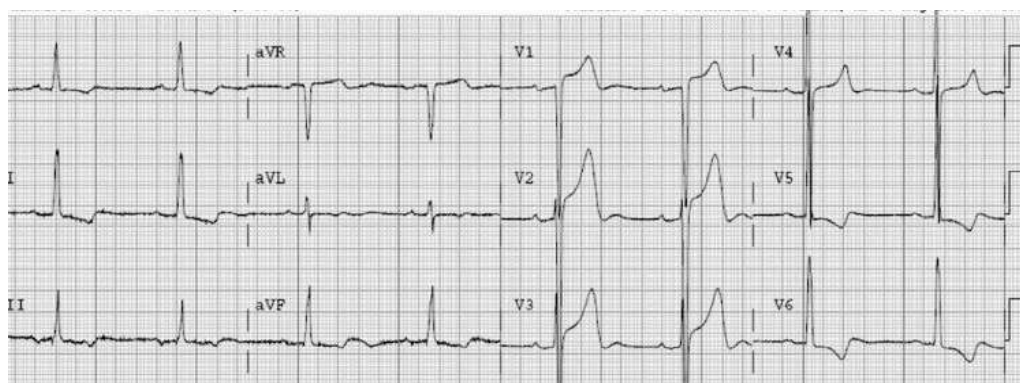
Reciprocal depression is an inherent characteristic of bundle branch blocks (BBB). Below is an example of a left bundle branch block (LBBB). It exhibits STE in V1-V2 and ST depression (STD) in V5-V6. In this case, the reciprocal depression is not the result of a STEMI. The STE and STD are a secondary 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.



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]

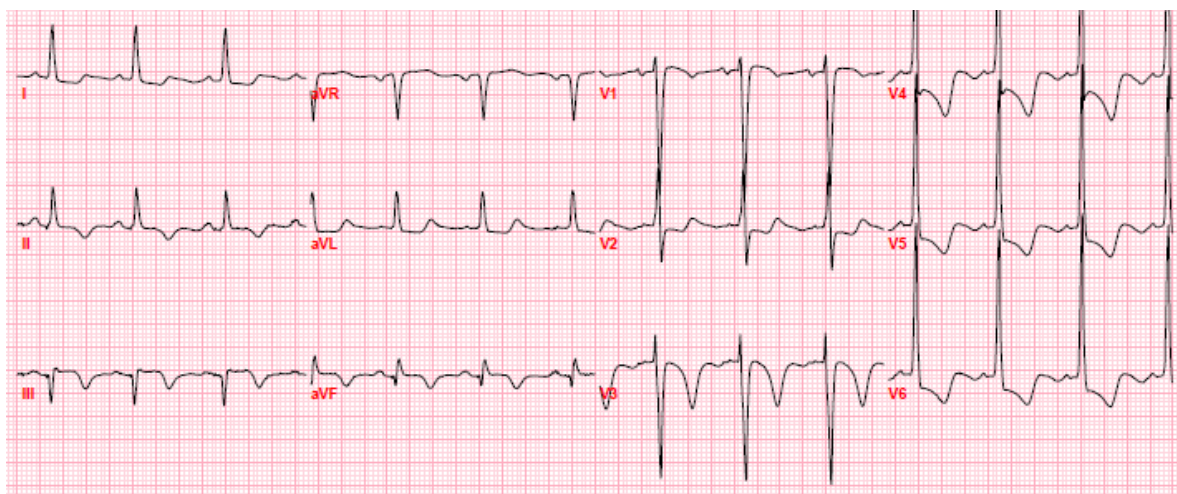
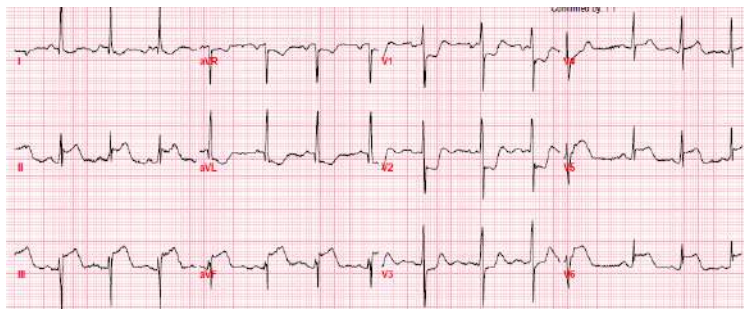
To properly apply the clue of reciprocal depression, one must also take into account the changes in repolarization due to a conduction abnormality or hypertrophy.[182, 189] The 12SL program has rules which stipulate when it can use reciprocal depression. Although the details are provided via this [hyperlink](#), 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.

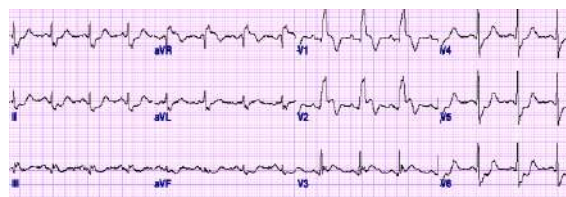
Due to the voltage and ST/T pattern in aVL, some programs would identify this as LVH and skip whether the ECG has evidence of a STEMI.

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.

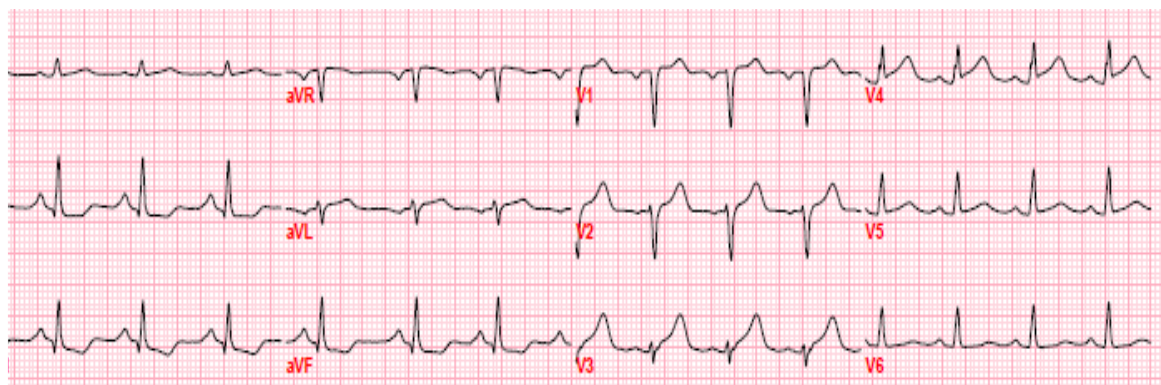
In the ECG below, some programs would not attempt analyzing this for STEMI because it meets voltage criteria for LVH and the ST/T in V5-V6 is typical of LVH. Despite the signs of LVH, this is an inferior STEMI. The STE in aVF and the STD evident in V2 is not typical of LVH. The T-wave in V3 is concordant 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.

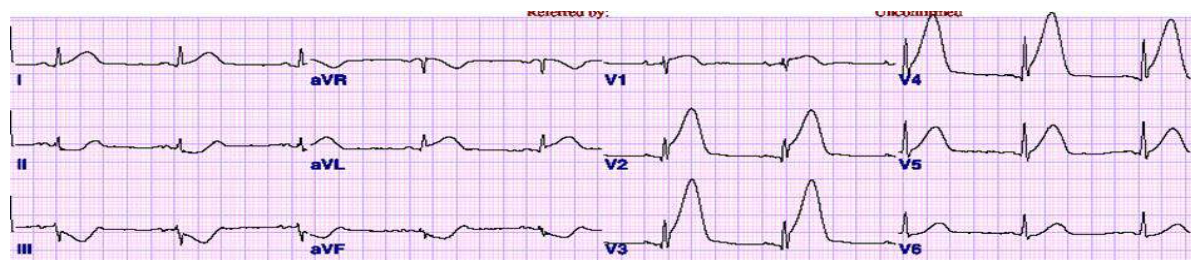


The rule of when to apply reciprocal depression can also be useful for discriminating hyperacute T-waves. See the two tracings below.

The first ECG has STE > 200 μ V 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 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 STEMI. 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:

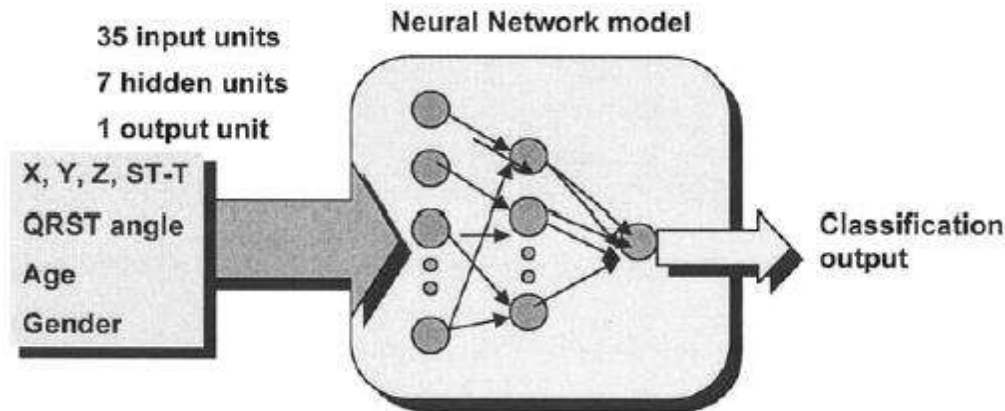
- detection of abnormal Q-waves,
- quantification of the amount of ST segment elevation or depression, and
- quantification of the amount of T wave magnitude and polarities.

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:

$probability\% = 100 \times \left[1 - \frac{1}{1 + \exp(b_0 + \sum b_j x_j)} \right]$			
Variable	Coefficients (b _j)	Description	Value (X _j)
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_j is used per variable. Electrocardiogram (ECG) findings must be present in <i>at least</i> 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

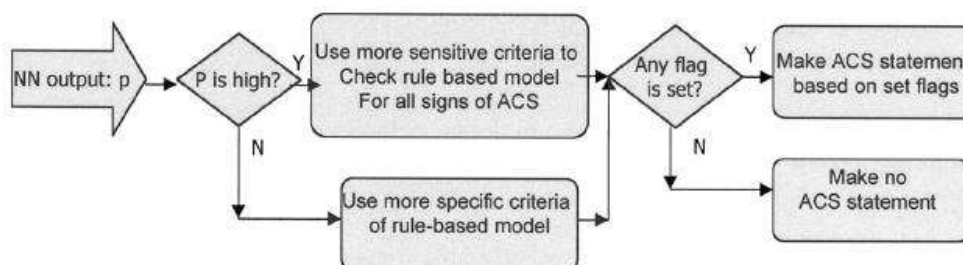
ACI Probability Group	TIPI Scores ^a		Development Phase			Test Phase		
	Range	Midpoint	n	% with ACI	% with AMI ^b	n	% with ACI	% with AMI
LOW	I	0-10%	734	3.8%	1.8%	552	1.6%	0.7%
MEDIUM	II	10-25%	939	17.6%	6.0%	657	12.0%	4.4%
	III	25-55%	869	39.8%	14.7%	627	36.7%	12.3%
HIGH	IV	55-100%	911	77.9%	49.7%	484	51.6%	33.3%
			3,453			2,320		
			(100%)			(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 the 12SL 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”.

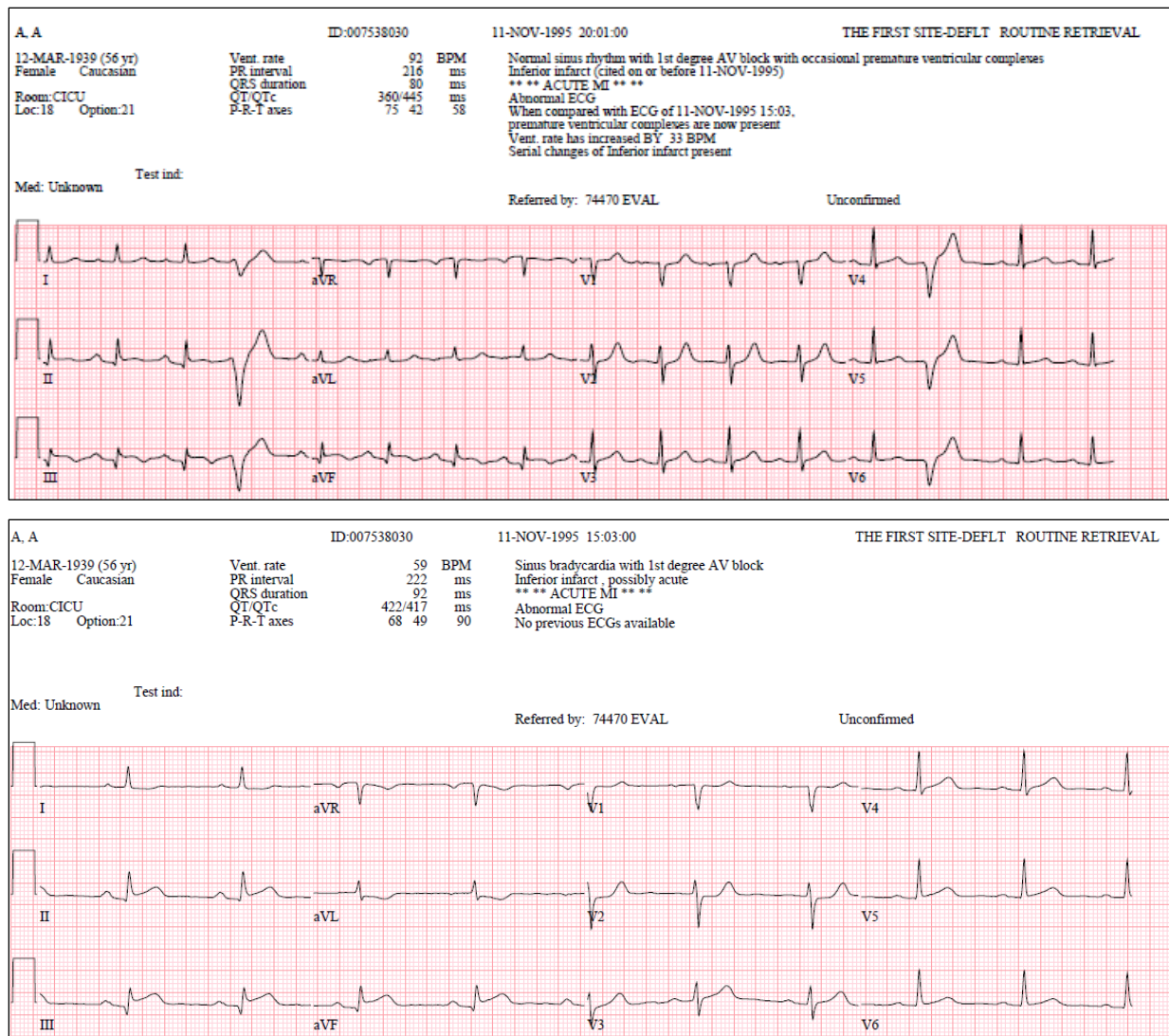
Additional ACC/AHA guidelines focus primarily on the issue of the assessment of serial ECGs in patients suspected of ACS.[200, 202, 203] This is because a significant change across serial ECGs is, in and of itself, the evidence necessary to identify a significant subset of heart attacks (see unstable 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 $\geq$ 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 $\geq$ 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 $\leq$ 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 $\leq$ 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 $\geq$ 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
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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 STEMI 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 STEMI 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 STEMI 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 STEMI 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 STEMI 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:

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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 come 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 uncondacted 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:

- uncondacted 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

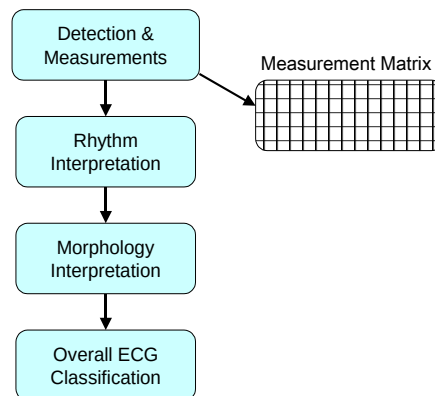
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Below is a simple block diagram of GE's Marquette 12SL™ Program. Note that all the interpretative statements are generated following the measurement portion of the program.

All measurements generated by the program are stored in a measurement matrix, which are then later accessed by the interpretative 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 interpretative 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%

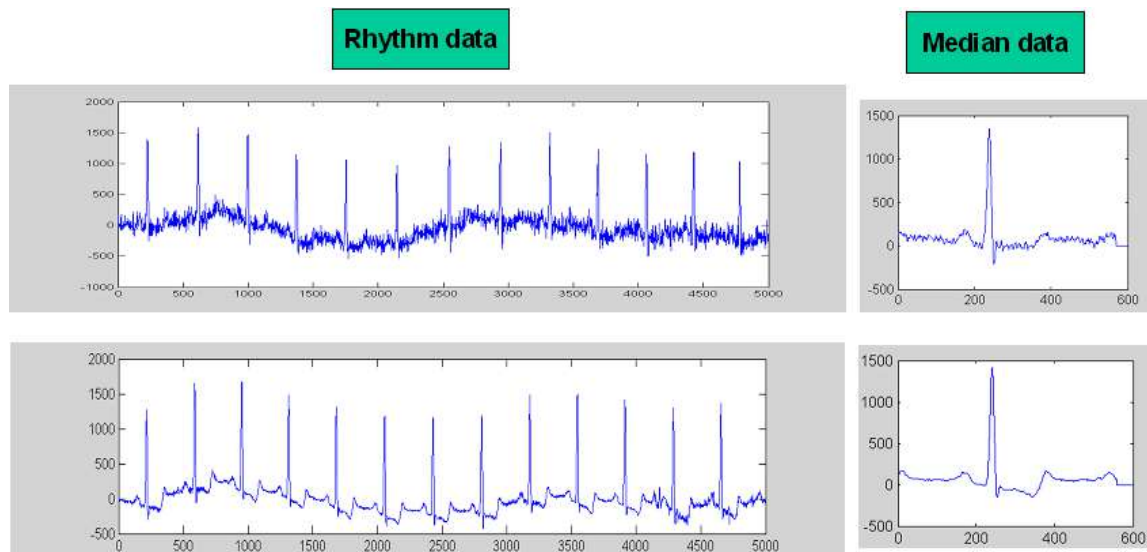
Overall, 95.4% of all ECGs were categorized as green (good) lead quality, 4.3% were assessed as yellow (marginal) lead quality, and 0.3% as red (poor) lead quality. As the primary rhythm from the 12SL reanalysis was compared to the primary rhythm in the confirmed ECG, the discordance of these two interpretations 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.

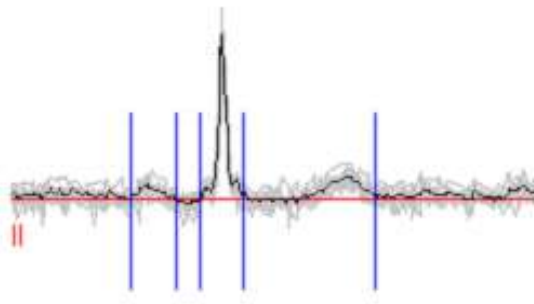
MEDIAN BEAT/SIGNAL AVERAGING

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 Zywiez[288] also showed that programs analyzing an averaged beat exhibited less variability than programs that measure every complex or a selected beat. Zywiez 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.

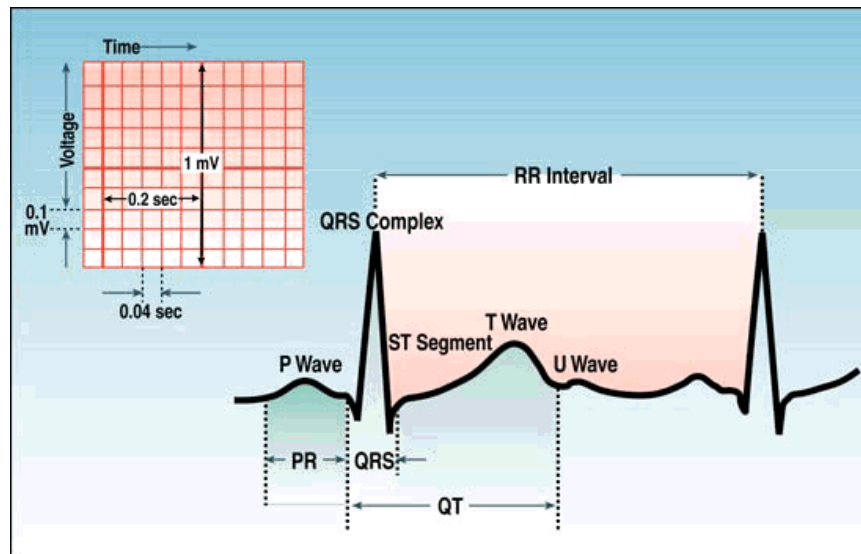
QRS ONSET/OFFSET AND DETERMINATION OF GLOBAL INTERVALS

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.

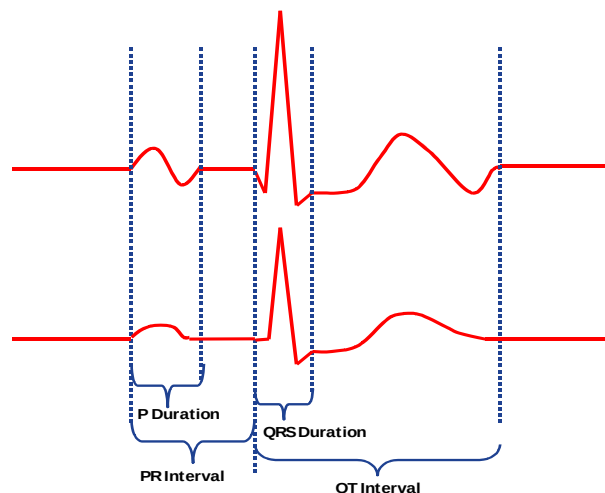
P onset and P offset are also determined via the median complexes unless the computer detects asynchronous P wave activity or an inconsistent PR coupling interval in the rhythm data. In this case, P onset and P offset remain undefined.

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



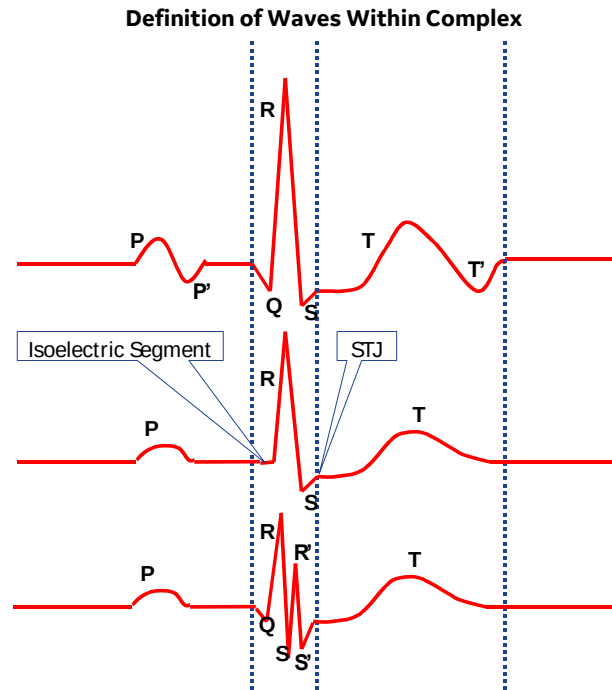
DEFINITION AND MEASUREMENT OF WAVES

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 $\mu\text{V}\cdot\text{ms}$, 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 $\mu\text{V}\cdot\text{ms}$ are combined with the adjacent significant wave.

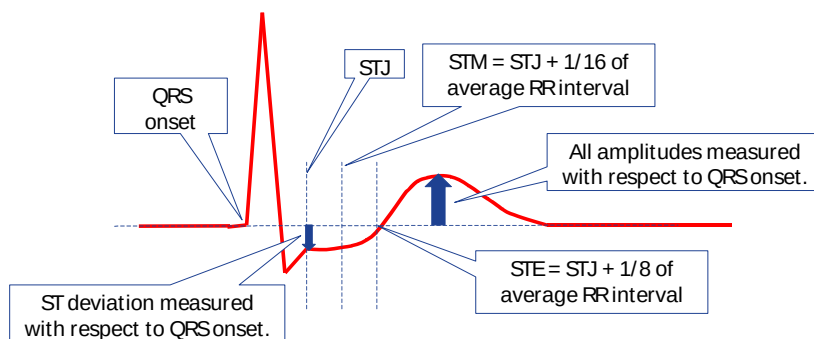
Since the wave of depolarization is a spatial entity, the onset of the wave will not be evident in all leads at the same time. Isoelectric sections starting at QRS onset of the complex are treated as part of the subsequent

significant wave. Isoelectric sections at the end of the QRS will be incorporated into the preceding significant wave.

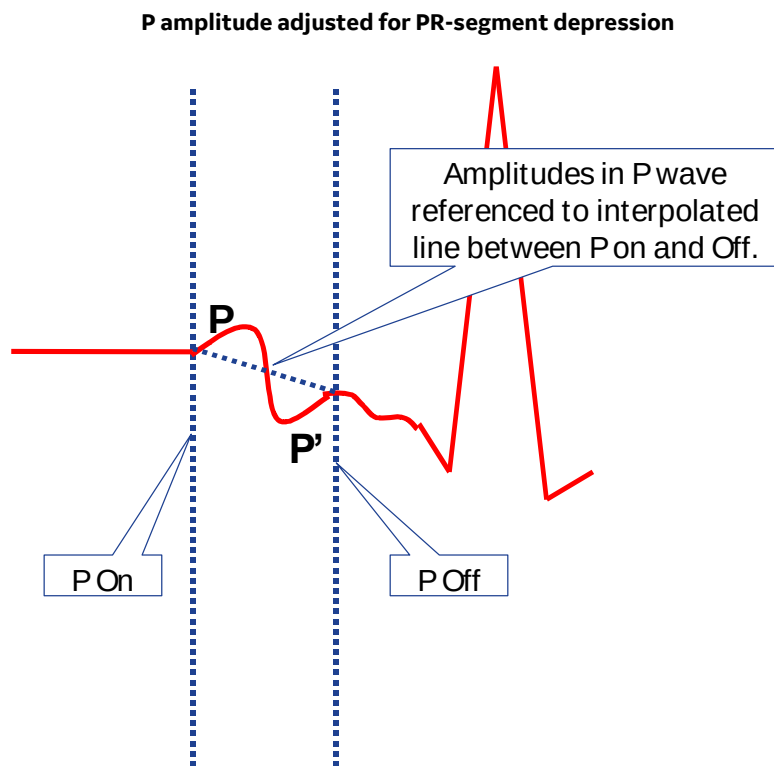


Amplitudes of significant waves within the QRS as well as the T wave are measured with respect to QRS onset. Deviation of the ST segment is also measured in relation to QRS onset. STJ is defined as QRS offset. Further definition of the ST segment is defined by STM and STE, which are two additional points 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.



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

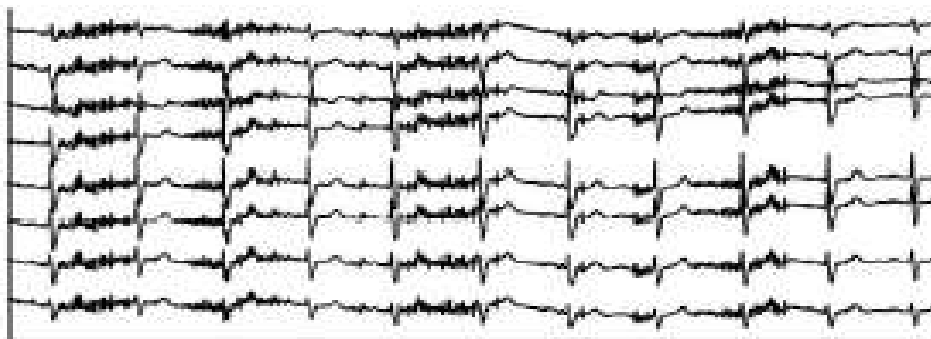
Global Measurement	Type of added noise	Mean Difference (ms)	Standard deviation (ms)
P duration	high frequency	-43.5	9.9
P duration	line frequency	-2.8	6.7
P duration	baseline	1.5	3.7
PR interval	high frequency	-18.5	11.0
PR interval	line frequency	-1.5	2.8
PR interval	baseline	0.3	1.3
QRS duration	high 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.

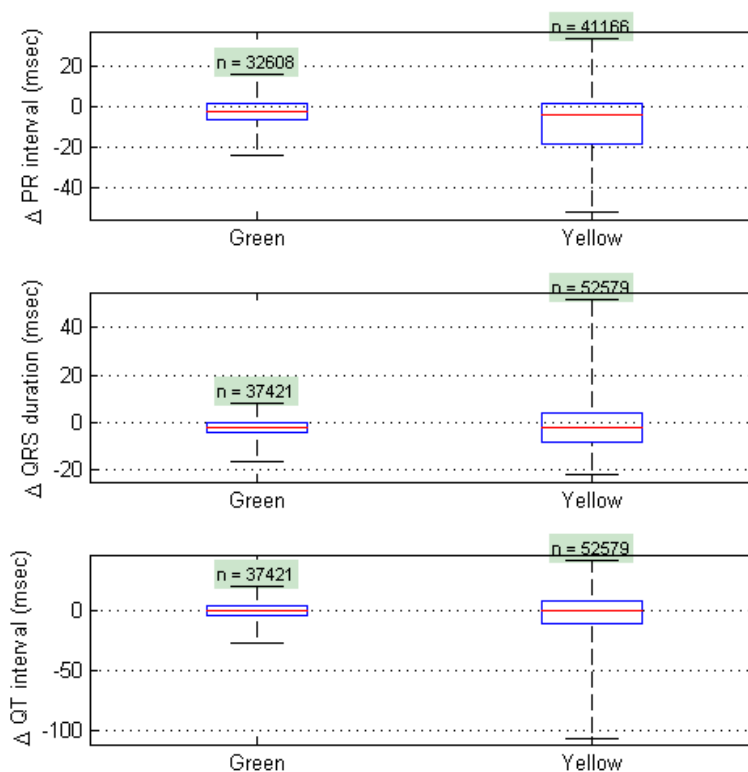
Example of CSE ECG combined with MIT-NST Record



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]

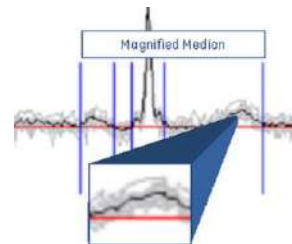
INTERVAL MEASUREMENT COMPARISON ACROSS MANUFACTURERS

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]

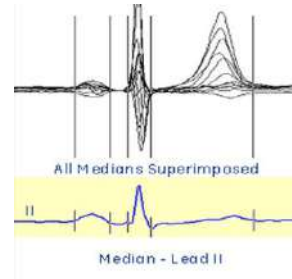
In an interval comparison study published in 2014,[298] the mean PR interval determined via Mortara on LQTS patients had a standard deviation roughly double that of the other ECG vendors.[298] "Since that publication, some algorithms have been adjusted, while other large manufacturers of automated ECGs 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

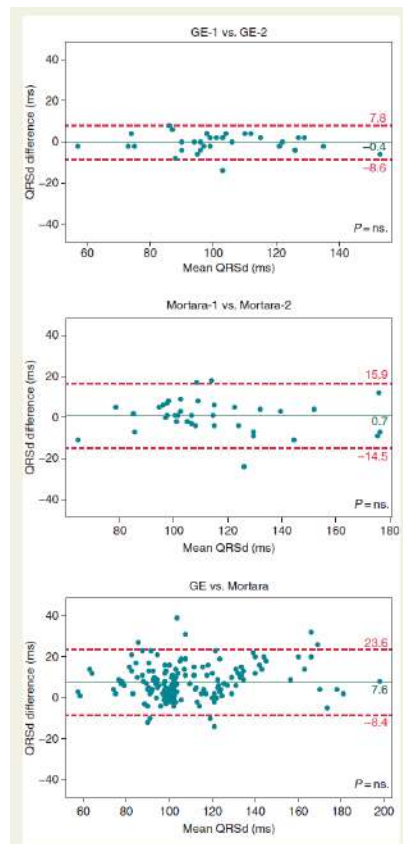
ECGs from 152,759 primary care patients aged 50 to 90 years were collected from 2001 to 2011 and analyzed by GE's Marquette™ 12SL™ ECG Analysis Program.[301] “Excellent agreement” was found between the 12SL algorithm and manual identification of intra-atrial block (IAB), as defined by the following categories: “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]

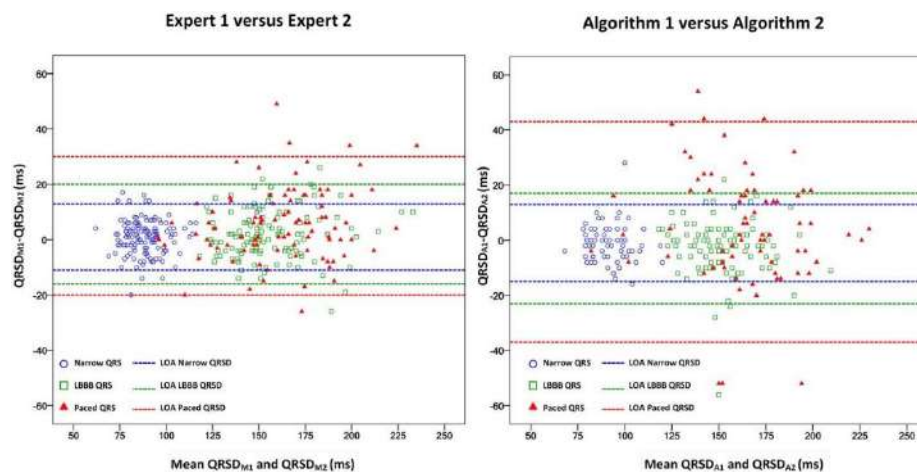
Below are the results of the pair-wise comparison, including intra-manufacture (first two Bland-Altman plots) and inter-manufacture (last Bland-Altman plot.) Note that there was systematic difference in QRSd of 7.6+8.1 ms with GE Healthcare being shorter than Mortara's.

“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:

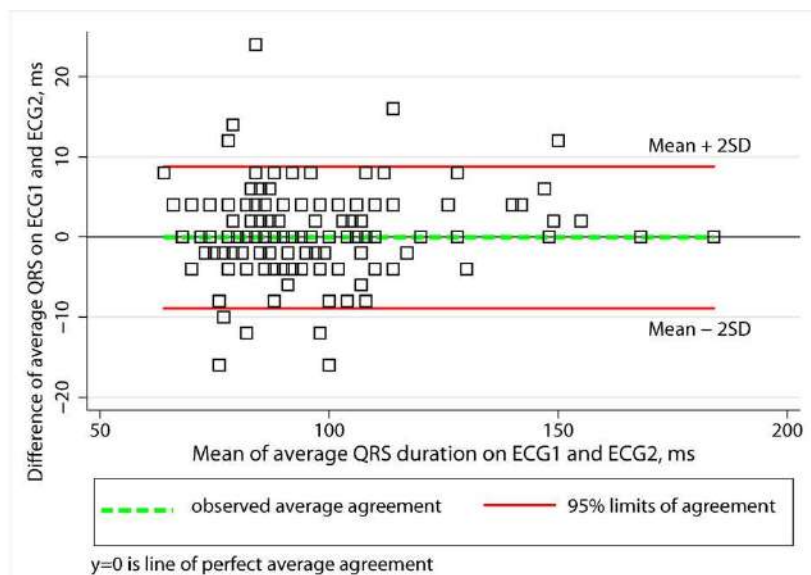
- In the presence of narrow QRS complexes, “analyzing QRSD within individual ECGs (pairwise), absolute differences in QRSD between the automated algorithms QRSDA1 versus QRSDA2 are 4 [2–9] ms ($p = 0.010$) and between QRSDM1 versus QRSDM2 4 [2–6] ms, $p = \text{NS}$. Absolute inter-manufacturer and interobserver variability were comparable in narrow QRS ECGs (4 [2–9] ms versus 4 [2–6], $p = \text{NS}$).”
- “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, $p = \text{NS}$). ... 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 -0.10 ms [95% limits of agreement -12.77 to 12.56 ms], V2 QRS duration bias -0.09 ms [-11.13 to 10.96 ms]; V1 TAD bias 0.14 ms [-13.23 to 13.51 ms], V2 TAD bias 0.008 ms [-12.42 to 12.44 ms].”^[303]

For global QRS duration, the following Bland-Altman diagram was provided:



FRAMINGHAM HEART STUDY: 12SL VERSUS DIGITAL CALIPERS

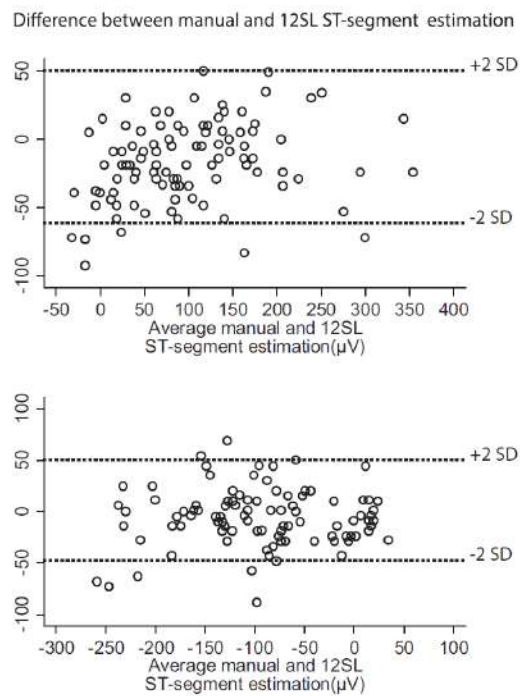
The Framingham Heart Study (FHS) data repository stored on GE Healthcare's MUSE™ system includes ECGs from 1986 to 2012. For this study, ECGs were randomly selected to account for temporal changes in ECG acquisition and recording techniques. ECGs were excluded if they had a paced rhythm, atrial fibrillation, 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 of 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

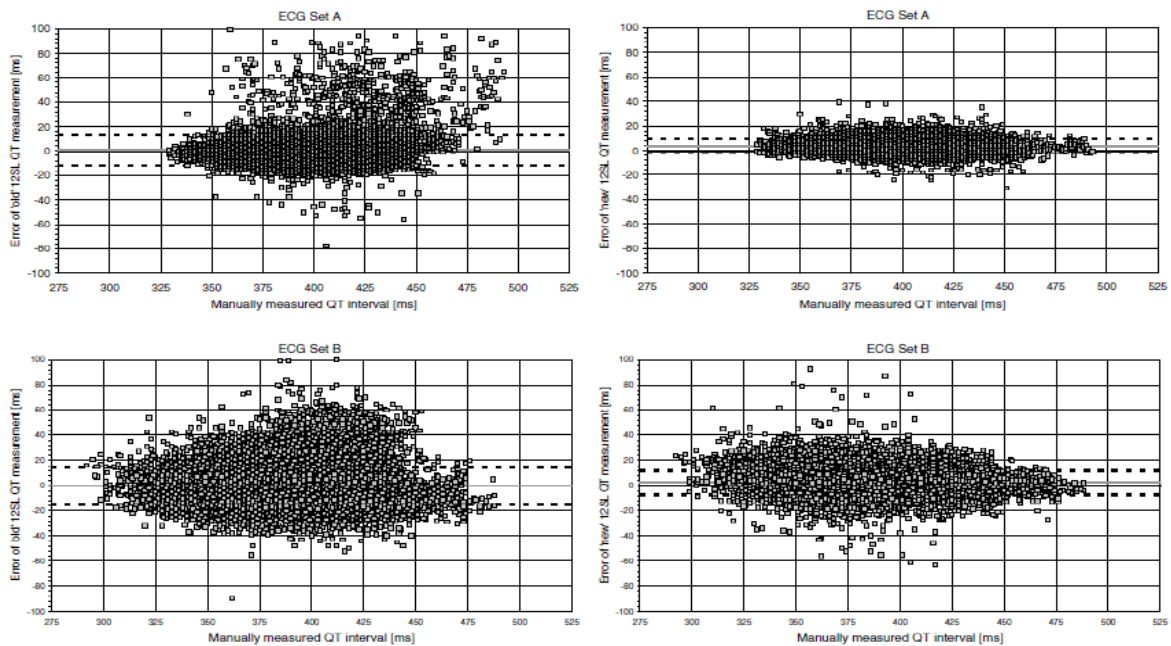
significantly better, and (b) the precision of automatic measurement by the 12SL algorithm is substantially dependent on the quality of processed ECG recordings.”[32]

Percentages of ECGs with successful automatic QT measurement (n=45,060)[32]

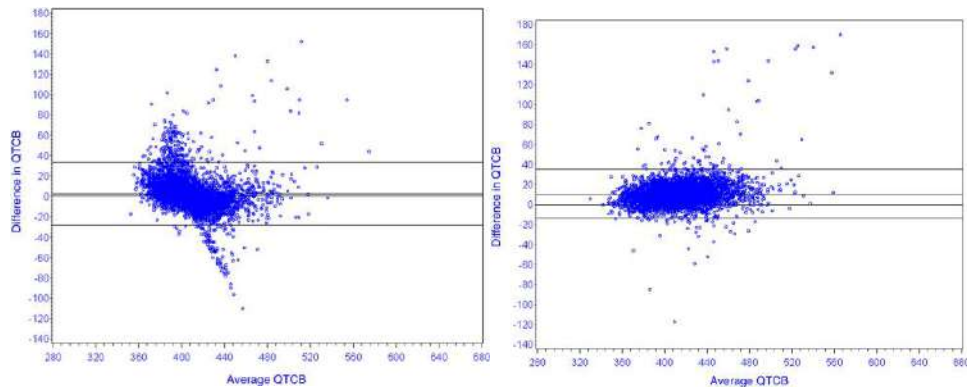
Absolute measurement error	ECG set A		ECG set B	
	“New” 12SL	“Old” 12SL	“New” 12SL	“Old” 12SL
≤ 5 ms	73.7	47.8	54.4	33.5
≤ 10 ms	95.9	76.6	83.9	59.5
≤ 15 ms	99.3	91.7	94.0	77.3

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]

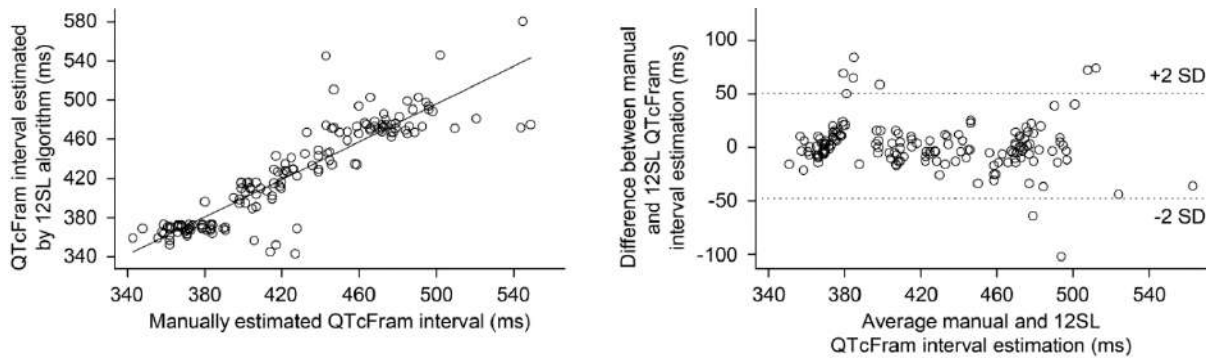
To assess agreement between two quantitative methods of measurement, Bland-Altman (B&A) scatter plots are recommended.[314] Each difference in milliseconds between the automated and manual QT measurement is presented on the vertical axis versus the manually measured QT along the horizontal axis.

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 $\pm$ SD) $+3.95 \pm 5.50$ ms. ... In recording set B, these numbers were $+2.41 \pm 9.47$ ms."[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.

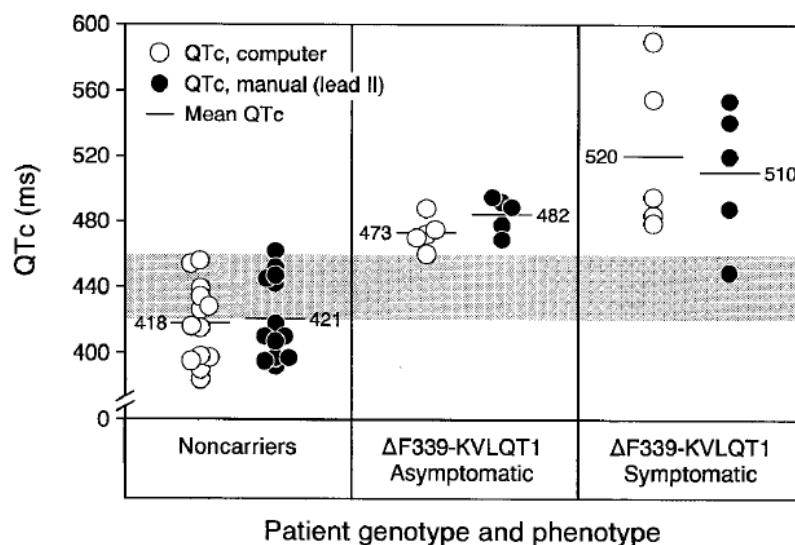


In the second instance, a GE Healthcare MUSE ECG database consisting of 225,117 ECGs from 63,286 unique patients collected over 11 years was searched using the following criteria: QTc (Bazett's formula) ≥ 500 ms, QRS width ≤ 120 ms, age $15 \geq$ years, normal heart rate, no acute ST-elevation infarction, 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 ± 10 ms of the manual measurement, which was the case in 88% of ECGs exhibiting sinus rhythm and adequate technical quality. [313]

For QTc values ≥ 500 ms, "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 < 500 ms and found none that should have exceeded a QTc ≥ 500 ms. "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 is 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.

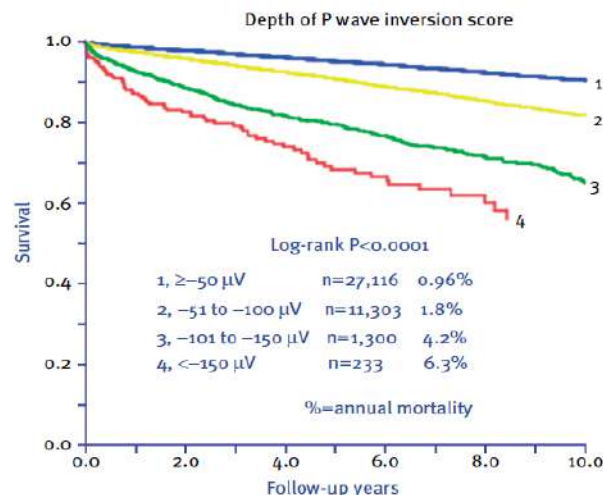
- Similarly, automated 12SL™ PR interval measurements on 50,870 patients of which 5,199 developed AF over 3.72 mean years of follow-up were used to define normative values. The study settled on “a PR interval value of 200 ms as a criterion in African Americans and Hispanics for the development of AF. 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.

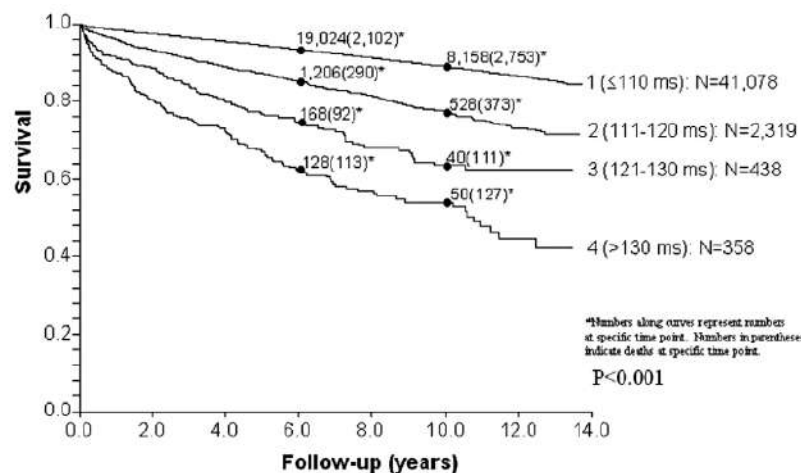
- “During a mean follow-up of 6 years there were 3,417 CV and 1,213 pulmonary deaths.” P-wave amplitude in inferior leads, right axis deviation, left atrial abnormality and P-wave duration > 120 ms were all predictive of pulmonary death. “P-wave abnormalities are common findings that should not be ignored.”[328]
- 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 (μ V) of $\leq -50 = 1$; -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 $< -150 \mu$ V, 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 ($\leq -100 \mu$ V) 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 ≥ 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 - $5.545\mu\text{V}$ (95% CI -11.07 to 0.02) with limits of agreement between -74.64 to $41.320\mu\text{V}$.”[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 $\text{ST} \geq 100\mu\text{V}$. “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 $\geq$ 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 $\geq$ 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 $\leq$ 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 difficulty 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 $(360^\circ - \text{angle})$ for an angle $>180^\circ$ 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 ($\geq 100^\circ$) 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 100 μ V tall, a large study (>43,000 ECGs) was undertaken to determine the prognostic value of UDMI Q-wave criteria versus conventional Q wave criteria ≥ 40 ms 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 ≥ 40 msec 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 ≥ 40 msec 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 ≥ 40 msec as significantly associated with infarct size as determined by cardiovascular magnetic resonance (CVMR).

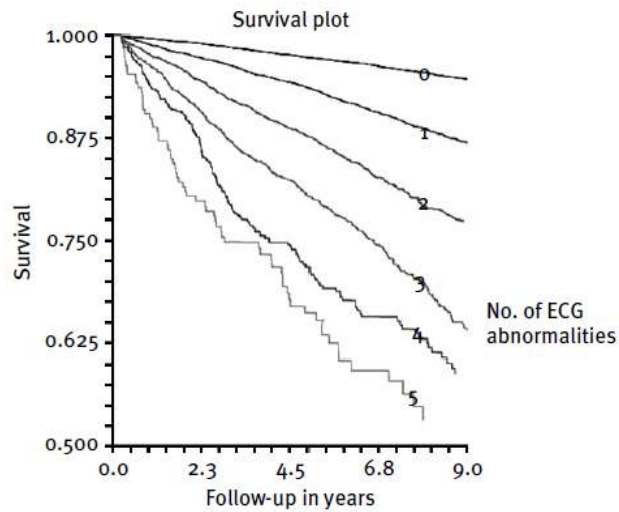
There is renewed interest in MI-sizing via ECG, since CVMR (as opposed to autopsy) provides a practical gold-standard reference for myocardial size.[376, 377] There continues to be a need for an inexpensive and accessible method for determining MI size it could have implications for finding patients 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 $\approx 80\%$ 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”

$$\text{Sensitivity} = TP / (TP + FN) \times 100\%$$

Specificity: probability that a “True normal” would be classified as “Normal”.

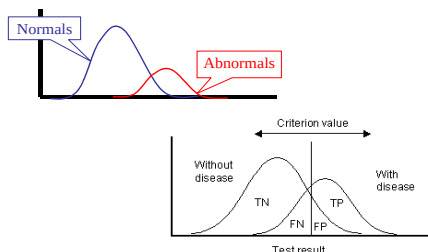
$$\text{Specificity} = TN / (TN + FP) \times 100\%$$

Positive predictive value (PPV): probability that a classified “Pathologic” is a “True pathologic”.

$$\text{PPV} = TP / (TP + FP) \times 100\%$$

Negative predictive value (NPV): Probability that a classified “Normal” is a “True normal”.

$$\text{NPV} = TN / (TN + FN) \times 100\%$$

Performance Metrics

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
2 nd /3 rd 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
2 nd degree AV block	1	100	99.7	14.3
RHYTHM MODIFIERS				
1 st 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				
1 st 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:

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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).

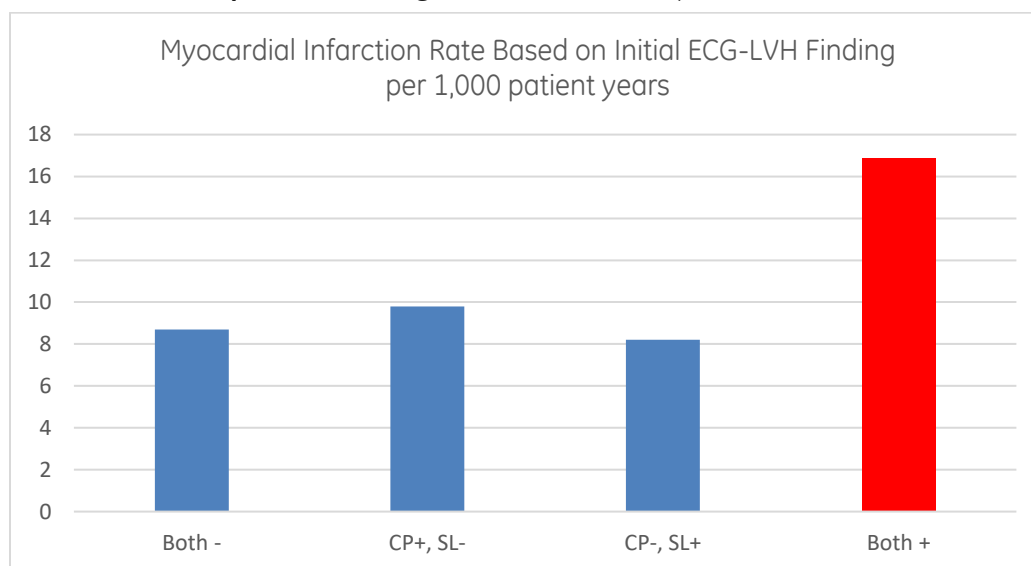
In 2017, a study by Okin et. al. found that in 9,193 patients followed 4.8±0.9 years, “persistence or development of ECG LVH by both Cornell product (CP) and Sokolow-Lyon (SL) voltage criteria during antihypertensive therapy is associated with markedly increased risks of cardiovascular end points and 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]

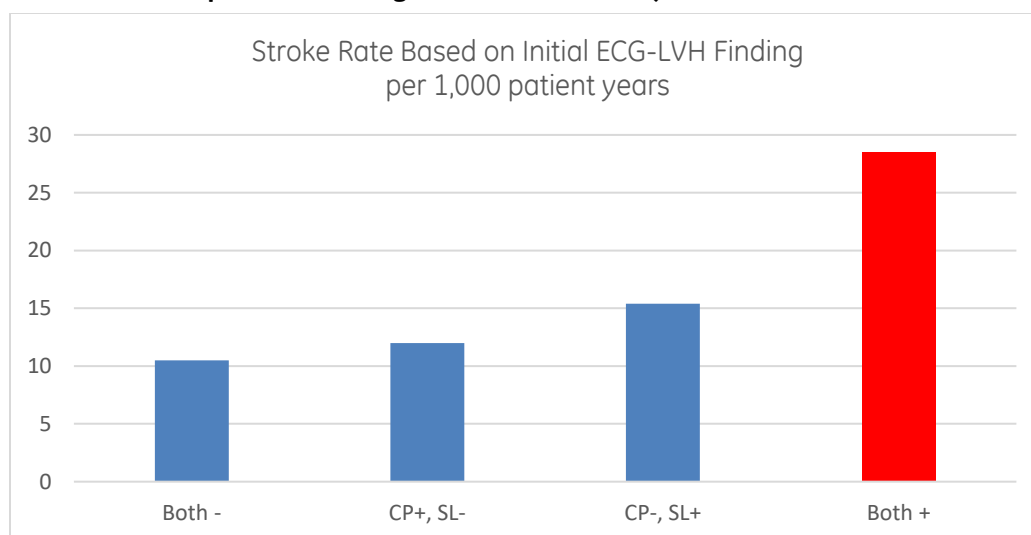
This paper by Okin et. al. also reiterated “the well-recognized limited sensitivity of any one ECG LVH criterion as compared with imaging modalities.”[49] Given that serial ECG testing is inexpensive, this study suggests “that serial assessment of both CP and SL can improve risk stratification in patients with hypertension during treatment.”[49]

Below, in graphical form, are some of the outcomes measured via this study. See full paper for completeness.[49]

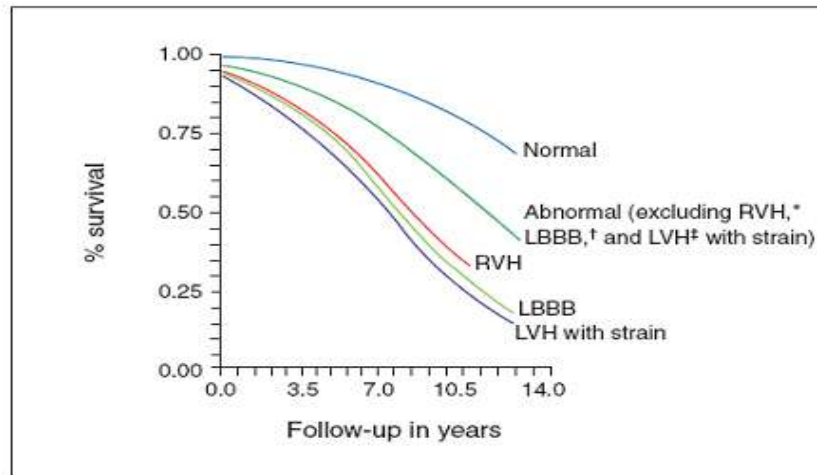
Impact of Combining Cornell and Sokolow Lyon: MI rate[49]



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 sloping) 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 STEMI (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]

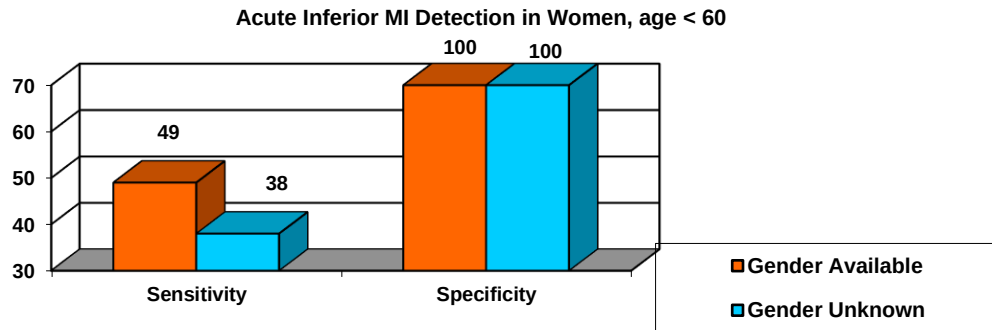
This paper states that “strict reliance on measured electrocardiographic criteria alone would have resulted in overuse of thrombolysis among all 3 raters. Based on the consensus opinion, the absolute overuse of thrombolysis would have been approximately 15% (P <.0034).” In contrast, the computer had 100% specificity.

ECGs from cardiac care unit (CCU) evaluated by 3 cardiologists, consensus opinion[452]

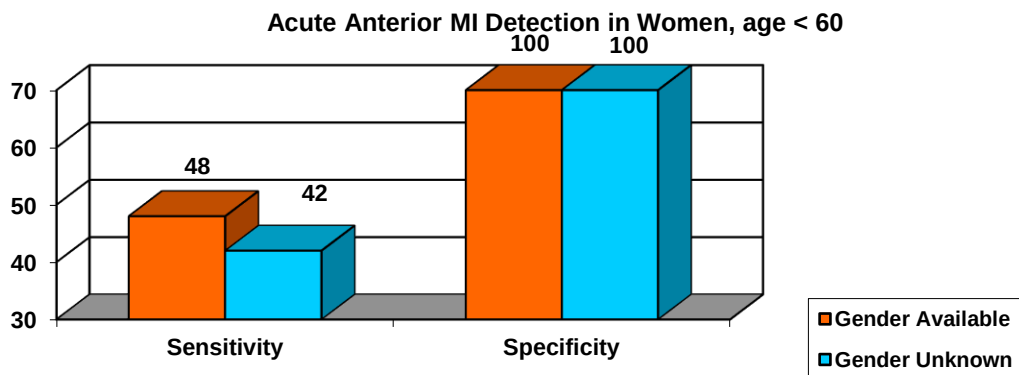
Representative test population:		Emergency Department		
Additional demographic data:		Specific ages, gender and race are unavailable.		
Total number of test ECGs:		75		
Method(s) used to verify diagnosis:		Consensus of 3 Cardiologists		
Verified Diagnosis	N	Sensitivity (%)	Specificity (%)	PPA (%)
STEMI	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, 307 μ V for females versus 432 μ V for males, P value < .007). Over age 60 years, this difference becomes less pronounced (lead V2 STE average, 336 μ V for females versus 421 μ V 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 μ V 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 μ V 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 μ V in lead V4r is a highly specific indicator of right ventricular involvement in the presence of acute inferior infarction. A threshold of 100 μ V 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 μ V 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 μ V, 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

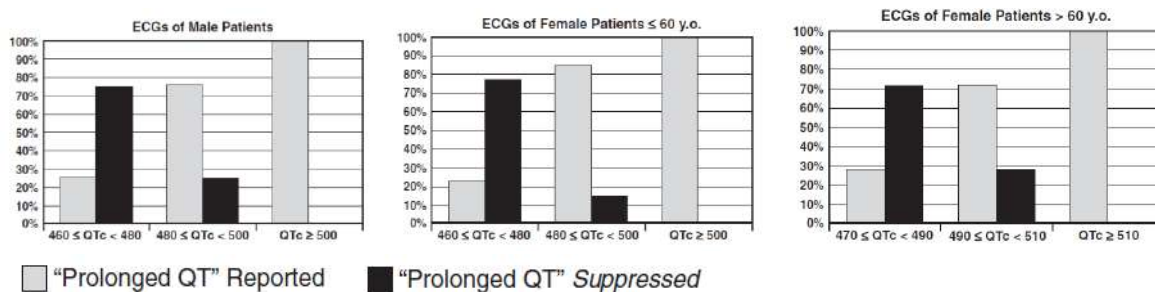
Due to the increased interest in early repolarization (ER) and whether it is predictive of sudden cardiac death, studies have evaluated the accuracy of ER as identified via 12SL. "To ensure diagnostic accuracy, a subset of 2,200 randomly selected electrocardiograms were carefully examined manually. The 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 than 16,000 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), Teleded 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	Junctional 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	DPCCK	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	NSTD LDS	** 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-INV	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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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-INT	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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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 Advisor¹	12SL²	Serial Comparison³	Class⁴
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	NSTD LDS	** Nonstandard lead placement, ECG interpretation not available **		X		N
1680	PO	Possible		X	X	N

Code	MUSE Acronym	Text - English	Hookup Advisor¹	12SL²	Serial Comparison³	Class⁴
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

<i>Item</i>	<i>Value</i>	<i>Description</i>
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

<i>Item</i>	<i>Value</i>	<i>Description</i>
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

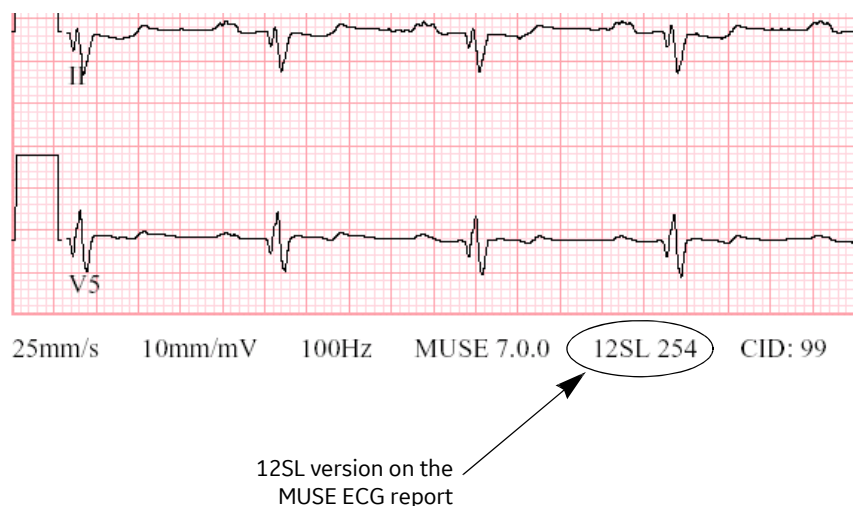
Duration in milliseconds

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		

Bibliography

1. *International Standard IEC 60601-2-51:2003 Medical electrical equipment. Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs*, I.E.C. (IEC), Editor. 2003, International Electrotechnical Commission (IEC). p. 86.
2. Burch, G.E. and N.P. De-Pasquale, *A History of Electrocardiography*. 1964, Chicago: Year Book Medical Publishers. 309.
3. Pipberger, H.V., R.A. Dunn, and A.S. Berson, *Computer methods in electrocardiography*. Annu Rev Biophys Bioeng, 1975. **4**(00): p. 15-42.
4. Kligfield, P., et al., *Comparison of automated interval measurements by widely used algorithms in digital electrocardiographs*. American Heart Journal, 2018.
5. Macfarlane, P.W., et al., *Comprehensive Electrocardiology*. 2010: Springer London.
6. Carel, R.S., *Cost-effectiveness analysis of computerized ECG interpretation system in an ambulatory health care organization*. J Med Syst, 1982. **6**(2): p. 121-30.
7. Schläpfer, J. and H.J. Wellens, *Computer-Interpreted Electrocardiograms: Benefits and Limitations*. Journal of the American College of Cardiology, 2017. **70**(9): p. 1183-1192.
8. Welch, R.D., et al., *Prognostic value of a normal or nonspecific initial electrocardiogram in acute myocardial infarction*. Jama, 2001. **286**(16): p. 1977-84.
9. Pelliccia, A., et al., *Clinical Significance of Abnormal Electrocardiographic Patterns in Trained Athletes*. Circulation, 2000. **102**(3): p. 278-284.
10. Hill, A.C., et al., *Accuracy of interpretation of preparticipation screening electrocardiograms*. J Pediatr, 2011. **159**(5): p. 783-8.
11. Rowlandson, I., *Computerized electrocardiography. A historical perspective*. Ann N Y Acad Sci, 1990. **601**: p. 343-52.
12. Rautaharju, P.M., *Eyewitness to history: Landmarks in the development of computerized electrocardiography*. Journal of Electrocardiology, 2016. **49**(1): p. 1-6.
13. Rowlandson, I., *Strategy for Serial Comparison*. Proceedings of the 1986 Engineering Foundation Conference, Computerized Interpretation of the Electrocardiogram XI. New York: Engineering Foundation., 1986: p. 106-109.
14. Rowlandson, I., *New Techniques in Criteria Development*. Proceedings of the 1985 Engineering Foundation Conference, Computerized Interpretation of the Electrocardiogram X, 1985(New York: Engineering Foundation 1985): p. 177-184.
15. Drazen, E., et al., *Survey of computer-assisted electrocardiography in the United States*. J Electrocardiol, 1988. **21 Suppl**: p. S98-104.
16. Reddy, B.R., D.W. Christenson, and G.I. Rowlandson, *High-resolution ECG on a standard ECG cart*. J Electrocardiol, 1988. **21 Suppl**: p. S74-9.
17. Rowlandson, I., P.J. Kudenchuk, and P.P. Elko, *Computerized recognition of acute infarction. Criteria advances and test results*. J Electrocardiol, 1990. **23 Suppl**: p. 1-5.
18. *K903644 SERIES 1500 12-LEAD ANALYSIS OPTION - 510K*, 1991, U.S. Food and Drug Administration, Center for Devices and Radiological Health.
19. Reddy, B.R.S., et al., *Data compression for storage of resting ECGs digitized at 500 samples/second*. Biomed Instrum Technol, 1992. **26**(2): p. 133-49.
20. *K921669, MARQUETTE SL SERIES TRANSPORT REMOTE ACQUISITION - 510K*, in *U.S. Food and Drug Administration, Center for Devices and Radiological Health*. 1993.
21. Aufderheide, T.P., et al., *Test of the acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI) for prehospital use*. Ann Emerg Med, 1996. **27**(2): p. 193-8.
22. Aufderheide, T.P., et al., *QT dispersion and principal component analysis in prehospital patients with chest pain*. Computers in Cardiology, 1997: p. 665-668.
23. Xue, Q. and B.R. Reddy, *Clinical research workstation*, U.S.P. Office, Editor. 2002 GE Medical Systems Information Technologies, Inc. (Waukesha, WI): United States.
24. *K981024, QT DISPERSION AND T WAVE ANALYSIS PROGRAM (QT GUARD ANALYSIS SYSTEM)*, in *U.S. Food and Drug Administration, Center for Devices and Radiological Health*. 1998.

25. Xue, Q. and S. Reddy, *Algorithms for computerized QT analysis*. J Electrocardiol, 1998. **30 Suppl**: p. 181-6.
26. Reddy, B.R., et al., *Prospective evaluation of a microprocessor-assisted cardiac rhythm algorithm: results from one clinical center*. J Electrocardiol, 1998. **30 Suppl**: p. 28-33.
27. 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, 2001. **34 Suppl**: p. 229-34.
28. Taha, B. and S. Reddy, *Method and apparatus for automatically detecting and interpreting paced electrocardiograms*, U.S.P. Office, Editor. 2001, GE Medical Systems Information Technologies, Inc. (Waukesha, WI): United States.
29. Batchvarov, V., K. Hnatkova, and M. Malik, *Assessment of noise in digital electrocardiograms*. Pacing Clin Electrophysiol, 2002. **25**(4 Pt 1): p. 499-503.
30. Batchvarov, V., *Short and Long Term Reproducibility of the QT/RR Relationship in Healthy Subjects*. Journal of American College of Cardiology, 2001. **37**(2_Suppl_A): p. 1A-648A.
31. Batchvarov, V., *Bazett Formula is not Suitable for Assessment of the Circadian Variation of the Heart Rate Corrected QT Interval*. Journal of American College of Cardiology, 2001. **37**(2_Suppl_A): p. 1A-648A.
32. Hnatkova, K., et al., *Precision of QT Interval Measurement by Advanced Electrocardiographic Equipment*. Pacing Clin Electrophysiol, 2006. **29**(11): p. 1277-84.
33. Farrell, R. and B. Young, *Effect of Lead Quality on Computerized ECG Interpretation*. Computers in Cardiology, 2004. **31**: p. 173-176.
34. K042782, SEER MC, in U.S. Food and Drug Administration, Center for Devices and Radiological Health. 2005.
35. K060833, 12SL ECG ANALYSIS PROGRAM; *Computerized detection of right ventricular involvement in acute inferior myocardial infarction*, in U.S. Food and Drug Administration, Center for Devices and Radiological Health. 2006.
36. Ricke, A.D., et al., *Improved pacemaker pulse detection: clinical evaluation of a new high-bandwidth electrocardiographic system*. J Electrocardiol, 2011. **44**(2): p. 265-74.
37. Xue, J., et al., *Added value of new acute coronary syndrome computer algorithm for interpretation of prehospital electrocardiograms*. J Electrocardiol, 2004. **37 Suppl**: p. 233-9.
38. Graff, C., et al., *Identifying drug-induced repolarization abnormalities from distinct ECG patterns in congenital long QT syndrome: a study of sotalol effects on T-wave morphology*. Drug safety : an international journal of medical toxicology and drug experience, 2009. **32**(7): p. 599-611.
39. Graff, C., et al., *T-wave morphology reveals greater effect of d,l-sotalol than QTc*. Journal of Electrocardiology, 2008. **41**(6): p. 644.
40. Andersen, M.P., et al., *A Robust Method for Quantification of IKr-Related T-Wave Morphology Abnormalities*. Computers in Cardiology, 2007: p. 341-344.
41. Andersen, M.P., et al., *Repeatability of T-wave morphology measurements: superiority of a principal component analysis-based lead*. Journal of Electrocardiology, 2007. **40**(6): p. Pages S81-S81.
42. Graff, C., et al., *T-wave convexity measure outperforms notch criterion as diagnostic marker for the HERG genotype*. Journal of Electrocardiology, 2007. **40**(6S): p. S82-S83.
43. Haarmark, C., et al., *Independent novel T-wave descriptors of repolarization*. Journal of Electrocardiology, 2007. **40**: p. S131.
44. Graff, C., et al., *T-wave Morphology as a Covariate in Drug-induced QTc Prolongation*. Comput. Cardiol, 2009. **36**: p. 589-592.
45. Porta-Sánchez, A., et al., *T-Wave Morphology Analysis in Congenital Long QT Syndrome Discriminates Patients From Healthy Individuals*. JACC: Clinical Electrophysiology, 2016.
46. Xue, J., et al., *Study of repolarization heterogeneity and electrocardiographic morphology with a modeling approach*. Journal of Electrocardiology, 2008. **41**(6): p. 581-587.
47. Hancock, E.W., et al., *AHA/ACCF/HRS Recommendations for the Standardization and Interpretation of the Electrocardiogram: Part V: Electrocardiogram Changes Associated With Cardiac Chamber Hypertrophy A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society Endorsed by the International Society for Computerized Electrocardiology*. Journal of the American College of Cardiology, 2009: p. j.jacc.2008.12.015.
48. Priori, S.G., et al., *2015 ESC Guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death*. The Task Force for the Management of Patients with

- Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death of the European Society of Cardiology (ESC) Endorsed by: Association for European Paediatric and Congenital Cardiology (AEPC), 2015.
49. Okin, P.M., et al., *Combining ECG Criteria for Left Ventricular Hypertrophy Improves Risk Prediction in Patients With Hypertension*. Journal of the American Heart Association, 2017. **6**(11).
 50. Willems, J.L., et al., *A reference data base for multilead electrocardiographic computer measurement programs*. J Am Coll Cardiol, 1987. **10**(6): p. 1313-21.
 51. Kligfield, P., et al., *Recommendations for the Standardization and Interpretation of the Electrocardiogram. Part I: The Electrocardiogram and Its Technology. A Scientific Statement From the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology*. Circulation, 2007.
 52. ANSI/AAMI, *Diagnostic electrocardiographic devices*, EC11:1991/(R)2001, Editor. 1992. p. 39.
 53. Ricke, A. and G.I. Rowlandson, *System and method of detecting and diagnosing pacing system malfunctions* US Patent: 7,970,472. 2011, General Electric Company (Schenectady, NY) United States.
 54. Ricke, A. and G.I. Rowlandson, *Module and device for discerning therapeutic signals from noise in physiological data* US Patent: 8,170,655. 2012, General Electric Company (Schenectady, NY) United States.
 55. Ricke, A.D., et al., *The relationship between programmed pacemaker pulse amplitude and the surface electrocardiogram recorded amplitude: application of a new high-bandwidth electrocardiogram system*. Journal of Electrocardiology, 2008. **41**(6): p. 526-530.
 56. Petrutiu, S., et al., *High Resolution Electrocardiography Optimised for Recording Pulses from Electronic Pacemakers: Evaluation of a New Pacemaker Sensing System*, in *Computers in Cardiology*. 2007, IEEE: Durham, North Carolina, USA.
 57. Ricke, A., et al., *Advanced pacemaker detection*. Journal of Electrocardiology, 2007. **40**(6, Supplement 1): p. S33-S33.
 58. Wiese, S.R., et al., *Electrocardiographic motion artifact versus electrode impedance*. IEEE Trans Biomed Eng, 2005. **52**(1): p. 136-9.
 59. Farrell, R.M. and G.I. Rowlandson, *The effects of noise on computerized electrocardiogram measurements*. J Electrocardiol, 2006. **39**(4 Suppl): p. S165-73.
 60. Farrell, R.M., et al., *Effects of limb electrode placement on the 12- and 16-lead electrocardiogram*. J Electrocardiol, 2008. **41**(6): p. 536-545.
 61. Zema, M.J., et al., *Electrocardiographic poor R wave progression III. The normal variant*. J Electrocardiol, 1980. **13**(2): p. 135-42.
 62. Kania, M., et al., *The effect of precordial lead displacement on ECG morphology*. Medical & Biological Engineering & Computing, 2014. **52**(2): p. 109-119.
 63. Welinder, A., et al., *Differences in QRS Axis Measurements, Classification of Inferior Myocardial Infarction, and Noise Tolerance for 12-Lead Electrocardiograms Acquired From Monitoring Electrode Positions Compared to Standard Locations*. Am J Cardiol, 2010. **106**(4): p. 581-586.
 64. Drew, B.J., M.M. Pelter, and M.G. Adams, *Frequency, characteristics, and clinical significance of transient ST segment elevation in patients with acute coronary syndromes*. Eur Heart J, 2002. **23**(12): p. 941-7.
 65. Fesmire, F.M., *Which chest pain patients potentially benefit from continuous 12-lead ST-segment monitoring with automated serial ECG?* Am J Emerg Med, 2000. **18**(7): p. 773-8.
 66. Takasugi, N., et al., *Continuous T-wave alternans monitoring to predict impending life-threatening cardiac arrhythmias during emergent coronary reperfusion therapy in patients with acute coronary syndrome*. Europace, 2011.
 67. Zairis, M.N., et al., *Continuous 12-lead electrocardiographic ST monitoring adds prognostic information to the thrombolysis in myocardial infarction risk score in patients with non-ST-elevation acute coronary syndromes*. Clin Cardiol, 2005. **28**(4): p. 189-92.
 68. Sarapa, N., et al., *Electrocardiographic identification of drug-induced QT prolongation: assessment by different recording and measurement methods*. Ann Noninvasive Electrocardiol, 2004. **9**(1): p. 48-57.
 69. Nof, E., W.G. Stevenson, and R.M. John, *Catheter Ablation for Ventricular Arrhythmias*. Arrhythmia & Electrophysiology Review, 2013. **2**(1): p. 45-52.

70. Van Den Hoogen, J.P., et al., *Reproducibility of electrocardiographic criteria for left ventricular hypertrophy in hypertensive patients in general practice*. Eur Heart J, 1992. **13**(12): p. 1606-10.
71. Farb, A., R.B. Devereux, and P. Kligfield, *Day-to-day variability of voltage measurements used in electrocardiographic criteria for left ventricular hypertrophy*. J Am Coll Cardiol, 1990. **15**(3): p. 618-23.
72. Willems, J.L., P.F. Poblete, and H.V. Pipberger, *Day-to-day variation of the normal orthogonal electrocardiogram and vectorcardiogram*. Circulation, 1972. **45**(5): p. 1057-64.
73. Schijvenaars, B.J.A., et al., *Effect of electrode positioning on ECG interpretation by computer*. Journal of Electrocardiology, 1997. **30**(3): p. 247-256.
74. Schijvenaars, B.J., G. van Herpen, and J.A. Kors, *Intraindividual variability in electrocardiograms*. J Electrocardiol, 2008. **41**(3): p. 190-6.
75. Okin, P.M., et al., *All-cause and cardiovascular mortality in relation to changing heart rate during treatment of hypertensive patients with electrocardiographic left ventricular hypertrophy*. Eur Heart J, 2010.
76. Okin, P.M., et al., *Incidence of heart failure in relation to QRS duration during antihypertensive therapy: the LIFE study*. J Hypertens, 2009.
77. Jongh, M.C.d., et al. *Serial ECG analysis after myocardial infarction: When heart failure develops, the ECG becomes increasingly discordant*. in 2016 Computing in Cardiology Conference (CinC). 2016.
78. Shamim, W., et al., *Incremental changes in QRS duration in serial ECGs over time identify high risk elderly patients with heart failure*. Heart, 2002. **88**(1): p. 47-51.
79. Wenger, W. and P. Kligfield, *Variability of precordial electrode placement during routine electrocardiography*. J Electrocardiol, 1996. **29**(3): p. 179-84.
80. Garcia-Niebla, J., et al., *Technical mistakes during the acquisition of the electrocardiogram*. Ann Noninvasive Electrocardiol, 2009. **14**(4): p. 389-403.
81. Thaler, T., et al., *The frequency of electrocardiographic errors due to electrode cable switches: a before and after study*. Journal of Electrocardiology, 2010. **43**(6): p. 676-681.
82. Campbell, B., et al., *Clinical Guidelines by Consensus: Recording a standard 12-lead electrocardiogram. An approved method by the Society for Cardiological Science and Technology (SCST) 2017*. , in *Resting ECG*, S.f.C.S.T. (SCST), Editor. 2017, SCST.
83. Mond, H.G. and A. Proclemer, *The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009--a World Society of Arrhythmia's project*. Pacing Clin Electrophysiol, 2011. **34**(8): p. 1013-27.
84. Zanon, F., et al., *Multipoint pacing by a left ventricular quadripolar lead improves the acute hemodynamic response to CRT compared with conventional biventricular pacing at any site*. Heart Rhythm, 2015. **12**(5): p. 975-81.
85. Mulpuru, S.K., et al., *Cardiac Pacemakers: Function, Troubleshooting, and Management*. Part 1 of a 2-Part Series, 2017. **69**(2): p. 189-210.
86. AAMI/ANSI/ISO 60601-2-27:2011, *Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*, I.E.C. (IEC), Editor. 2011, International Electrotechnical Commission (IEC).
87. Chien, C.H.S., et al., *A software algorithm for detection of biventricular pacemaker pulses in the surface ECG*. Journal of Electrocardiology, 2013. **46**(6): p. 622-623.
88. Poon, K., P.M. Okin, and P. Kligfield, *Diagnostic performance of a computer-based ECG rhythm algorithm*. J Electrocardiol, 2005. **38**(3): p. 235-8.
89. Guglin, M.E. and N. Datwani, *Electrocardiograms with pacemakers: accuracy of computer reading*. Journal of Electrocardiology, 2007. **40**(2): p. 144-146.
90. Kenny, T., *The Nuts and bolts of Paced ECG Interpretation*. 2011: Wiley.
91. Bogun, F., et al., *Misdiagnosis of atrial fibrillation and its clinical consequences*. Am J Med, 2004. **117**(9): p. 636-42.
92. ANSI/AAMI/ISO 60601-2-25:2011 *Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs*, I.E.C. (IEC), Editor. 2011, International Electrotechnical Commission (IEC).
93. Bailey, J.J., et al., *Recommendations for standardization and specifications in automated electrocardiography: bandwidth and digital signal processing. A report for health professionals by an ad hoc writing group of the Committee on Electrocardiography and Cardiac Electrophysiology of the Council on Clinical Cardiology, American Heart Association*. Circulation, 1990. **81**(2): p. 730-9.

94. Tayler, D.I. and R. Vincent, *Artefactual ST segment abnormalities due to electrocardiograph design*. Br Heart J, 1985. **54**(2): p. 121-8.
95. Das, M.K., et al., *Significance of a fragmented QRS complex versus a Q wave in patients with coronary artery disease*. Circulation, 2006. **113**(21): p. 2495-501.
96. Strauss, D.G., R.H. Selvester, and G.S. Wagner, *Defining left bundle branch block in the era of cardiac resynchronization therapy*. The American Journal of Cardiology, 2011. **107**(6): p. 927-34.
97. Ahlstrom, M.L. and W.J. Tompkins, *Digital filters for real-time ECG signal processing using microprocessors*. IEEE Trans Biomed Eng, 1985. **32**(9): p. 708-13.
98. Albulbul, A., *Evaluating Major Electrode Types for Idle Biological Signal Measurements for Modern Medical Technology*. Bioengineering (Basel), 2016. **3**(3).
99. Burri, H., H. Sunthorn, and D. Shah, *Simulation of anteroseptal myocardial infarction by electrocardiographic filters*. J Electrocardiol, 2006. **39**(3): p. 253-8.
100. Buendia-Fuentes, F., et al., *High-Bandpass Filters in Electrocardiography: Source of Error in the Interpretation of the ST Segment*. ISRN Cardiol, 2012. **2012**: p. 706217.
101. Rijnbeek, P.R., J.A. Kors, and M. Witsenburg, *Minimum bandwidth requirements for recording of pediatric electrocardiograms*. Circulation, 2001. **104**(25): p. 3087-90.
102. Rijnbeek, P.R., et al., *Electrocardiographic criteria for left ventricular hypertrophy in children*. Pediatr Cardiol, 2008. **29**(5): p. 923-8.
103. Venkatachalam, K.L., J.E. Herbrandson, and S.J. Asirvatham, *Signals and Signal Processing for the Electrophysiologist. Part I: Electrogram Acquisition*, 2011. **4**(6): p. 965-973.
104. Slocum, J., et al., *Computer detection of atrioventricular dissociation from surface electrocardiograms during wide QRS complex tachycardias*. Circulation, 1985. **72**(5): p. 1028-36.
105. Reddy, B.R., P. Elko, and S. Swiryn. *A new arrhythmia analysis program, MAC-RHYTHM, for resting ECG*. in *International Congress on Electrocardiology*. 1996. Singapore.
106. Farrell, R., J. Xue, and B. Young, *Enhanced Rhythm Analysis for Resting ECG Using Spectral and Time-Domain Techniques*. Computers in Cardiology, 2003. **30**: p. 733-736.
107. Kumar, A. and C.P. Cannon, *Acute coronary syndromes: diagnosis and management, part I*. Mayo Clin Proc, 2009. **84**(10): p. 917-38.
108. Mokhtari, A., et al., *Diagnostic values of chest pain history, ECG, troponin and clinical gestalt in patients with chest pain and potential acute coronary syndrome assessed in the emergency department*. SpringerPlus, 2015. **4**: p. 219-219.
109. Scirica, B.M., *Acute Coronary Syndrome: Emerging Tools for Diagnosis and Risk Assessment*. Journal of the American College of Cardiology, 2010. **55**(14): p. 1403-1415.
110. Rokos, I.C., et al., *Appropriate cardiac cath lab activation: optimizing electrocardiogram interpretation and clinical decision-making for acute ST-elevation myocardial infarction*. Am Heart J, 2010. **160**(6): p. 995-1003, 1003 e1-8.
111. Larson, D.M., et al., *"False-Positive" Cardiac Catheterization Laboratory Activation Among Patients With Suspected ST-Segment Elevation Myocardial Infarction*. JAMA, 2007. **298**(23): p. 2754-2760.
112. Kushner, F.G., et al., *2009 focused updates: ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction (updating the 2004 guideline and 2007 focused update) and ACC/AHA/SCAI guidelines on percutaneous coronary intervention (updating the 2005 guideline and 2007 focused update) a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines*. J Am Coll Cardiol, 2009. **54**(23): p. 2205-41.
113. Ibanez, B., et al., *2017 ESC Guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation; The Task Force for the management of acute myocardial infarction in patients presenting with ST-segment elevation of the European Society of Cardiology (ESC)*. European Heart Journal, 2018. **39**(2): p. 119-177.
114. Neumar, R.W., et al., *Part 1: Executive Summary: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*. Circulation, 2015. **132**(18 Suppl 2): p. S315-67.
115. Roffi, M., et al., *2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC)*, 2016. **37**(3): p. 267-315.

116. Quinn, T., et al., *Effects of prehospital 12-lead ECG on processes of care and mortality in acute coronary syndrome: a linked cohort study from the Myocardial Ischaemia National Audit Project*. Heart, 2014. **100**(12): p. 944-950.
117. Yiadom, M.Y.A.B., et al., *Performance of Emergency Department Screening Criteria for an Early ECG to Identify ST-Segment Elevation Myocardial Infarction*. Journal of the American Heart Association, 2017. **6**(3): p. e003528.
118. Yiadom, M., et al., *Measuring outcome differences associated with STEMI screening and diagnostic performance: a multicentred retrospective cohort study protocol*. BMJ Open, 2018. **8**(5): p. e022453.
119. Peterson, E.D., et al., *A call to ACTION (acute coronary treatment and intervention outcomes network): a national effort to promote timely clinical feedback and support continuous quality improvement for acute myocardial infarction*. Circulation. Cardiovascular quality and outcomes, 2009. **2**(5): p. 491-9.
120. Peterson, E.D., et al., *The NCDR ACTION Registry-GWTG: transforming contemporary acute myocardial infarction clinical care*. Heart, 2010. **96**(22): p. 1798-802.
121. Phelan, M.P., et al., *Improving emergency department door-to-electrocardiogram time in ST segment elevation myocardial infarction*. Crit Pathw Cardiol, 2009. **8**(3): p. 119-21.
122. Jneid, H., et al., *2017 AHA/ACC Clinical Performance and Quality Measures for Adults With ST-Elevation and Non-ST-Elevation Myocardial Infarction*. A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures, 2017. **70**(16): p. 2048-2090.
123. Kudenchuk, P.J., et al., *Accuracy of computer-interpreted electrocardiography in selecting patients for thrombolytic therapy*. MITI Project Investigators. J Am Coll Cardiol, 1991. **17**(7): p. 1486-91.
124. Shah, A.S.V., et al., *High-sensitivity troponin in the evaluation of patients with suspected acute coronary syndrome: a stepped-wedge, cluster-randomised controlled trial*. Lancet, 2018. **392**(10151): p. 919-928.
125. Park, K.C., et al., *Cardiac troponins: from myocardial infarction to chronic disease*. Cardiovascular research, 2017. **113**(14): p. 1708-1718.
126. Cervellin, G., et al., *Diagnostic algorithms for acute coronary syndrome-is one better than another?* Annals of translational medicine, 2016. **4**(10): p. 193-193.
127. Twerenbold, R., et al., *Clinical Use of High-Sensitivity Cardiac Troponin in Patients With Suspected Myocardial Infarction*. Journal of the American College of Cardiology, 2017. **70**(8): p. 996-1012.
128. P, R. and K. K., *National Hospital Ambulatory Medical Care Survey: 2015 emergency department summary tables; Available from: http://www.cdc.gov/nchs/data/ahcd/nhamcs_emergency/2015_ed_web_tables.pdf*. 2015, National Center for Health Statistics.
129. Pitts, S., et al., *National Hospital Ambulatory Medical Care Survey: 2006 emergency department summary*, in *National health statistics reports; no 7*. 2008, National Center for Health Statistics: Hyattsville, MD.
130. Naouri, D., et al., *The French Emergency National Survey: A description of emergency departments and patients in France*. PLoS One, 2018. **13**(6): p. e0198474.
131. Ko, M., et al., *Prevalence of and Predictors for Frequent Utilization of Emergency Department: A Population-Based Study*. Medicine, 2015. **94**(29): p. e1205-e1205.
132. Mol, K.A., et al., *Non-cardiac chest pain: prognosis and secondary healthcare utilisation*. Open Heart, 2018. **5**(2).
133. Van Severen, E., et al., *How do patients with chest pain access Emergency Department care?* European journal of emergency medicine : official journal of the European Society for Emergency Medicine, 2017. **24**(6): p. 423-427.
134. Münzel, T. and G. Heusch, *Chest Pain Unit Network in Germany: Its Effect on Patients With Acute Coronary Syndromes*. Journal of the American College of Cardiology, 2017. **69**(19): p. 2459-2460.
135. Graff, L., et al., *Triage of patients for a rapid (5-minute) electrocardiogram: A rule based on presenting chief complaints*. Ann Emerg Med, 2000. **36**(6): p. 554-60.
136. Svensson, L., et al., *Elevation of biochemical markers for myocardial damage prior to hospital admission in patients with acute chest pain or other symptoms raising suspicion of acute coronary syndrome*. J Intern Med, 2003. **253**(3): p. 311-9.

137. Pope, J.H., et al., *Missed diagnoses of acute cardiac ischemia in the emergency department*. N Engl J Med, 2000. **342**(16): p. 1163-70.
138. Moy, E., et al., *Missed diagnoses of acute myocardial infarction in the emergency department: variation by patient and facility characteristics*. Diagnosis (Berl), 2015. **2**(1): p. 29-40.
139. Wilson, M., et al., *Hospital and emergency department factors associated with variations in missed diagnosis and costs for patients age 65 years and older with acute myocardial infarction who present to emergency departments*. Acad Emerg Med, 2014. **21**(10): p. 1101-8.
140. Westfall, J.M., et al., *Triage and diagnosis of chest pain in rural hospitals: implementation of the ACL-TIPI in the High Plains Research Network*. Ann Fam Med, 2006. **4**(2): p. 153-8.
141. Bruyninckx, R., et al., *Signs and symptoms in diagnosing acute myocardial infarction and acute coronary syndrome: a diagnostic meta-analysis*. The British journal of general practice : the journal of the Royal College of General Practitioners, 2008. **58**(547): p. 105-111.
142. Hollander, J.E., M. Than, and C. Mueller, *State-of-the-Art Evaluation of Emergency Department Patients Presenting With Potential Acute Coronary Syndromes*. Circulation, 2016. **134**(7): p. 547-564.
143. Amsterdam, E.A., et al., *2014 AHA/ACC Guideline for the Management of Patients With Non-ST-Elevation Acute Coronary Syndromes: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines*. Circulation, 2014.
144. Julicher, P., et al., *The organisational value of diagnostic strategies using high-sensitivity troponin for patients with possible acute coronary syndromes: a trial-based cost-effectiveness analysis*. BMJ Open, 2017. **7**(6): p. e013653.
145. Forberg, J.L., et al., *Direct hospital costs of chest pain patients attending the emergency department: a retrospective study*. BMC emergency medicine, 2006. **6**: p. 6-6.
146. Westfall, J.M. and J. McGloin, *Impact of double counting and transfer bias on estimated rates and outcomes of acute myocardial infarction*. Med Care, 2001. **39**(5): p. 459-68.
147. Ornato, J.P., *Chest pain emergency centers: improving acute myocardial infarction care*. Clin Cardiol, 1999. **22**(8 Suppl): p. IV3-9.
148. Rusnak, R.A., et al., *Litigation against the emergency physician: common features in cases of missed myocardial infarction*. Ann Emerg Med, 1989. **18**(10): p. 1029-34.
149. Barstow, C., M. Rice, and J.D. McDivitt, *Acute Coronary Syndrome: Diagnostic Evaluation*. Am Fam Physician, 2017. **95**(3): p. 170-177.
150. Biesemans, L., et al., *Managing chest pain patients in general practice: an interview-based study*. BMC family practice, 2018. **19**(1): p. 80-80.
151. Sequist, T.D., et al., *Missed opportunities in the primary care management of early acute ischemic heart disease*. Arch Intern Med, 2006. **166**(20): p. 2237-43.
152. Kentsch, M., et al., *Factors predisposing to a nonadmission of patients with acute myocardial infarction*. Cardiology, 2002. **98**(1-2): p. 75-80.
153. Masoudi, F.A., et al., *Implications of the failure to identify high-risk electrocardiogram findings for the quality of care of patients with acute myocardial infarction: results of the Emergency Department Quality in Myocardial Infarction (EDQMI) study*. Circulation, 2006. **114**(15): p. 1565-71.
154. Cheng, C.I., et al., *Comparison of baseline characteristics, clinical features, angiographic results, and early outcomes in men vs women with acute myocardial infarction undergoing primary coronary intervention*. Chest, 2004. **126**(1): p. 47-53.
155. Lundberg, V., et al., *Exploring sex differences in case fatality in acute myocardial infarction or coronary death events in the northern Sweden MONICA Project*. J Intern Med, 2002. **251**(3): p. 235-44.
156. Glaser, R., et al., *Benefit of an Early Invasive Management Strategy in Women With Acute Coronary Syndromes*. JAMA, 2002. **288**(24): p. 3124-3129.
157. Coronado, B.E., et al., *Hospital mortality in women and men with acute cardiac ischemia: a prospective multicenter study*. J Am Coll Cardiol, 1997. **29**(7): p. 1490-6.
158. de Gevigney, G., et al., *Are women with acute myocardial infarction managed as well as men? Does it have consequences on in-hospital mortality? Analysis of an unselected cohort of 801 women and 1,718 men*. Acta Cardiol, 2001. **56**(3): p. 169-79.
159. Mahon, N.G., et al., *Gender differences in the management and outcome of acute myocardial infarction in unselected patients in the thrombolytic era*. Am J Cardiol, 2000. **85**(8): p. 921-6.

160. Vaccarino, V., et al., *Sex and racial differences in the management of acute myocardial infarction, 1994 through 2002*. N Engl J Med, 2005. **353**(7): p. 671-82.
161. Chandrasekhar, J., A. Gill, and R. Mehran, *Acute myocardial infarction in young women: current perspectives*. International journal of women's health, 2018. **10**: p. 267-284.
162. Anderson, R.D. and C.J. Pepine, *Gender differences in the treatment for acute myocardial infarction: bias or biology?* Circulation, 2007. **115**(7): p. 823-6.
163. Lee, T.H., et al., *Impact of the availability of a prior electrocardiogram on the triage of the patient with acute chest pain*. J Gen Intern Med, 1990. **5**(5): p. 381-8.
164. Fesmire, F.M., R.F. Percy, and R.L. Wears, *Diagnostic and prognostic importance of comparing the initial to the previous electrocardiogram in patients admitted for suspected acute myocardial infarction*. South Med J, 1991. **84**(7): p. 841-6.
165. Grim, P., et al., *Cellular telephone transmission of 12-lead electrocardiograms from ambulance to hospital*. Am J Cardiol, 1987. **60**(8): p. 715-20.
166. Weaver, W.D., et al., *Myocardial Infarction Triage and Intervention Project--phase I: patient characteristics and feasibility of prehospital initiation of thrombolytic therapy*. J Am Coll Cardiol, 1990. **15**(5): p. 925-31.
167. 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. **118**(10): p. 1066-79.
168. Scholz, K.H., et al., *Impact of treatment delay on mortality in ST-segment elevation myocardial infarction (STEMI) patients presenting with and without haemodynamic instability: results from the German prospective, multicentre FITT-STEMI trial*. European Heart Journal, 2018. **39**(13): p. 1065-1074.
169. *National Hospital Ambulatory Medical Care Survey: 2008 emergency department summary tables*. 2008, National Center for Health Statistics: Hyattsville, MD.
170. Kainth, A., et al., *Systematic review of interventions to reduce delay in patients with suspected heart attack*. Emergency Medicine Journal, 2004. **21**(4): p. 506-508.
171. de Champlain, F., et al., *Computerized interpretation of the prehospital electrocardiogram: predictive value for ST segment elevation myocardial infarction and impact on on-scene time*. CJEM, 2014. **16**(2): p. 94-105.
172. Potter, B.J., et al., *Performance of a New "Physician-Less" Automated System of Prehospital ST-Segment Elevation Myocardial Infarction Diagnosis and Catheterization Laboratory Activation*. The American Journal of Cardiology, 2013.
173. Hughes, K.E., et al., *Safety of Computer Interpretation of Normal Triage Electrocardiograms*. Acad Emerg Med, 2017. **24**(1): p. 120-124.
174. Menown, I.B., G. Mackenzie, and A.A. Adgey, *Optimizing the initial 12-lead electrocardiographic diagnosis of acute myocardial infarction*. Eur Heart J, 2000. **21**(4): p. 275-83.
175. Denktas, A.E., et al., *Reduced-dose fibrinolytic acceleration of ST-segment elevation myocardial infarction treatment coupled with urgent percutaneous coronary intervention compared to primary percutaneous coronary intervention alone results of the AMICO (Alliance for Myocardial Infarction Care Optimization) Registry*. JACC Cardiovasc Interv, 2008. **1**(5): p. 504-10.
176. Macfarlane, P.W., et al., *Modification of ACC/ESC criteria for acute myocardial infarction*. Journal of Electrocardiology, 2004. **37**(Supplement 1): p. 98-103.
177. Wang, K., R.W. Asinger, and H.J. Marriott, *ST-segment elevation in conditions other than acute myocardial infarction*. N Engl J Med, 2003. **349**(22): p. 2128-35.
178. Tikkanen, J.T., et al., *Early repolarization: electrocardiographic phenotypes associated with favorable long-term outcome*. Circulation, 2011. **123**(23): p. 2666-73.
179. Brady, W.J., et al., *Electrocardiographic ST-segment Elevation: The Diagnosis of Acute Myocardial Infarction by Morphologic Analysis of the ST Segment*. Academic Emergency Medicine, 2001. **8**(10): p. 961-967.
180. Brady, W.J. and T.C. Chan, *Electrocardiographic manifestations: benign early repolarization*. Journal of Emergency Medicine, 1999. **17**(3): p. 473-478.
181. Engel, J., et al., *Electrocardiographic ST segment elevation: left ventricular aneurysm*. Am J Emerg Med, 2002. **20**(3): p. 238-42.

182. Brady, W.J., et al., *Reciprocal ST segment depression: impact on the electrocardiographic diagnosis of ST segment elevation acute myocardial infarction*. Am J Emerg Med, 2002. **20**(1): p. 35-8.
183. Otto, L.A. and T.P. Aufderheide, *Evaluation of ST segment elevation criteria for the prehospital electrocardiographic diagnosis fo acute myocardial infarction*. Ann Emerg Med, 1994. **23**(1): p. 17-24.
184. Nour, M.K., *Significance of reciprocal ST segment depression in ST elevation myocardial infarction*. The Egyptian Journal of Critical Care Medicine, 2017. **5**(1): p. 23-27.
185. Kozuch, M., et al., *Lack of ST-segment depression normalization after PCI is a predictor of 5-year mortality in patients with ST-elevation myocardial infarction*. Circ J, 2007. **71**(12): p. 1851-6.
186. McCabe, J.M., et al., *Prevalence and factors associated with false-positive ST-segment elevation myocardial infarction diagnoses at primary percutaneous coronary intervention-capable centers: a report from the Activate-SF registry*. Arch Intern Med, 2012. **172**(11): p. 864-71.
187. Shamim, S., et al., *Electrocardiographic findings resulting in inappropriate cardiac catheterization laboratory activation for ST-segment elevation myocardial infarction*. Cardiovascular Diagnosis and Therapy, 2014. **4**(3): p. 215-223.
188. Garvey, J.L., et al., *Rates of cardiac catheterization cancelation for ST-segment elevation myocardial infarction after activation by emergency medical services or emergency physicians: results from the North Carolina Catheterization Laboratory Activation Registry*. Circulation, 2012. **125**(2): p. 308-13.
189. Brady, W.J., et al., *Cause of ST Segment Abnormality in ED chest pain patients*. The American Journal of Emergency Medicine, 2001. **19**(1): p. 25-28.
190. Brady, W.J., et al., *ECG patterns confounding the ECG diagnosis of acute coronary syndrome: left bundle branch block, right ventricular paced rhythms, and left ventricular hypertrophy*. Emerg Med Clin North Am, 2005. **23**(4): p. 999-1025.
191. Pozen, M.W., et al., *A predictive instrument to improve coronary-care-unit admission practices in acute ischemic heart disease. A prospective multicenter clinical trial*. N Engl J Med, 1984. **310**(20): p. 1273-8.
192. 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. **129**(11): p. 845-55.
193. Selker, H.P., et al., *Emergency medical service predictive instrument-aided diagnosis and treatment of acute coronary syndromes and ST-segment elevation myocardial infarction in the IMMEDIATE trial*. Prehosp Emerg Care, 2011. **15**(2): p. 139-48.
194. Ilgen, J.S., et al., *Prognostic utility of the acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI)*. International journal of emergency medicine, 2011. **4**(1): p. 49-49.
195. Mitchell, A.M., et al., *Prospective multicenter study of quantitative pretest probability assessment to exclude acute coronary syndrome for patients evaluated in emergency department chest pain units*. Ann Emerg Med, 2006. **47**(5): p. 447.
196. Aufderheide, T.P., et al., *Milwaukee Prehospital Chest Pain Project--phase I: feasibility and accuracy of prehospital thrombolytic candidate selection*. Am J Cardiol, 1992. **69**(12): p. 991-6.
197. Selker, H.P., R.B. D'Agostino, and M.M. Laks, *A predictive instrument for acute ischemic heart disease to improve coronary care unit admission practices: a potential on-line tool in a computerized electrocardiograph*. J Electrocardiol, 1988. **21 Suppl**: p. S11-7.
198. Antman, E.M., et al., *ACC/AHA guidelines for the management of patients with ST-elevation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction)*. Circulation, 2004. **110**(9): p. e82-292.
199. Braunwald, E., et al., *ACC/AHA guidelines for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients With Unstable Angina)*. J Am Coll Cardiol, 2000. **36**(3): p. 970-1062.
200. Anderson, J.L., et al., *ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non ST-Elevation Myocardial Infarction: Executive Summary. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the 2002 Guidelines for the Management of Patients With Unstable Angina/Non ST-Elevation Myocardial Infarction)*. Circulation, 2007.

201. Fesmire, F.M., et al., *Clinical policy: critical issues in the evaluation and management of adult patients with non-ST-segment elevation acute coronary syndromes*. Ann Emerg Med, 2006. **48**(3): p. 270-301.
202. Anderson, J.L., et al., *2011 ACCF/AHA Focused Update Incorporated Into the ACC/AHA 2007 Guidelines for the Management of Patients With Unstable Angina/Non-ST-Elevation Myocardial Infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines*. Circulation, 2011. **123**(18): p. e426-579.
203. Braunwald, E., et al., *ACC/AHA 2002 Guideline Update for the Management of Patients With Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients With Unstable Angina) (Full text)*. Circulation, 2002. **106**(14).
204. Angeli, F., et al., *Day-to-day variability of electrocardiographic diagnosis of left ventricular hypertrophy in hypertensive patients. Influence of electrode placement*. J Cardiovasc Med (Hagerstown), 2006. **7**(11): p. 812-6.
205. Jowett, N.I., et al., *Modified electrode placement must be recorded when performing 12-lead electrocardiograms*. Postgrad Med J, 2005. **81**(952): p. 122-5.
206. Drew, B.J., et al., *AHA scientific statement: practice standards for electrocardiographic monitoring in hospital settings: an American Heart Association Scientific Statement from the Councils on Cardiovascular Nursing, Clinical Cardiology, and Cardiovascular Disease in the Young: endorsed by the International Society of Computerized electrocardiology and the American Association of Critical-Care Nurses*. J Cardiovasc Nurs, 2005. **20**(2): p. 76-106.
207. Drew, B.J., et al., *Bedside diagnosis of myocardial ischemia with ST-segment monitoring technology: measurement issues for real-time clinical decision making and trial designs*. J Electrocardiol, 1998. **30 Suppl**: p. 157-65.
208. Kannel, W.B., *Silent myocardial ischemia and infarction: insights from the Framingham Study*. Cardiol Clin, 1986. **4**(4): p. 583-91.
209. *Marquette 12SL ECG Analysis Program Physician's Guide, 2036070-006 Revision A*. 2010, GE Healthcare: Milwaukee, WI.
210. Hollander, J.E., *High-Sensitivity Troponin: Time to Implement*. Annals of Emergency Medicine, 2018. **72**(6): p. 665-667.
211. Hamm, C.W., et al., *ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: The Task Force for the management of acute coronary syndromes (ACS) in patients presenting without persistent ST-segment elevation of the European Society of Cardiology (ESC)*. European Heart Journal, 2011. **32**(23): p. 2999-3054.
212. Bandstein, N., et al., *Undetectable High Sensitivity Cardiac Troponin T Level in the Emergency Department and Risk of Myocardial Infarction*. Journal of the American College of Cardiology, 2014.
213. Ambavane, A., et al., *Economic evaluation of the one-hour rule-out and rule-in algorithm for acute myocardial infarction using the high-sensitivity cardiac troponin T assay in the emergency department*. PLoS One, 2017. **12**(11): p. e0187662.
214. *High-Sensitivity Cardiac Troponin for the Rapid Diagnosis of Acute Coronary Syndrome in the Emergency Department: A Clinical and Cost-Effectiveness Evaluation*. 2013: Ottawa (ON).
215. Odqvist, M., et al., *High-Sensitivity Troponins and Outcomes After Myocardial Infarction*. Journal of the American College of Cardiology, 2018. **71**(23): p. 2616-2624.
216. Crevasse, L. and M. Ariet, *Clinical usefulness of computerized ECG systems*. J Med Syst, 1987. **11**(1): p. 21-4.
217. Saner, H., et al., *Comparison of 3 ECG computer programs with interpretation by physicians*. Schweiz Med Wochenschr, 1987. **117**(27-28): p. 1035-9.
218. Willems, J.L., et al., *The diagnostic performance of computer programs for the interpretation of electrocardiograms*. N Engl J Med, 1991. **325**(25): p. 1767-73.
219. Guglin, M.E. and D. Thatai, *Common errors in computer electrocardiogram interpretation*. Int J Cardiol, 2006. **106**(2): p. 232-7.
220. Swartz, M.H. and L.E. Teichholz, *Marquette 12SL ECG analysis program: evaluation of physician changes*. Computers in Cardiology, 1982: p. 437-440.
221. Brailer, D.J., E. Kroch, and M.V. Pauly, *The impact of computer-assisted test interpretation on physician decision making: the case of electrocardiograms*. Med Decis Making, 1997. **17**(1): p. 80-6.

222. Willems, J.L., et al., *Effect of combining electrocardiographic interpretation results on diagnostic accuracy*. Eur Heart J, 1988. **9**(12): p. 1348-55.
223. Salerno, S.M., P.C. Alguire, and H.S. Waxman, *Training and competency evaluation for interpretation of 12-lead electrocardiograms: recommendations from the American College of Physicians*. Ann Intern Med, 2003. **138**(9): p. 747-50.
224. Osei, F.A., et al., *Improving ECG Services at a Children's Hospital: Implementation of a Digital ECG System*. Int J Pediatr, 2015. **2015**: p. 697149.
225. Anh, D., S. Krishnan, and F. Bogun, *Accuracy of electrocardiogram interpretation by cardiologists in the setting of incorrect computer analysis*. J Electrocardiol, 2006. **39**(3): p. 343-5.
226. Woolley, D., M. Henck, and J. Luck, *Comparison of electrocardiogram interpretations by family physicians, a computer, and a cardiology service*. J Fam Pract, 1992. **34**(4): p. 428-32.
227. Snyder, C.S., et al., *The emergency department versus the computer: which is the better electrocardiographer?* Pediatr Cardiol, 2003. **24**(4): p. 364-8.
228. Goodacre, S., A. Webster, and F. Morris, *Do computer generated ECG reports improve interpretation by accident and emergency senior house officers?* Postgrad Med J, 2001. **77**(909): p. 455-7.
229. Aufderheide, T.P., et al., *A prospective evaluation of prehospital 12-lead ECG application in chest pain patients*. J Electrocardiol, 1992. **24 Suppl**: p. 8-13.
230. Kereiakes, D.J., et al., *Time delays in the diagnosis and treatment of acute myocardial infarction: a tale of eight cities. Report from the Pre-hospital Study Group and the Cincinnati Heart Project*. Am Heart J, 1990. **120**(4): p. 773-80.
231. Foster, D.B., et al., *Prehospital recognition of AMI using independent nurse/paramedic 12-lead ECG evaluation: impact on in-hospital times to thrombolysis in a rural community hospital*. Am J Emerg Med, 1994. **12**(1): p. 25-31.
232. Millar-Craig, M.W., et al., *Reduction in treatment delay by paramedic ECG diagnosis of myocardial infarction with direct CCU admission*. Heart, 1997. **78**(5): p. 456-61.
233. Aufderheide, T.P., et al., *The diagnostic impact of prehospital 12-lead electrocardiography*. Ann Emerg Med, 1990. **19**(11): p. 1280-7.
234. Jacobs, A.K., *Regional systems of care for patients with ST-elevation myocardial infarction: being at the right place at the right time*. Circulation, 2007. **116**(7): p. 689-92.
235. Clemmensen, P., et al., *Pre-hospital diagnosis and transfer of patients with acute myocardial infarction--a decade long experience from one of Europe's largest STEMI networks*. J Electrocardiol, 2013. **46**(6): p. 546-52.
236. Baran, K.W., et al., *Very Rapid Treatment of ST-Segment-Elevation Myocardial Infarction. Utilizing Prehospital Electrocardiograms to Bypass the Emergency Department*, 2010. **3**(4): p. 431-437.
237. Tubaro, M., et al., *Pre-hospital treatment of STEMI patients. A scientific statement of the Working Group Acute Cardiac Care of the European Society of Cardiology*. Acute Card Care, 2011. **13**(2): p. 56-67.
238. Brown, J.P., et al., *Effect of prehospital 12-lead electrocardiogram on activation of the cardiac catheterization laboratory and door-to-balloon time in ST-segment elevation acute myocardial infarction*. The American Journal of Cardiology, 2008. **101**(2): p. 158-61.
239. Kudenchuk, P.J., et al., *Utility of the prehospital electrocardiogram in diagnosing acute coronary syndromes: the Myocardial Infarction Triage and Intervention (MITI) Project*. J Am Coll Cardiol, 1998. **32**(1): p. 17-27.
240. Bhalla, M.C., et al., *Prehospital Electrocardiographic Computer Identification of ST-segment Elevation Myocardial Infarction*. Prehospital emergency care : official journal of the National Association of EMS Physicians and the National Association of State EMS Directors, 2012.
241. Cloutier, J., C. Hayes, and D. Allen, *REDUCING DOOR TO DEVICE TIME: THE POTENTIAL IMPACT OF COMPUTERIZED DIAGNOSIS OF ST-ELEVATION MYOCARDIAL INFARCTION AND AUTOMATED ACTIVATION OF THE CARDIAC CATHETERIZATION LAB*. Canadian Journal of Cardiology, 2017. **33**(10, Supplement): p. S82-S83.
242. Verbeek, P.R., et al., *Serial Prehospital 12-Lead Electrocardiograms Increase Identification of ST-segment Elevation Myocardial Infarction*. Prehosp Emerg Care, 2012. **16**(1): p. 109-14.
243. Graham, *User Evaluation of a Commercially Available Computerized Electrocardiographic Interpretation System*, in *Computer ECG analysis--towards standardization : proceedings of the IFIP-IMIA Working Conference on Computer ECG Analysis, Towards Standardization*, J.L. Willems, J.H. VanBemmel, and C. Zywiets, Editors. 1986. p. 399.

244. Froelicher, V., R. Marcus, and P. Heidenreich, *Prognostic Value of Computer Electrocardiography in Veteran Outpatients*. Fed Pract., 2004. **21**(3): p. 11-12, 17-20.
245. Magnani, J.W., et al., *P-wave Indices and Atrial Fibrillation: Cross-Cohort Assessments from the Framingham Heart Study and Atherosclerosis Risk in Communities Study*. American heart journal, 2015. **169**(1): p. 53-61.e1.
246. Soliman, E.Z., et al., *Reference ranges of PR duration and P-wave indices in individuals free of cardiovascular disease: the Multi-Ethnic Study of Atherosclerosis (MESA)*. Journal of electrocardiology, 2013. **46**(6): p. 10.1016/j.jelectrocard.2013.05.006.
247. Burke, G.M., et al., *Assessment of reproducibility--automated and digital caliper ECG measurement in the Framingham Heart Study*. Journal of electrocardiology, 2014. **47**(3): p. 288-293.
248. Vaidean, G.D., et al., *The association of spatial T wave axis deviation with incident coronary events. The ARIC cohort*. BMC Cardiovasc Disord, 2005. **5**(1): p. 2.
249. Rautaharju, P.M., et al., *Assessment of prolonged QT and JT intervals in ventricular conduction defects*. Am J Cardiol, 2004. **93**(8): p. 1017-21.
250. Zhang, Z.M., et al., *Comparison of the prognostic significance of the electrocardiographic QRS/T angles in predicting incident coronary heart disease and total mortality (from the atherosclerosis risk in communities study)*. Am J Cardiol, 2007. **100**(5): p. 844-9.
251. Deo, R., et al., *Electrocardiographic Measures and Prediction of Cardiovascular and Noncardiovascular Death in CKD*. Journal of the American Society of Nephrology, 2015.
252. Wang, Y.G., et al., *Automated J wave detection from digital 12-lead electrocardiogram*. J Electrocardiol, 2015. **48**(1): p. 21-8.
253. Soliman, E.Z. and P.M. Rautaharju, *Heart rate adjustment of PR interval in middle-aged and older adults*. J Electrocardiol, 2012. **45**(1): p. 66-9.
254. S ndergaard, M.M., et al., *Associations between common ECG abnormalities and out-of-hospital cardiac arrest*. Open Heart, 2019. **6**(1): p. e000905.
255. Tison, G.H., et al., *Automated and Interpretable Patient ECG Profiles for Disease Detection, Tracking, and Discovery*. Circulation: Cardiovascular Quality and Outcomes, 2019. **12**(9): p. e005289.
256. Aagaard, P., et al., *Prognostic value of automatically detected early repolarization*. Am J Cardiol, 2014. **114**(9): p. 1431-6.
257. Zhang, Z.-m., et al., *Prognostic significance of serial Q/ST-T changes by the Minnesota Code and Novacode in the Atherosclerosis Risk in Communities (ARIC) study*. European journal of preventive cardiology, 2012. **19**(6): p. 1430-1436.
258. Elias, P., et al., *The Prognostic Value of Electrocardiogram at Presentation to Emergency Department in Patients With COVID-19*. Mayo Clinic Proceedings, 2020. **95**(10): p. 2099-2109.
259. Pavri, B.B., et al., *Behavior of the PR interval with increasing heart rate in patients with COVID-19. Heart rhythm*, 2020. **17**(9): p. 1434-1438.
260. Ramireddy, A., et al., *Experience With Hydroxychloroquine and Azithromycin in the Coronavirus Disease 2019 Pandemic: Implications for QT Interval Monitoring*. Journal of the American Heart Association, 2020. **9**(12): p. e017144-e017144.
261. Becker, M.L., et al., *QTc Prolongation in COVID-19 Patients Using Chloroquine*. Cardiovascular toxicology, 2021. **21**(4): p. 314-321.
262. Polcwiartek, C., et al., *Association Between ECG Abnormalities and Fatal Cardiovascular Disease Among Patients With and Without Severe Mental Illness*. Journal of the American Heart Association, 2021. **10**(2): p. e019416-e019416.
263. Du, X., et al., *Atrial fibrillation prevalence, awareness and management in a nationwide survey of adults in China*. Heart, 2021. **107**(7): p. 535-541.
264. Attia, Z.I., et al., *An artificial intelligence-enabled ECG algorithm for the identification of patients with atrial fibrillation during sinus rhythm: a retrospective analysis of outcome prediction*. Lancet, 2019. **394**(10201): p. 861-867.
265. Attia, Z.I., et al., *Screening for cardiac contractile dysfunction using an artificial intelligence-enabled electrocardiogram*. Nature Medicine, 2019. **25**(1): p. 70-74.
266. Giudicessi John, R., et al., *Artificial Intelligence-Enabled Assessment of the Heart Rate Corrected QT Interval Using a Mobile Electrocardiogram Device*. Circulation, 2021. **143**(13): p. 1274-1286.
267. van de Leur, R.R., et al., *Discovering and Visualizing Disease-Specific Electrocardiogram Features Using Deep Learning: Proof-of-Concept in Phospholamban Gene Mutation Carriers*. Circulation. Arrhythmia and electrophysiology, 2021. **14**(2): p. e009056-e009056.

268. O'Neal, W.T., et al., *Electrocardiographic Predictors of Heart Failure With Reduced Versus Preserved Ejection Fraction: The Multi-Ethnic Study of Atherosclerosis*. Journal of the American Heart Association, 2017. **6**(6).
269. Zhang, Z.-m., et al., *Gender Differences Between the Minnesota Code and Novacode Electrocardiographic Prognostication of Coronary Heart Disease in the Cardiovascular Health Study*. The American journal of cardiology, 2011. **107**(6): p. 817-820.e1.
270. Kim, Y.G., et al., *ECG-ViEW II, a freely accessible electrocardiogram database*. PLoS One, 2017. **12**(4): p. e0176222.
271. Walsh, J.A., et al., *Prevalence of Electrocardiographic Abnormalities in a Middle-Aged, Biracial Population: Coronary Artery Risk Development in Young Adults (CARDIA) Study*. Journal of electrocardiology, 2010. **43**(5): p. 385.e1-385.e9.
272. Shah, A.P. and S.A. Rubin, *Errors in the computerized electrocardiogram interpretation of cardiac rhythm*. J Electrocardiol, 2007. **40**(5): p. 385-90.
273. Salerno, S.M., P.C. Alguire, and H.S. Waxman, *Competency in interpretation of 12-lead electrocardiograms: a summary and appraisal of published evidence*. Ann Intern Med, 2003. **138**(9): p. 751-60.
274. Tsai, T.L., D.B. Fridsma, and G. Gatti, *Computer decision support as a source of interpretation error: the case of electrocardiograms*. J Am Med Inform Assoc, 2003. **10**(5): p. 478-83.
275. Mawri, S., et al., *The comparison of physician to computer interpreted electrocardiograms on ST-elevation myocardial infarction door-to-balloon times*. Critical Pathways in Cardiology, 2016. **15**(1): p. 22-25.
276. Southern, W.N. and J.H. Arnsten, *The effect of erroneous computer interpretation of ECGs on resident decision making*. Medical decision making : an international journal of the Society for Medical Decision Making, 2009. **29**(3): p. 372-6.
277. Garg, A. and M.H. Lehmann, *Prolonged QT interval diagnosis suppression by a widely used computerized ECG analysis system*. Circ Arrhythm Electrophysiol, 2013. **6**(1): p. 76-83.
278. Huffman, D., *A Method for the Construction of Minimum-Redundancy Codes*. Proceedings of the Insitute of Radio Engineers, 1952. **40**: p. 1098-110.
279. Zywiets, C., J.L. Willems, and R. Degani, *Data compression for computerized electrocardiography*. in *Proc of the 1st Working Conf of the SCP-ECG Project AIM 1015*. 1990. Belgium: Leuven ACCO Press.
280. ANSI/AAMI, *Standard communications protocol - Computer assisted electrocardiography*, EC71:2001, Editor. 2002. p. 156.
281. JA, A., D. LS, and A. M, *10th Bethesda Conference: optimal electrocardiography*. Am J Cardiol. , 1978. **41**: p. 111-191.
282. Jain, A.K., R.P.W. Duin, and J. Mao, *Statistical Pattern Recognition: A Review* IEEE Transactions on Pattern Analysis and Machine Intelligence, 2000. **22**:1: p. 4-37.
283. Zywiets, C., D. Celikag, and G. Joseph, *Influence of ECG measurement accuracy on ECG diagnostic statements*. J Electrocardiol, 1996. **29** **Suppl**: p. 67-72.
284. Schmitt, O., *Inter- and Intra-Individual Variability in ECG Electrode-Skin Impedance*. Biophysical Society Abstracts, 1970. **Feb. 25-27**.
285. Brodnick, D.E., *Method of removing signal interference from sampled data and apparatus for effecting the same*, U.S.P. Office, Editor. 2002, GE Medical Systems Information Technologies, Inc. (Waukesha, WI) United States.
286. Farrell, R. and G.I. Rowlandson, *The Effects of Noise on Computerized ECG Measurements*. Journal of Electrocardiology, 2006.
287. Willems, J.L., et al., *Influence of noise on wave boundary recognition by ECG measurement programs. Recommendations for preprocessing*. Comput Biomed Res, 1987. **20**(6): p. 543-62.
288. Zywiets, C., et al., *Stability of computer ECG amplitude measurements in the presence of noise. The CSE Working Party*. Comput Biomed Res, 1990. **23**(1): p. 10-31.
289. Reddy, B.R., Q. Xue, and C. Zywiets, *Analysis of interval measurements on CSE multilead reference ECGs*. J Electrocardiol, 1996. **29** **Suppl**: p. 62-6.
290. *Recommendations for measurement standards in quantitative electrocardiography. The CSE Working Party*. Eur Heart J, 1985. **6**(10): p. 815-25.
291. Willems, J.L., et al., *Common standards for quantitative electrocardiography: goals and main results. CSE Working Party*. Methods Inf Med, 1990. **29**(4): p. 263-71.

292. Willems, J.L., et al., *Assessment of the performance of electrocardiographic computer programs with the use of a reference data base*. *Circulation*, 1985. **71**(3): p. 523-34.
293. Moody, G.B., W.I. Muldrow, and R.G. Mark, *A noise stress test for arrhythmia detectors*. *Computers in Cardiology*, 1984: p. 381-384.
294. ANSI/AAMI, *Ambulatory electrocardiographs*, EC38:1998, Editor. 1999. p. 58.
295. Mulcahy, D., et al., *Can a computer assisted electrocardiograph replace a cardiologist for ECG measurements?* *Ir J Med Sci*, 1986. **155**(12): p. 410-4.
296. Kors, J.A. and G. van Herpen, *The coming of age of computerized ECG processing: can it replace the cardiologist in epidemiological studies and clinical trials?* *Medinfo*, 2001. **10**(Pt 2): p. 1161-7.
297. Vancura, V., et al., *The variability of automated QRS duration measurement*. *Europace*, 2017. **19**(4): p. 636-643.
298. Kligfield, P., et al., *Comparison of automated measurements of electrocardiographic intervals and durations by computer-based algorithms of digital electrocardiographs*. *Am Heart J*, 2014. **167**(2): p. 150-159 e1.
299. Burke, G.M., et al., *Assessment of Reproducibility – Automated and Digital Caliper ECG Measurement in the Framingham Heart Study*. *Journal of electrocardiology*, 2014. **47**(3): p. 288-293.
300. Zywert, C. and J.L. Willems, *Stability of ECG amplitude measurements in systematic noise tests. Results and recommendations from the CSE project*. *J Electrocardiol*, 1987. **20 Suppl**: p. 61-7.
301. Skov, M.W., et al., *Risk Prediction of Atrial Fibrillation Based on Electrocardiographic Interatrial Block*. *J Am Heart Assoc*, 2018. **7**(11).
302. De Pooter, J., et al., *Accuracy of computer-calculated and manual QRS duration assessments: Clinical implications to select candidates for cardiac resynchronization therapy*. *International Journal of Cardiology*, 2017. **236**: p. 276-282.
303. Huang, T., et al., *Statistical evaluation of reproducibility of automated ECG measurements: an example from arrhythmogenic right ventricular dysplasia/cardiomyopathy clinic*. *Biomed Signal Process Control*, 2014. **13**: p. 23-30.
304. Eskola, M.J., et al., *Comparative accuracy of manual versus computerized electrocardiographic measurement of J-, ST- and T-wave deviations in patients with acute coronary syndrome*. *Am J Cardiol*, 2005. **96**(11): p. 1584-8.
305. Rasmussen, P.V., et al., *Electrocardiographic Precordial ST-Segment Deviations and the Risk of Cardiovascular Death: Results From the Copenhagen ECG Study*. *Journal of the American Heart Association: Cardiovascular and Cerebrovascular Disease*, 2014. **3**(3): p. e000549.
306. *Guidance for Industry: E14 Clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs.*, ICH, Editor. 2005, International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER).
307. Darpo, B., *The thorough QT/QTc study 4 years after the implementation of the ICH E14 guidance*. *British Journal of Pharmacology*, 2010. **159**(1): p. 49-57.
308. Fossier, C., et al., *Comparison of Manual and Automated Measurements of the QT Interval in Healthy Volunteers: An Analysis of Five Thorough QT Studies*. *Clin Pharmacol Ther*, 2009.
309. Couderc, J.-P., et al., *Highly-Automated QT Measurement Techniques in Seven Thorough QT Studies Implemented under ICH E14 Guidelines*. *Annals of noninvasive electrocardiology : the official journal of the International Society for Holter and Noninvasive Electrocardiology, Inc*, 2011. **16**(1): p. 13-24.
310. Malik, M., et al., *Sample size, power calculations, and their implications for the cost of thorough studies of drug induced QT interval prolongation*. *Pacing Clin Electrophysiol*, 2004. **27**(12): p. 1659-69.
311. Malik, M., *Errors and misconceptions in ECG measurement used for the detection of drug induced QT interval prolongation*. *J Electrocardiol*, 2004. **37 Suppl**: p. 25-33.
312. Tyl, B., et al., *Improvement and limitation of the reliability of automated QT measurement by recent algorithms*. *Journal of Electrocardiology*, 2011. **44**(3): p. 320-5.
313. Thalamus, J., et al. *Pitfalls in automated QTc measurements. Experience from a manual review*. in *European Society of Cardiology*. 2017. Barcelona.
314. Bland, J.M. and D.G. Altman, *Statistical methods for assessing agreement between two methods of clinical measurement*. *Lancet*, 1986. **1**(8476): p. 307-10.

315. Nielsen, J.B., et al., *Risk prediction of cardiovascular death based on the QTc interval: evaluating age and gender differences in a large primary care population*. European Heart Journal, 2014. **35**(20): p. 1335-1344.
316. Gibbs, C., et al., *Predictors of mortality in high-risk patients with QT prolongation in a community hospital*. Europace, 2017.
317. Miller, M.D., C. Porter, and M.J. Ackerman, *Diagnostic accuracy of screening electrocardiograms in long QT syndrome I*. Pediatrics, 2001. **108**(1): p. 8-12.
318. Savelieva, I., et al., *Agreement and reproducibility of automatic versus manual measurement of QT interval and QT dispersion*. Am J Cardiol, 1998. **81**(4): p. 471-7.
319. Rautaharju, P.M., et al., *Normal standards for QT and QT subintervals derived from a large ethnically diverse population of women aged 50 to 79 years (the Women's Health Initiative [WHI])*. Am J Cardiol, 2006. **97**(5): p. 730-7.
320. Dmitrienko, A.A., et al., *Electrocardiogram Reference Ranges Derived from a Standardized Clinical Trial Population*. Drug Information Journal, 2005. **39**: p. 395-405.
321. Perez, M.V., et al., *Electrocardiographic predictors of atrial fibrillation*. Am Heart J, 2009. **158**(4): p. 622-8.
322. Nielsen, J.B., et al., *Risk of atrial fibrillation as a function of the electrocardiographic PR interval: results from the Copenhagen ECG Study*. Heart Rhythm, 2013. **10**(9): p. 1249-56.
323. Okin, P.M., et al., *Electrocardiographic left atrial abnormalities and risk of incident stroke in hypertensive patients with electrocardiographic left ventricular hypertrophy*. J Hypertens, 2016. **34**(9): p. 1831-7.
324. Shulman, E., et al., *Validation of PR interval length as a criterion for development of atrial fibrillation in non-Hispanic whites, African Americans and Hispanics*. Journal of Electrocardiology, 2015. **48**(4): p. 703-709.
325. Sigurdsson, M.I., et al., *Genetic Variants Associated With Atrial Fibrillation and PR Interval Following Cardiac Surgery*. Journal of cardiothoracic and vascular anesthesia, 2015. **29**(3): p. 605-610.
326. Rasmussen, P.V., et al., *Electrocardiographic PR Interval Duration and Cardiovascular Risk: Results From the Copenhagen ECG Study*. Canadian Journal of Cardiology, 2017. **33**(5): p. 674-681.
327. Skov, M.W., et al., *Electrocardiographic Preexcitation and Risk of Cardiovascular Morbidity and Mortality: Results From the Copenhagen ECG Study*. Circ Arrhythm Electrophysiol, 2017. **10**(6).
328. Kaykha, A., et al., *The prognostic importance of isolated P-Wave abnormalities*. Clin Cardiol, 2010. **33**(6): p. E87-93.
329. Ha, L.D., et al., *Electrocardiographic left atrial abnormalities predict cardiovascular mortality*. Journal of Electrocardiology, 2018. **51**(4): p. 652-657.
330. Dhingra, R., et al., *Electrocardiographic QRS duration and the risk of congestive heart failure: the Framingham Heart Study*. Hypertension, 2006. **47**(5): p. 861-7.
331. Turner, M.S., et al., *Electrical and Mechanical Components of Dyssynchrony in Heart Failure Patients With Normal QRS Duration and Left Bundle-Branch Block: Impact of Left and Biventricular Pacing*. Circulation, 2004. **109**(21): p. 2544-2549.
332. Sanderson, J.E., *Assessment of ventricular dyssynchrony: global or regional function?* Eur Heart J, 2006. **27**(20): p. 2380-2381.
333. Bleeker, G.B., et al., *Relationship Between QRS Duration and Left Ventricular Dyssynchrony in Patients with End-Stage Heart Failure*. 2004. **15**(5): p. 544-549.
334. Murkofsky, R.L., et al., *A prolonged QRS duration on surface electrocardiogram is a specific indicator of left ventricular dysfunction*. J Am Coll Cardiol, 1998. **32**(2): p. 476-82.
335. Iuliano, S., et al., *QRS duration and mortality in patients with congestive heart failure*. Am Heart J, 2002. **143**(6): p. 1085-91.
336. Korhonen, P., et al., *QRS duration in high-resolution methods and standard ECG in risk assessment after first and recurrent myocardial infarctions*. Pacing Clin Electrophysiol, 2006. **29**(8): p. 830-6.
337. Desai, A.D., et al., *Prognostic Significance of Quantitative QRS Duration*. The American Journal of Medicine, 2006. **119**(7): p. 600-606.
338. Elhendy, A., et al., *Relation of QRS duration on the surface 12-lead electrocardiogram with mortality in patients with known or suspected coronary artery disease*. Am J Cardiol, 2005. **96**(8): p. 1082-8.
339. Shenkman, H.J., et al., *Congestive heart failure and QRS duration: establishing prognosis study*. Chest, 2002. **122**(2): p. 528-34.

340. Selvester, R.H., et al., *Intraventricular conduction defect (IVCD), real or fancied, QRS duration in 1,254 normal adult white males by a multilead automated algorithm*. J Electrocardiol, 1990. **23 Suppl**: p. 118-22.
341. Luliano, S., et al., *QRS duration and mortality in patients with congestive heart failure*. Am Heart J, 2002. **143**(6): p. 1085-91.
342. Gupta, S., et al., *Association between QRS duration and obstructive sleep apnea*. J Clin Sleep Med, 2012. **8**(6): p. 649-54.
343. Okin, P.M., et al., *Computerized ST depression analysis improves prediction of all-cause and cardiovascular mortality: the strong heart study*. Ann Noninvasive Electrocardiol, 2001. **6**(2): p. 107-16.
344. Okin, P.M., et al., *Quantitative assessment of electrocardiographic strain predicts increased left ventricular mass: the Strong Heart Study*. J Am Coll Cardiol, 2002. **40**(8): p. 1395-400.
345. Okin, P.M., et al., *Electrocardiographic strain pattern and prediction of new-onset congestive heart failure in hypertensive patients: the Losartan Intervention for Endpoint Reduction in Hypertension (LIFE) study*. Circulation, 2006. **113**(1): p. 67-73.
346. Okin, P.M., et al., *Combination of the electrocardiographic strain pattern and albuminuria for the prediction of new-onset heart failure in hypertensive patients: the LIFE study*. Am J Hypertens, 2008. **21**(3): p. 273-9.
347. Inoue, Y.Y., et al., *Electrocardiographic Strain Pattern Is Associated With Left Ventricular Concentric Remodeling, Scar, and Mortality Over 10 Years: The Multi-Ethnic Study of Atherosclerosis*. Journal of the American Heart Association, 2017. **6**(9).
348. Uberoi, A., et al., *Prognostic Implications of Q Waves and T-Wave Inversion Associated With Early Repolarization*. Mayo Clinic Proceedings, 2012. **87**(7): p. 614-619.
349. Haugaa, K.H., et al., *Institution-wide QT alert system identifies patients with a high risk of mortality*. Mayo Clin Proc, 2013. **88**(4): p. 315-25.
350. Kinoshita, T., et al., *Time Course and Prognostic Implications of QT Interval in Patients with Coronary Artery Disease Undergoing Coronary Bypass Surgery*. Journal of Cardiovascular Electrophysiology, 2012. **23**(6): p. 645-649.
351. Reinsch, N., et al., *Prolongation of the QTC interval in HIV infected individuals compared to the general population*. Europace, 2016. **18**: p. i110.
352. Lehmann, M.H., et al., *Sex difference in risk of torsade de pointes with d,l-sotalol*. Circulation, 1996. **94**(10): p. 2535-41.
353. Rosenthal, T.M., et al., *Optimal method of measuring the T-peak to T-end interval for risk stratification in primary prevention*. Europace, 2017.
354. Sánchez, A.P., et al. *T wave Morphology Analysis in Congenital Long QT Syndrome Discriminates Patients from Healthy Individuals*. in Heart Rhythm Society. 2016.
355. Okin, P.M., et al., *Principal Component Analysis of the T Wave and Prediction of Cardiovascular Mortality in American Indians: The Strong Heart Study*. Circulation, 2002. **105**(6): p. 714-719.
356. Okin, P.M., et al., *Assessment of QT interval and QT dispersion for prediction of all-cause and cardiovascular mortality in American Indians: The Strong Heart Study*. Circulation, 2000. **101**(1): p. 61-6.
357. Zabel, M., et al., *Assessment of QT dispersion for prediction of mortality or arrhythmic events after myocardial infarction: results of a prospective, long-term follow-up study*. Circulation, 1998. **97**(25): p. 2543-50.
358. Zabel, M., et al., *Analysis of T-wave morphology from the 12-lead electrocardiogram for prediction of long-term prognosis in male US veterans*. Circulation, 2002. **105**(9): p. 1066-70.
359. Potter, L., et al., *QT Dispersion in Acute Myocardial Infarction: A Tool for Identification of Patients with Initially Normal Electrocardiograms*. Acad Emerg Med, 1999. **6**(5): p. 424-.
360. Kesek, M., et al., *Non-dipolar content of the T-wave as a measure of repolarization inhomogeneity in ST-elevation myocardial infarction*. Clin Physiol Funct Imaging, 2006. **26**(6): p. 362-70.
361. Kesek, M., et al., *Principal Component Analysis of the T Wave in Patients with Chest Pain and Conduction Disturbances*. Pacing Clin Electrophysiol, 2004. **27**(10): p. 1378-1387.
362. Kowalski, M., et al., *Temporal Relationship between QTc Prolongation and ST-segment Elevation in Early Transmural Myocardial Ischemia Measured by a Continuous 12-lead ECG Monitor in American Heart Association*. 2006

363. Vicente, J., et al., *Comprehensive T wave Morphology Assessment in a Randomized Clinical Study of Dofetilide, Quinidine, Ranolazine, and Verapamil*. Journal of the American Heart Association, 2015. **4**(4).
364. Oehler, A., et al., *QRS-T Angle: A Review*. Annals of noninvasive electrocardiology : the official journal of the International Society for Holter and Noninvasive Electrocardiology, Inc, 2014. **19**(6): p. 534-542.
365. Voulgari, C., et al., *The Spatial QRS-T Angle: Implications in Clinical Practice*. Current Cardiology Reviews, 2013. **9**(3): p. 197-210.
366. Chen, S., et al., *Electrocardiographic Predictors of Morbidity and Mortality in Patients With Acute Myocarditis: The Importance of QRS-T Angle*. Journal of Cardiac Failure, 2018. **24**(1): p. 3-8.
367. Chua, K.C.M., et al., *Wide QRS-T angle on the 12-lead ECG as a Predictor of Sudden Death beyond the LV Ejection Fraction*. Journal of cardiovascular electrophysiology, 2016. **27**(7): p. 833-839.
368. Reichlin, T., et al., *Advanced ECG in 2016: is there more than just a tracing?* Swiss Med Wkly, 2016. **146**: p. w14303.
369. Yamazaki, T., et al., *Spatial QRS-T angle predicts cardiac death in a clinical population*. Heart Rhythm, 2005. **2**(1): p. 73-78.
370. Gotsman, I., et al., *Temporal changes in electrocardiographic frontal QRS-T angle and survival in patients with heart failure*. PLoS One, 2018. **13**(3): p. e0194520.
371. Selvester, R.H., G.S. Wagner, and N.B. Hindman, *The Selvester QRS scoring system for estimating myocardial infarct size. The development and application of the system*. Arch Intern Med, 1985. **145**(10): p. 1877-81.
372. Pope, J.E., et al., *Development and validation of an automated method of the Selvester QRS scoring system for myocardial infarct size*. Am J Cardiol, 1988. **61**(10): p. 734-8.
373. Rautaharju, P.M., et al., *Cardiac infarction injury score: an electrocardiographic coding scheme for ischemic heart disease*. Circulation, 1981. **64**(2): p. 249-56.
374. Richardson, K., et al., *Electrocardiographic damage scores and cardiovascular mortality*. Am Heart J, 2005. **149**(3): p. 458-63.
375. Perino, A.C., et al., *The long-term prognostic value of the Q wave criteria for prior myocardial infarction recommended in the universal definition of myocardial infarction*. Journal of electrocardiology, 2015. **48**(5): p. 798-802.
376. Engblom, H., et al., *Size and transmural extent of first-time reperfused myocardial infarction assessed by cardiac magnetic resonance can be estimated by 12-lead electrocardiogram*. Am Heart J, 2005. **150**(5): p. 920.
377. Wagner, G.S., et al., *A method for assembling a collaborative research team from multiple disciplines and academic centers to study the relationships between ECG estimation and MRI measurement of myocardial infarct size*. J Electrocardiol, 2001. **34 Suppl**: p. 1-6.
378. Engel, G., et al., *Electrocardiographic arrhythmia risk testing*. Curr Probl Cardiol, 2004. **29**(7): p. 365-432.
379. Strauss, D.G., et al., *Screening Entire Health System ECG Databases to Identify Patients at Increased Risk of Death*. Circulation: Arrhythmia and Electrophysiology, 2013. **6**(6): p. 1156-1162.
380. *Magellan ECG Research Workstation Software - Operator's Manual, Software Version 2.0, PN 421681-001 Revision C*. 2000, GE Healthcare.
381. Tan, S.Y., et al., *A simplified clinical electrocardiogram score for the prediction of cardiovascular mortality*. Clin Cardiol, 2009. **32**(2): p. 82-6.
382. Soofi, M., et al., *A New 12-Lead ECG Prognostic Score*. Ann Noninvasive Electrocardiol, 2015. **20**(6): p. 554-60.
383. Perino, A.C., et al., *The long-term prognostic value of the ST depression criteria for ischemia recommended in the universal definition of myocardial infarction in 43,661 veterans*. Int J Cardiol, 2014. **173**(3): p. 494-8.
384. Perez, M.V., et al., *The prognostic value of early repolarization with ST-segment elevation in African Americans*. Heart Rhythm, 2012. **9**(4): p. 558-65.
385. Le, V.V., et al., *Rest premature ventricular contractions on routine ECG and prognosis in heart failure patients*. Ann Noninvasive Electrocardiol, 2010. **15**(1): p. 56-62.
386. Tan, S.Y., et al., *The prognostic value of T wave amplitude in lead aVR in males*. Ann Noninvasive Electrocardiol, 2008. **13**(2): p. 113-9.

387. Engel, G., et al., *Prognostic significance of PVCs and resting heart rate*. Ann Noninvasive Electrocardiol, 2007. **12**(2): p. 121-9.
388. Perez, M.V., et al., *Prognostic value of the computerized ECG in Hispanics*. Clin Cardiol, 2007. **30**(4): p. 189-94.
389. Beckerman, J., et al., *T-wave abnormalities are a better predictor of cardiovascular mortality than ST depression on the resting electrocardiogram*. Ann Noninvasive Electrocardiol, 2005. **10**(2): p. 146-51.
390. Hsieh, B.P., M.X. Pham, and V.F. Froelicher, *Prognostic value of electrocardiographic criteria for left ventricular hypertrophy*. American Heart Journal, 2005. **150**(1): p. 161-167.
391. Yamazaki, T., J. Myers, and V.F. Froelicher, *Prognostic importance of isolated T-wave abnormalities*. Am J Cardiol, 2005. **95**(2): p. 300-4.
392. Shah, B.R., et al., *Computerized QT dispersion measurement and cardiovascular mortality in male veterans*. The American Journal of Cardiology, 2004. **93**(4): p. 483-486.
393. Pargaonkar, V.S., et al., *Long-term prognosis of early repolarization with j-wave and qrs slur patterns on the resting electrocardiogram: A cohort study*. Annals of Internal Medicine, 2015. **163**(10): p. 747-755.
394. Ha, L.D., A. Elbadawi, and V.F. Froelicher, *Limited Relationship of Voltage Criteria for Electrocardiogram Left Ventricular Hypertrophy to Cardiovascular Mortality*. Am J Med, 2018. **131**(1): p. 101.e1-101.e8.
395. Hassamal, S., et al., *QTc Prolongation in Veterans With Heroin Dependence on Methadone Maintenance Treatment*. International Journal of High Risk Behaviors & Addiction, 2015. **4**(2): p. e23819.
396. Grunkemeier, G.L. and N. Payne, *Bayesian analysis: A new statistical paradigm for new technology*. Ann Thorac Surg, 2002. **74**(6): p. 1901-1908.
397. Mieres, J.H., et al., *Role of Noninvasive Testing in the Clinical Evaluation of Women With Suspected Coronary Artery Disease: Consensus Statement From the Cardiac Imaging Committee, Council on Clinical Cardiology, and the Cardiovascular Imaging and Intervention Committee, Council on Cardiovascular Radiology and Intervention, American Heart Association*. Circulation, 2005. **111**(5): p. 682-696.
398. Nessmith Jr, M.G., T.W. Simmons, and W.K. Haisty Jr, *Computerized Detection of Paced Rhythms in the Resting 12-Lead Electrocardiogram*. 2001, Wake Forest University Medical Center.
399. Kazi W., M. and R. Mauerman S.K., *New algorithm improves detection accuracy of paced rhythms in the resting ECG*. 2002, Division of Cardiology/Electrophysiology. Medical College of Wisconsin-Milwaukee.
400. Reddy, B.R., et al., *Detection of P waves in resting ECG: A preliminary study*. Los Alamitos, CA: IEEE Computer Society Press, 1992. **Computers in Cardiology 1992**: p. 87-90.
401. Reddy, B.R., P.P. Elko, and G.I. Rowlandson, *Contextual information in atrial arrhythmia analysis*. J Electrocardiol, 1993. **26 Suppl**: p. cccddd.
402. Reddy, B.R., et al., *Detection of complex atrial arrhythmias in resting ECG*. Los Alamitos, CA: IEEE Computer Society Press, 1994(Computers in Cardiology, 1994): p. 777-780.
403. Takatori, *Arrhythmia diagnosis by the Marquette 12SL ECG analysis program*. Computerized interpretation of the electrocardiogram. Proceedings of the Engineering Foundation Conference, 1983. **VII**: p. 63-74.
404. Swiryn, S. and J. Jenkins, *Arrhythmia diagnosis by computer. The Marquette 12SL program*. Computerized interpretation of the electrocardiogram. Proceedings of the Engineering Foundation Conference, 1983: p. 35-54.
405. Bossone, E., et al., *The interpretation of the electrocardiogram in patients with pulmonary hypertension: the need for clinical correlation*. Ital Heart J, 2003. **4**(12): p. 850-4.
406. Hongo, R.H. and N. Goldschlager, *Overreliance on computerized algorithms to interpret electrocardiograms*. The American Journal of Medicine, 2004. **117**(9): p. 706-708.
407. Chiu, C.C., et al., *Evaluation of computerized interpretation of the pediatric electrocardiogram*. J Electrocardiol, 2006.
408. Hammill, S.C., *Comparison of a Computerized Interpretive ECG Program Using XYZ Leads with a Program using Scalar Leads*. J Electrocardiol, 1988. **88**(Supp).
409. Hammill, S., *Accuracy of automated electrocardiographic detection as performed at the Mayo Clinic; personal communication*. 1989.

410. Santra, S., et al., *Comparison of left ventricular mass in normotensive type 2 diabetes mellitus patients with that in the nondiabetic population*. J Cardiovasc Dis Res, 2011. **2**(1): p. 50-6.
411. Brown, D.W., W.H. Giles, and J.B. Croft, *Left ventricular hypertrophy as a predictor of coronary heart disease mortality and the effect of hypertension*. Am Heart J, 2000. **140**(6): p. 848-56.
412. Gradman, A.H. and F. Alfayoumi, *From left ventricular hypertrophy to congestive heart failure: management of hypertensive heart disease*. Prog Cardiovasc Dis, 2006. **48**(5): p. 326-41.
413. Larstorp, A.C., et al., *Changes in electrocardiographic left ventricular hypertrophy and risk of major cardiovascular events in isolated systolic hypertension: The LIFE study*. J Hum Hypertens, 2010.
414. Okin, P.M., et al., *Regression of electrocardiographic left ventricular hypertrophy is associated with less hospitalization for heart failure in hypertensive patients*. Ann Intern Med, 2007. **147**(5): p. 311-9.
415. Mancia, G., et al., *2007 Guidelines for the Management of Arterial Hypertension: The Task Force for the Management of Arterial Hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC)*. J Hypertens, 2007. **25**(6): p. 1105-87.
416. Katholi, R.E. and D.M. Couri, *Left Ventricular Hypertrophy: Major Risk Factor in Patients with Hypertension: Update and Practical Clinical Applications*. International Journal of Hypertension, 2011. **2011**.
417. Pewsner, D., et al., *Accuracy of electrocardiography in diagnosis of left ventricular hypertrophy in arterial hypertension: systematic review*. Bmj, 2007. **335**(7622): p. 711.
418. Milan, A., et al., *Anti-hypertensive drugs and left ventricular hypertrophy: a clinical update*. Intern Emerg Med, 2010.
419. Hill, J.A. and E.N. Olson, *Cardiac plasticity*. N Engl J Med, 2008. **358**(13): p. 1370-80.
420. Bacharova, L., et al., *Effect of changes in left ventricular anatomy and conduction velocity on the QRS voltage and morphology in left ventricular hypertrophy: a model study*. J Electrocardiol, 2010. **43**(3): p. 200-8.
421. Oikarinen, L., et al., *QRS Duration and QT Interval Predict Mortality in Hypertensive Patients With Left Ventricular Hypertrophy: The Losartan Intervention for Endpoint Reduction in Hypertension Study*. Hypertension, 2004. **43**(5): p. 1029-1034.
422. Sundstrom, J., et al., *Echocardiographic and electrocardiographic diagnoses of left ventricular hypertrophy predict mortality independently of each other in a population of elderly men*. Circulation, 2001. **103**(19): p. 2346-51.
423. Okin, P.M., et al., *Combined echocardiographic left ventricular hypertrophy and electrocardiographic ST depression improve prediction of mortality in American Indians: the Strong Heart Study*. Hypertension, 2004. **43**(4): p. 769-74.
424. Verdecchia, P., et al., *Comparison of electrocardiographic criteria for diagnosis of left ventricular hypertrophy in hypertension: the MAVI study*. Ital Heart J, 2000. **1**(3): p. 207-15.
425. Salles, G., et al., *Combined QT interval and voltage criteria improve left ventricular hypertrophy detection in resistant hypertension*. Hypertension, 2005. **46**(5): p. 1207-12.
426. Calderon, A., et al., *Detection of left ventricular hypertrophy by different electrocardiographic criteria in clinical practice. Findings from the Sara study*. Clin Exp Hypertens, 2010. **32**(3): p. 145-53.
427. Hancock, E.W., et al., *AHA/ACCF/HRS recommendations for the standardization and interpretation of the electrocardiogram: part V: electrocardiogram changes associated with cardiac chamber hypertrophy: a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society. Endorsed by the International Society for Computerized Electrocardiology*. J Am Coll Cardiol, 2009. **53**(11): p. 992-1002.
428. Okin, P.M., et al., *Electrocardiographic identification of increased left ventricular mass by simple voltage-duration products*. J Am Coll Cardiol, 1995. **25**(2): p. 417-23.
429. Bacharova, L., *Electrocardiography-left ventricular mass discrepancies in left ventricular hypertrophy: electrocardiography imperfection or beyond perfection?* J Electrocardiol, 2009. **42**(6): p. 593-6.
430. Davignon, A., et al., *Normal ECG standards for infants and children*. Pediatric Cardiology, 1979. **1**: p. 123-52.
431. Schwartz, P.J., et al., *Guidelines for the interpretation of the neonatal electrocardiogram. A task force of the European Society of Cardiology*. Eur Heart J, 2002. **23**(17): p. 1329-44.

432. Alpert, J.S., et al., *Myocardial infarction redefined--a consensus document of The Joint European Society of Cardiology/American College of Cardiology Committee for the redefinition of myocardial infarction*. J Am Coll Cardiol, 2000. **36**(3): p. 959-69.
433. Pope, J.E., *Performance of the Marquette 12SL ECG analysis program*. Computerized interpretation of the electrocardiogram. Proceedings of the Engineering Foundation Conference, 1986. **X**: p. 185-193.
434. Haisty, W.K. *Multivariate Q-Wave Criteria for Inferior Myocardial Infarction*. in *Computerized Interpretation of the ECG*. 1987.
435. Elko, P. and R.A. Warner, *Using directly acquired digital ECG data to optimize the diagnostic criteria for anterior myocardial infarction*. J Electrocardiol, 1994. **27 Suppl**: p. 10-3.
436. Garvey, J.L., et al., *Pre-Hospital 12-Lead Electrocardiography Programs: A Call for Implementation by Emergency Medical Services Systems Providing Advanced Life Support--National Heart Attack Alert Program (NHAAP) Coordinating Committee; National Heart, Lung, and Blood Institute (NHLBI); National Institutes of Health*. Journal of the American College of Cardiology, 2006. **In Press, Corrected Proof**.
437. Elko, P.P. and I. Rowlandson, *A statistical analysis of the ECG measurements used in computerized interpretation of acute anterior myocardial infarction with applications to interpretive criteria development*. J Electrocardiol, 1992. **25 Suppl**: p. 113-9.
438. Elko, P.P., et al., *The dilemma of sensitivity versus specificity in computer-interpreted acute myocardial infarction*. J Electrocardiol, 1992. **24 Suppl**: p. 2-7.
439. Tighe, M., et al., *The early diagnosis of acute myocardial infarction. Comparison of a simple algorithm with a computer program for electrocardiogram interpretation*. Ir J Med Sci, 1996. **165**(3): p. 159-63.
440. O'Rourke, M.F., et al., *Accuracy of a portable interpretive ECG machine in diagnosis of acute evolving myocardial infarction*. Aust N Z J Med, 1992. **22**(1): p. 9-13.
441. K99190, *LIFEPAK 12 BIPHASIC*, in U.S. Food and Drug Administration, Center for Devices and Radiological Health. 1999.
442. K991556 - *Zoll M Series 12SL Option - 510K*. 1999, U.S. Food and Drug Administration, Center for Devices and Radiological Health.
443. K002209, *GE MARQUETTE ECG ANALYSIS PROGRAM*, in U.S. Food and Drug Administration, Center for Devices and Radiological Health, P. Monitor, Patient (with Arrhythmia Detection or Alarms) Editor. 2002. p. MHX.
444. Garza, M.A., *Cellular technology. Revolutionizing EMS communications*. Jems, 1990. **15**(5): p. 46-7, 50-3, 55-6.
445. Ewy, G.A. and J.P. Ornato, *Emergency cardiac care: introduction*. J Am Coll Cardiol, 2000. **35**: p. 825-880.
446. Martin, J.S., P.E. Litwin, and W.D. Weaver, *Early recognition and treatment of the patient suffering from acute myocardial infarction. A description of the Myocardial Infarction Triage and Intervention Project*. Crit Care Nurs Clin North Am, 1990. **2**(4): p. 681-8.
447. Bradley, E.H., et al., *Strategies for Reducing the Door-to-Balloon Time in Acute Myocardial Infarction*. N Engl J Med, 2006.
448. Cloutier, J., C. Hayes, and D. Allen, *SCINET: Software ECG interpretation of ST-elevation myocardial infarction and activation of the cath lab*. Journal of the American College of Cardiology, 2017. **70**(18): p. B203.
449. Cloutier, J.M., et al., *Reducing Delay to Treatment of ST-Elevation Myocardial Infarction With Software Electrocardiographic Interpretation and Transmission (SCINET)*. CJC Open, 2020. **2**(3): p. 111-117.
450. McClelland, A.J., et al., *Comparison of the 80-lead body surface map to physician and to 12-lead electrocardiogram in detection of acute myocardial infarction*. Am J Cardiol, 2003. **92**(3): p. 252-7.
451. Braunwald, E., et al., *ACC/AHA 2002 guideline update for the management of patients with unstable angina and non-ST-segment elevation myocardial infarction--summary article: a report of the American College of Cardiology/American Heart Association task force on practice guidelines (Committee on the Management of Patients With Unstable Angina)*. J Am Coll Cardiol, 2002. **40**(7): p. 1366-74.

452. Massel, D., J.A. Dawdy, and L.J. Melendez, *Strict reliance on a computer algorithm or measurable ST segment criteria may lead to errors in thrombolytic therapy eligibility*. Am Heart J, 2000. **140**(2): p. 221-6.
453. Wright, R.S., et al., *Women with Acute Anterior Myocardial Infarction Have Less Precordial ST Elevation Than Men Independent of Age of Presentation*. J Am Coll Cardiol., 2001. **37**(2001): **361A**.
454. Wellens, H.J., *The value of the right precordial leads of the electrocardiogram*. N Engl J Med, 1999. **340**(5): p. 381-3.
455. Zehender, M., et al., *Right ventricular infarction as an independent predictor of prognosis after acute inferior myocardial infarction*. N Engl J Med, 1993. **328**(14): p. 981-8.
456. Saw, J., et al., *Value of ST elevation in lead III greater than lead II in inferior wall acute myocardial infarction for predicting in-hospital mortality and diagnosing right ventricular infarction*. Am J Cardiol, 2001. **87**(4): p. 448-50, A6.
457. Wong, T.W., et al., *New electrocardiographic criteria for identifying the culprit artery in inferior wall acute myocardial infarction-usefulness of T-wave amplitude ratio in leads II/III and T-wave polarity in the right V5 lead*. Am J Cardiol, 2004. **94**(9): p. 1168-71.
458. Zimetbaum, P.J., et al., *Usefulness of ST-segment elevation in lead III exceeding that of lead II for identifying the location of the totally occluded coronary artery in inferior wall myocardial infarction*. Am J Cardiol, 1998. **81**(7): p. 918-9.
459. Braat, S.H., et al., *Right ventricular involvement with acute inferior wall myocardial infarction identifies high risk of developing atrioventricular nodal conduction disturbances*. Am Heart J, 1984. **107**(6): p. 1183-7.
460. Kinch, J.W. and T.J. Ryan, *Right ventricular infarction*. N Engl J Med, 1994. **330**(17): p. 1211-7.
461. Rodrigues, E.A., et al., *Diagnosis and prognosis of right ventricular infarction*. Br Heart J, 1986. **56**(1): p. 19-26.
462. Morgera, T., et al., *Right precordial ST and QRS changes in the diagnosis of right ventricular infarction*. Am Heart J, 1984. **108**(1): p. 13-8.
463. Zalenski, R.J., et al., *Assessing the diagnostic value of an ECG containing leads V4R, V8, and V9: the 15-lead ECG*. Ann Emerg Med, 1993. **22**(5): p. 786-93.
464. Zalenski, R.J., et al., *Value of posterior and right ventricular leads in comparison to the standard 12-lead electrocardiogram in evaluation of ST-segment elevation in suspected acute myocardial infarction*. Am J Cardiol, 1997. **79**(12): p. 1579-85.
465. Taha, B., et al., *Normal limits of ST segment measurements in posterior ECG leads*. J Electrocardiol, 1998. **31 Suppl**: p. 178-9.
466. Farrell, R.M. and I. Rowlandson, *Computerized detection of right ventricular involvement in acute inferior infarction*. Journal of Electrocardiology, 2006. **39**(4, Supplement 1): p. S128-S129.
467. Selker, H.P., J.L. Griffith, and R.B. D'Agostino, *A tool for judging coronary care unit admission appropriateness, valid for both real-time and retrospective use. A time-insensitive predictive instrument (TIPI) for acute cardiac ischemia: a multicenter study*. Med Care, 1991. **29**(7): p. 610-27.
468. Schwartz, P.J. and R.L. Woosley, *Predicting the Unpredictable: Drug-Induced QT Prolongation and Torsades de Pointes*. J Am Coll Cardiol, 2016. **67**(13): p. 1639-50.
469. Prasad, S., et al., *Baseline values from the electrocardiograms of children and adolescents with ADHD*. Child Adolesc Psychiatry Ment Health, 2007. **1**(1): p. 11.
470. Pickham, D., et al., *Optimizing QT Interval Measurement for the Preparticipation Screening of Young Athletes*. Med Sci Sports Exerc, 2016. **48**(9): p. 1745-50.
471. Poncet, A., et al., *Electrocardiographic Screening for Prolonged QT Interval to Reduce Sudden Cardiac Death in Psychiatric Patients: A Cost-Effectiveness Analysis*. PLoS ONE, 2015. **10**(6): p. e0127213.
472. Martin, J.A., et al., *QT Interval Screening in Methadone Maintenance Treatment: Report of a SAMHSA Expert Panel*. Journal of addictive diseases, 2011. **30**(4): p. 283-306.
473. Al-Khatib, S.M., et al., *What clinicians should know about the QT interval*. JAMA, 2003. **289**(16): p. 2120-7.
474. Drew, B.J., et al., *Prevention of torsade de pointes in hospital settings: a scientific statement from the American Heart Association and the American College of Cardiology Foundation*. Circulation, 2010. **121**(8): p. 1047-60.
475. Denny, J.C., et al., *Identifying QT prolongation from ECG impressions using a general-purpose Natural Language Processor*. International journal of medical informatics, 2009. **78**(Suppl 1): p. S34-S42.

- 476. Estes, N.A., 3rd, *Computerized interpretation of ECGs: supplement not a substitute*. Circ Arrhythm Electrophysiol, 2013. **6**(1): p. 2-4.
- 477. Terkelsen, C.J., et al., *Potential significance of spontaneous and interventional ST-changes in patients transferred for primary percutaneous coronary intervention: observations from the ST-MONitoring in Acute Myocardial Infarction study (The MONAMI study)*. Eur Heart J, 2006. **27**(3): p. 267-75.
- 478. Jernberg, T., B. Lindahl, and L. Wallentin, *The combination of a continuous 12-lead ECG and troponin T; a valuable tool for risk stratification during the first 6 hours in patients with chest pain and a non-diagnostic ECG*. Eur Heart J, 2000. **21**(17): p. 1464-72.
- 479. Zairis, M.N., et al., *C-reactive protein and ST-segment monitoring by continuous 12-lead electrocardiogram in patients with primary unstable angina pectoris*. Am J Cardiol, 2003. **91**(5): p. 600-3.
- 480. Zairis, M.N., et al., *Continuous 12-lead electrocardiographic ST monitoring and long-term prognosis after successful coronary stenting*. Am Heart J, 2006. **151**(4): p. 892-7.
- 481. Lee, K.S., et al., *Relation of electrocardiographic criteria for left atrial enlargement to two-dimensional echocardiographic left atrial volume measurements*. Am J Cardiol, 2007. **99**(1): p. 113-8.



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



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





GE HealthCare

MAC[™] 3 Resting ECG Analysis System

Service Manual

Software Version 1.01



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General Service Documentation

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Publication information

This document describes version 1.01 of the MAC™ 3 Resting ECG Analysis System, also referred to as the “product” or “system” or “device”. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this document are subject to change without notice.

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Date of first CE mark - 2025.

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	28 May 2025	Initial release
2	18 November 2025	Updated content for Software V1.01

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This document describes the MAC™ 3 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™ 3 Resting ECG Analysis system.

Installation should be performed by a qualified personnel.

The MAC™ 3 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.

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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.

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Service manual language information

WARNING English (EN)	This service manual is available in English only. • If a customer's service provider requires a language other than English, it is the customer's responsibility to provide translation services. • Do not attempt to service the equipment unless this service manual has been consulted and is understood. • Failure to heed this warning may result in injury to the service provider, operator, or patient, from electric shock, mechanical or other hazards.
ПРЕДУПРЕЖДЕНИЕ Bulgarian (BG)	Това упътване за работа е налично само на английски език. • Ако доставчикът на услугата на клиента изиска друг език, задължение на клиента е да осигури превод. • Не използвайте оборудването, преди да сте се консултирали и разбрали упътването за работа. • Неспазването на това предупреждение може да доведе до нараняване на доставчика на услугата, оператора или пациент в резултат на токов удар или механична или друга опасност.
警告 Chinese-Simplified (ZH-CN)	本维修手册仅提供英文版本。 • 如果维修服务提供商需要非英文版本，客户需自行提供翻译服务。 • 未详细阅读和完全理解本维修手册之前，不得进行维修。 • 忽略本警告可能对维修人员，操作员或患者造成触电、机械伤害或其他形式的伤害。
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UPOZORENJE Croatian (HR)	Ove upute za servisiranje dostupne su samo na engleskom jeziku. • Ukoliko korisnički servis zahtijeva neki drugi jezik, korisnikova je odgovornost osigurati odgovarajući prijevod. • Nemojte pokušavati servisirati opremu ukoliko niste konzultirali i razumjeli ove upute. • Nepoštivanje ovog upozorenja može rezultirati ozljedama servisnog osoblja, korisnika ili pacijenta prouzročenim električnim udarom te mehaničkim ili nekim drugim opasnostima.
VAROVÁNÍ Czech (CS)	Tento provozní návod existuje pouze v anglickém jazyce. • Vpřípadě, že externí služba zákazníkům potřebuje návod v jiném jazyce, je zajištění překladu do odpovídajícího jazyka úkolem zákazníka. • Nesnažte se oúdržbu tohoto zařízení, aniž byste si přečetli tento provozní návod a pochopili jeho obsah. • Vpřípadě nedodržování této varování může dojít k poranění pracovníka prodejního servisu, obslužného personálu nebo pacientů vlivem elektrického proudu, respektive vlivem mechanických či jiných rizik.
ADVARSEL Danish (DA)	Denne servicemanual findes kun på engelsk. • Hvis en kundes tekniker har brug for et andet sprog end engelsk, er det kundens ansvar at sørge for oversættelse. • Forsøg ikke at servicere udstyret medmindre denne servicemanual har været konsulteret og er forstået. • Manglende overholdelse af denne advarsel kan medføre skade på grund af elektrisk, mekanisk eller anden fare for teknikeren, operatøren eller patienten.
WAARSCHUWING Dutch (NL)	Deze service manual is alleen in het Engels verkrijgbaar. • Indien het onderhoudspersoneel een andere taal nodig heeft, dan is de klant verantwoordelijk voor de vertaling ervan. • Probeer de apparatuur niet te onderhouden voordat deze service manual geraadpleegd en begrepen is. • Indien deze waarschuwing niet wordt opgevolgd, zou het onderhoudspersoneel, de gebruiker of een patiënt gewond kunnen raken als gevolg van een elektrische schok, mechanische of andere gevaren.
HOIATUS Estonian (ET)	Käesolev teenindusjuhend on saadaval ainult inglise keeles. • Kui klienditeeninduse osutaja nõuab juhendit inglise keelest erinevas keeles, vastutab klient tõlketeenuse osutamise eest. • Ärge üritage seadmeid teenindada enne eelnevalt käesoleva teenindusjuhendiga tutvumist ja sellest aru saamist. • Käesoleva hoiatuse eiramine võib põhjustada teenuseosutaja, operaatori või patsiendi vigastamist elektrilöögi, mehaanilise või muu ohu tagajärjel.
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WARNUNG German (DE)	Diese Serviceanleitung ist nur in englischer Sprache verfügbar. • Falls der Kundendienst eine andere Sprache benötigt, muss er für eine entsprechende Übersetzung sorgen. • Keine Wartung durchführen, ohne diese Serviceanleitung gelesen und verstanden zu haben. • Bei Zuwiderhandlung kann es zu Verletzungen des Kundendiensttechnikers, des Anwenders oder des Patienten durch Stromschläge, mechanische oder sonstige Gefahren kommen.
ΠΡΟΕΙΔΟΠΟΙΗΣΗ Greek (EL)	Το παρόν εγχειρίδιο σέρβις διατίθεται στα αγγλικά μόνο. • Εάν το άτομο παροχής σέρβις ενός πελάτη απαιτεί το παρόν εγχειρίδιο σε γλώσσα εκτός των αγγλικών, αποτελεί ευθύνη του πελάτη να παρέχει υπηρεσίες μετάφρασης. • Μην επιχειρήσετε την εκτέλεση εργασιών σέρβις στον εξοπλισμό εκτός εάν έχετε συμβουλευτεί και έχετε κατανοήσει το παρόν εγχειρίδιο σέρβις. • Εάν δεν λάβετε υπόψη την προειδοποίηση αυτή, ενδέχεται να προκληθεί τραυματισμός στο άτομο παροχής σέρβις, στο χειριστή ή στον ασθενή από ηλεκτροπληξία, μηχανικούς ή άλλους κινδύνους.
FIGYELMEZTETÉS Hungarian (HU)	Ez a szerviz kézikönyv kizárólag angol nyelven érhető el. • Ha a vevő szerviz ellátója angoltól eltérő nyelvre tart igényt, akkor a vevő felelőssége a fordítás elkészíttetése. • Ne próbálja elkezdni használni a berendezést, amíg a szerviz kézikönyvben leírtakat nem értelmezték és értették meg. • Ezen figyelmeztetés figyelmen kívül hagyása a szerviz ellátó, a működtető vagy a páciens áramütés, mechanikai vagy egyéb veszélyhelyzet miatti sérülését eredményezheti.
AÐVÖRUN Icelandic (IS)	Þessi þjónustuhandbók er eingöngu áánleg á ensku. • Ef að þjónustuveitandi viðskiptamanns þarfnast annars tungumáls en ensku, er það skylda viðskiptamanns að skaffa tungumálþjónustu. • Reynið ekki að afgreiða tækið nema þessi þjónustuhandbók hefur verið skoðuð og skilin. • Brot á að sinna þessari aðvörun getur leitt til meiðsla á þjónustuveitanda, stjórnanda eða sjúklingi frá raflosti, vélrænum eða öðrum áhættum.
PERINGATAN Indonesian (ID)	Manual servis ini hanya tersedia dalam bahasa Inggris. • Jika penyedia jasa servis pelanggan memerlukan bahasa lain selain dari Bahasa Inggris, merupakan tanggung jawab dari penyedia jasa servis tersebut untuk menyediakan terjemahannya. • Jangan mencoba melakukan servis terhadap perlengkapan kecuali telah membaca dan memahami manual servis ini. • Mengabaikan peringatan ini bisa mengakibatkan cedera pada penyedia servis, operator, atau pasien, karena terkena kejut listrik, bahaya mekanis atau bahaya lainnya.

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AVVERTENZA Italian (IT)	Il presente manuale di manutenzione è disponibile soltanto in Inglese. • Se un addetto alla manutenzione richiede il manuale in una lingua diversa, il cliente è tenuto a provvedere direttamente alla traduzione. • Si proceda alla manutenzione dell'apparecchiatura solo dopo aver consultato il presente manuale ed averne compreso il contenuto. • Il non rispetto della presente avvertenza potrebbe far compiere operazioni da cui derivino lesioni all'addetto, alla manutenzione, all'utilizzatore ed al paziente per folgorazione elettrica, per urti meccanici od altri rischi.
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ĮSPĖJIMAS Lithuanian (LT)	Šis eksploataavimo vadovas yra prieinamas tik anglų kalba. • Jei kliento paslaugų tiekėjas reikalauja vadovo kita kalba - ne anglų, numatyti vertimo paslaugas yra kliento atsakomybė. • Nemėginkite atlikti įrangos techninės priežiūros, nebent atsižvelgėte į šį eksploataavimo vadovą ir jį supratote. • Jei neatkreipsite dėmesio į šį perspėjimą, galimi sužalojimai dėl elektros šoko, mechaninių ar kitų paslaugų tiekėjui, operatoriui ar pacientui.

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ADVARSEL Norwegian (NO)	Denne servicehåndboken finnes bare på engelsk. • Hvis kundens serviceleverandør trenger et annet språk, er det kundens ansvar å sørge for oversettelse. • Ikke forsøk å reparere utstyret uten at denne servicehåndboken er lest og forstått. • Manglende hensyn til denne advarselen kan føre til at serviceleverandøren, operatøren eller pasienten skades på grunn av elektrisk støt, mekaniske eller andre farer.
OSTRZEŻENIE Polish (PL)	Niniejszy podręcznik serwisowy dostępny jest jedynie w języku angielskim. • Jeśli dostawca usług klienta wymaga języka innego niż angielski, zapewnienie usługi tłumaczenia jest obowiązkiem klienta. • Nie należy serwisować wyposażenia bez zapoznania się i zrozumienia niniejszego podręcznika serwisowego. • Niezastosowanie się do tego ostrzeżenia może spowodować urazy dostawcy usług, operatora lub pacjenta w wyniku porażenia elektrycznego, zagrożenia mechanicznego bądź innego.
AVISO Portuguese-Brazilian (PT-BR)	Este manual de assistência técnica só se encontra disponível em inglês. • Se o serviço de assistência técnica do cliente não for GE, e precisar de outro idioma, será da responsabilidade do cliente fornecer os serviços de tradução. • Não tente reparar o equipamento sem ter consultado e compreendido este manual de assistência técnica. • O não cumprimento deste aviso pode por em perigo a segurança do técnico, operador ou paciente devido a choques elétricos, mecânicos ou outros.
AVISO Portuguese-European (PT-PT)	Este manual técnico só se encontra disponível em inglês. • Se a assistência técnica do cliente solicitar estes manuais noutra língua, é da responsabilidade do cliente fornecer os serviços de tradução. • Não tente reparar o equipamento sem ter consultado e compreendido este manual técnico. • O não cumprimento deste aviso pode provocar lesões ao técnico, ao utilizador ou ao paciente devido a choques eléctricos, mecânicos ou outros.
AVERTISMENT Romanian (RO)	Acest manual de service este disponibil numai în limba engleză. • Dacă un furnizor de servicii pentru clienți necesită o altă limbă decât cea engleză, este de datoria clientului să furnizeze o traducere. • Nu încercați să reparați echipamentul decât ulterior consultării și înțelegerii acestui manual de service. • Ignorarea acestui avertisment ar putea duce la rănirea depanatorului, operatorului sau pacientului în urma pericolelor de electrocutare, mecanice sau de altă natură.
ПРЕДУПРЕЖДЕНИЕ Russian (RU)	Настоящее руководство по обслуживанию предлагается только на английском языке. • Если сервисному персоналу клиента необходимо руководство не на английском, а на каком-то другом языке, клиенту следует обеспечить перевод самостоятельно. • Прежде чем приступать к обслуживанию оборудования, обязательно обратитесь к настоящему руководству и внимательно изучите изложенные в нем сведения. • Несоблюдение требований данного предупреждения может привести к тому, что специалисты по обслуживанию, операторы или пациенты получат удар электрическим током, механическую травму или другое повреждение.

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UPOZORENJE Serbian (SR)	Ovo servisno uputstvo je dostupno samo na engleskom jeziku. - Ako klijentov serviser zahteva neki drugi jezik, klijent je dužan da obezbedi prevodilačke usluge. - Ne pokušavajte da opravite uređaj ako niste pročitali i razumeli ovo servisno uputstvo. - Zanemarivanje ovog upozorenja može dovesti do povređivanja serviser, rukovaoca ili pacijenta usled strujnog udara, ili mehaničkih i drugih opasnosti.
VAROVANIE Slovak (SK)	Tento návod na obsluhu je k dispozícii len v angličtine. - Ak zákazníkovi poskytovateľ služieb vyžaduje iný jazyk ako angličtinu, poskytnutie prekladateľských služieb je zodpovednosťou zákazníka. - Nepokúšajte sa o obsluhu zariadenia skôr, ako si neprečítate návod na obsluhu a neporozumiete mu. - Zanedbanie tohto varovania môže vyústiť do zranenia poskytovateľa služieb, obsluhujúcej osoby alebo pacienta elektrickým prúdom, mechanickým alebo iným nebezpečenstvom.
OPOZORILO Slovenian (SL)	Ta servisni priročnik je na voljo samo v angleškem jeziku. - Če ponudnik storitve stranke potrebuje priročnik v drugem jeziku, mora stranka zagotoviti prevod. - Ne poskušajte servisirati opreme, če tega priročnika niste v celoti prebrali in razumeli. - Če tega opozorila ne upoštevate, se lahko zaradi električnega udara, mehanskih ali drugih nevarnosti poškoduje ponudnik storitev, operater ali bolnik.
ADVERTENCIA Spanish (ES)	Este manual de servicio sólo existe en inglés. - Si el encargado de mantenimiento de un cliente necesita un idioma que no sea el inglés, el cliente deberá encargarse de la traducción del manual. - No se deberá dar servicio técnico al equipo, sin haber consultado y comprendido este manual de servicio. - La no observancia del presente aviso puede dar lugar a que el proveedor de servicios, el operador o el paciente sufran lesiones provocadas por causas eléctricas, mecánicas o de otra naturaleza.
VARNING Swedish (SV)	Den här servicehandboken finns bara tillgänglig på engelska. - Om en kunds servicetekniker har behov av ett annat språk än engelska ansvarar kunden för att tillhandahålla översättningstjänster. - Försök inte utföra service på utrustningen om du inte har läst och förstår den här servicehandboken. - Om du inte tar hänsyn till den här varningen kan det resultera i skador på serviceteknikern, operatören eller patienten till följd av elektriska stötar, mekaniska faror eller andra faror.
UYARI Turkish (TR)	Bu servis klavuzunun sadece İngilizcesi mevcuttur. - Eğer müşteri teknisyeni bu klavuzu İngilizce dışında bir başka lisandan talep ederse, bunu tercüme ettirmek müşteriye düşer. - Servis klavuzunu okuyup anlamadan ekipmanlara müdahale etmeyiniz. - Bu uyarya uyulmaması, elektrik, mekanik veya diğer tehlikelerden dolayı teknisyen, operatör veya hastanın yaralanmasına yol açabilir.

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ЗАСТЕРЕЖЕННЯ Ukrainian (UK)	Дане керівництво з сервісного обслуговування постачається виключно англійською мовою. • Якщо сервісний інженер потребує керівництво іншою мовою, користувач зобов'язаний забезпечити послуги перекладача. • Не намагайтеся здійснювати технічне обслуговування даного обладнання, якщо ви не читали, або не зрозуміли інформацію, надану в керівництві з сервісного обслуговування. • Недотримання цього застереження може призвести до травмування сервісного інженера, користувача даного обладнання або пацієнта внаслідок електричного шоку, механічного ушкодження або з інших причин невірної обслуговування обладнання.
CẢNH BÁO Vietnamese (VI)	Tài Liệu Hướng Dẫn Sửa Chữa chỉ có bản tiếng Anh. • Nếu các đơn vị cung cấp dịch vụ cho khách hàng yêu cầu một ngôn ngữ nào khác tiếng Anh, thì khách hàng sẽ có trách nhiệm cung cấp các dịch vụ dịch thuật. • Không được sửa chữa thiết bị trừ khi đã tham khảo và hiểu Tài liệu Hướng dẫn Sửa chữa. • Không tuân thủ những cảnh báo này có thể dẫn đến các tổn thương cho người thực hiện sửa chữa, người vận hành hay bệnh nhân, do sốc điện, các rủi ro về cơ khí hay các rủi ro khác

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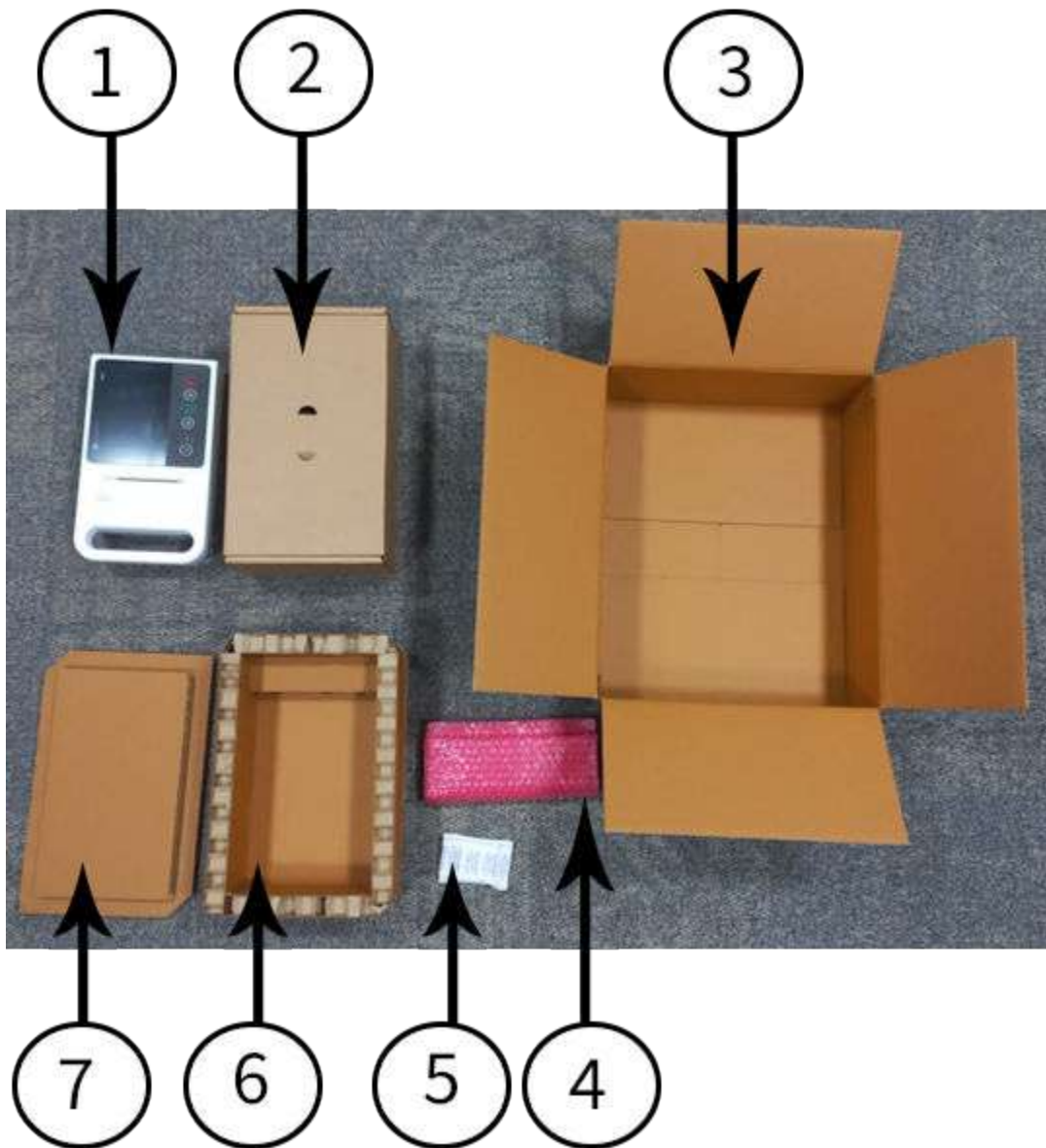
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1 Product overview

The MAC 3 Resting ECG Analysis System (referred to as "the device") is intended to acquire, analyze, display, and record electrocardiograph information for adult and pediatric populations. The basic system provides 3 or 12 lead ECGs and interpretive analysis. The transmission and receive of ECG and other clinical data, to and from, a central clinical information system is optional.

1.1 MAC 3 system kit

The MAC 3 system package box contains the below parts.



Item	Description
1	MAC 3 device.

Item	Description
2	MAC 3 self locking accessories package box (5920251-004). It contains the below parts: - Power supply SW 18W SL power (5920246). - Trunk cable 10-Lead IEC (2104722-001). - Reusable value bulb electrode 6/set (2104783-001). - Limb clamp AHA value 4/set (2104784-001). - Adapter clip, DCAR, wide mouth clip, 14 pack (2104729-001). - Power supply cord INDIA 6A 250V straight 2.5M (6736108-2). - MAC 3 e-Manual pack (3048726-130). - Honeywell barcode scanner with cable (5944816).
3	MAC 3 system kit package box.
4	Anti-static polythene pouch to put the MAC 3 device (5920251-005).
5	Desiccant bag (93109942).
6	Honeycomb buffer foam bottom for MAC 3 device (5920251-002).
7	Honeycomb buffer foam top for MAC 3 device (5920251-003).

1.2 Hardware label locations

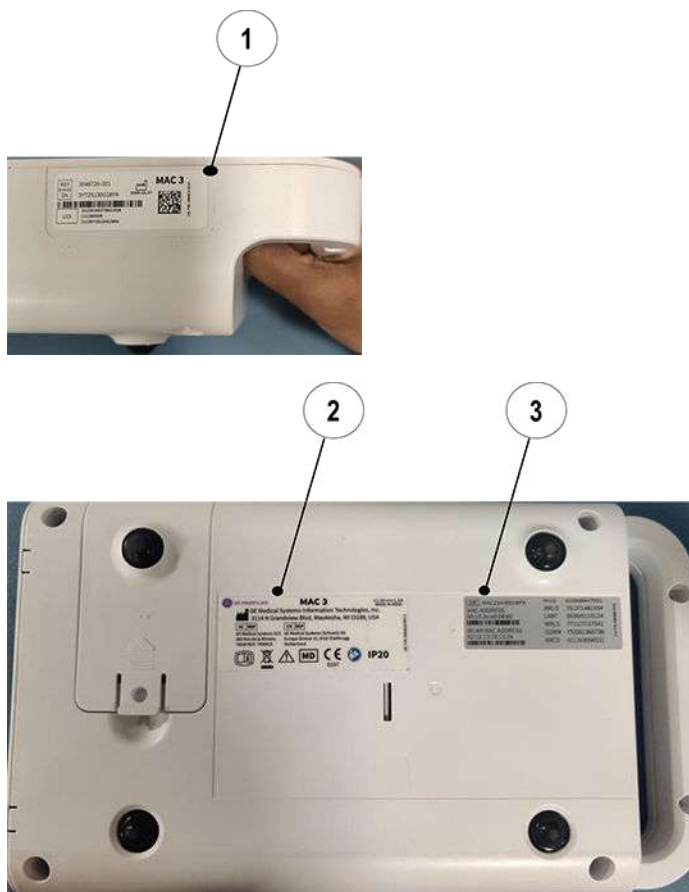


Table 1-1 Label descriptions on the device and packaging

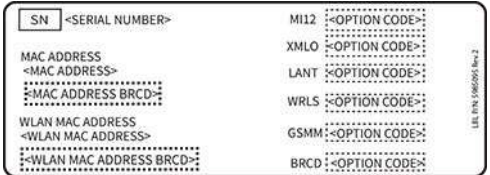
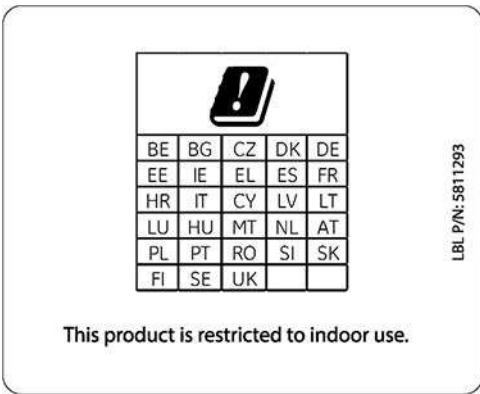
Item	Label	Location	Description
1	Serial number and UDI label	Back of the device.	Device identification. See 1.4 Serial number label on page 18 for a description of the label.
2	MAC 3 system product label	Bottom of the device.	Provides regulatory and cautionary information. See 1.5 Product label on page 18 for an explanation of the label.
3	Option code and MAC address label	Bottom of the device.	The MAC address of the wired network card. Use the option codes to set up the purchased options in your system. 



Table 1-2 Label descriptions on the shipping package of the device

Item	Label	Description
4	Shipping label	Regulatory and safety shipping information of MAC 3 system. 
5	Battery shipping label	
6	Radio Equipment Directive (RED) Label	The Radio Equipment Directive registration information. 
7	Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance.	The Radio Equipment Directive (RED) European Union Declaration of Conformity Guidance.
8	Environmental Symbols	Safety indicators required for shipping. For a full description of symbols, see 1.6 Symbol descriptions on page 19 .
9	Extended Produce Responsibility (EPR) compliance in India.	Compliance to take responsibility for the environmental impact of the batteries. 

1.3 Certification information

Table 1-3 Certification information

	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.

1.4 Serial number label

The serial number label is in the below format.

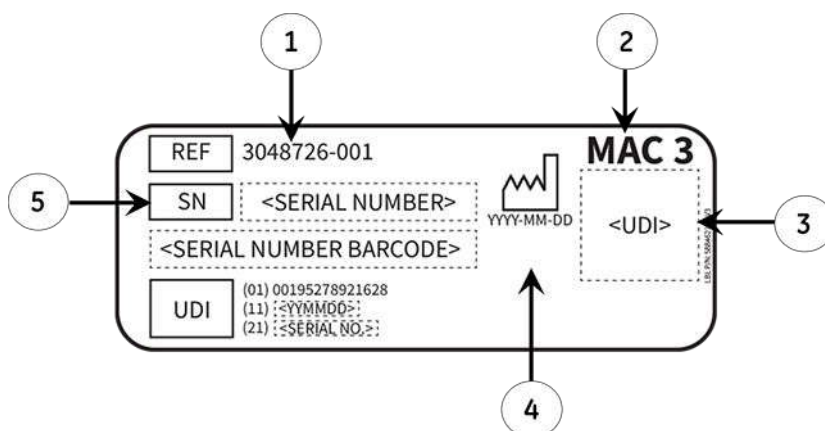


Table 1-4 Serial number label format

Item	Description
1	Product part number
2	Product mode (MAC 3)
3	UDI barcode
4	Date of manufacture in YYYY-MM-DD format
5	Device serial number

1.5 Product label

The product label is in the below format.

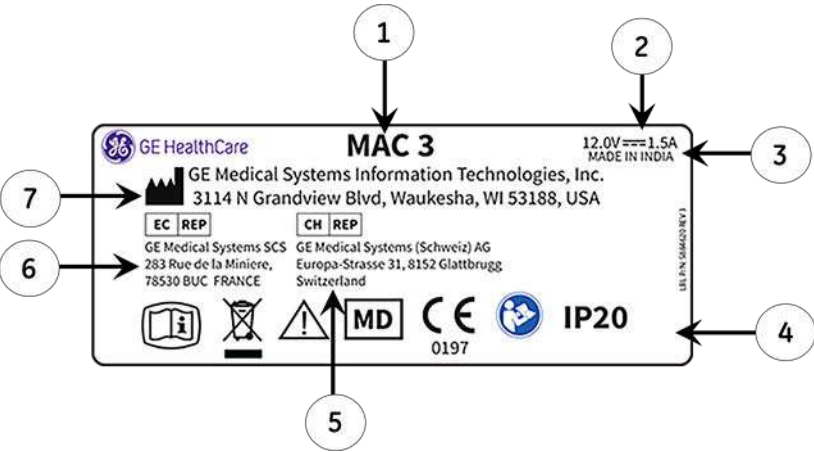


Table 1-5 Product label format

Item	Description
1	Product name
2	Electrical rating of the device
3	Country of origin
4	Symbols. See 1.6 Symbol descriptions on page 19 for a description of the symbols used on this label.
5	Authorized representative in Switzerland. See 1.6 Symbol descriptions on page 19 for the description of the CH REP symbol.
6	Authorized representative in the European Community. See 1.6 Symbol descriptions on page 19 for the EC REP symbol.
7	Manufacturer name and address

1.6 Symbol descriptions

For equipment symbols not shown, refer to the original equipment manufacturer (OEM) manuals.

Table 1-6 Symbols, icons, and descriptions on the device or packaging

Symbol	Description
	Catalog or Orderable Part Number The manufacturer's catalog or part number.
	Serial Number The manufacturer's serial number.
	Batch Code or Lot Number The manufacturer's batch code or lot number.
	Medical Device The device is used for medical purpose.
	Date of Manufacture (Year-Month-Date) The original manufacture date for this device.

Continues on the next page

Table 1-6 Symbols, icons, and descriptions on the device or packaging (Table continued)

Symbol	Description
	Manufacturer The name and address for the manufacturer of this device. It may also include the date it was manufactured.
	Authorized Representative in the European Community The name and address of the authorized representative in the European Community for this device.
	12SL The device uses the Marquette™ 12SL ECG Analysis Program to analyze and interpret ECG readings.
IP20	IP Code (Ingress Protection Rating) Protects the equipment inside the enclosure against ingress of solid foreign objects having a diameter of 12.5 mm and greater.
	CE Mark The device or product conforms with applicable EU (European Union) directives.
	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. <i>As a mandatory action sign, this symbol is identified by a blue background and white symbol.</i>
	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.

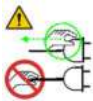
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Table 1-6 Symbols, icons, and descriptions on the device or packaging (Table continued)

Symbol	Description
	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 HealthCare 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.
	Can Be Recycled You may recycle this material or device. Recycle or dispose of in accordance with local, state, or country laws.
	Temperature Limits 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.
	Humidity Limits 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.
	Atmospheric Limits 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.
	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.
	Fragile The contents are fragile. Handle with care.

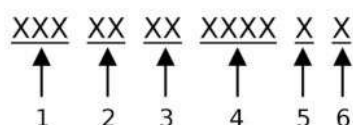
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Table 1-6 Symbols, icons, and descriptions on the device or packaging (Table continued)

Symbol	Description
	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.
	Unique Device Identification Indicates a unique marking for identification of the medical device.
	Authorised Representative in Switzerland The name and address of the authorised representative in Switzerland for this device.

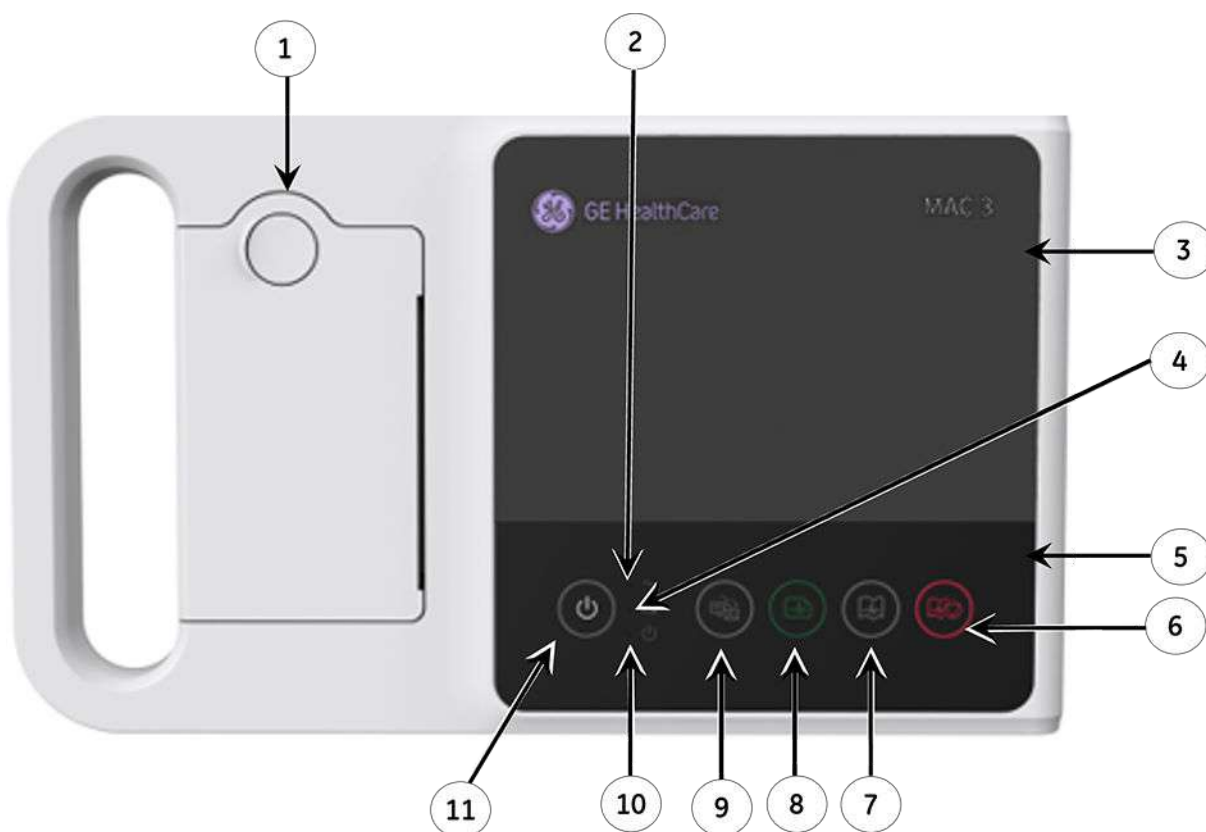
1.7 Serial number format

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 1-7 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.

1.8 Front view

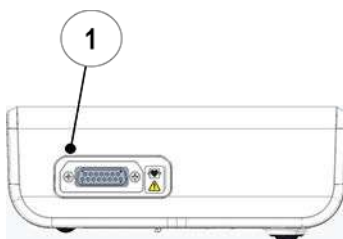


Item	Name	Description
1	Printer	Prints ECG reports.
2	AC Power LED	Shows if the device is on or off. - Green light - ON - external power connected. - No light - OFF - no external power.
3	Display	Displays waveform and text data. The touchscreen enables you to operate directly with the device through touch or tap.
4	Battery LED	Shows the battery status: - Amber light ON - battery charging. - Amber light blinking - battery low. - No light - battery is fully charged, not installed, or discharging.
5	Keysheet	Use the keysheet to: - Power on or off the device. - Start or stop the ECG acquisition. - Start or stop the rhythm record. - Start or stop to print the reports.
6	Stop print	Press this button to stop to print the ECG reports.
7	Start rhythm	Press this button to start the rhythm record.
8	Start ECG	Press this button to start the ECG acquisition.

Continues on the next page

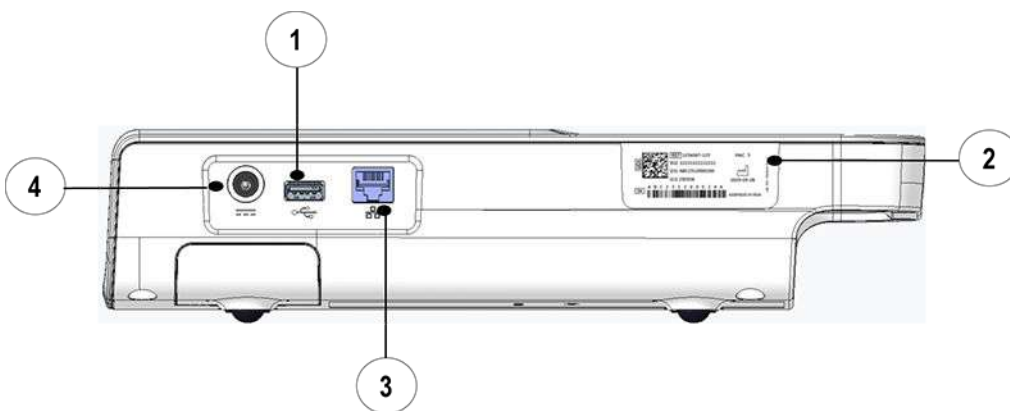
Item	Name	Description
9	Lead button	Press this button to configure the leads.
10	Power on LED	AC power status: - Green light - the device is plugged in and receiving power. - No light - the device is not plugged into AC power.
11	Power button	Turns the device on or off.

1.9 Side view



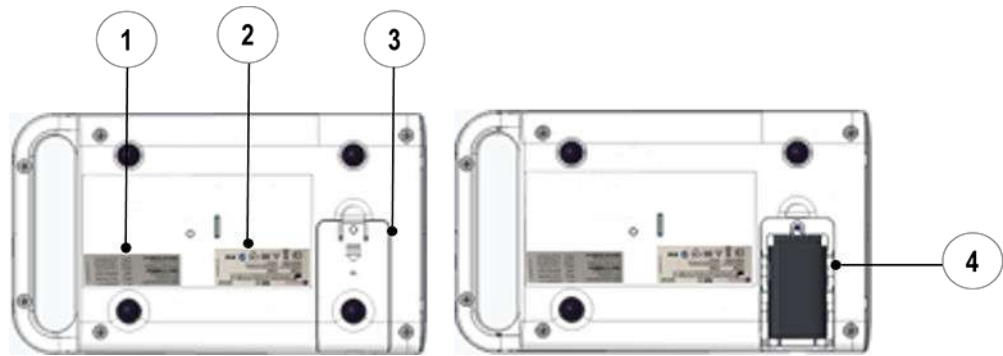
Item	Name	Description
1	Patient cable connector	Connect the patient cable to the device to acquire the ECG.

1.10 Rear view

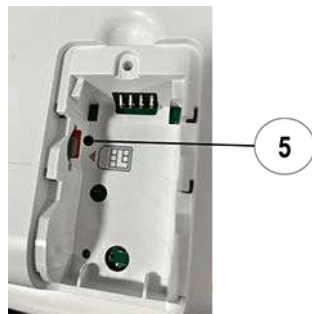


Item	Name	Description
1	USB port	Connect a USB flash drive or USB cable. You can connect a USB flash drive for a software update, backup/restore or export operations, or a barcode reader USB cable.
2	Serial number and UDI label	Shows the serial number and UDI label. For more information on the label details, see 1.4 Serial number label on page 18 .
3	Ethernet/LAN port	Connect an Ethernet cable for LAN network connection.
4	AC/DC power inlet	Connect a GE HealthCare specified AC/DC power adapter.

1.11 Bottom view



Item	Name	Description
1	Serial number and UDI label	Shows the serial number and UDI label of the device. For more information on the serial number label details, see 1.4 Serial number label on page 18 .
2	Product label	Shows the product label of the device. For more information on the device product label details, see 1.5 Product label on page 18 .
3	Battery compartment	Holds the rechargeable Lithium-ion battery.
4	Battery	Rechargeable Lithium-ion battery.



Item	Name	Description
5	GSM SIM slot	Insert the SIM card to connect the device to the mobile network.

2 Architecture

2.1 System architecture

The diagram below illustrates the system architecture of the device:

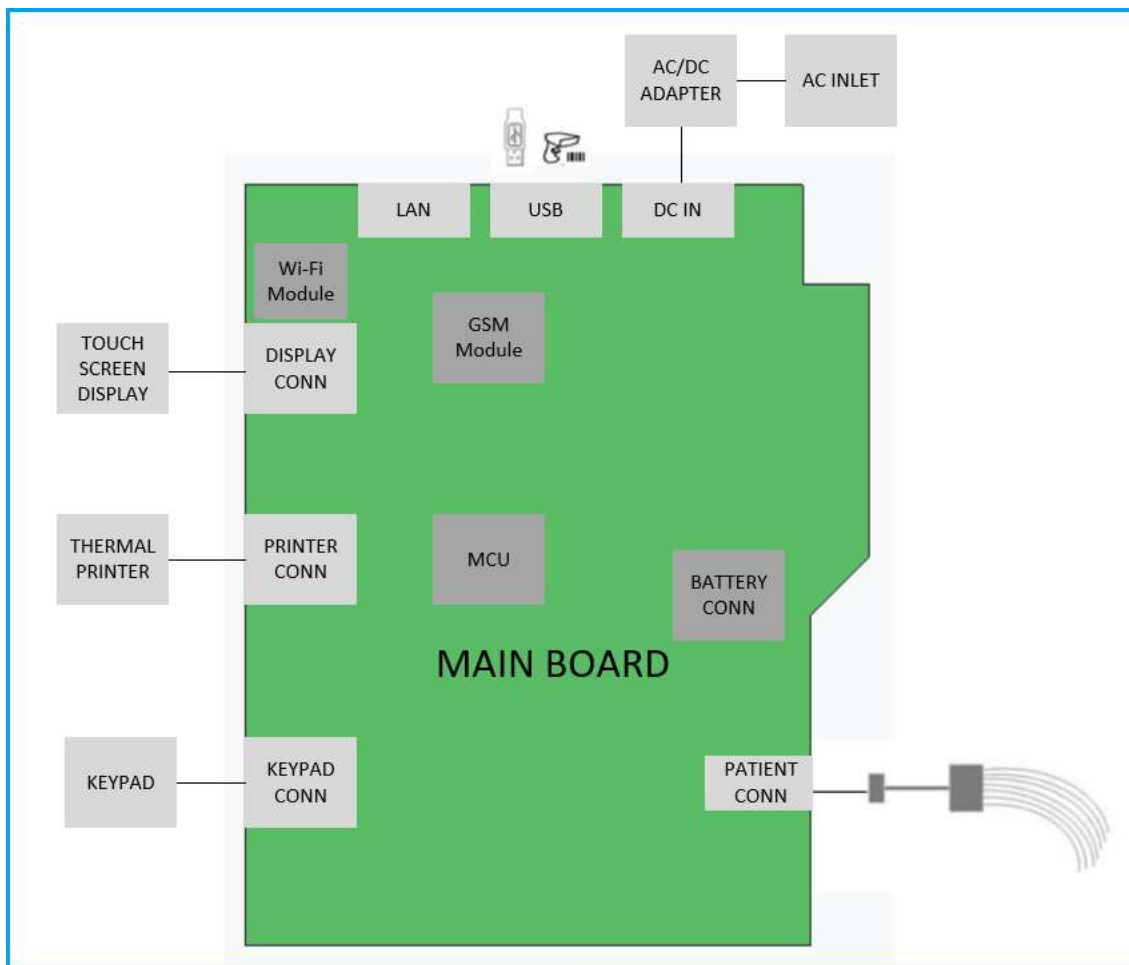


Table 2-1 MAC 3 system components

Component	Description
Main board	All of the peripherals, such as the touch screen display, keysheet, printer, LAN, Wireless, USB ports, power supply, and patient cable connection are interfaced and controlled by the CPU through the main board.
Power supply	The power inlet connector interfaces with the AC/DC module. The AC/DC is a 60 Watt power supply accepting a wide input AC voltage and delivering 24V DC to the main board.
Keysheet	A membrane keysheet with tactile feedback and 5 keys.
Printer	The printer has a Z-fold thermal printhead, roller, motor, paper sensors, and door sensor.

Continues on the next page

Table 2-1 MAC 3 system components (Table continued)

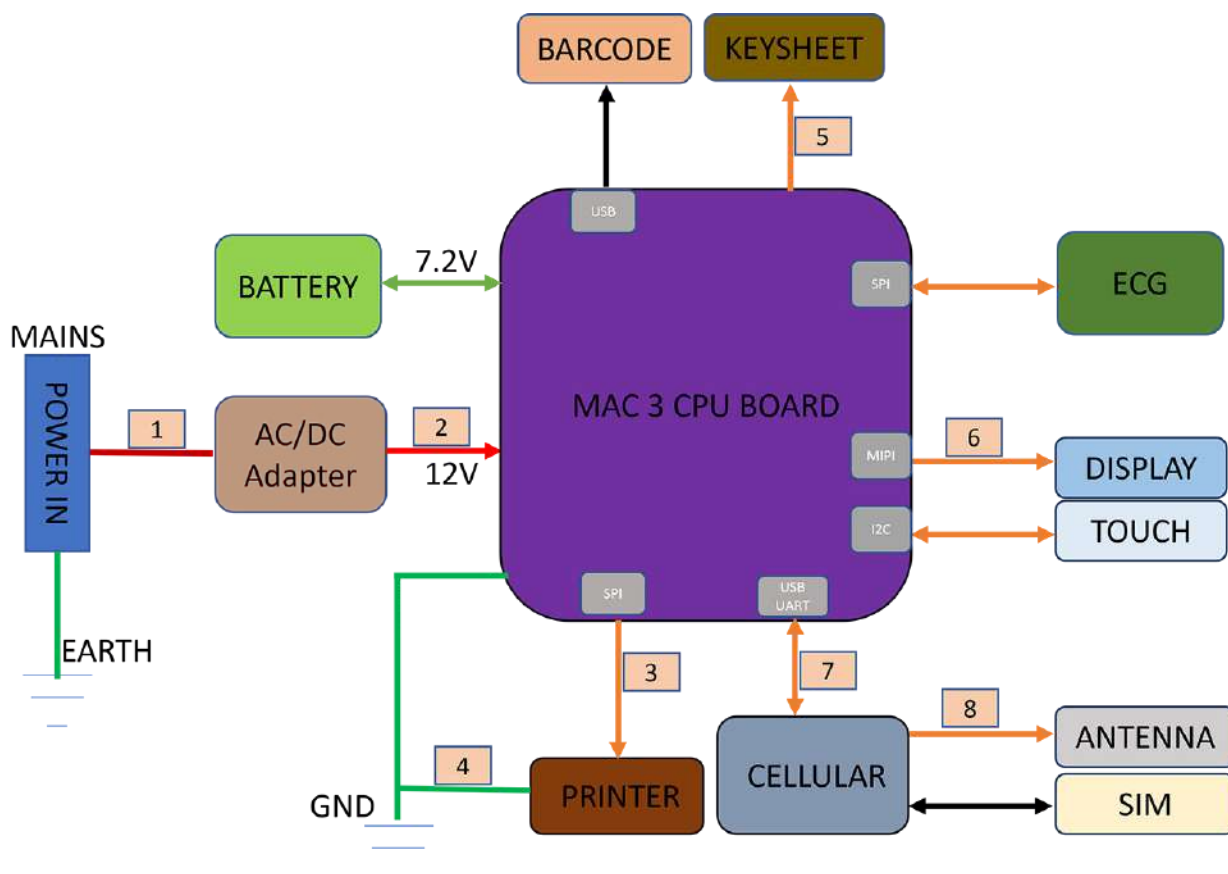
Component	Description
Display module	The display is a 5 inch diagonal graphics, LED backlight display with Projected Capacitive (P-CAP) multipoint touch input that works while wearing medical exam gloves, 720 x 1280 pixels resolution, and interfaced to the main board through the interface cable.
Wi-Fi module	The Wi-Fi module interfaces with 802.11a/b/g/n WLAN and controlled by the main board.
GSM board	The GSM network connection is interfaced and controlled by the GSM board.

2.2 Product interfaces external connections

Table 2-2 Product interfaces external connections

Type of port	Number of ports	Description
RJ45 port	1	Connects to an ethernet network using a 10/100Base-T Ethernet connector.
USB connector	1	Connects to USB-capable devices, for example, external barcode reader or external USB storage devices. Use the external USB storage device to: • Store ECGs • Flash the device with software updates • Connect memory or future I/O extensions
Patient cable connector	1	Connects the patient cable to acquire the ECG.

2.3 Harness diagram



Item	Description	Parts included in	
		FRU description	FRU part number
1	Mains power cable	Not Applicable	Not Applicable
2	AC/DC Adapter cable	MAC 3 power supply	5025600-106
3	Printer interface cable	MAC 3 printer module assembly	5025600-104
4	Earthing cable	MAC 3 mechanical kit	5025600-103
5	Keysheet interface cable	MAC 3 top cover assembly	5025600-102
6	Display interface cable	MAC 3 top cover assembly	5025600-102
7	GSM cable, MAC 3	MAC 3 GSM PWA kit	5025600-101
8	MAC 3 GSM and Antenna assembly	MAC 3 GSM PWA kit	5025600-101

3 Equipment setup

3.1 Connect GSM (cellular network)

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
- Disconnect the AC power cord from the device.

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 or LAN network, you can use a cellular network.



NOTE

This applies only if you use the device as a mobile device.

To connect to a cellular network:

1. Turn the device to view the bottom side.
2. Carefully lift the notch and move the battery cover in the direction shown on the cover to release from the battery compartment.



3. Remove the battery cover.



4. Remove the battery.



5. Put the SIM card in the slot in the direction to align to the SIM symbol on the battery compartment.



6. Replace the battery and battery cover.
7. Configure the device to connect to a cellular network. See section *Configure the GSM network* in *MAC™ 3 Operator's Manual*.

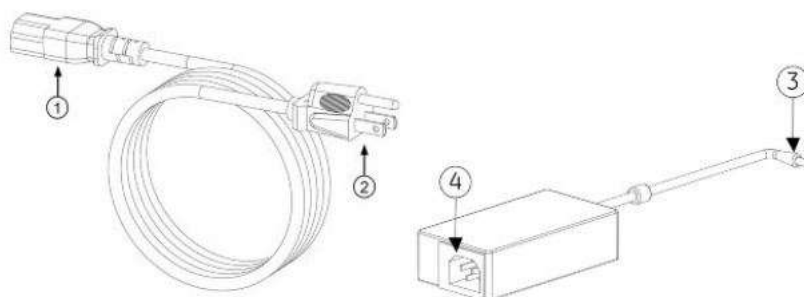
3.2 Connect the AC power

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 you are not sure on the condition of the protective ground conductor, operate the unit from its battery.



NOTE

Unplug the AC power cord (Item 2) to disconnect the MAC 3 device from the AC outlet.

Table 3-1 Power cord parts

Item	Description
1	Female end of the AC power cord connected to the back of the AC/DC adapter.
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 device label. If does not match, do not connect the system to the power line until you adjust the power source to match the device 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.

**NOTE**

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

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

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

3.3 Connect the patient cable

Make sure that all the lead wires connected correctly to the ECG lead block.

Turn the device to side view to show the patient cable connector. Connect the patient cable to the patient cable connector to acquire the ECG of a patient.



3.4 Connect the external barcode reader

If you purchase the optional barcode reader with the device, connect it to the USB port on the device. Make sure that you enable the **USB** settings in **Settings > System > Hardware** screen.



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.



1. Connect the barcode reader cable to the USB port of the device.



2. Make sure that you do the barcode test before you use the barcode reader for the first time. For more information, see [7.13 Perform barcode reader diagnostic test on page 99](#).

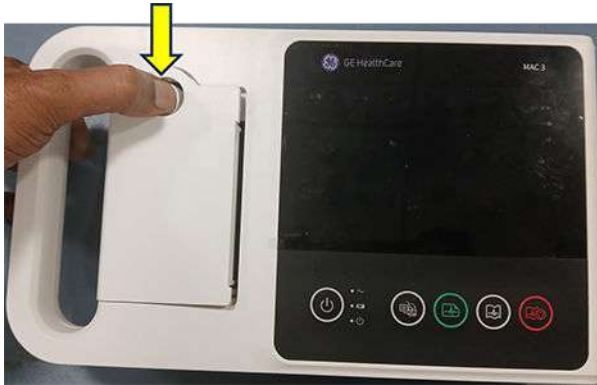
3.5 Insert the paper

Before you start this procedure, make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
- Put the device on a flat surface.
- Use the Z-fold paper.

To insert the paper:

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



2. Pull the paper lifting tape and place the paper above it, but do not remove the paper lifting tape from the device. Then slide the paper into the device until it is fully inserted.

**NOTE**

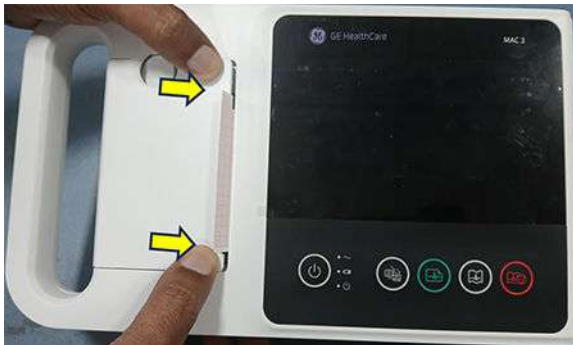
If the paper has Q marks, the Q marks must be on the top left side.



3. Advance the first sheet of paper.



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



3.6 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.



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.

To connect to a wired network:

1. Connect an Ethernet cable to the RJ45 port on the rear side of the device.



2. Configure the device to connect to a wired network. See section *Configure Ethernet network* in *MAC™ 3 Operator's Manual*.

3.7 Configure the device

When the device is ready for operation, use the information in the MAC 3 Operator's 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 sections *Export setting to USB* and *Import settings from USB* in the *MAC™ 3 Operator's Manual*.

3.8 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:

1. Record and print a resting ECG.
2. Save, print, delete, transmit, and export patient reports. See *MAC™ 3 Operator's Manual*.

4 Login and security

4.1 Power on the device

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

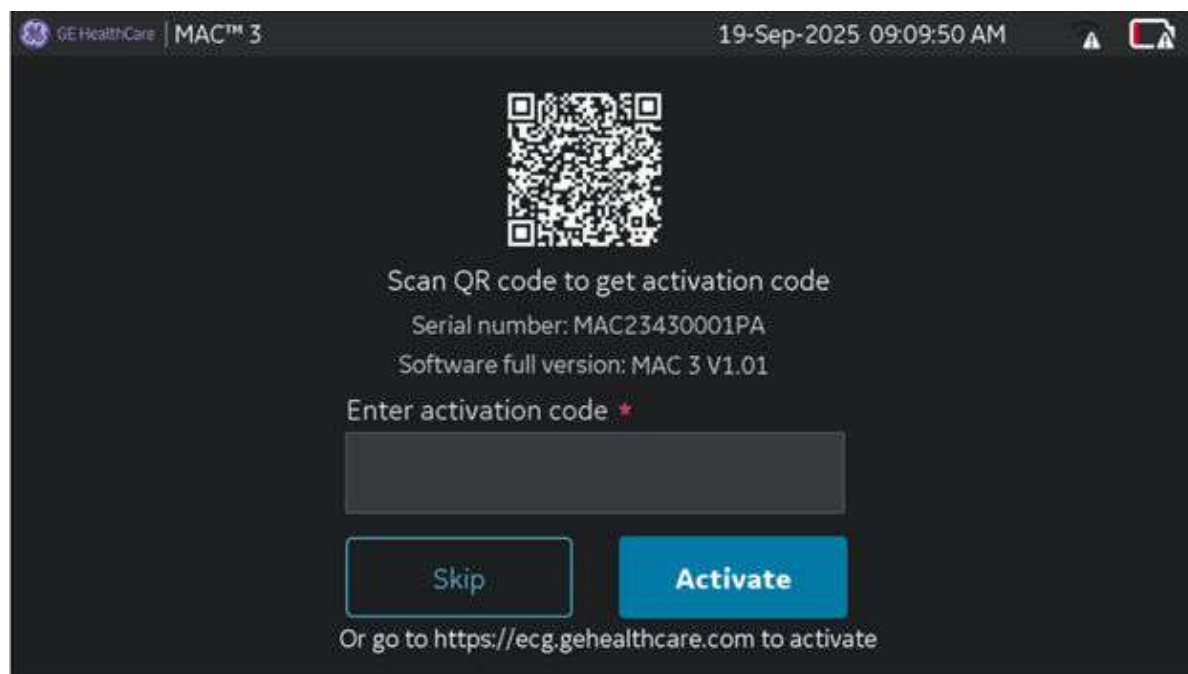
The device is powered on. The **Power on** LED on the front panel is green.

- If you use the device for the first time, the activation screen displays. You must complete the self registration before you log in. For more information on how to do the self registration, see [4.2 Self registration on page 38](#).
 - A notification message displays, if it is configured by the administrator.
2. Select **Accept**.
 - If you enable the **Device password**, you need to log on to the device.
 - If you disable the **Device password**, you can automatically logged on to the device.

4.2 Self registration

The self registration allows you to activate the device and create a GE HealthCare Electronic Software Delivery account. The warranty period for the device starts from the day you activate your device.

1. Perform one of the actions below to launch the online registration page:
 - Power on the device and scan the **QR code** on the device screen.
 - Go to <https://ecg.gehealthcare.com>.



2.

**NOTE**

Enter a valid email address in the **Email (owner / contact)** field and select anywhere to confirm. You will receive an One Time Passcode (OTP) via email. Enter the code in the **Email Verification Code** field and select **Verify** to complete the email verification.

Complete the required (*) fields in the online registration form.


GE HealthCare

Product Activation

To activate your device, please complete the fields below. This information should accurately reflect where the device is primarily located. The device will require a key for activation. To retrieve the activation key, complete the form below & click Submit.

Language Selection

ENGLISH
 

Activation Type

☒ MAC 3
 ☐ MAC 5
 ☐ MAC 7
 

* Serial Number
 

Contact Information

* Required fields

* First name (owner / contact)

* Last name (owner / contact)

* Institution / Hospital Name

* Role / Specialty

Please select one



* Country

Type to search...

* State / Province

* Street Address

* City

* Zip

* Phone Number

* Email (owner / contact)

Resend

* Email Verification Code

Verify

☐ Remember Me

If you use the "remember me" function to stay logged in between visits we place an identification cookie on your machine with an expiration date of 180 days from the day you last visited. This is not used for other purpose than to identify you on your next visit. This cookie contains a unique identifier that is used to match future visits with your account. At any time you may stop this feature by simply deleting your browser cookies. You may choose not to accept this cookie. You will still be able to use the site, but will have to provide your details each subsequent visit to the site when activating additional devices. To find out more about the cookies we use, see our privacy notice.

BIWX

Security Code

Enter security code shown above

Submit

3. Select **Submit**.

The **Activation Key** displays.



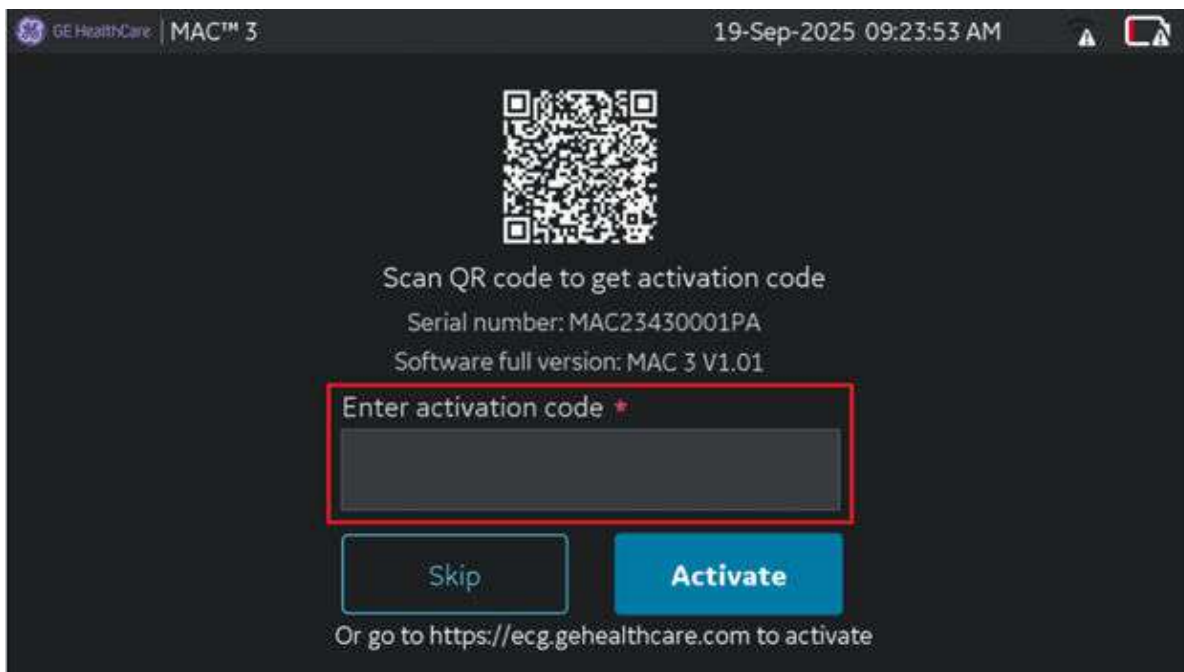
To resolve the self registration errors, see [13.1 Self registration errors](#) on page 163.



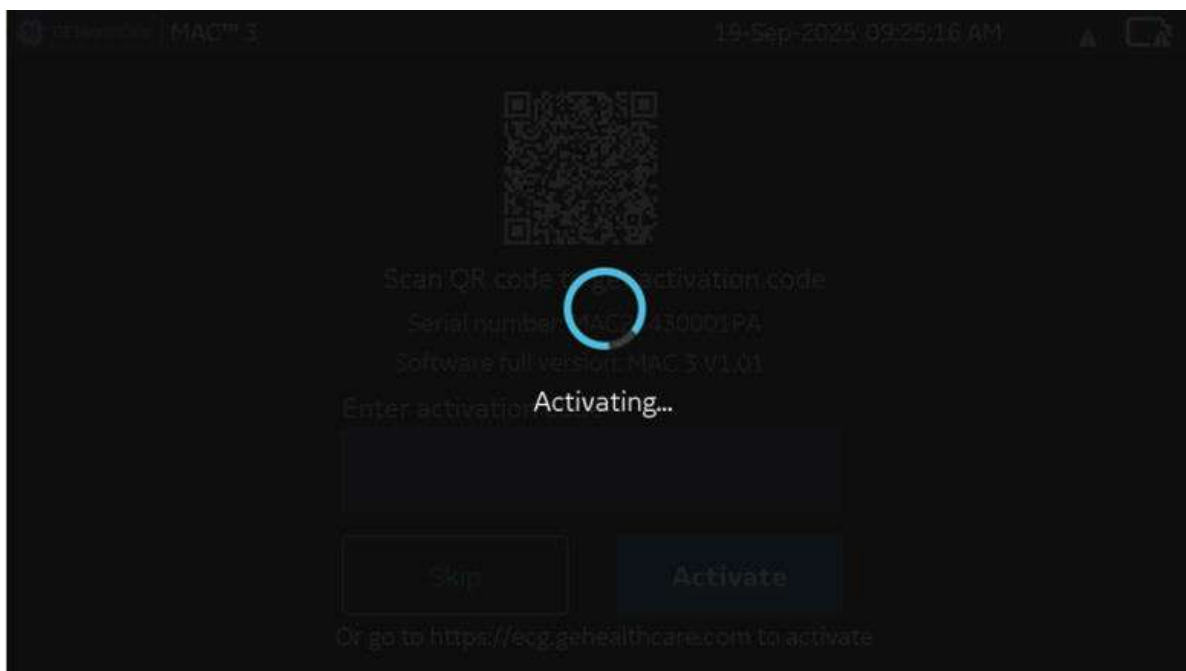
NOTE

If you register again with the same serial number, you will receive the same **Activation Key**. A new E-delivery account will not create, if you try with the same or a different email address.

4. Enter the activation key in the **Enter activation code** field on the device and select **Activate**.



The QR code activating progress displays.



After the device activation the Acquisition screen displays.



NOTE

If you select the **Skip** option, then the activation screen display each time when you power on the device.

4.2.1 E-Delivery welcome and entitlement emails

After, you complete the know your customer (KYC) process. You receive the E-Delivery Welcome email and the Entitlement email for the product that you have self registered.

1. Open the Welcome email.

The Welcome email display.



2. Click the **Software Portal**.

The **Login** displays.

3. Login with the supplied **User ID** and **Password**. You must change your password immediately.

The **License & Delivery Portal** displays.



NOTE

- E-delivery enables you access to all available software versions. After you complete the self-registration process, you will receive a Welcome email and an Entitlement email in less than 7 days.
- The KYC procedure can complete in 1 to 7 days. If a customer fails the KYC procedure, the International Trade Control (ITC) group communicate with region sales. The region sales group communicate to the customer about the issue.

If the **MAC 3** link is not available in the **Your Downloads** area, click **Home** or refresh your web browser.

4. Click the **MAC 3** link in the **Your Downloads** area.
The **Download Packages** display.
5. In the **New Versions** tab, click the description of the software version to download.
The **Downloads** display.
6.  **NOTE** Make sure that you download all files in the **Files** tab. If not, the software update cannot be successful.

In the **Files** tab, perform one of the below steps to download the files for software upgrade:

- a. Click each of the files separately.
- b. Select the file checkbox and click **Download Selected Files**.

You can download the below files:

- Production software application - Product image.
- Manuals - All the manual versions in PDF.
- Release notes - The release details and software upgrade instruction.

7. Extract the file that you downloaded.
8. Copy all the extracted files to a FAT32 formatted USB.
9. Update the software. For more information on how to update the software, see [6.1 Update the software on page 67](#).

4.2.2 E-Delivery entitlement email after bulk entitlement

After you complete the self registration, the device will be included in the bulk entitlement process for next software release. You need to complete the bulk entitlement and email wizard for the new software update. You receive an Entitlement email for a new software update if it is available for your device.

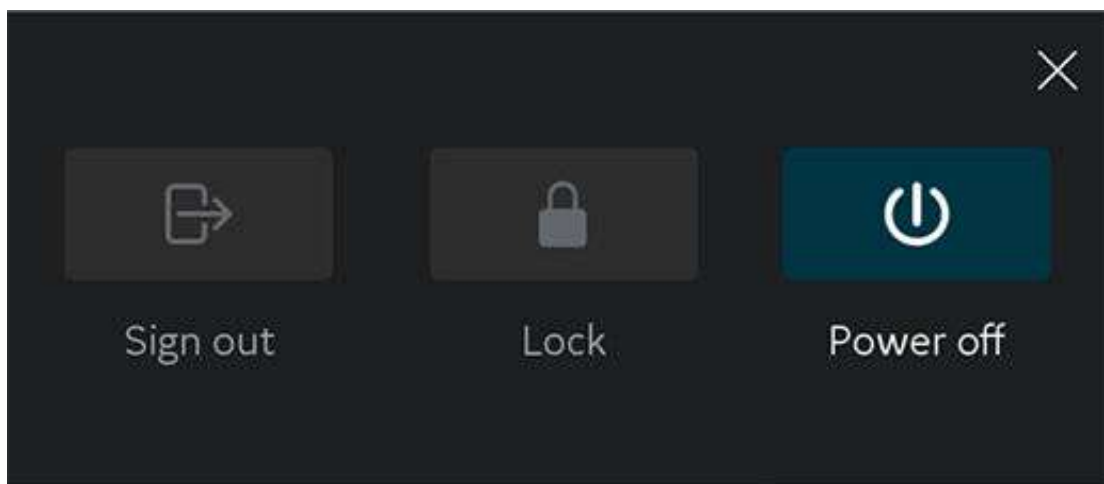


To download the software, see [Step 3](#) to [Step 6](#) in [4.2.1 E-Delivery welcome and entitlement emails on page 42](#).

4.3 Power off the device

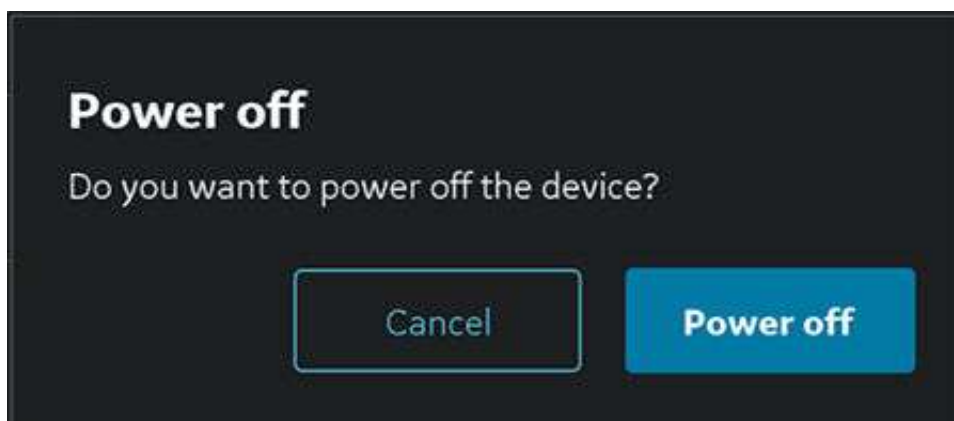
1. Before you power off the device, complete pending tasks, for example, acquire an ECG and save configuration settings.
2. Press the **Power** button on the front panel for a few seconds.

The **Power Options** display with **Sign out**, **Lock**, and **Power off** options.



3. Select **Power off**.

The **Power off** confirmation displays.



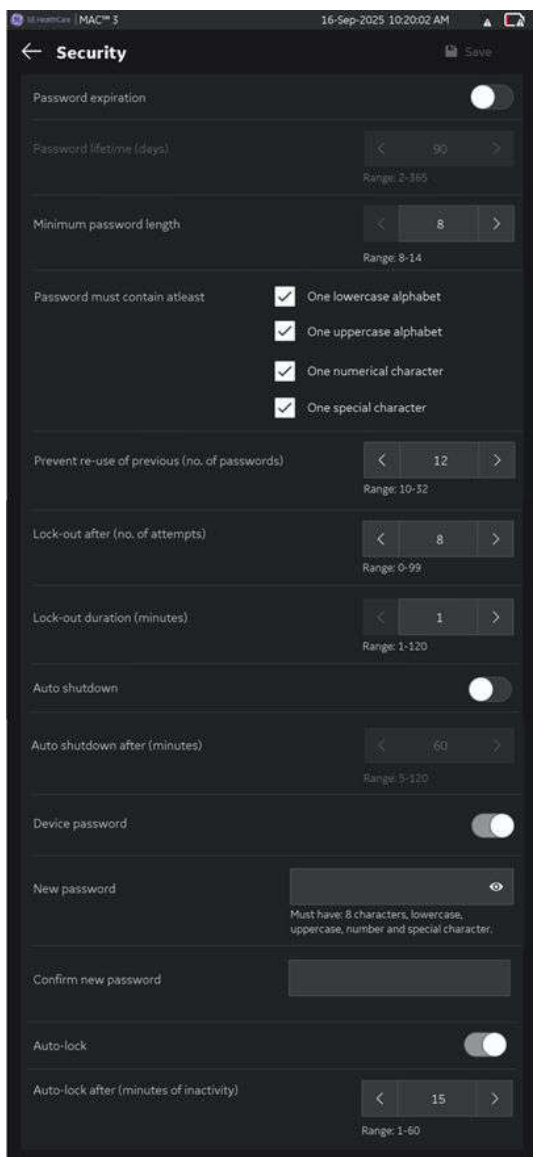
4. Select **Power off** to power off the device.

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

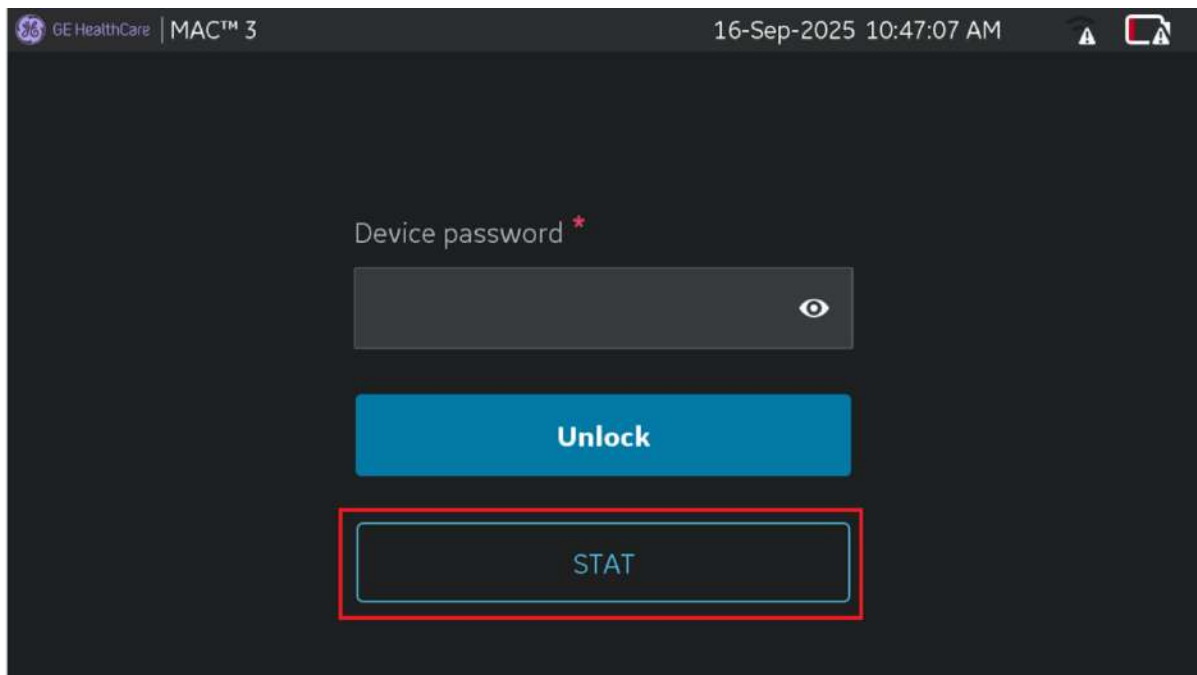
If you select **Cancel** the device does not power off.

4.4 Enter the device in STAT mode

If you enable the **Device password** setting in **Settings > System > Security** screen. A STAT user can log on to the device to get a patient ECG in an emergency.

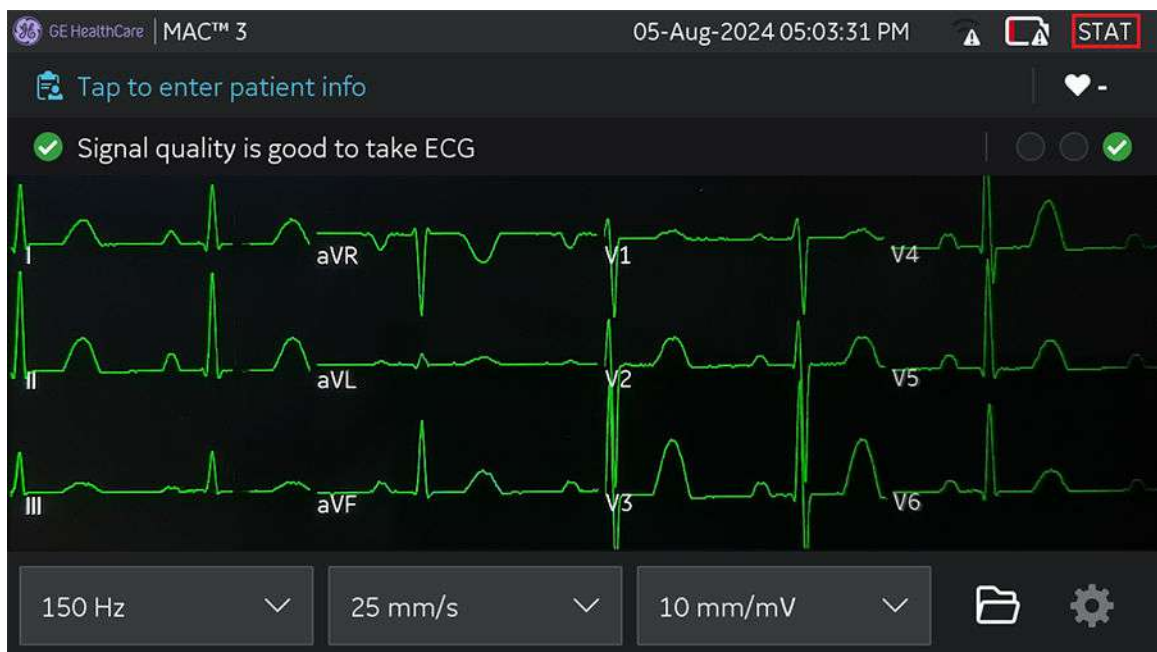


1. Press the **Power** button on the front panel for a few seconds to start the device.
The device is powered on. The **Power on** LED on the front panel is green. The login screen displays.



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

The **Acquisition** screen displays with **STAT** user.



You can do the below tasks in STAT mode:

- Enter patient information and acquire an ECG.
- If, you set the **Auto ECG Storage** to **All ECGs/Only abnormal ECG**, you can store the ECGs to file manager.
- Change the report format of the ECG in review screen, file manager, and retro review screen.
- Print the ECG report.
- Change the **Filter**, **Speed** and **Gain** in the Acquisition screen.

- Change the **Speed** and **Gain** in the review screen, file manager, and retro review screen.
- Enable/disable **Auto shift** and **Auto gain** in the review screen, file manager, and retro review screen.

You cannot do the below tasks in STAT mode:

- Configure the settings.
- Review the reports acquired in **Admin** user mode.
- Transmit the ECG reports.
- Export the ECG reports to USB flash drive.
- Delete the ECG reports.

4.5 Log on to the device

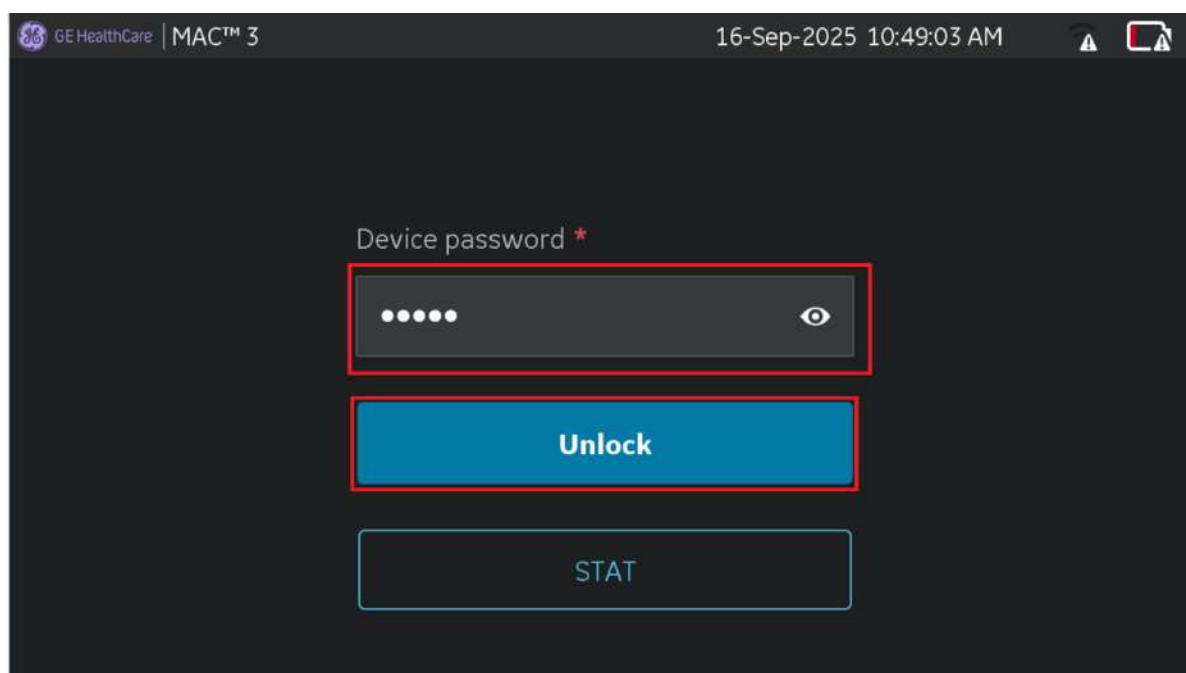
Make sure that you enable the **Device password** setting in **Settings > System > Security** screen. Enter the device password on the **Login** screen to enable user authentication to allow users to log on to the device.

Table 4-1 Types of device password

Type of password	Description
Device password	You can configure the device password in Security screen.
Admin password	You can change the default Admin password.

1. Do one of these steps:
 - If the device is shutdown, power on the device. See Power on the device.
 - If the device is locked, unlock the device. See [4.8 Unlock the device on page 54](#).

The **Login** screen displays.



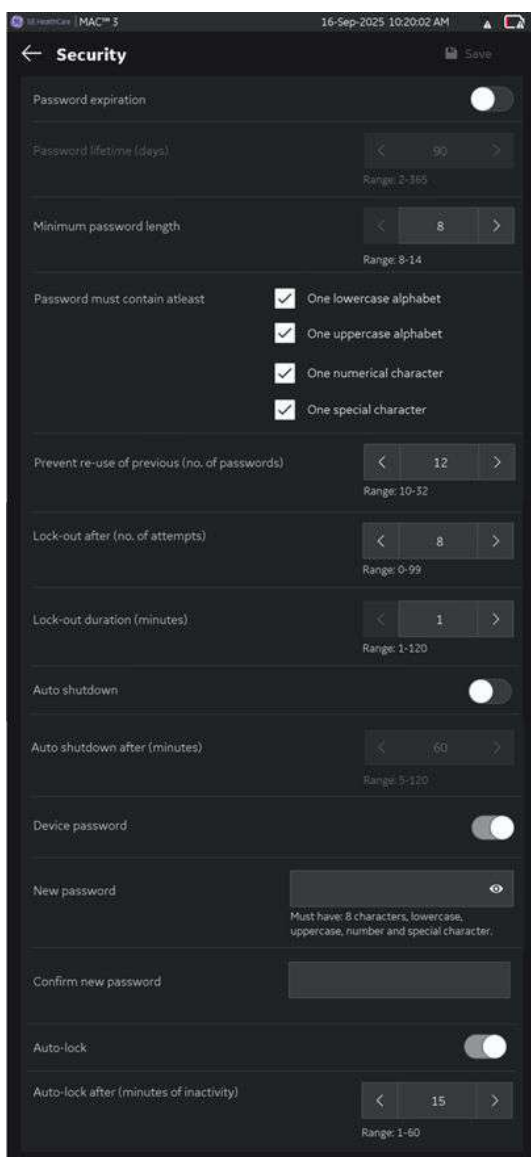
2. Enter the password.
 - To verify that you entered the correct password, select  icon to view the password.
 - Change the password immediately for security reasons.
 - If you are the Admin user and forgot your password, perform a system reset to reset the password to the default password. For more information, see [4.10 Perform system reset on page 58](#).
3. Select **Unlock**.
 - If the login credentials are correct, you are successfully logged on to the device.
 - If your login fails, see the table below:

Table 4-2 Login errors

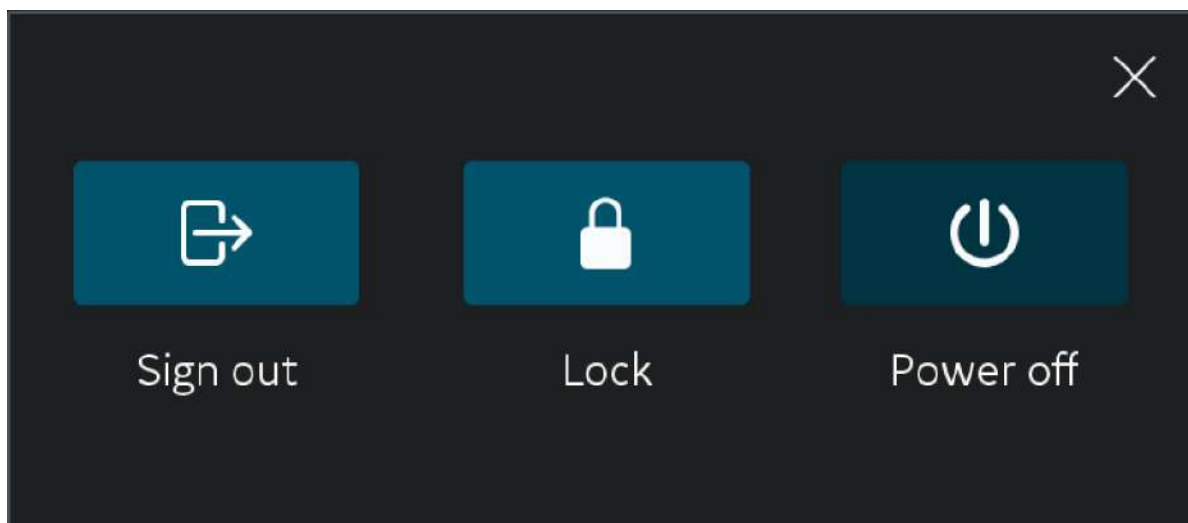
Error message	Cause	How to troubleshoot
Incorrect password	You entered your password incorrectly.	Re-enter your correct password again.
	You forgot your password.	Reset your password, then log on to the device again.
Change your password	Your password has expired.	Perform the procedure 4.9 Change the password on page 55 and log on to the device again.

4.6 Log out of the device

Log out of your user session when you complete to use the device. Make sure that you enable the **Device password** setting in **Settings > System > Security** screen.

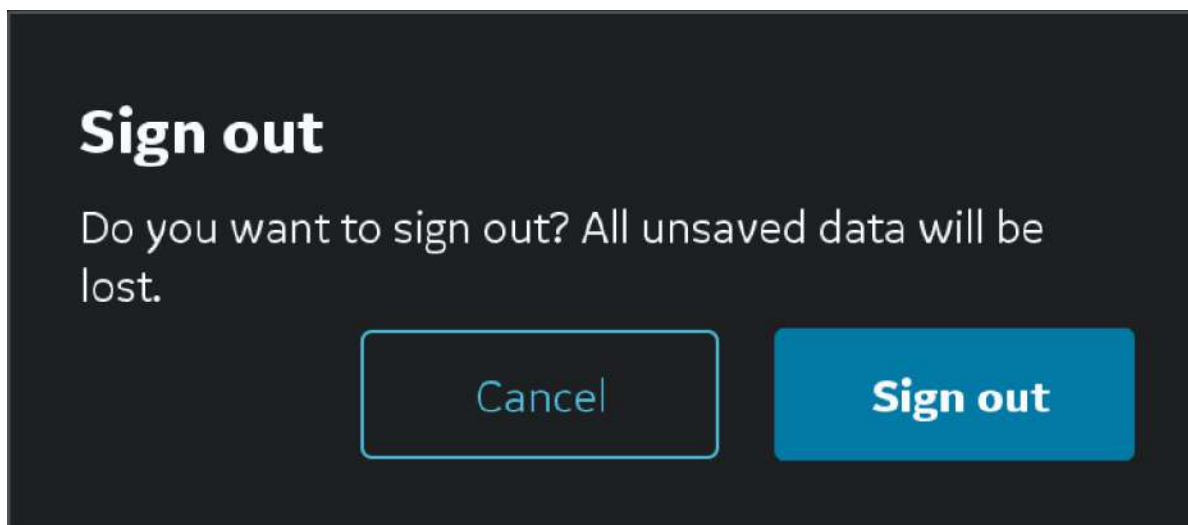


1. Complete pending tasks, for example, acquire an ECG or save the configuration settings, before you log off from your user session.
2. Press the **Power** button on the front panel for a few seconds.
The **Power options** display with **Sign out**, **Lock**, and **Power off** options enabled.



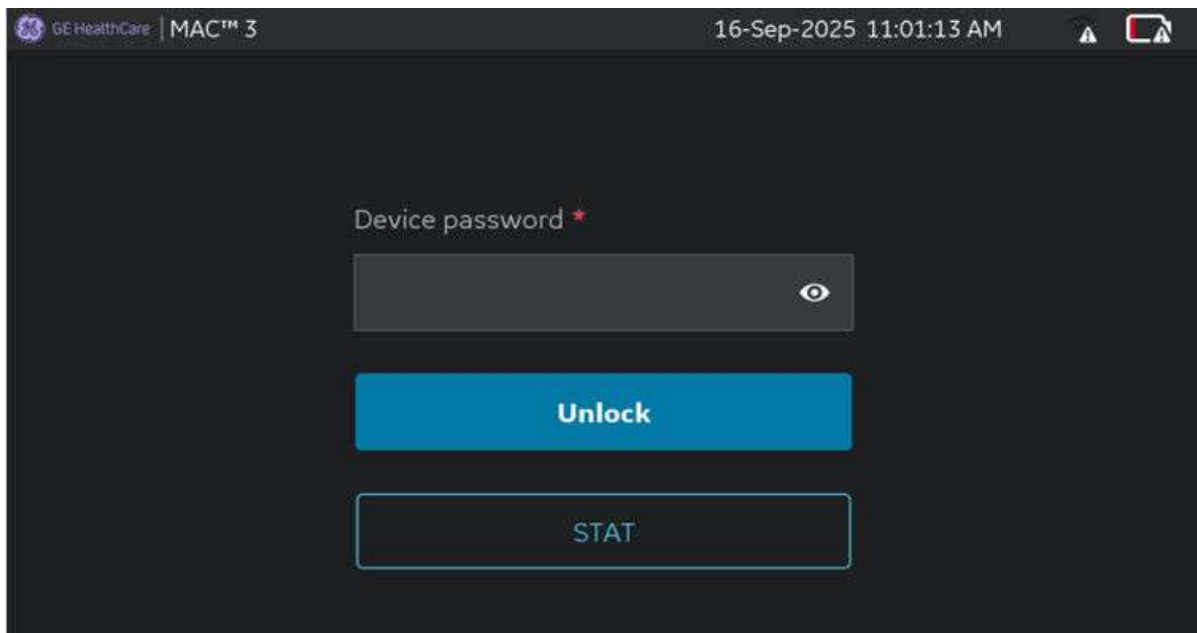
3. Select **Sign out**.

The **Sign out** confirmation displays.



4. Select **Sign out** to log out the device.

You will be logged out from your user session and displays the login screen.

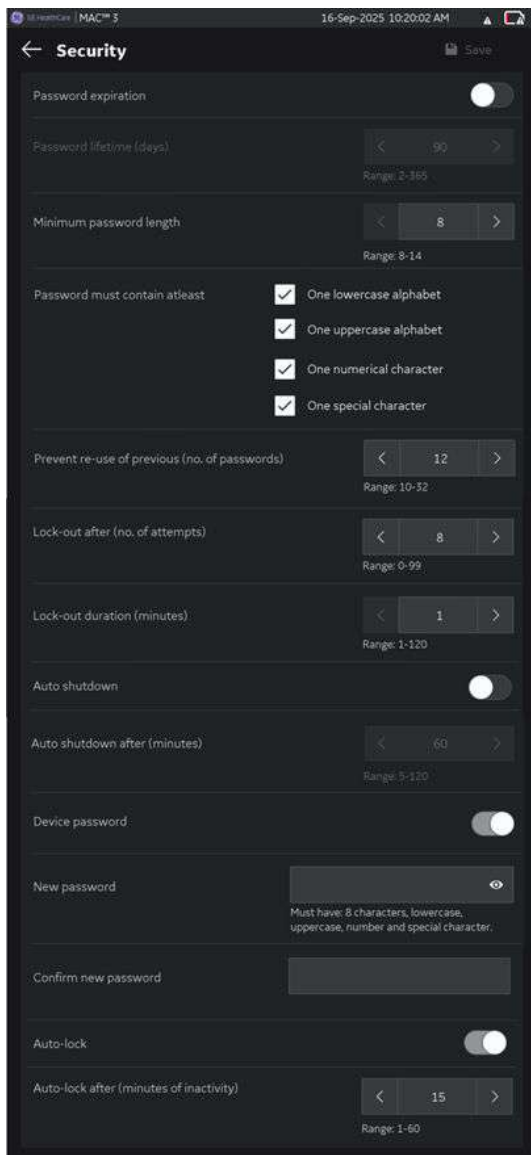


If you select **Cancel** the device does not sign out.

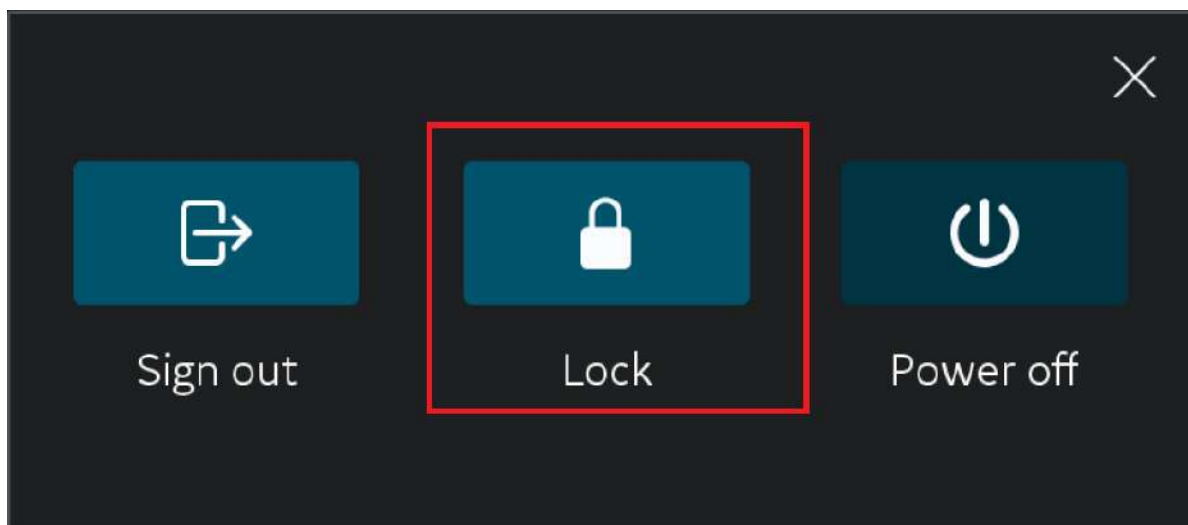
4.7 Lock the device

You cannot lock the device while the ECG or rhythm acquisition, or report print, transmission, deletion, saving of files, and export is in progress.

Make sure that you enable the **Device password** setting in **Settings > System > Security** screen.

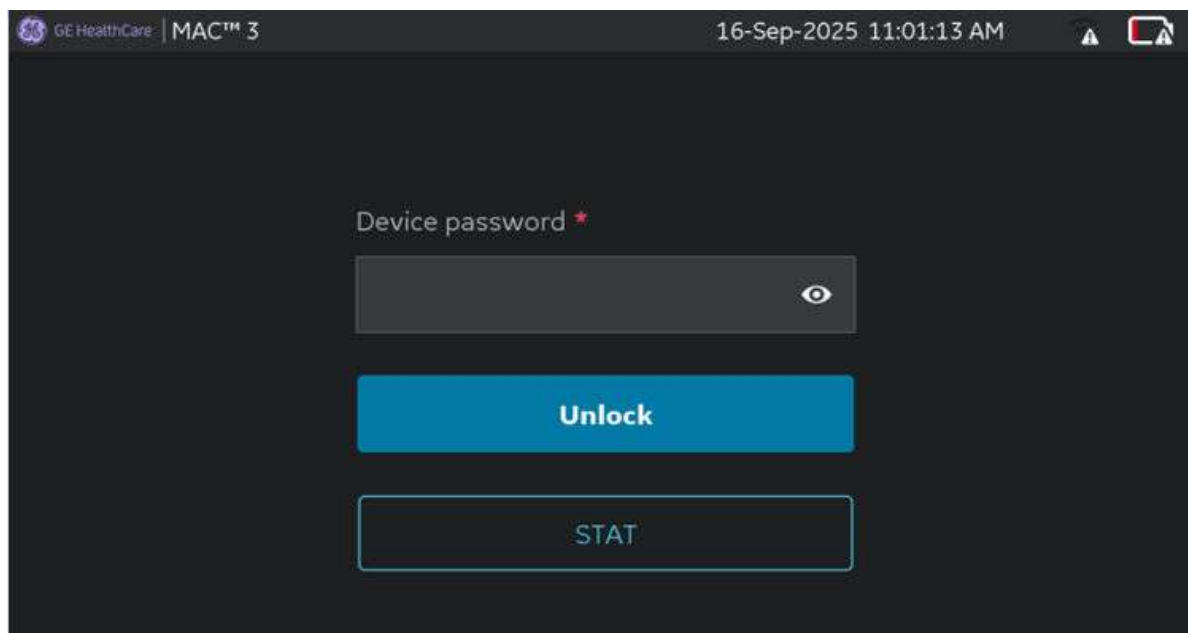


1. Complete your tasks.
2. Press the **Power** button on the front panel for a few seconds.
The **Power options** display with **Sign out**, **Lock**, and **Power off** options enabled.



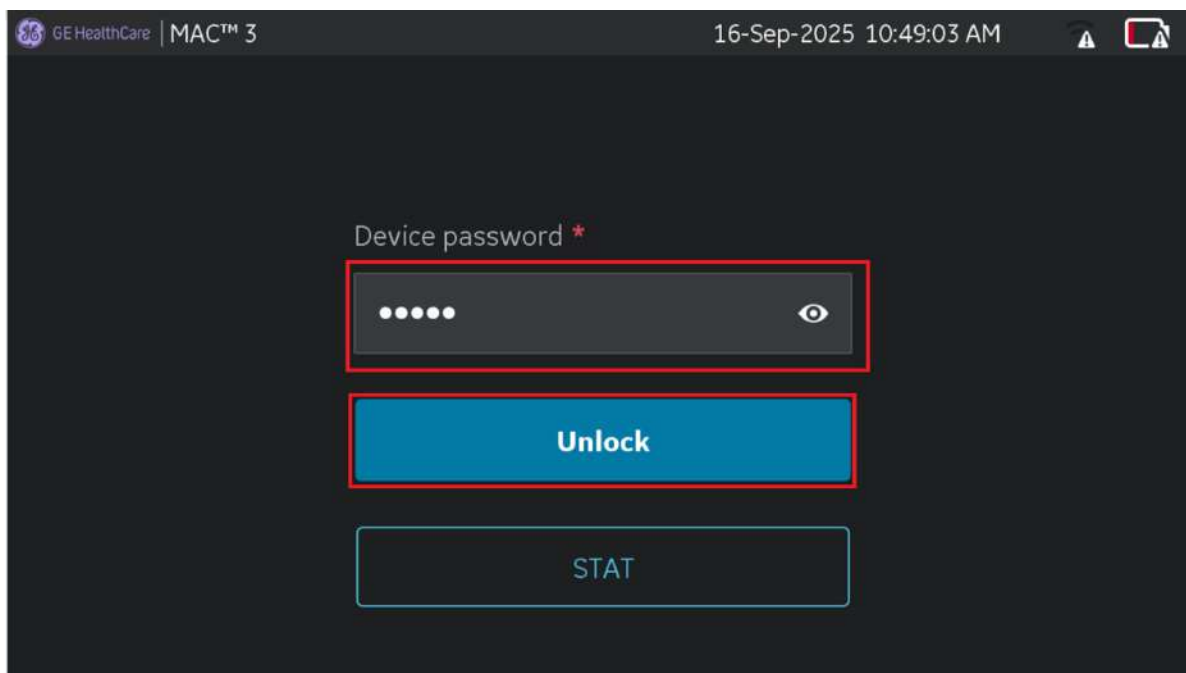
3. Select **Lock**.

The device is locked and the login screen displays.



4.8 Unlock the device

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



2. Enter the password.
3. Select **Unlock**.

If the login credentials are correct, you are successfully logged on to the device.

4.9 Change the password

This procedure applies to change the **Device password** and **Admin password**.

Make sure that the new password follows the password recommendations:

Password must contain at least 8 characters:

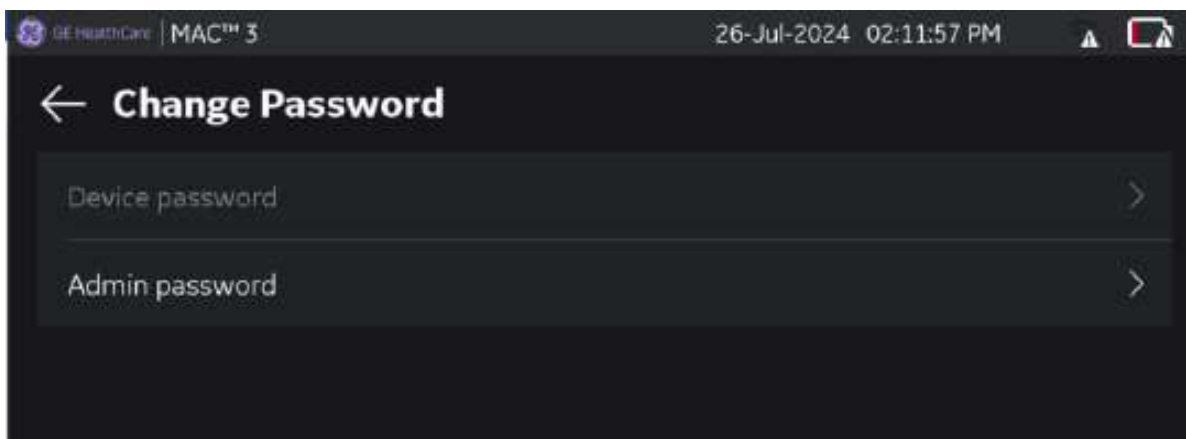
- One lowercase letter
- One uppercase letter
- One number
- One special character

4.9.1 Device password

You can change the device password from **Change Password** screen.

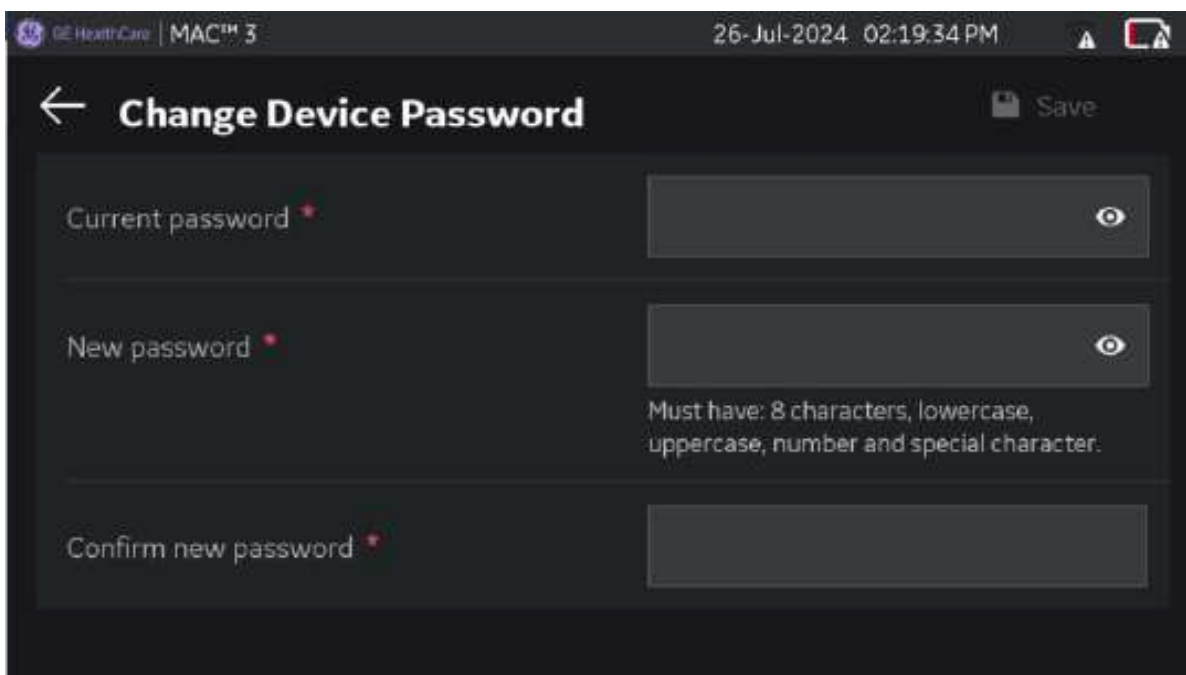
1. Select **Settings > System > Change Password**.

The **Change Password** screen displays.



2. Select **Device password** from the **Change Password** screen.

The **Change Device Password** screen displays.



3. Configure the fields as per the information in the table to change the device password.

Table 4-3 Device password settings

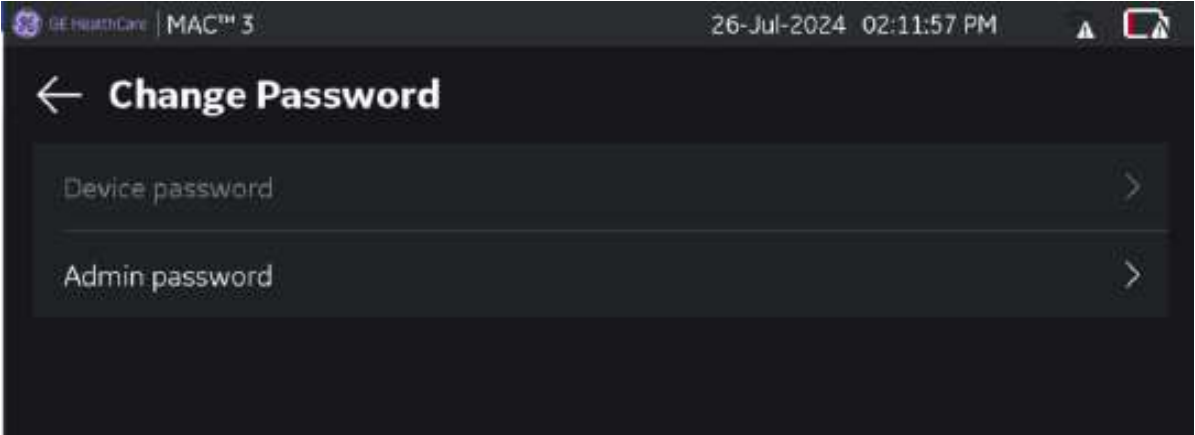
Field	Action	Description
Current password	Enter current password.	Enter the current or expired device password.
New password	Enter new password.	The new password must contain at least 8 characters: • One lowercase letter • One uppercase letter • One number • One special character
Confirm new password	Enter the same new password.	Make sure that you enter the same new password to confirm.

- 4. Select **Save**.

4.9.2 Admin password

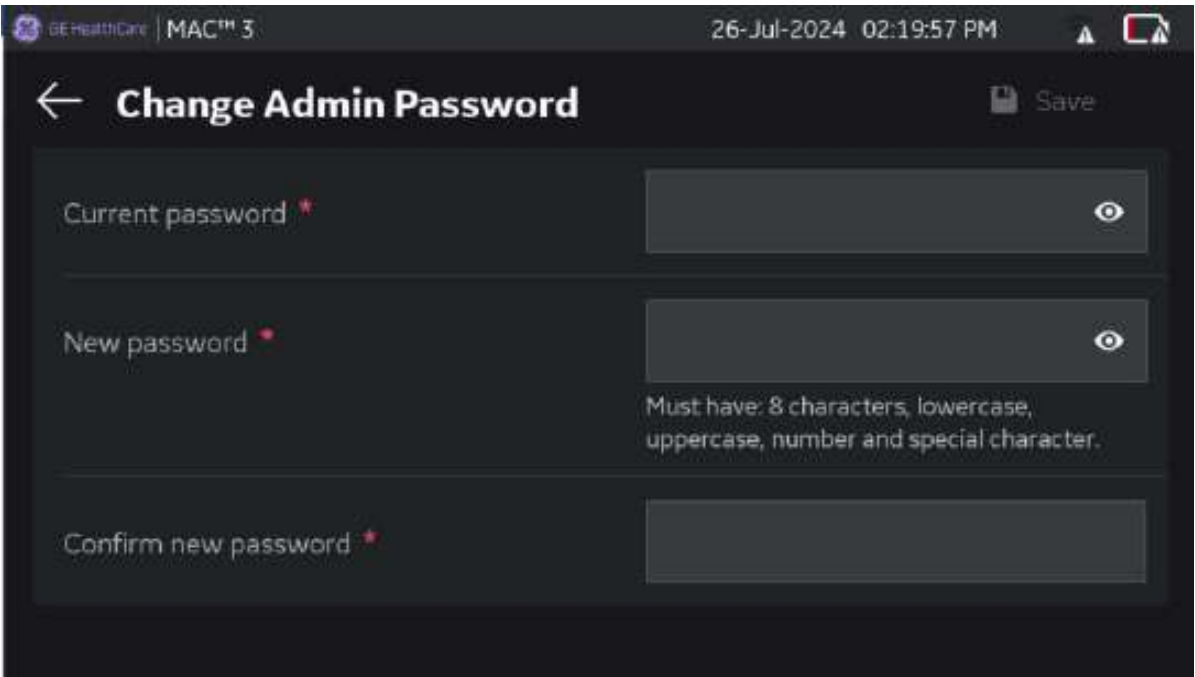
- 1. Select **Settings > System > Change password**.

The **Change Password** screen displays.



- 2. Select **Admin Password** from the **Change password** screen.

The **Change Admin Password** screen displays.



- 3. Configure the fields as per the information in the table to change the Admin password.

Table 4-4 Admin password settings

Field	Action	Description
Current password	Enter current password.	Enter the current or expired Admin password.

Continues on the next page

Table 4-4 Admin password settings (Table continued)

Field	Action	Description
New password	Enter new password.	The new password must contain at least 8 characters: • One lowercase letter • One uppercase letter • One number • One special character
Confirm new password	Enter the same new password.	Make sure that you enter the same new password to confirm.

4. Select **Save**.

4.10 Perform system reset

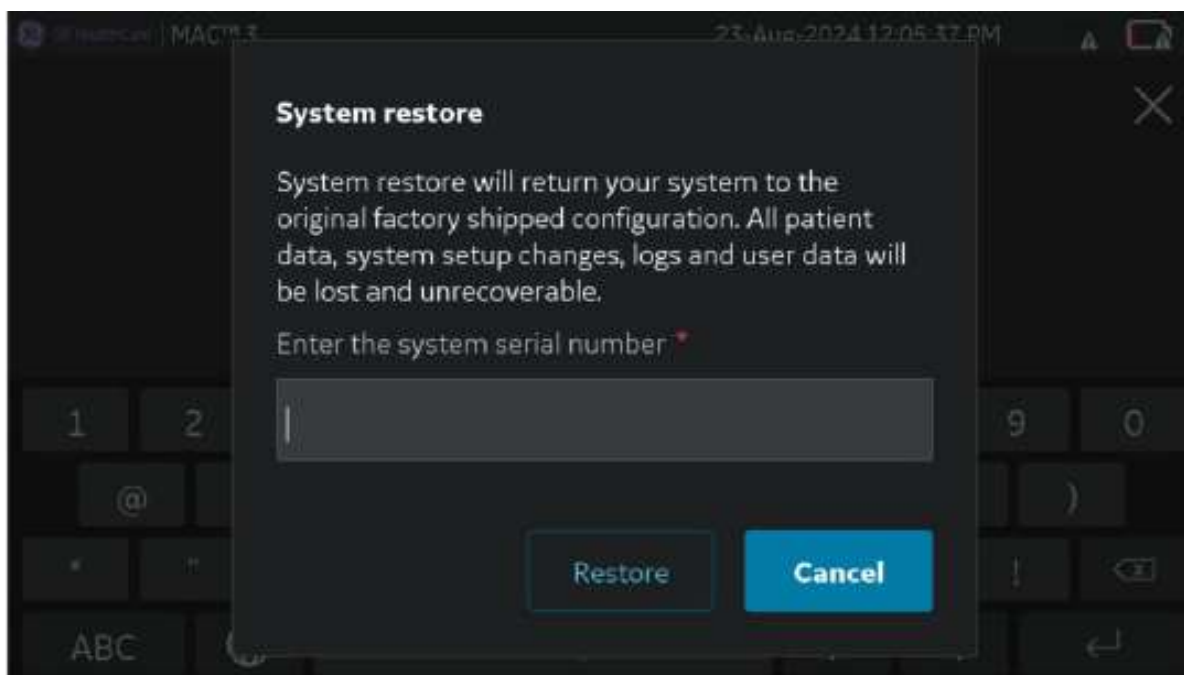
Before you start this procedure, make sure that:

- You have the serial number of the device.
- You connect the device to AC Power.
- Backup all the settings and data to USB flash drive.

Perform the below steps to reset the system to default settings, if you do not know the password.

1. When the **Login** screen opens, please contact the GE HealthCare Support team for assistance with system restore.

The **System restore** confirmation screen displays.



2. Enter the device serial number in the **Enter the system serial number** field.
The **Restore** button is enabled after you enter the correct serial number.
3. Select **Restore** to proceed with system restore.

The device restarts and set to factory default settings, all the patient data records and device certificate are deleted. You can access the device with **Admin** user credentials.

4. Select **Cancel** to cancel the system reset and continue to use the device with existed settings.

5 Service tasks

5.1 Configure device

1. Select **Settings** > **System** > **Device**.

The device setting screen displays.

The screenshot shows the 'Device' configuration screen on a GE Healthcare MAC 3 device. The screen has a dark background with white text. At the top, there is a status bar with 'GE Healthcare | MAC™ 3' on the left, '17-Sep-2025 11:08:02 AM' in the center, and a battery icon on the right. Below the status bar, there is a back arrow and the title 'Device'. To the right of the title is a 'Save' button. The main area contains three input fields: 'Cart ID' with the value '1' and a range of 'Range 0-255', 'Default location ID' with the value '0' and a range of 'Range 0-9999', and 'Site' with the value '1' and a range of 'Range 1-65535'.

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

Table 5-1 Device settings

Field	Action	Description
Cart ID	Set the device ID.	The device number is unique for each ECG device. Default value: 1
Default location ID	Set the default location ID.	For each patient test, the location ID is populated in the Location field of the Patient Data screen. Default value: 0
Site	Set the site number.	Default value: 1

3. Select **Save**.

5.2 Enable options

Before you begin this procedure, make sure that:

- The serial number of the device is configured. See [6.2 Installation procedure upon replacing the main PWA on page 69](#).

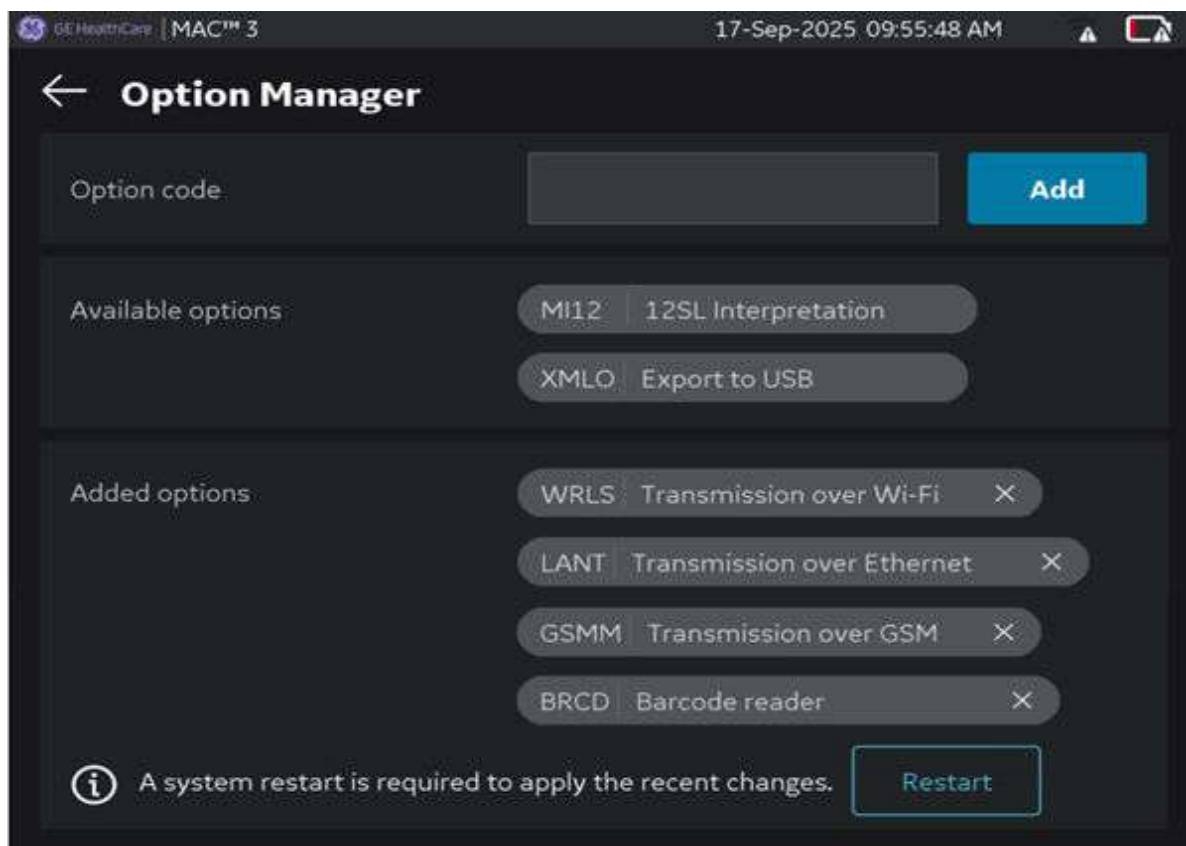
- You obtain the required option codes. Contact your GE HealthCare Service Support representative to obtain the unique code for your device. You cannot enable the options without the appropriate code.

**NOTE**

The enabled options are not reset when the device is reset to factory default settings.

- Select **Settings > System > Option Manager**.

The **Option Manager** screen displays.



- From the below option list, select the option you want to enable.

Table 5-2 Available device options

Option	Description
MI12 - 12SL interpretation	12SL interpretation
XMLO - Export to USB	You can save Sapphire XML formatted record files to USB flash drive.
WRLS - Transmission over Wi-Fi	You can configure the default wireless network to transmit the ECG reports through Wi-Fi.
LANT - Transmission over Ethernet	You can configure the default Ethernet network to transmit the ECG reports through LAN.

Continues on the next page

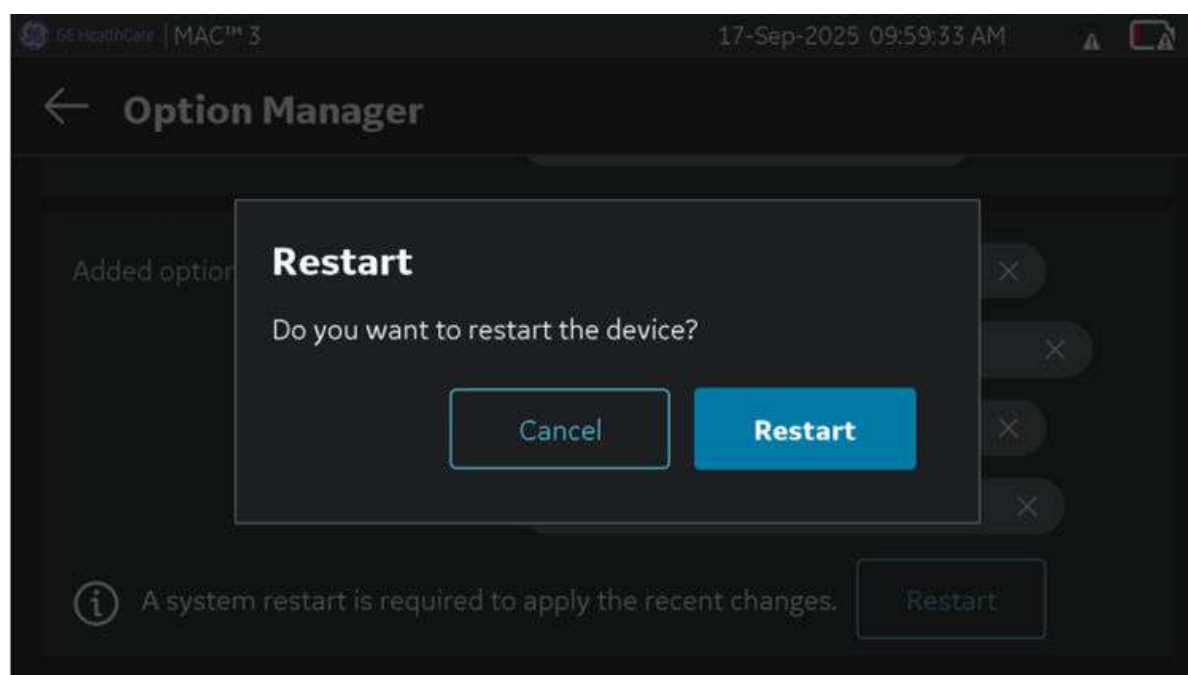
Table 5-2 Available device options (Table continued)

Option	Description
GSMM - Transmission over GSM	You can configure the below default cellular network, to transmit the ECG reports through GSM. • LTE only • 3g only • 2g only • LTE/3g/2g(auto-connect)
BRCD - Barcode reader	You can enter the patient information through a barcode reader.

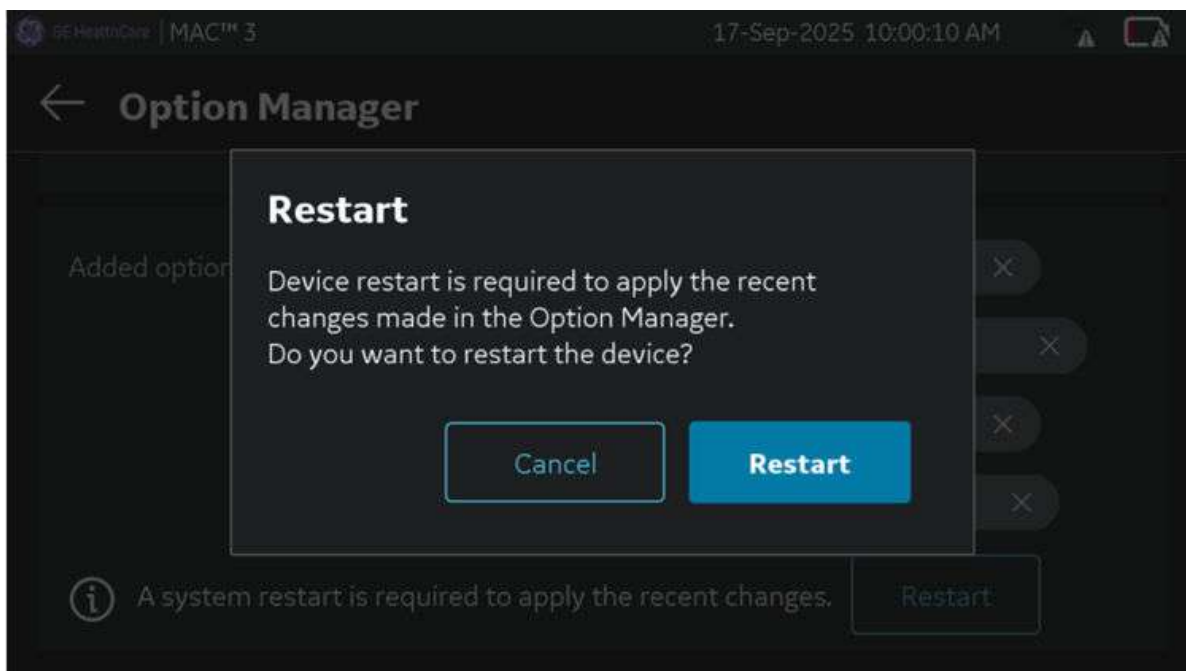
3.  **NOTE**
Because each option has a unique option code, you can enable only one option at a time.

Enter the option code for the selected option in the **Option Code** field.

4. Select **Add** to enable the selected option.
An error message displays if you enter an invalid option code.
A **Restart** confirmation screen displays.



5. Select **Restart** to restart the device and to apply the changes.
After restart of the device, the selected option is added to the **Added options** list.
6. Repeat [Step 3](#) to [Step 5](#) for each option you want to enable.
7. If you cancel the added option or switch to other screen.
A **Restart** confirmation screen displays.



8. Select **Restart** to restart the device and to apply the changes.

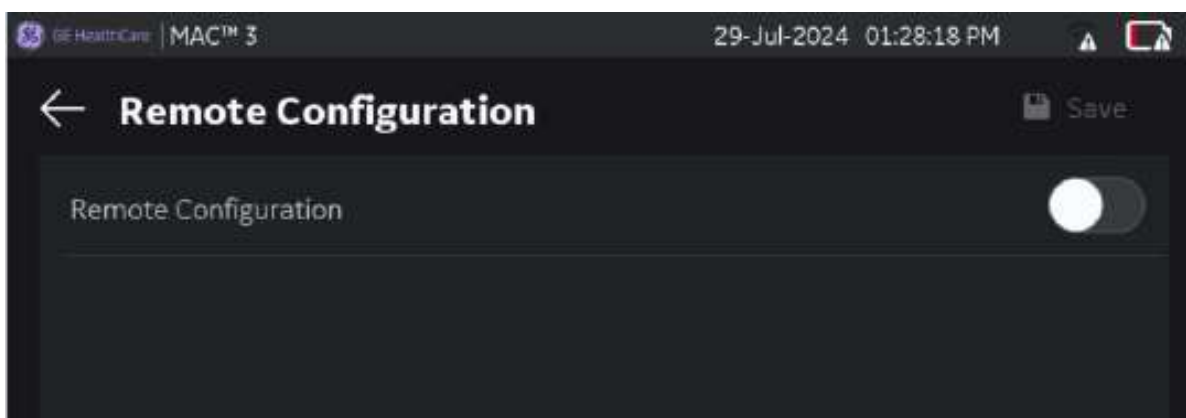
After restart of the device, the selected option is deleted from the **Added options** list.

5.3 Configure remote server

You can configure the remote server to the device through the default InSite server.

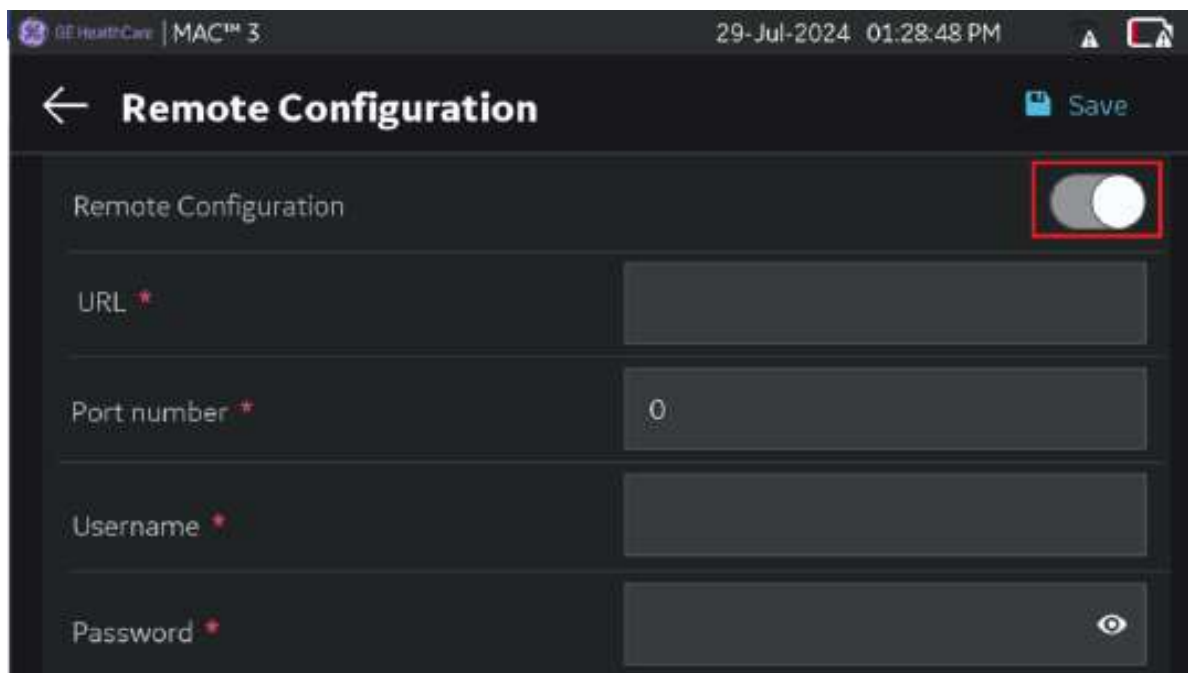
1. Select **Settings > System > Remote Configuration**.

The **Remote Configuration** screen displays.



2. Enable the **Remote Configuration** option to configure the remote server settings.

The remote server settings display.



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

Table 5-3 Remote server settings

Field	Action	Description
URL	Configure the remote server URL.	Enter the IP address or the hostname of the remote server to configure the URL.
Port Number	Configure the remote server port number.	Enter the remote server port number. The port number is always a 4 digit number.
Username	Configure the username for the remote server.	Enter the username for the remote server.
Password	Configure the password for the remote server.	Enter the password for the remote server.

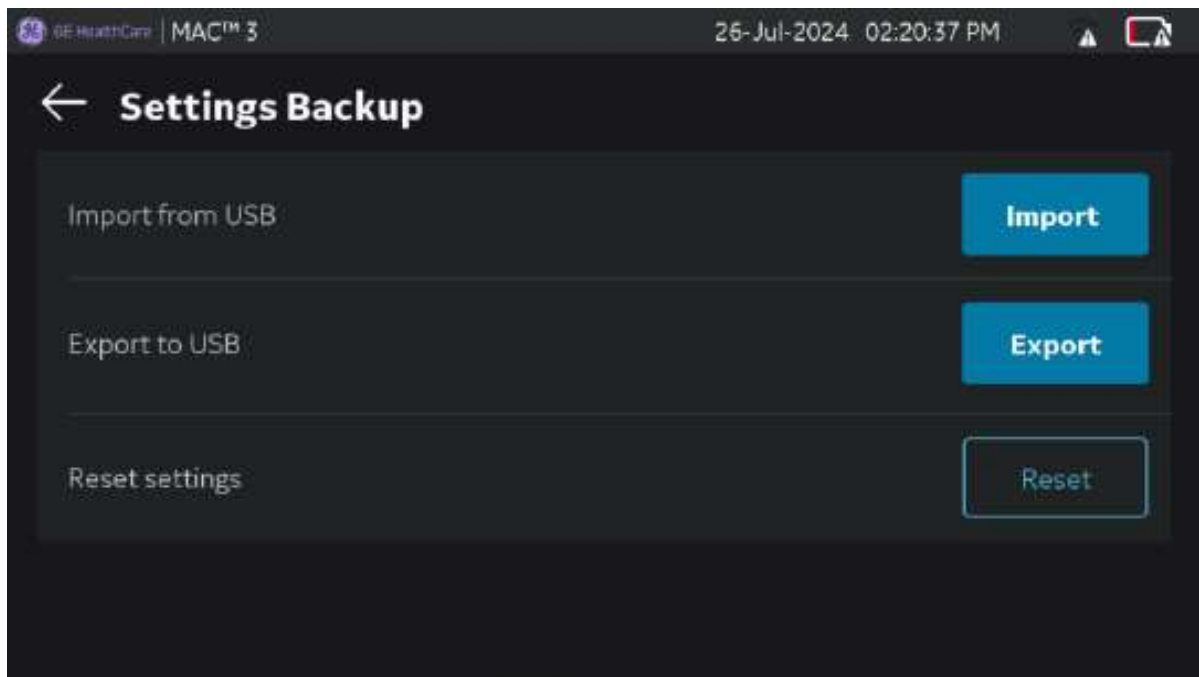
4. Select **Save**.

5.4 Reset settings to factory defaults

Make sure that you exported the settings to USB flash drive before you reset to factory defaults.

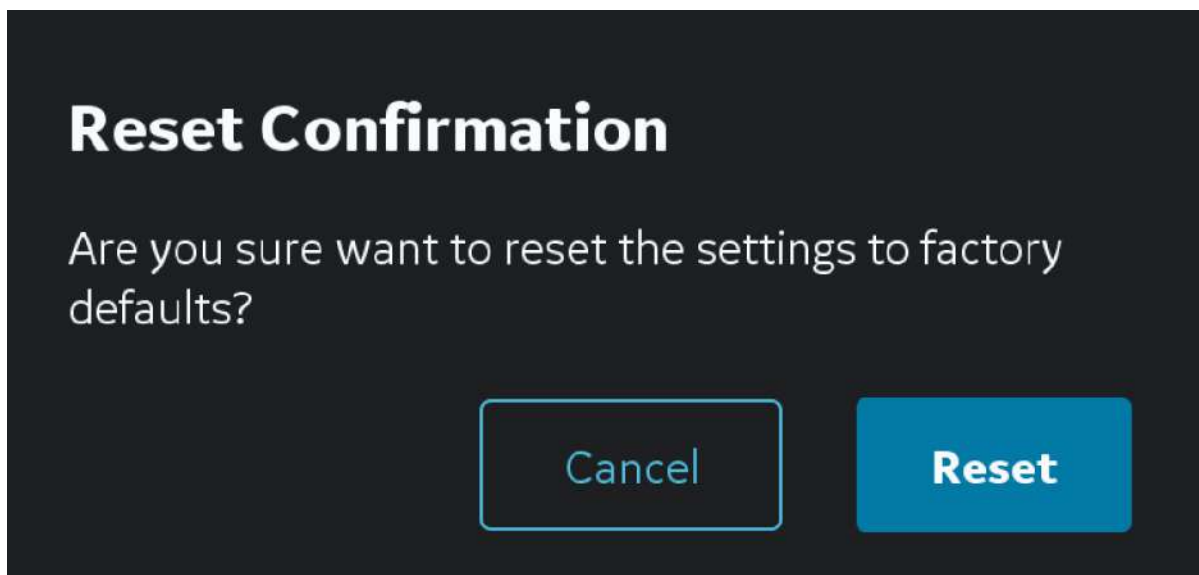
1. Select **Settings > System > Settings Backup**.

The **Settings Backup** screen displays.



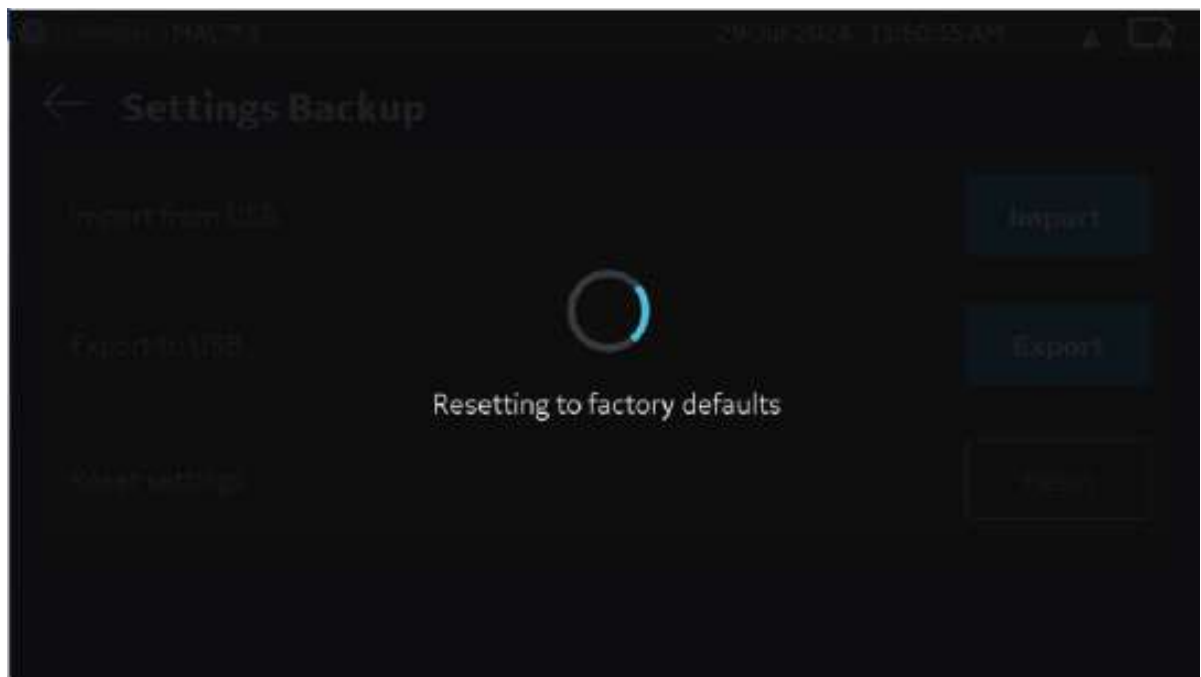
2. Select **Reset** to reset the settings to factory defaults.

The **Reset Confirmation** screen displays.



3. Select **Reset** to confirm and continue to reset the settings to factory defaults.

The resetting to factory defaults progress screen displays.



4. Select **Cancel** to cancel reset the settings to factory defaults and go back to **Settings Backup** screen.

6 Software update

6.1 Update the software

Perform this procedure to:

- Update the software version from the current version to a newer version.
- Downgrade the software version from the current version to a previous version.



NOTE

Make sure that you save the configuration settings to the USB flash drive when you change/update any settings. This helps to import the configuration settings without you enter manually for each setting when you replace the main PWA board.

Connect the battery to the device and connect the power cable. Make sure that the device is 50% charged.

Make sure that you enable the **USB** and **Allow USB storage** settings in **Settings > System > Hardware**.

1.  **NOTE** The USB flash drive supports the FAT32 file system. Delete if any previous .tar files from the USB flash drive.

Copy the software image files to the USB flash drive.

2. Connect the USB flash drive to the device.
3. Select **Settings > Software Update**.

The **Software Update** screen displays.

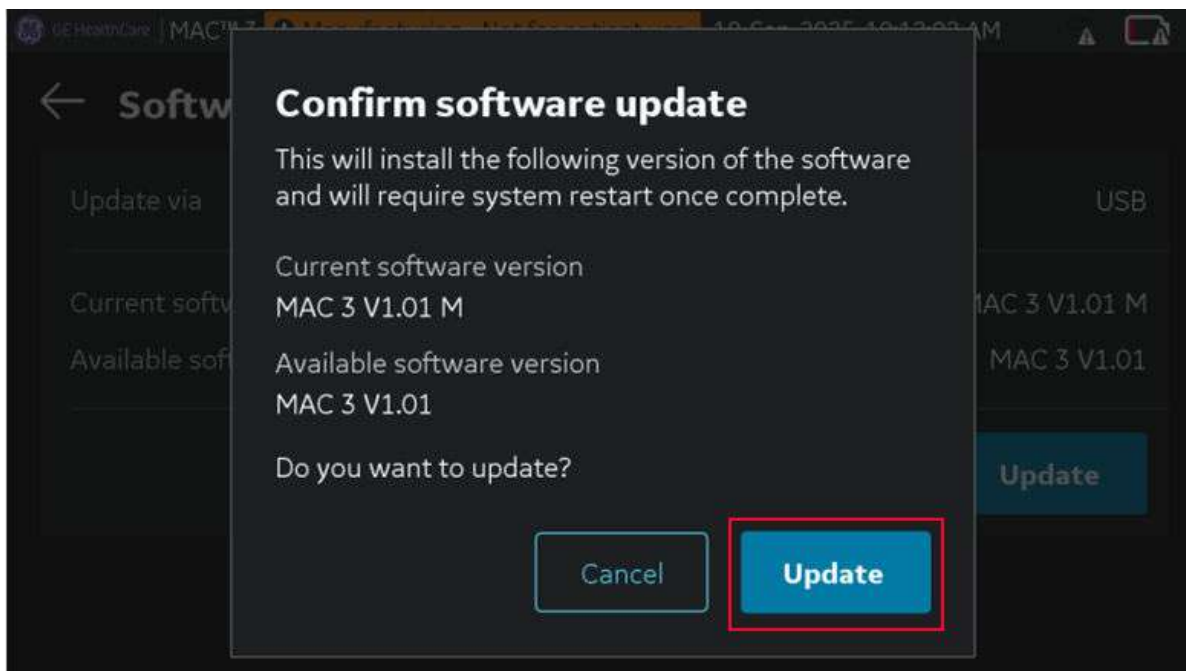


The version of the currently installed software and the available software displays.

If the available software version is higher or lower than the current installed version, the **Update** option displays.

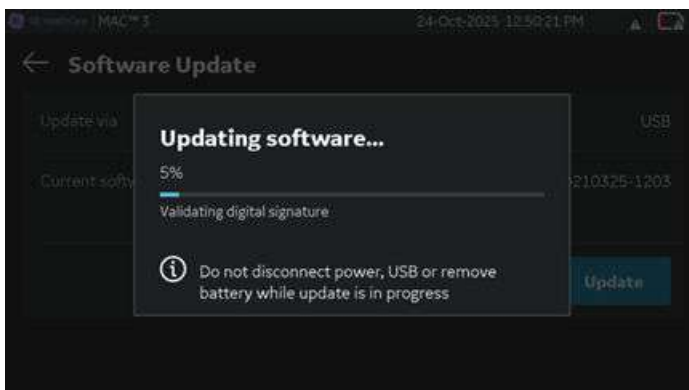
4. Select the **Update** option.

The **Confirm software update** screen displays.



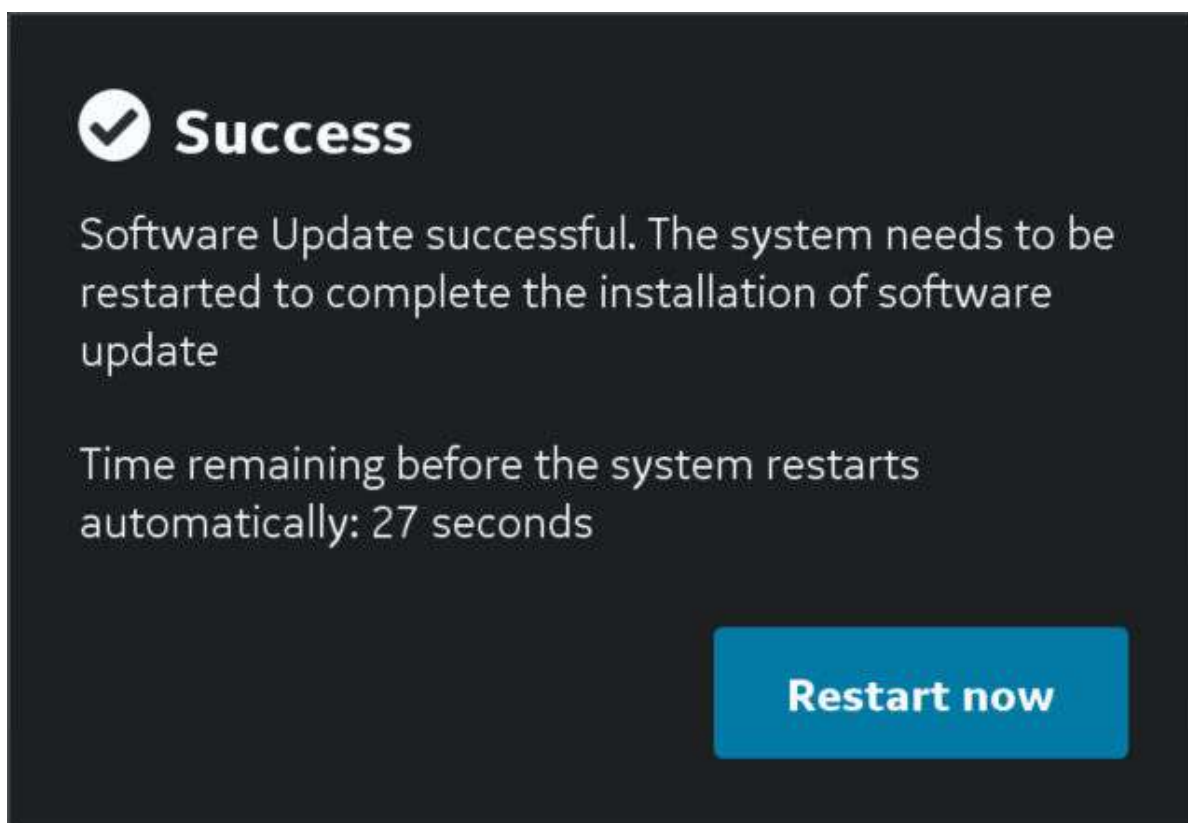
5. Select **Update** to update the software.

The software update progress screen displays.



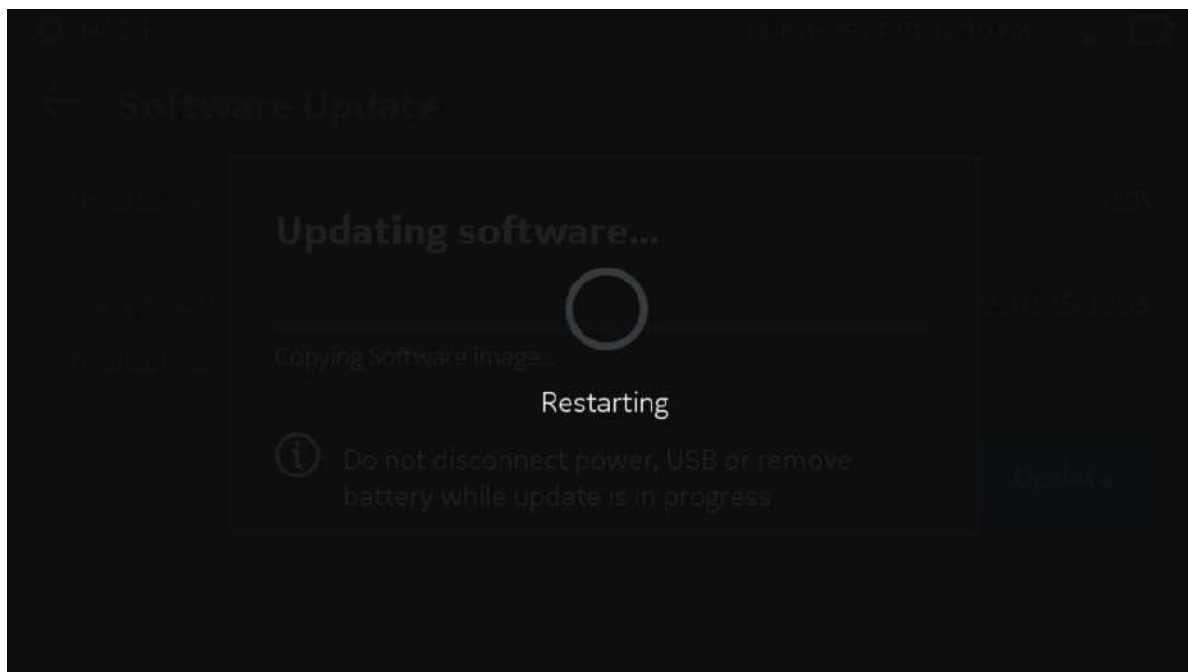
If the software update is unsuccessful, an error message displays. Troubleshoot the error. For more information, see [13.3 Software update errors on page 164](#). Return to the **Software Update** screen and restart the update procedure.

If the update is a success, a message displays to confirm the device restart.



6. Select **Restart now** to complete the software update.

The device restarts to update the software. Wait until the software update process is completed.



6.2 Installation procedure upon replacing the main PWA

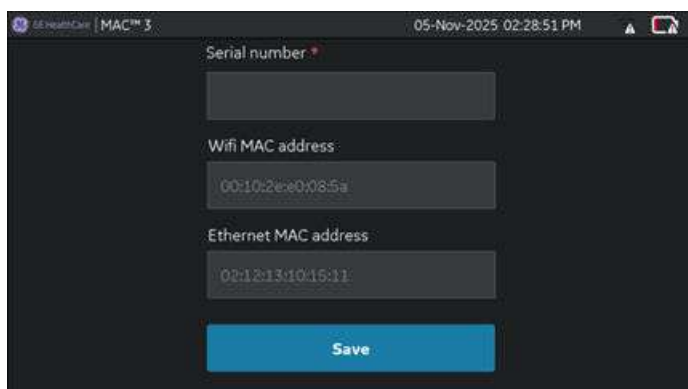
1. Press **Power ON** button.



The **Serial number** screen displays.

2. Enter the **Serial number**.

By default the **Wifi MAC address** and **Ethernet MAC address** details will be shown on the screen.



3. Activate the device. See [4.2 Self registration on page 38](#).
4. Enable the option codes. See [5.2 Enable options on page 60](#).
5. Open the **Settings** screen and perform diagnostics tests. See [7.1 System diagnostics overview on page 71](#).
6. Configure the settings manually in the **Settings** screen. For more information see *MAC™ 3 Resting ECG Analysis System Operator's Manual*.

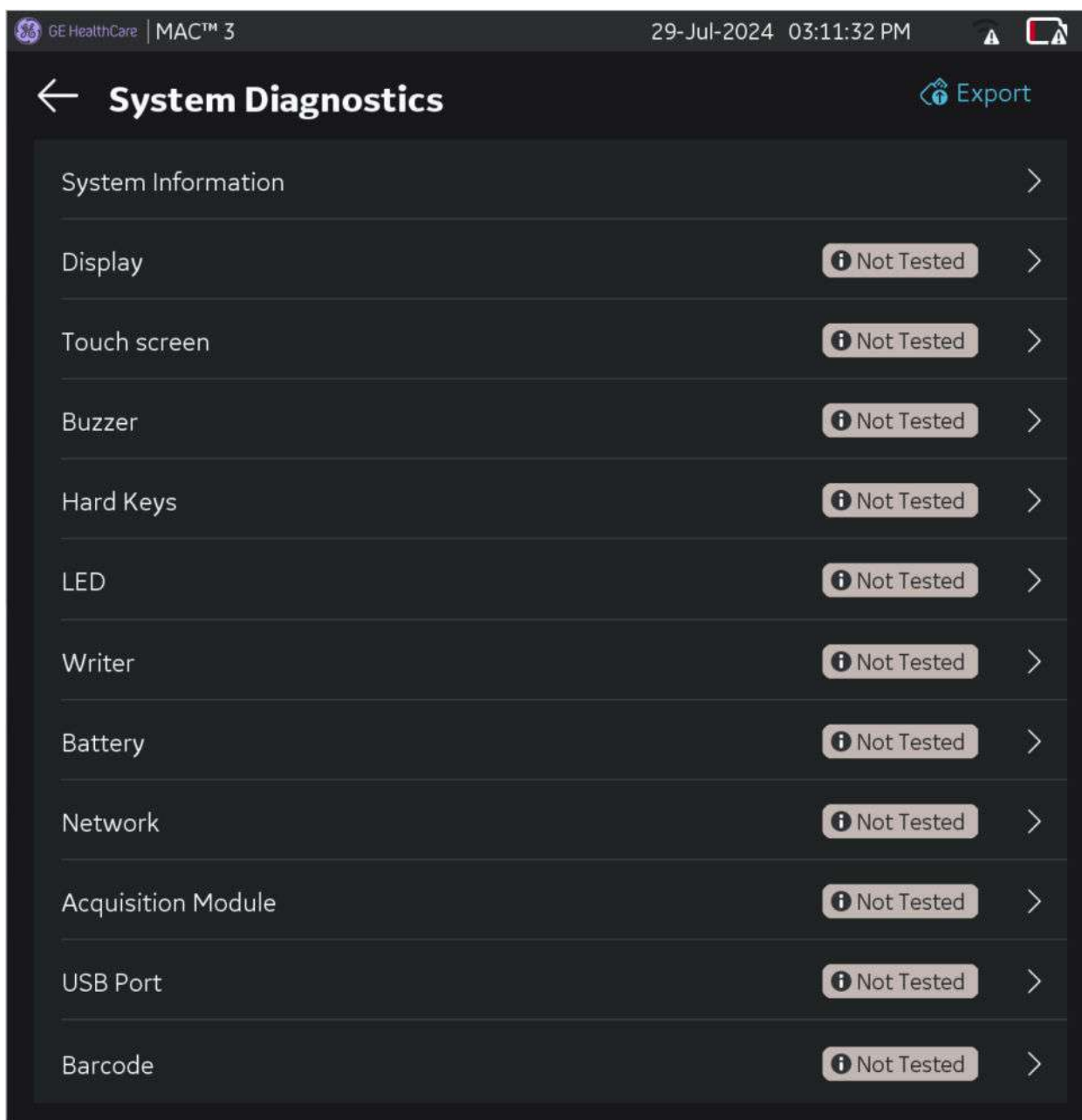
7 Diagnostics

7.1 System diagnostics overview

In the **System Diagnostics** screen, you can perform the different system diagnostic tests.

Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



If the diagnostic test fails, refer to the relevant troubleshooting procedure.

**NOTE**

To enable **Network** diagnostic test, make sure that you must configure either one of the **Ethernet**, **Wi-Fi**, or **GSM** network mode.

To enable **Barcode** diagnostic test, make sure that you:

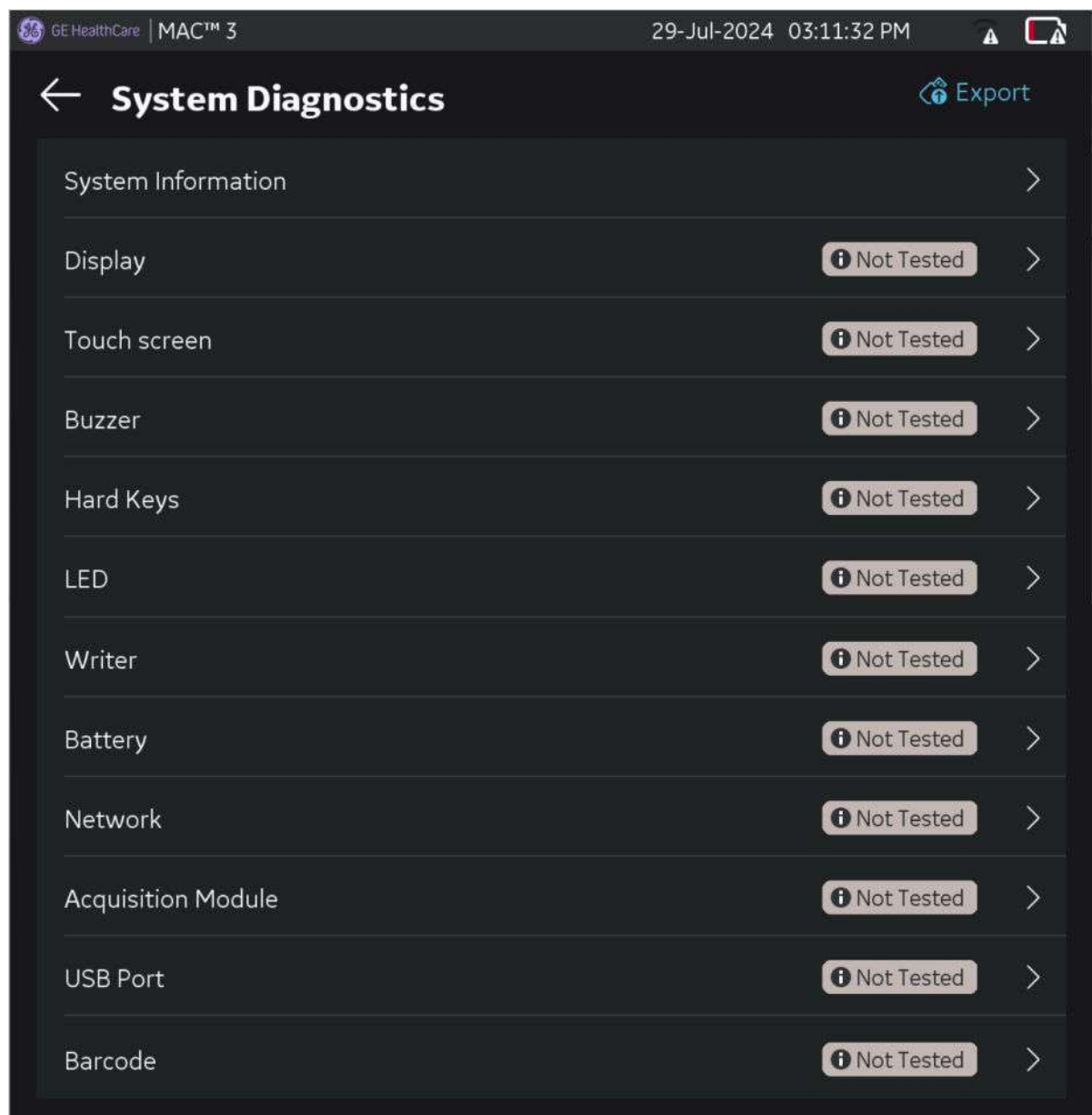
- Purchase and enable the **Barcode** option in **Enable option** settings.
- Enable the USB port in **Settings > System > Hardware > USB** settings.

To enable the **USB Port** diagnostic test, make sure that you must enable the **USB** and **Allow USB storage** settings in **Settings > System > Hardware**.

7.2 Display system information

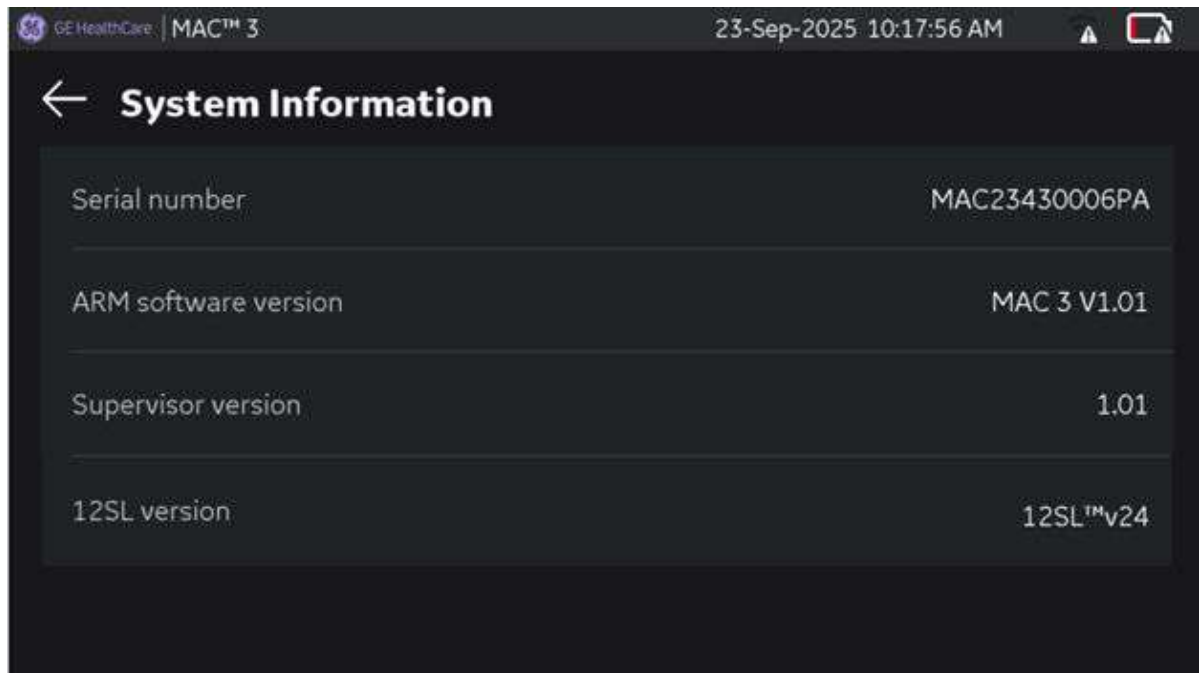
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



2. Select **System Information**.

The **System Information** screen displays.



The system displays the information on:

- **Serial number**
- **ARM software version**
- **Supervisor version**
- **12SL version**

7.3 Perform the display test

This test confirms if the screen displays all pixels correctly. It requires you to verify that you can see the screen in the five colors below:

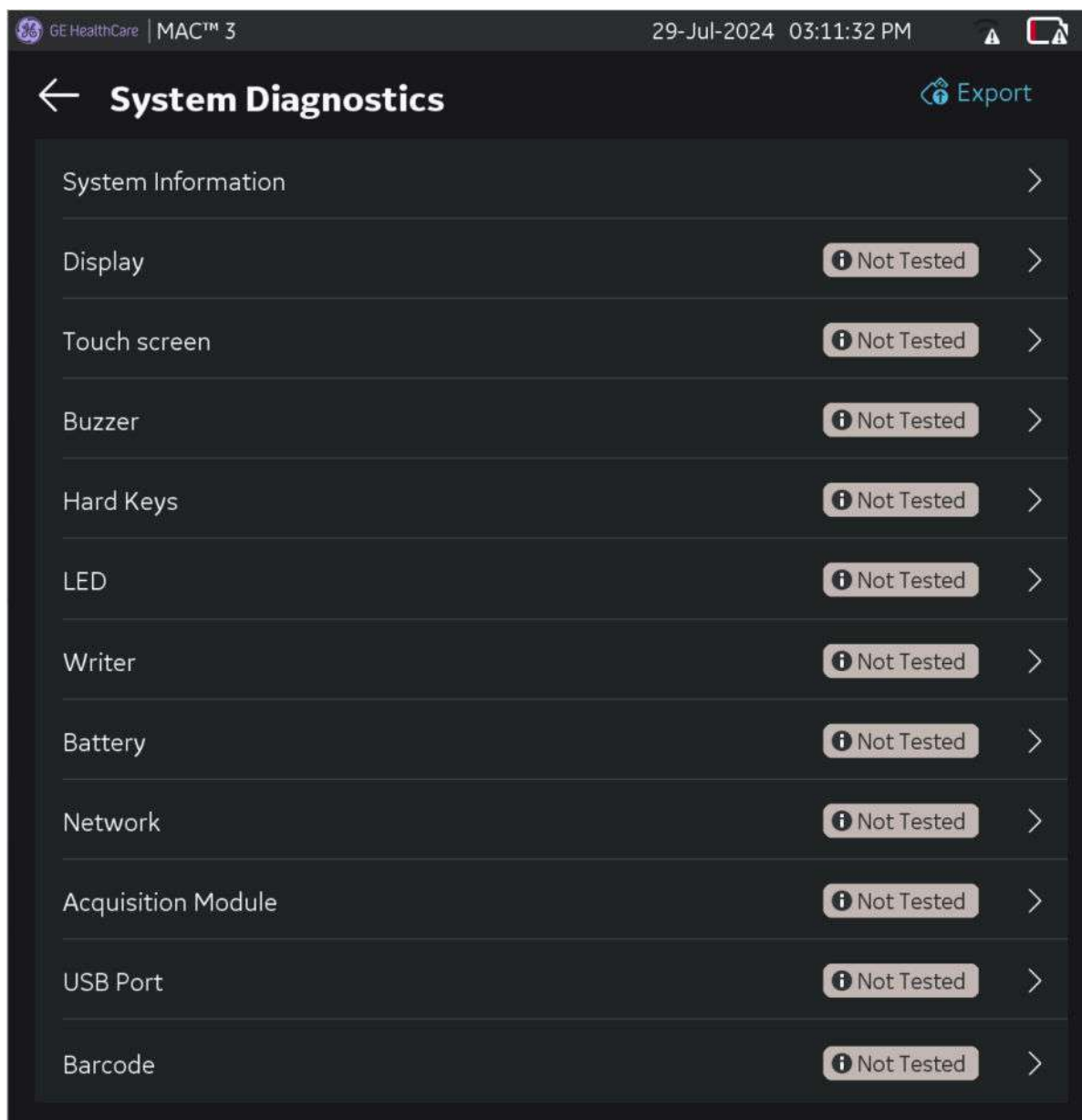
- Red
- Blue
- Green
- Black
- White

The color must cover the entire screen.

Also, you can test and confirm the gray scale.

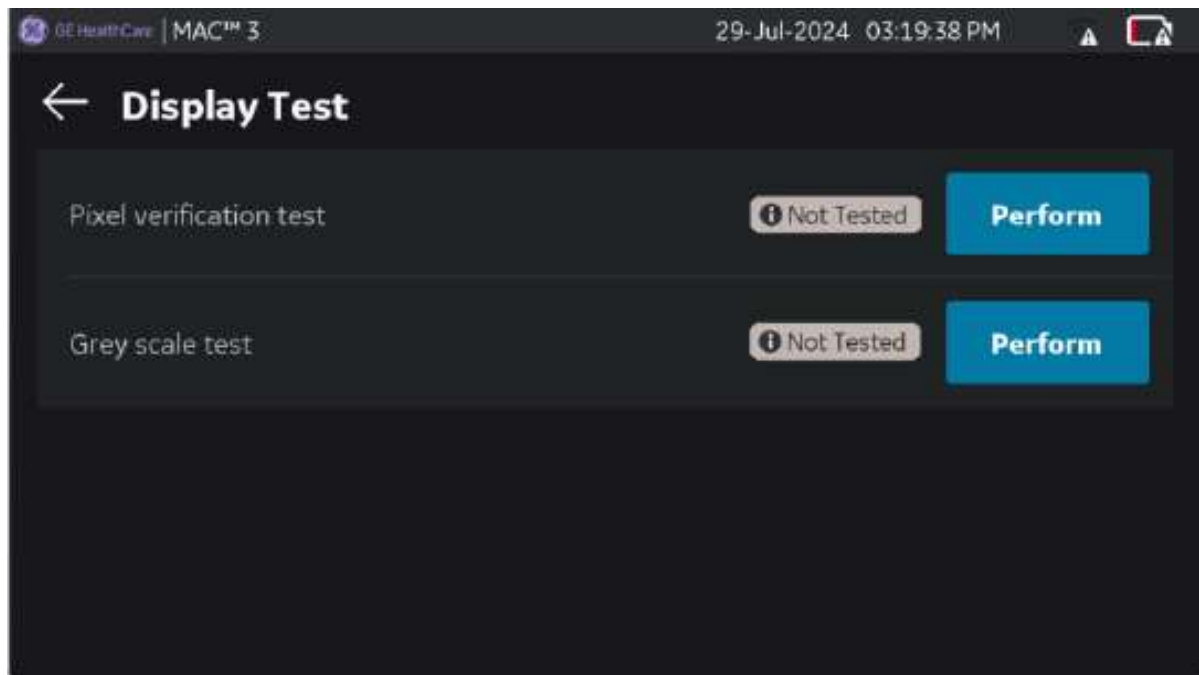
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



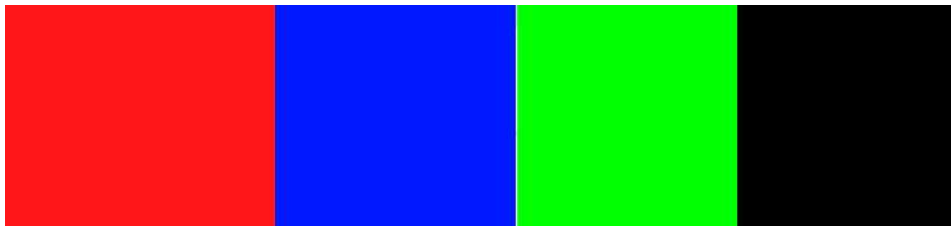
2. Select **Display**.

The **Display Test** screen displays.

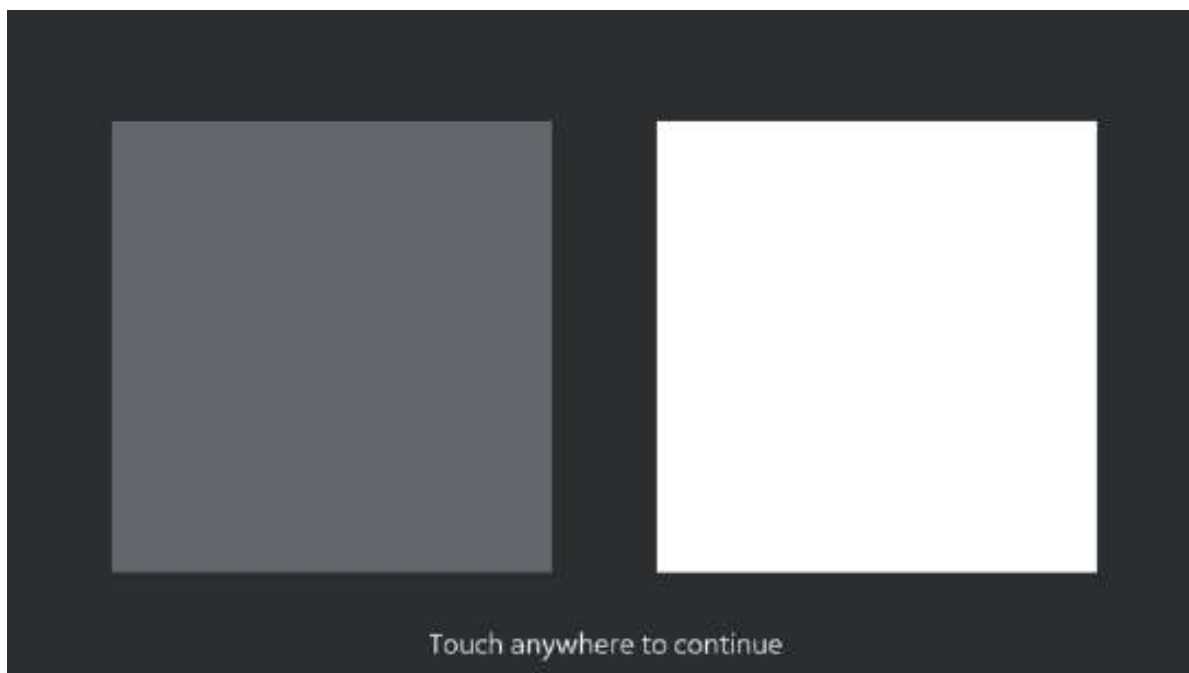


3. Select **Perform** next to **Pixel verification test**.

The red, blue, green, black, and white screen opens.



4. Tap the red screen.
The blue screen opens.
5. Tap the blue screen.
The green screen opens.
6. Tap the green screen.
The black screen opens.
7. Tap the black screen.
The white screen opens.
8. Tap the white screen.
A message displays asking you to confirm if you can see the screen in white.
9. Based on the test result, select **Yes** or **No**.
10. Select **Perform** next to **Grey scale test**.
The gray scale screen opens.



11. Tap the gray or white screen.
12. Based on the test result, select **Yes** or **No**.

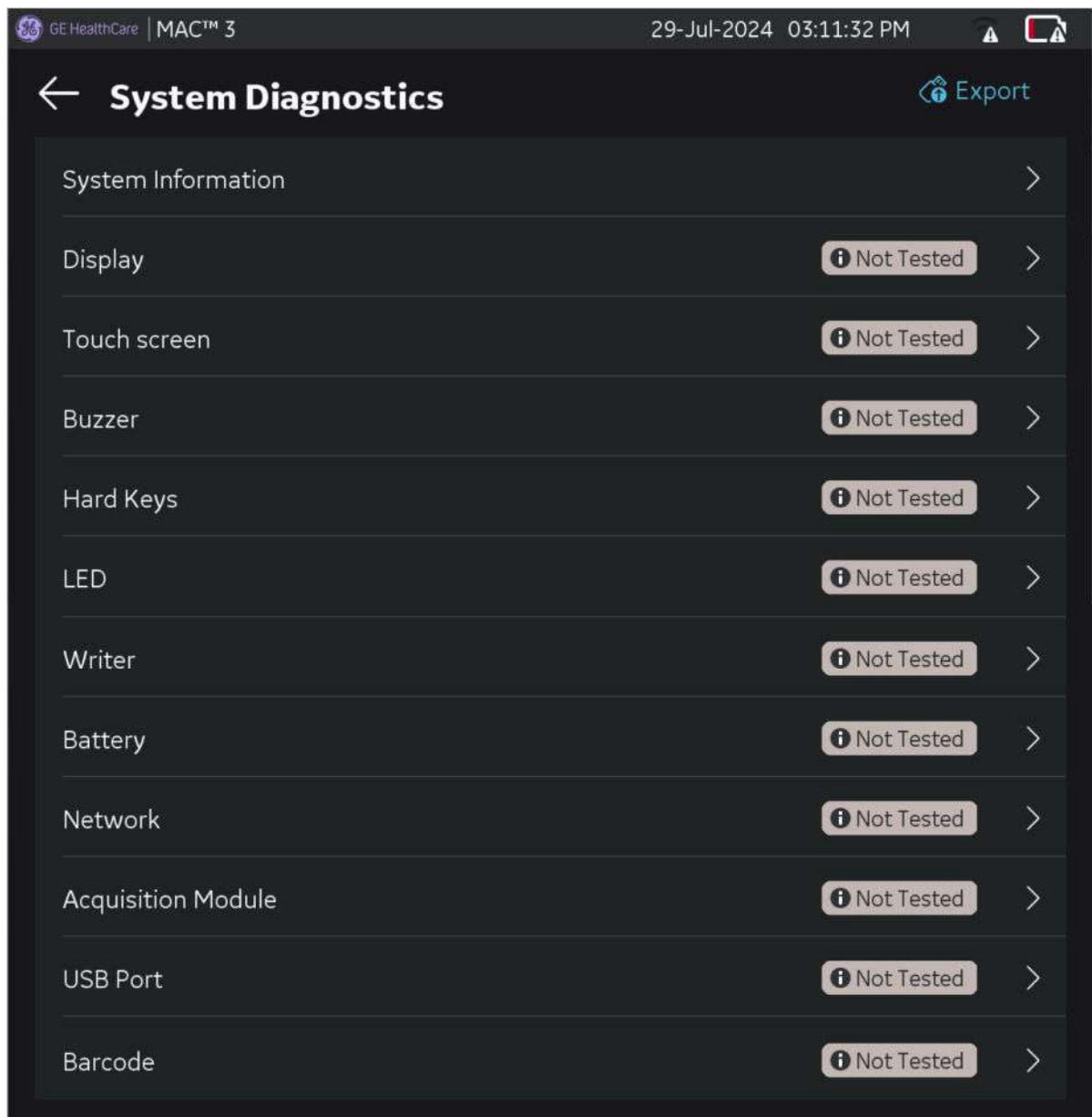
The **Display Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

7.4 Perform touchscreen diagnostic test

This test helps you to verify if the sensor of the touchscreen operates correctly.

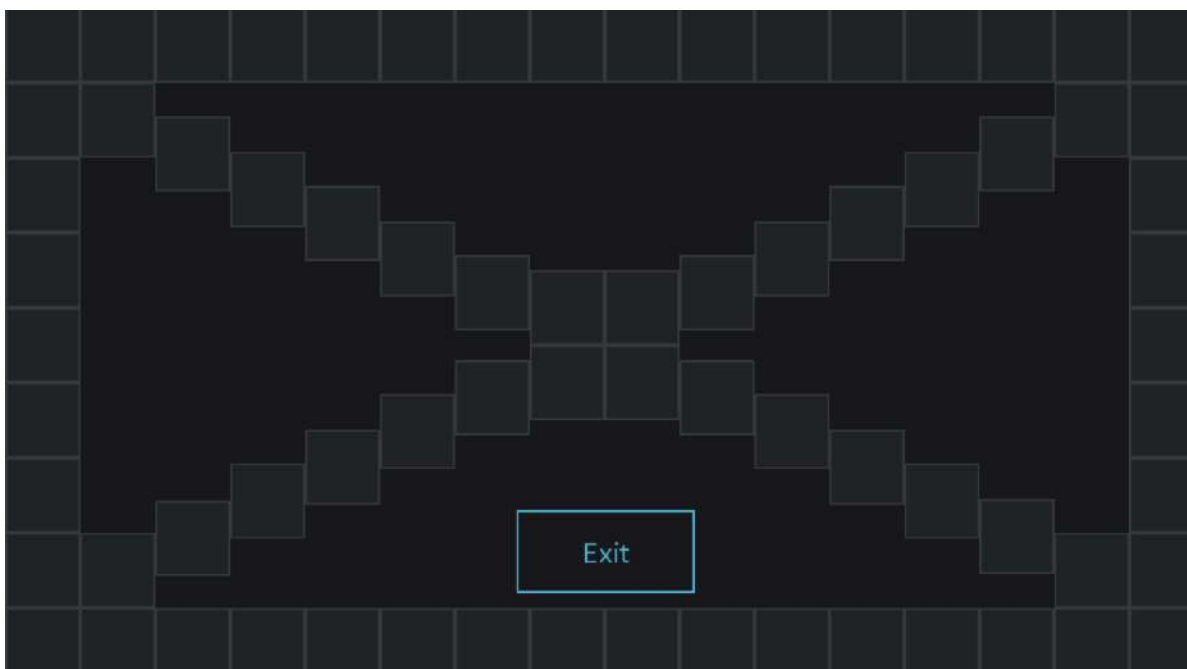
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



2. Select **Touch screen**.

The **Touch test** screen displays.



3. Tap each square of the touchscreen to verify that the area works correctly.
 - If the touchscreen sensor in the area works correctly, the square turns to green color.
 - If the touchscreen sensor in the area works incorrectly, the square stay in gray color.



4. When the test is complete, select **Exit**.
A message displays asking you to confirm whether the test passed.
5. Based on the test results, select one of the following:
 - If the test passed, select **Yes**. The test result displays in the **System Diagnostics** screen as **Success**.

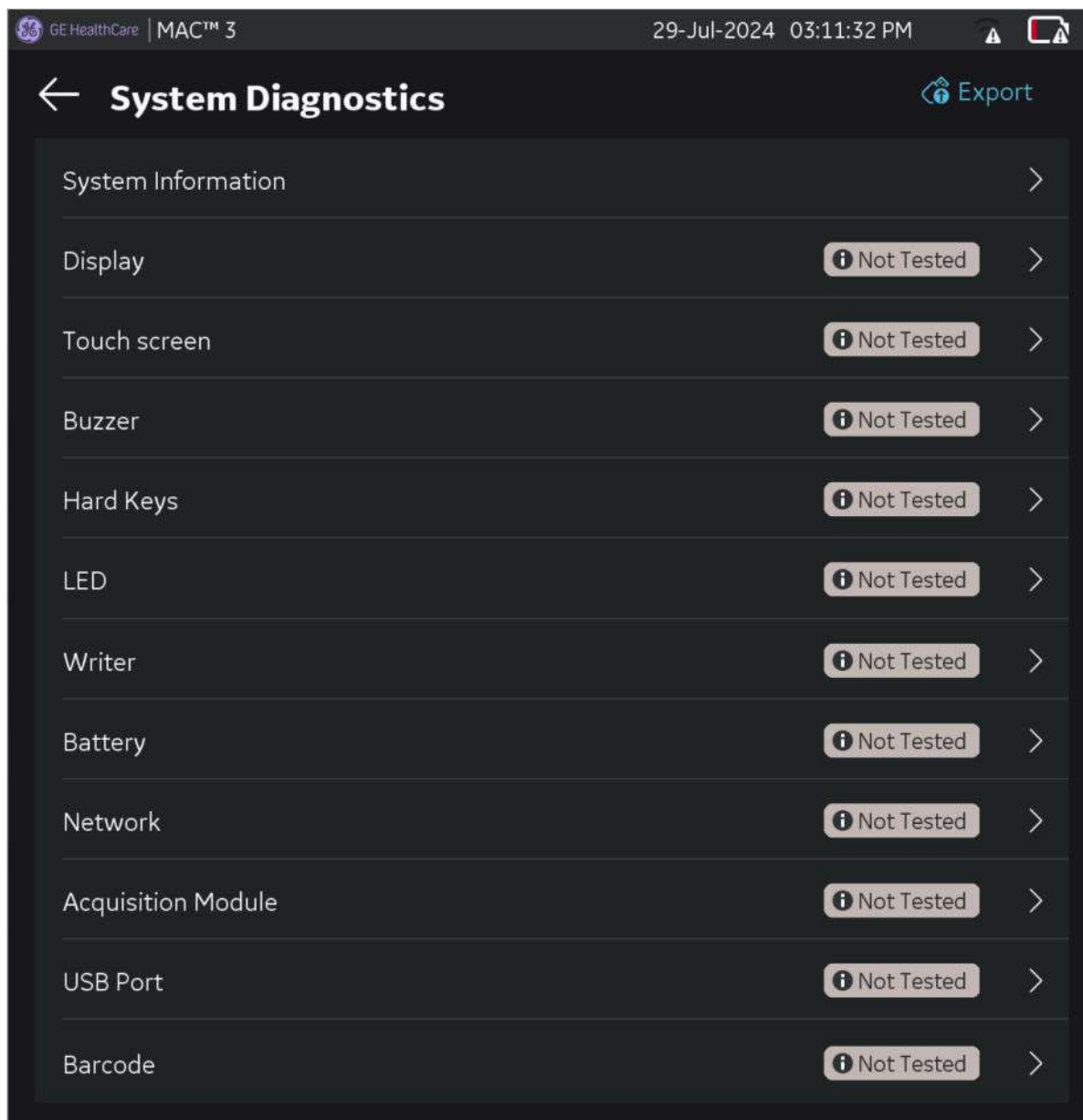
- If the test failed, select **No**. The test result displays in the **System Diagnostics** screen as **Failure**.

7.5 Perform buzzer diagnostic test

This test determines if the buzzer works correctly.

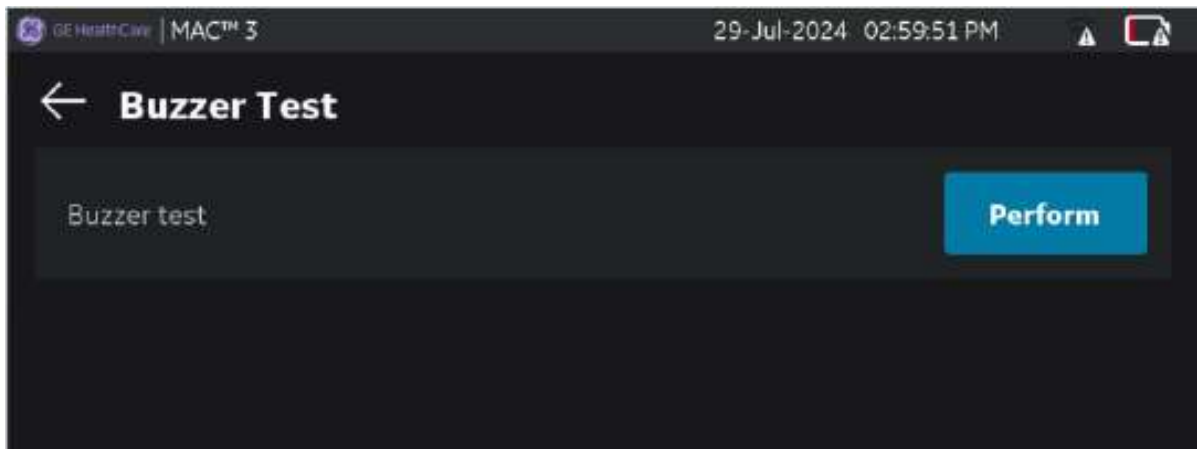
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



2. Select **Buzzer**.

The **Buzzer Test** screen displays.



3. Select **Perform** next to **Buzzer test**.
4. Verify if you can listen the buzzer tone for 2 to 3 seconds.
5. When the test is complete, close the screen.

A message displays asking you to confirm whether the test is passed.

6. Based on the test result, select **Yes** or **No**.

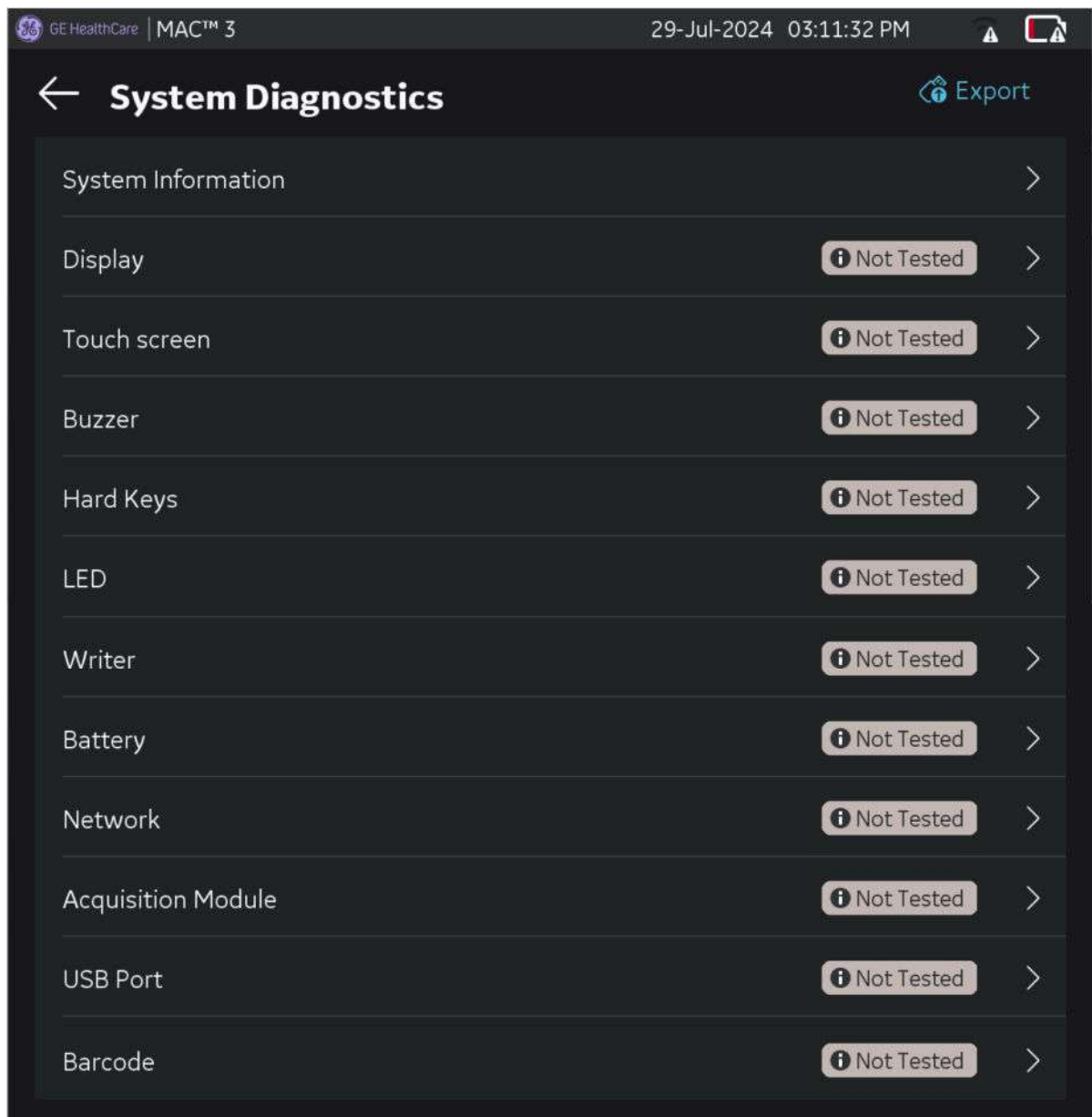
The **Buzzer Test** screen closes. The **System Diagnostics** screen updates with the test result: **Success** or **Failure**.

7.6 Perform the hard keys diagnostic test

This test verifies that all the keys on the keysheet works correctly.

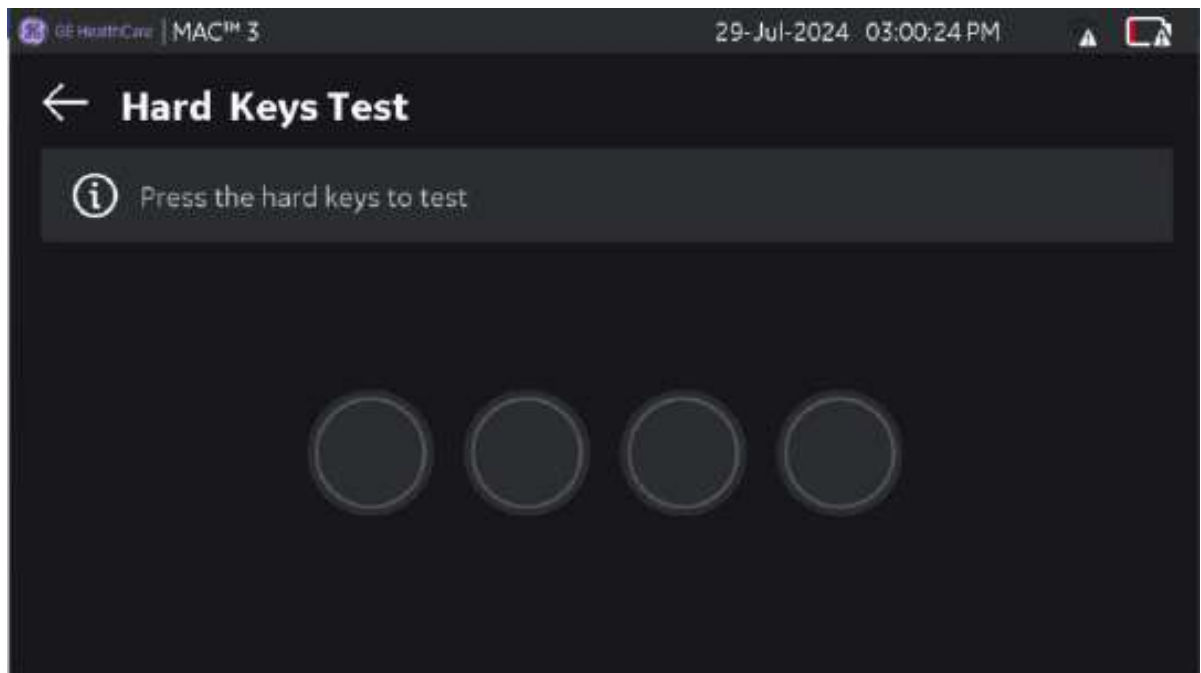
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



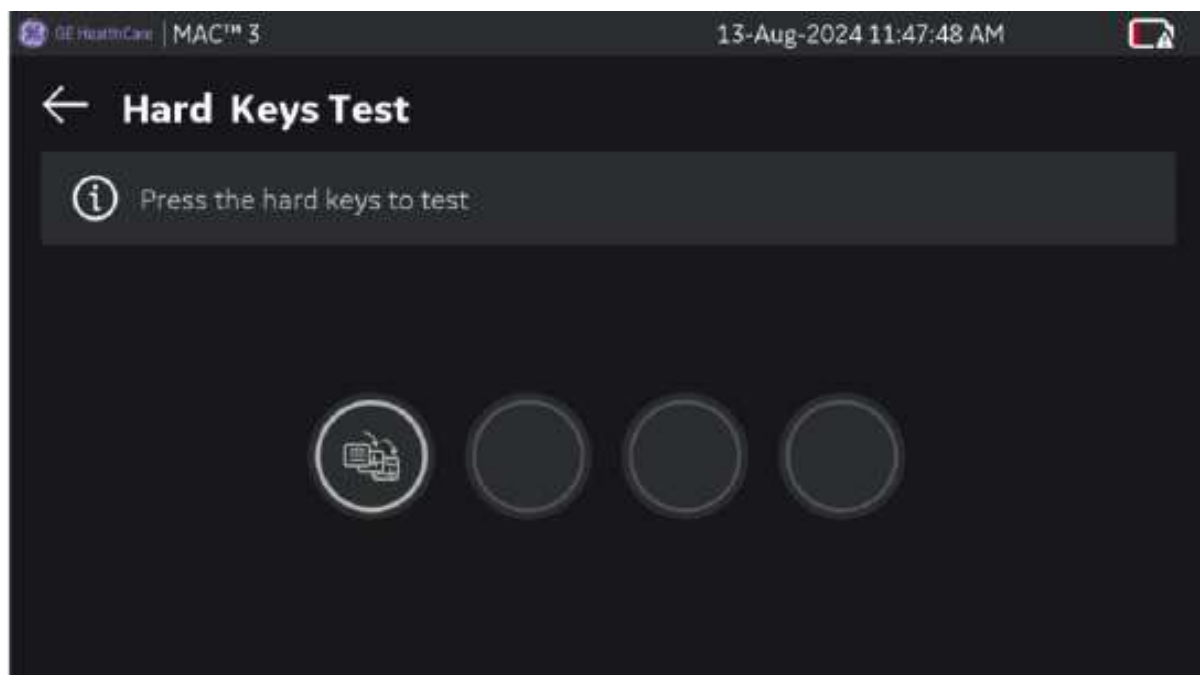
2. Select **Hard Keys**.

The **Hard Keys Test** screen displays.



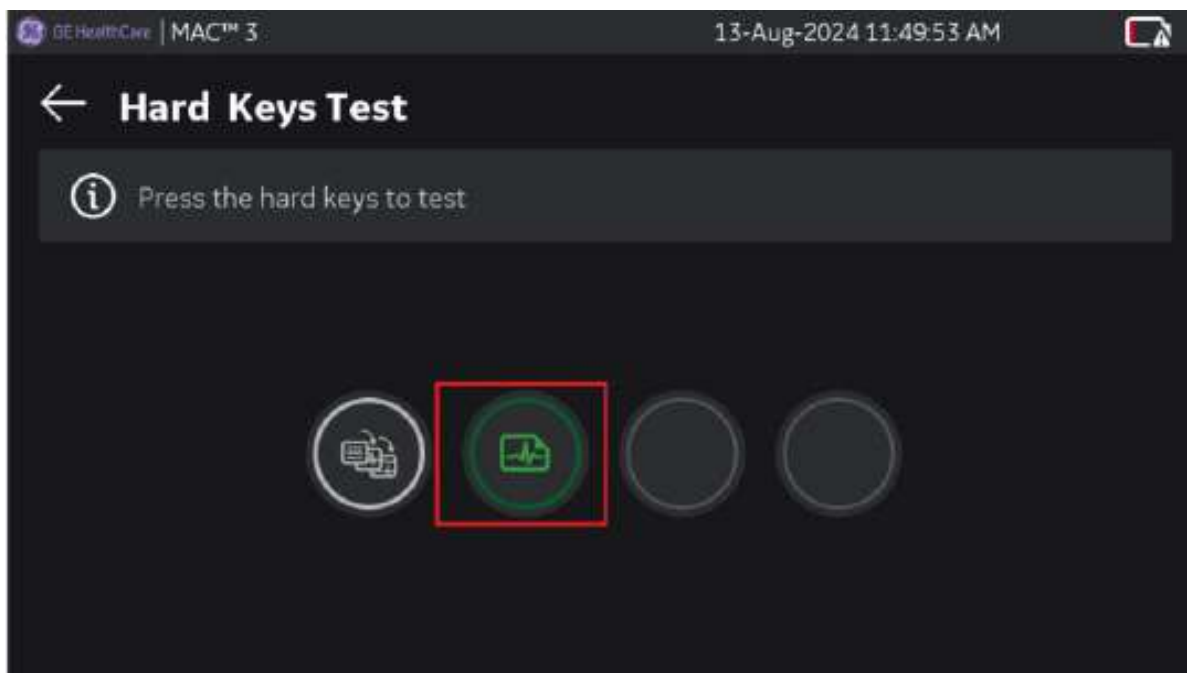
3. Press lead key on the keysheet to test.

The lead key on the keysheet image displays on the test screen.

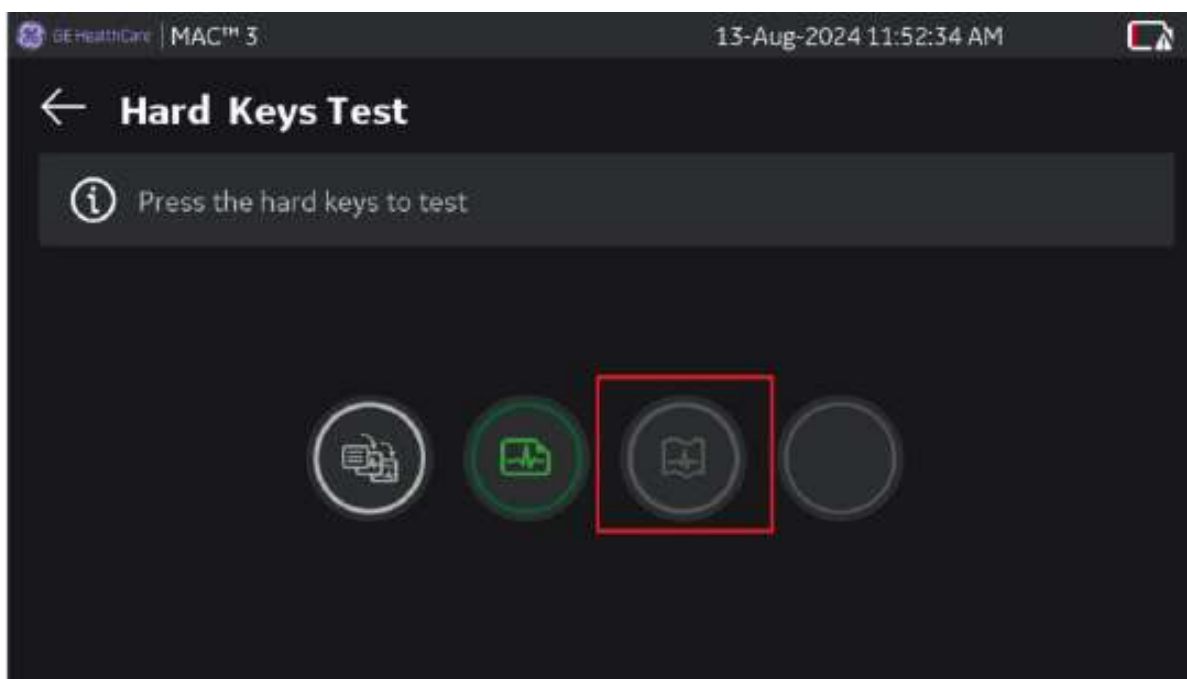


4. Press the ECG key on the keysheet to test.

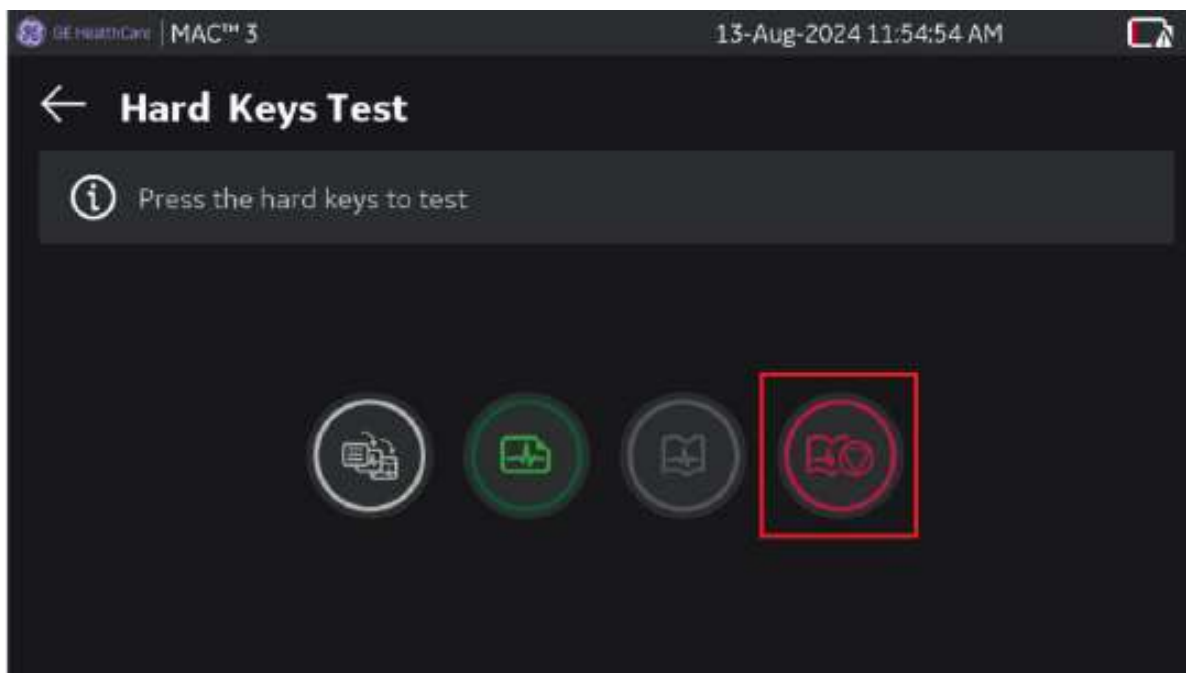
The ECG key on the keysheet image displays on the test screen.



5. Press the Rhythm key on the keysheet to test.
The Rhythm key on the keysheet image displays on the test screen.



6. Press the stop print key on the keysheet to test.
The stop print key on the keysheet image displays on the test screen.

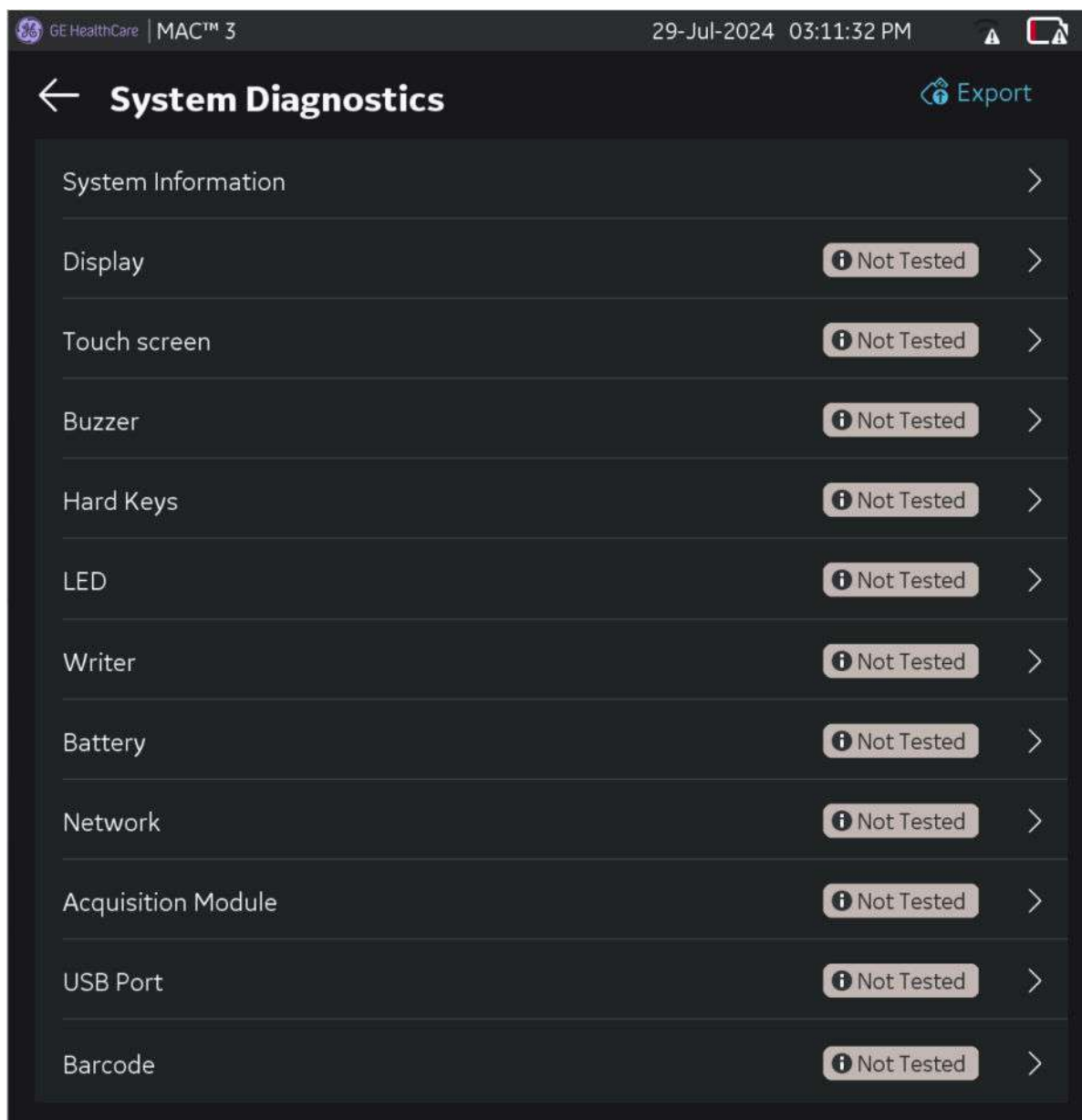


7. When the test is complete, close the screen.
A message displays asking you to confirm whether the test is passed.
8. Based on the test result, select **Yes** or **No**.
The **Hard Keys Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

7.7 Perform LED diagnostic test

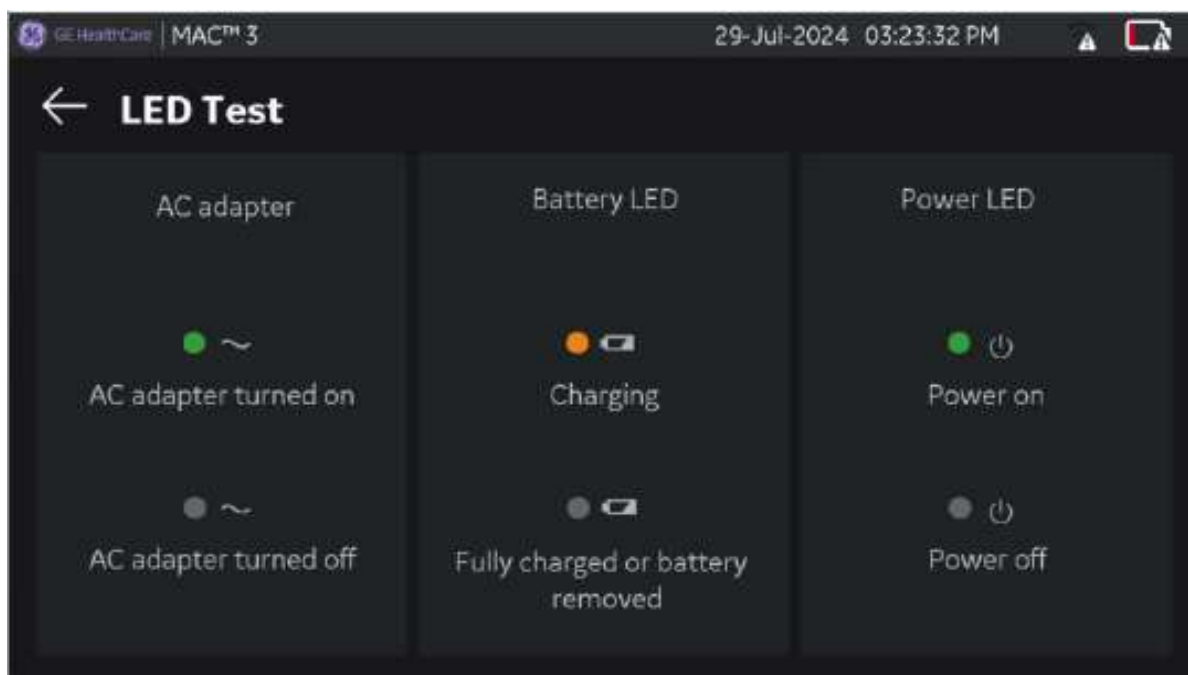
This test determines if the LEDs on the keysheet work correctly.

1. Select **Settings > System Diagnostics**.
The **System Diagnostics** screen displays.



2. Select **LED**.

The **LED Test** screen displays.



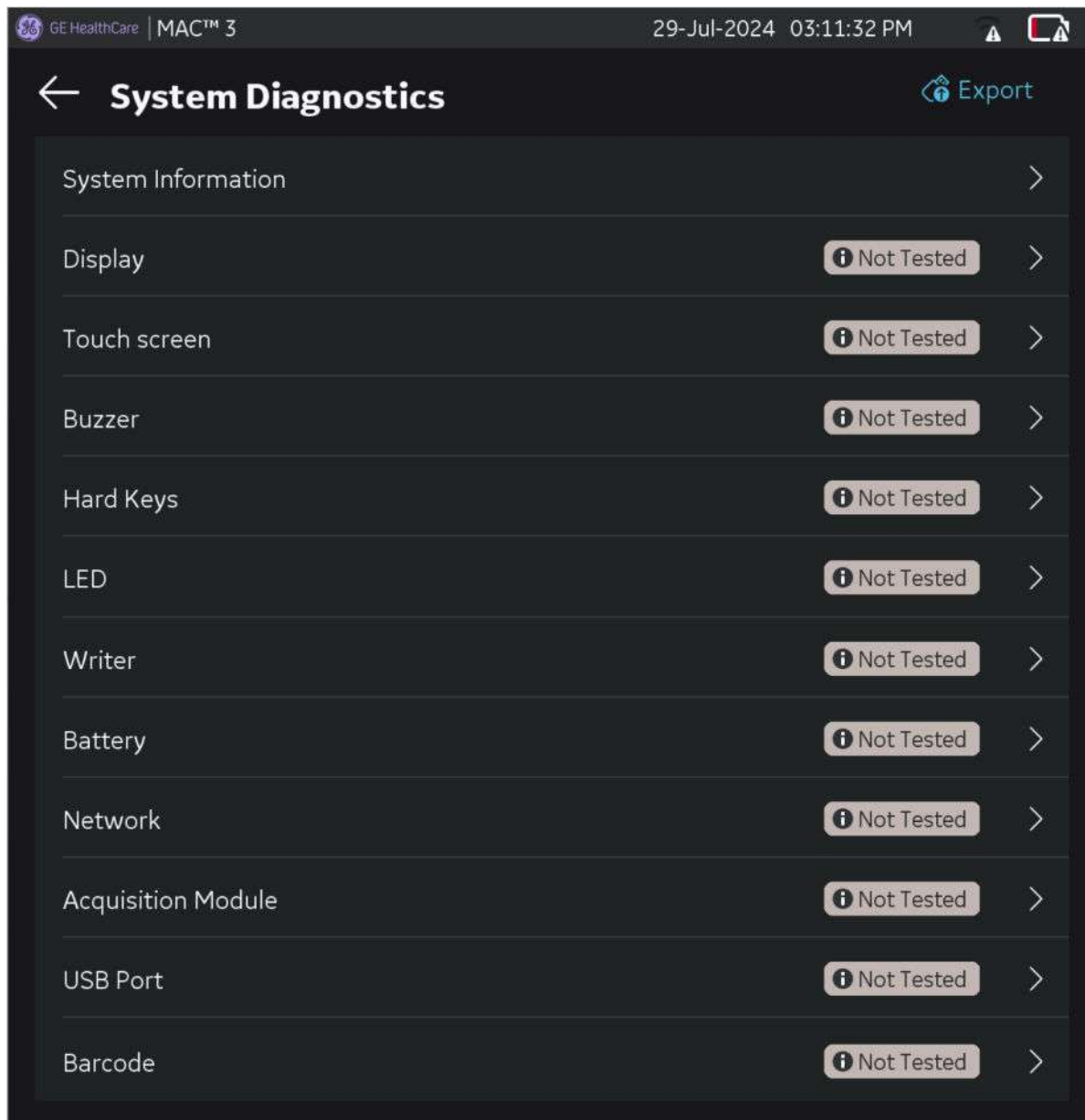
3. To test the AC adapter LED, do the below steps:
 - a. Insert the battery.
 - b. Connect the device to AC power, and verify that the AC adapter LED on the keysheet is on.
 - c. Disconnect the device from AC power, and verify that the AC adapter LED on the keysheet is off.
4. To test the battery LED, do the below steps:
 - a. Connect the device to AC power.
 - b. Insert a battery that is not fully charged into the device, and verify the battery LED on the keysheet is on.
 - c. Insert a fully charged battery into the device, and verify that the battery LED on the keysheet is off.
 - d. Remove the battery from the device, and verify that the battery LED on the keysheet is off.
5. To test the Power LED, verify it is on when AC power is connected and off when the AC power is disconnected.
The test fails if the LED is not on when AC power is connected.
6. When the test is complete, close the screen.
A message displays asking you to confirm whether the test is passed.
7. Based on the test result, select **Yes** or **No**.
The **LED Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

7.8 Perform writer diagnostic test

This test determines if the writer prints correctly. It provides some more test options to allow you to confirm the writer can correctly print at different settings.

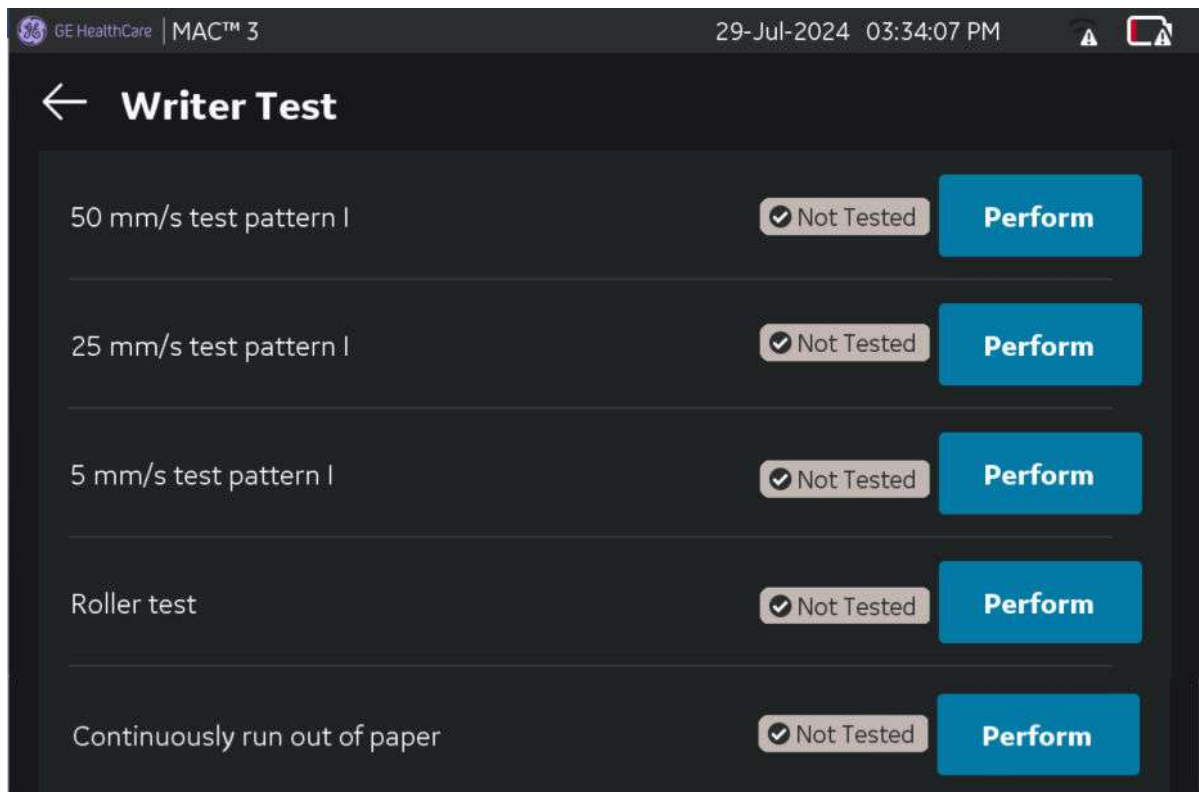
1. Select **Settings** > **System Diagnostics**.

The **System Diagnostics** screen displays.

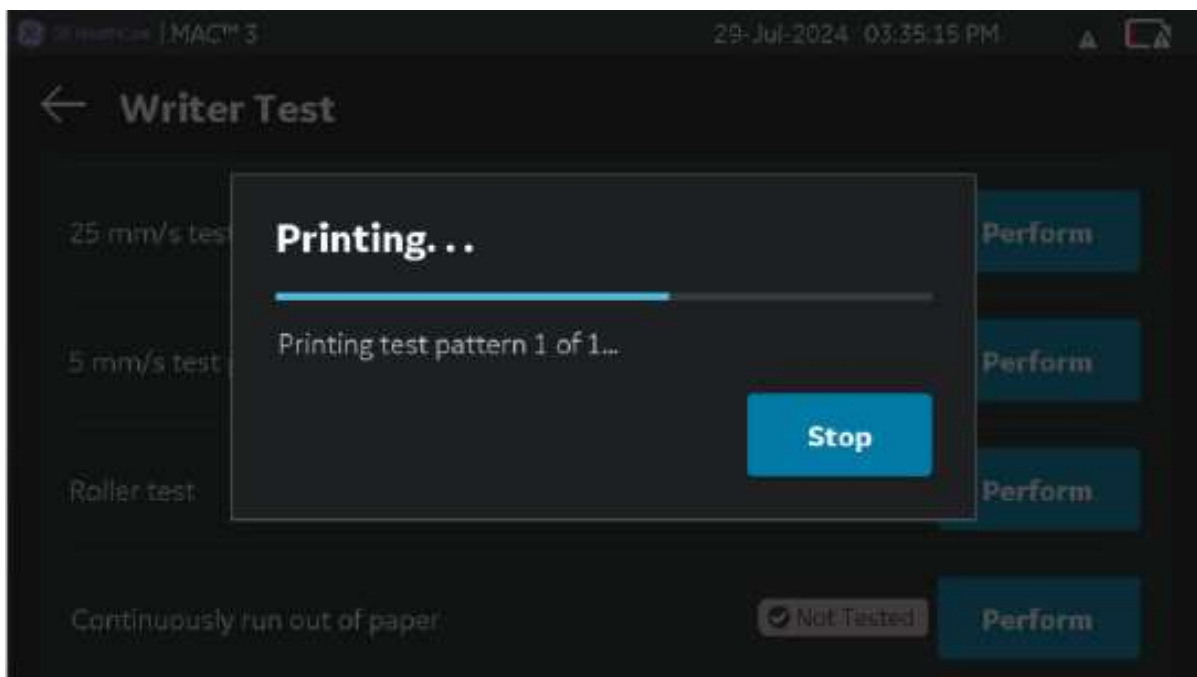


2. Select **Writer**.

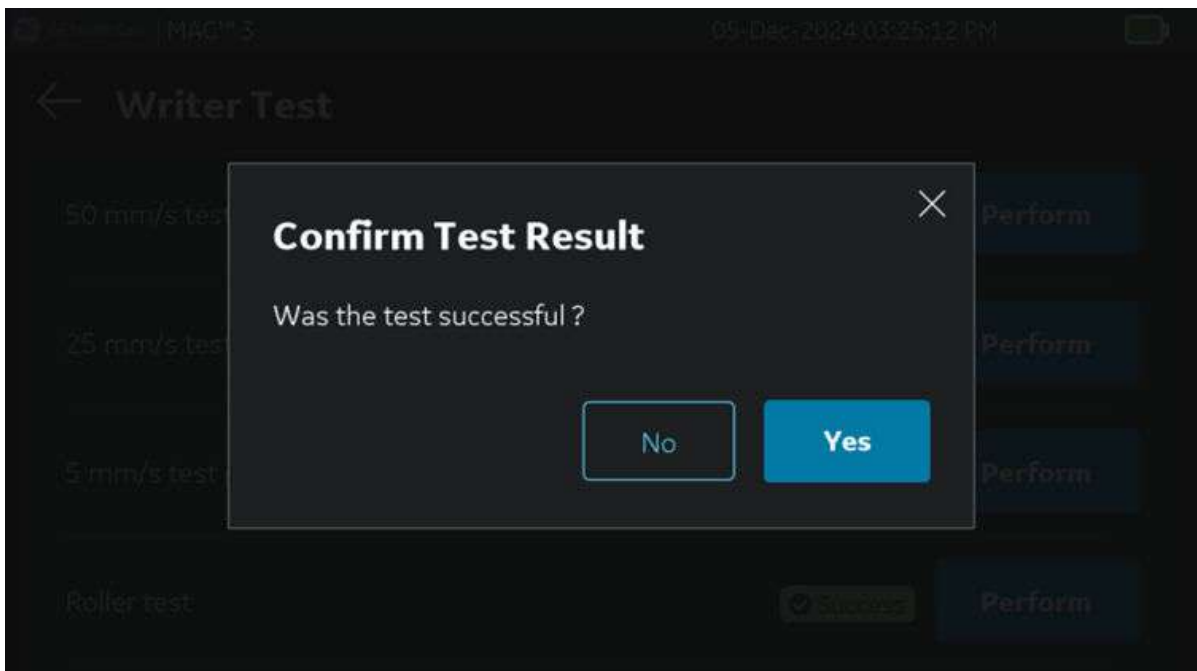
The **Writer Test** screen displays.



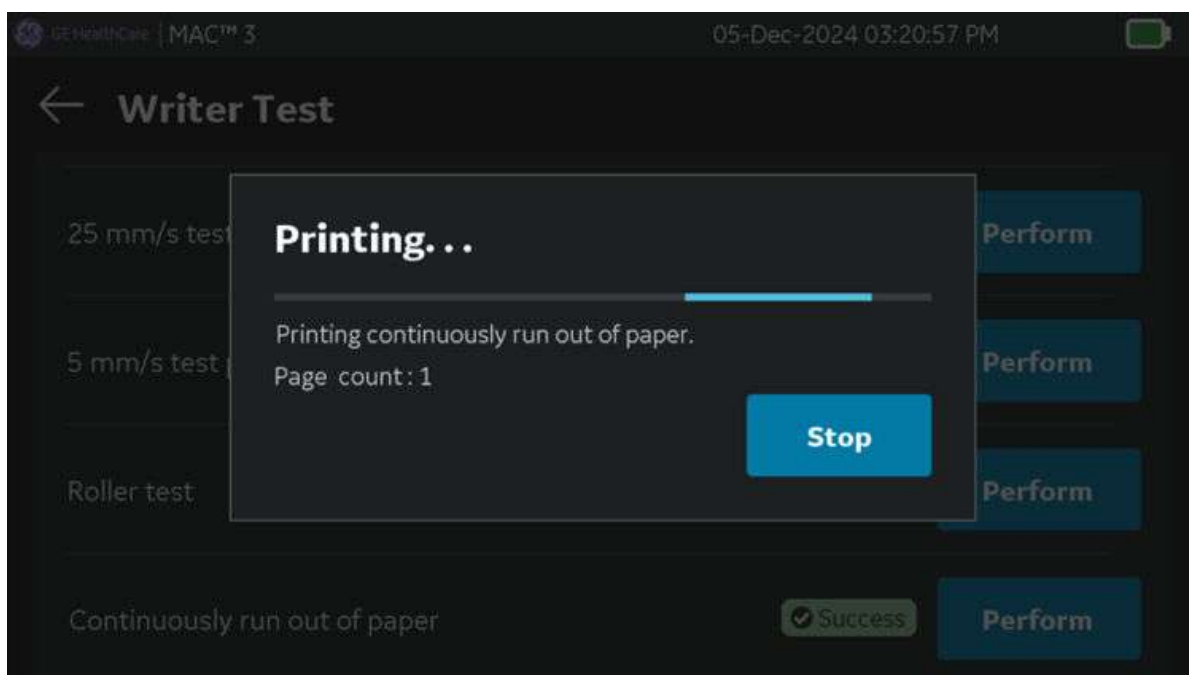
3. Select **Perform** adjacent to **50 mm/s test pattern**.
Verify if the test pattern prints at 50 mm/s.
4. Select **Perform** adjacent to **25 mm/s test pattern**.
Verify if the test pattern prints at 25 mm/s.
5. Select **Perform** adjacent to **5 mm/s test pattern**.
Verify if the test pattern prints at 5 mm/s.
6. Select **Perform** adjacent to **Roller test**.
Verify if the test pattern prints at 25 mm/s and print starts with a mark at each page.
A message displays for each test pattern to confirm if you can print the pattern.



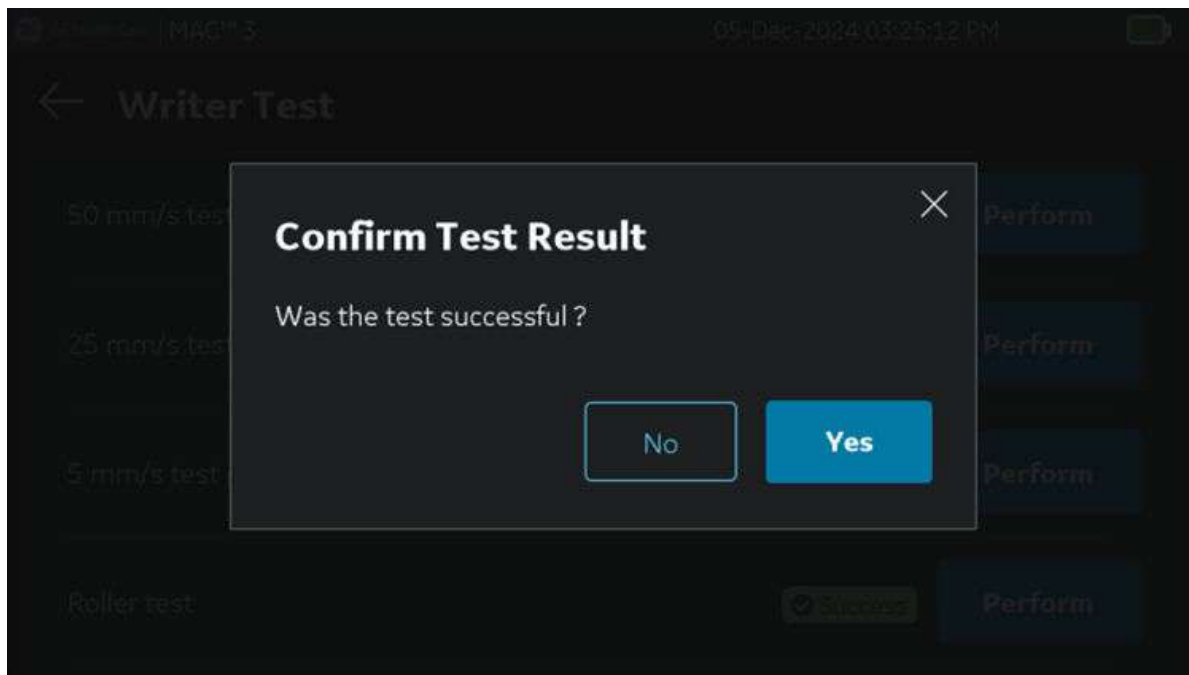
If you press **Stop** button, a message displays to confirm if you can successfully test the pattern.



- If you select **Yes**, the test result displays on the **Writer Test** screen as **Success**.
 - If you select **No**, the test result displays on the **Writer Test** screen as **Failure**.
7. Select **Perform** adjacent to **Continuously run out of paper**.
Verify if all the paper is fully rolled out and displays the count on the screen.



If you press **Stop** button, a message displays to confirm if you can continuously run out of paper test pattern.



- If you select **Yes**, the test result displays on the **Writer Test** screen as **Success**.
 - If you select **No**, the test result displays on the **Writer Test** screen as **Failure**.
8. When the test is complete, close the screen.

A message displays asking you to confirm whether the test is passed.

9. Based on the test result, select **Yes** or **No**.

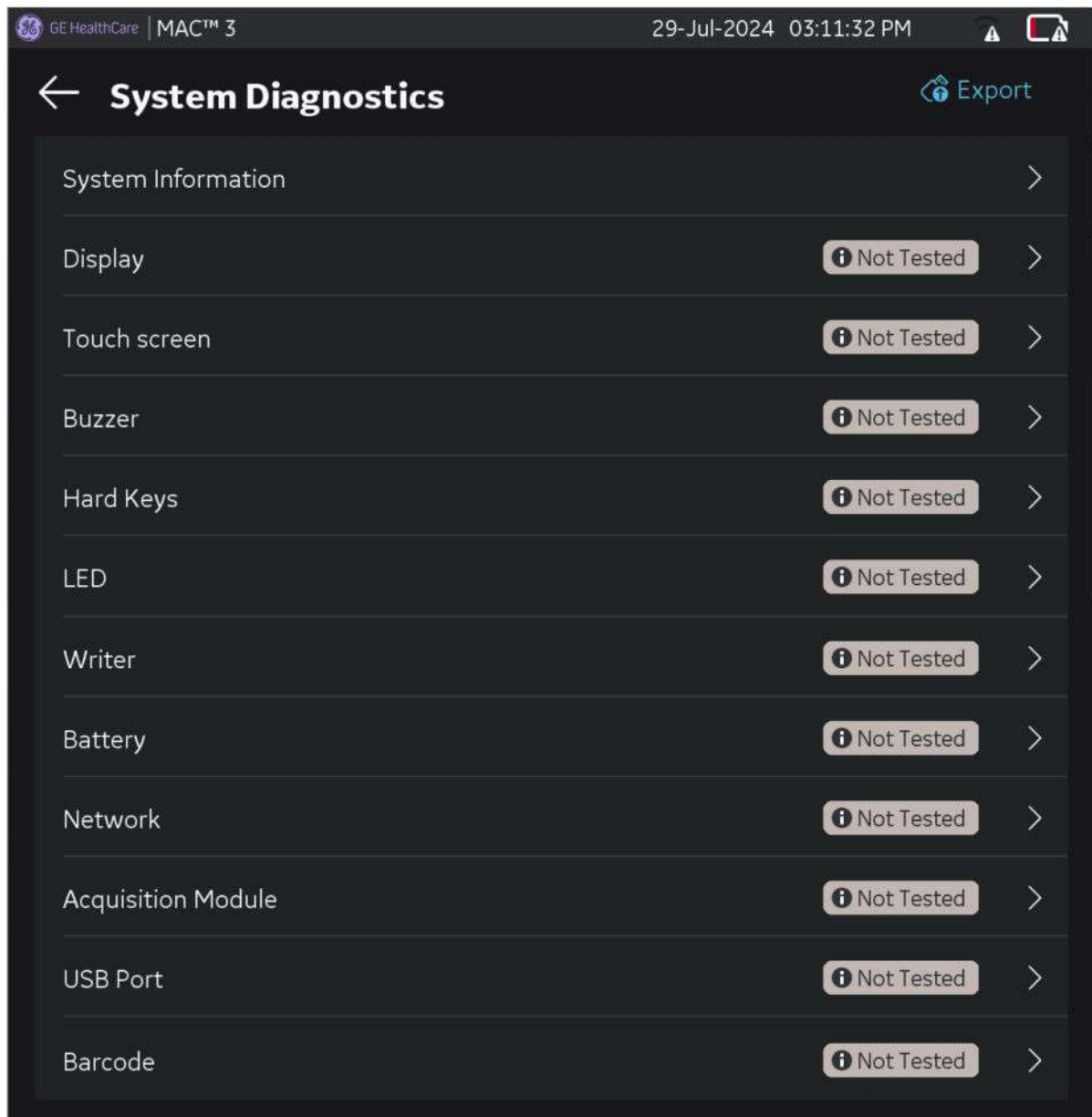
The **Writer Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

7.9 Perform battery test

Make sure that you disconnect the AC adapter before you start this test.

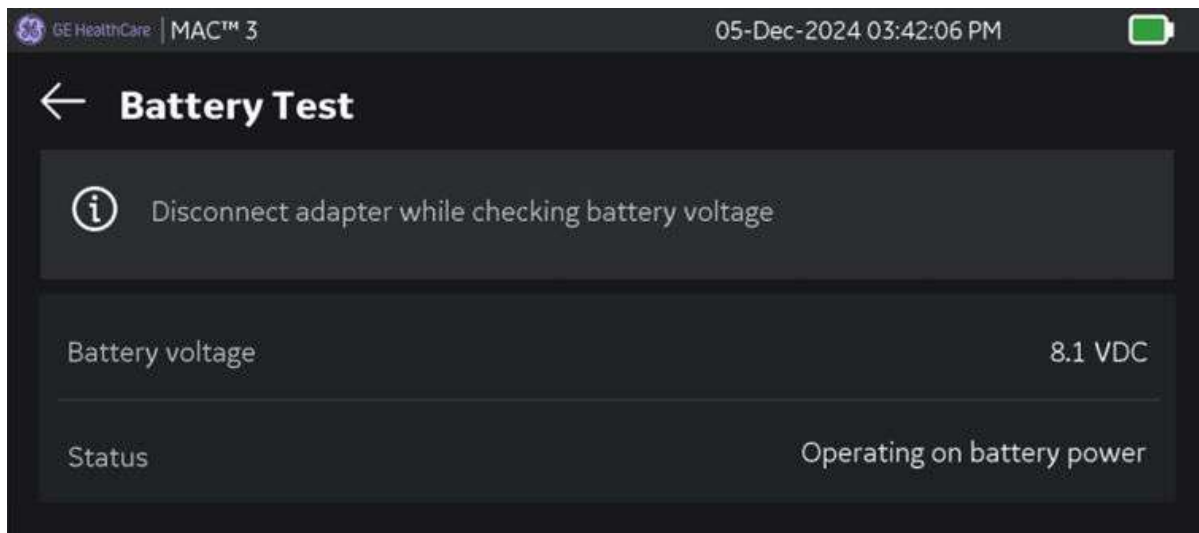
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



2. Select **Battery**.

The **Battery Test** screen displays.



3. Verify if the battery is on, then battery voltage and battery status display.

The **Battery voltage** field shows the current voltage value.

The **Status** field shows the operating battery power.

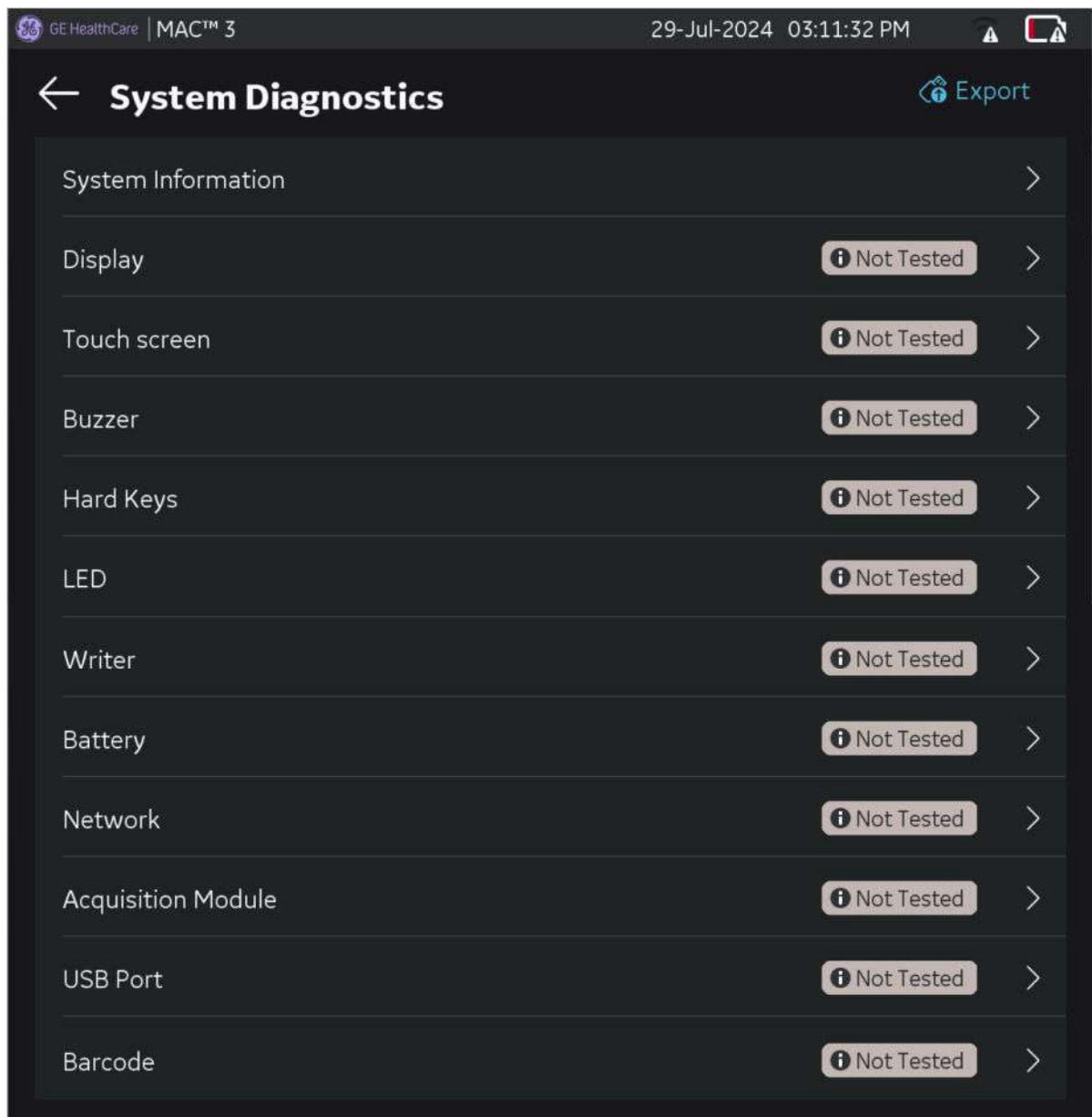
- If you operate from battery, the system displays **Operating on battery power**.
- If the battery is fully charged, the system displays **AC power on but not charging**.

7.10 Perform network diagnostics test

This test determines if a device is available for the Ethernet (LAN), wireless (Wi-Fi), and mobile (GSM) network connection.

1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.

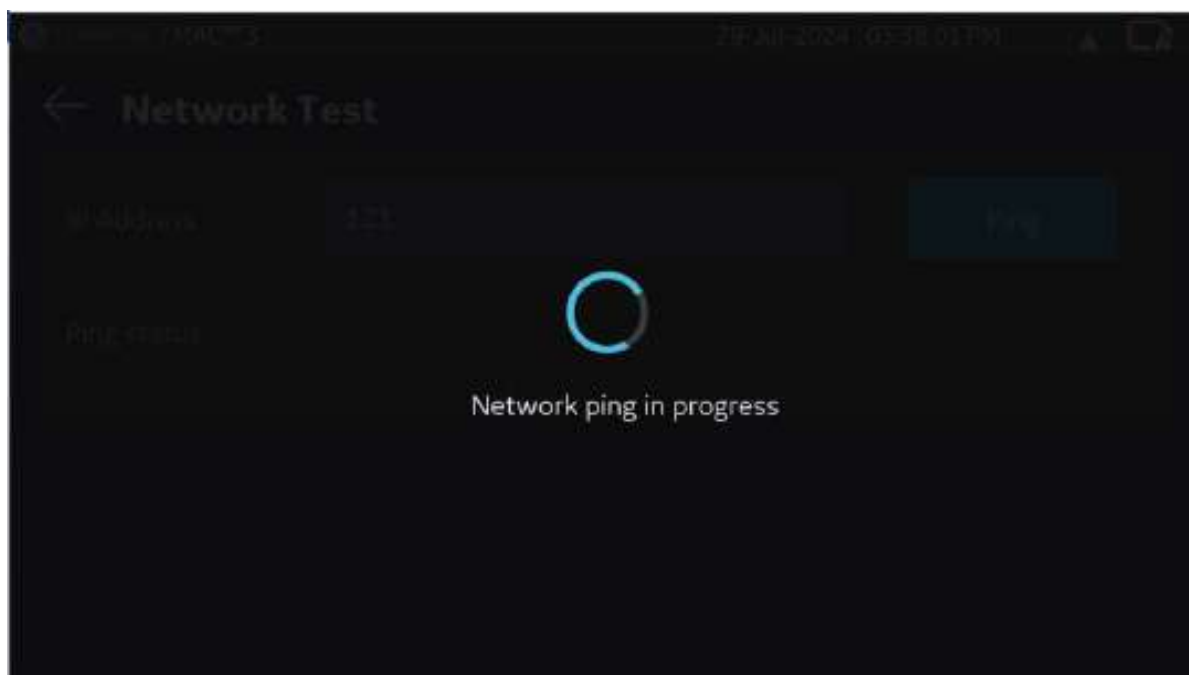


2. Select **Network**.

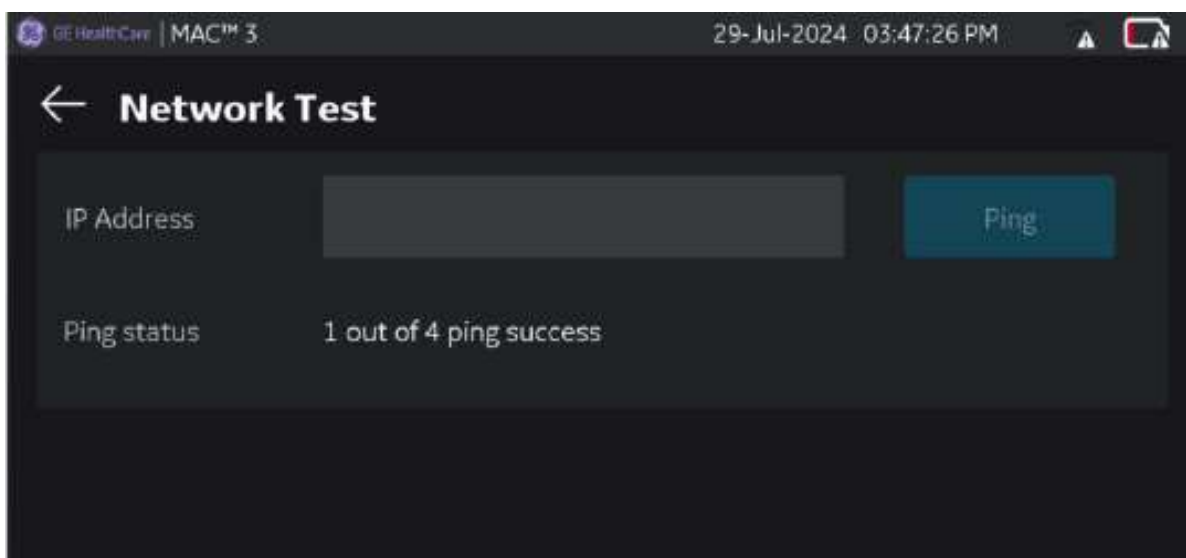
The **Network Test** screen displays.



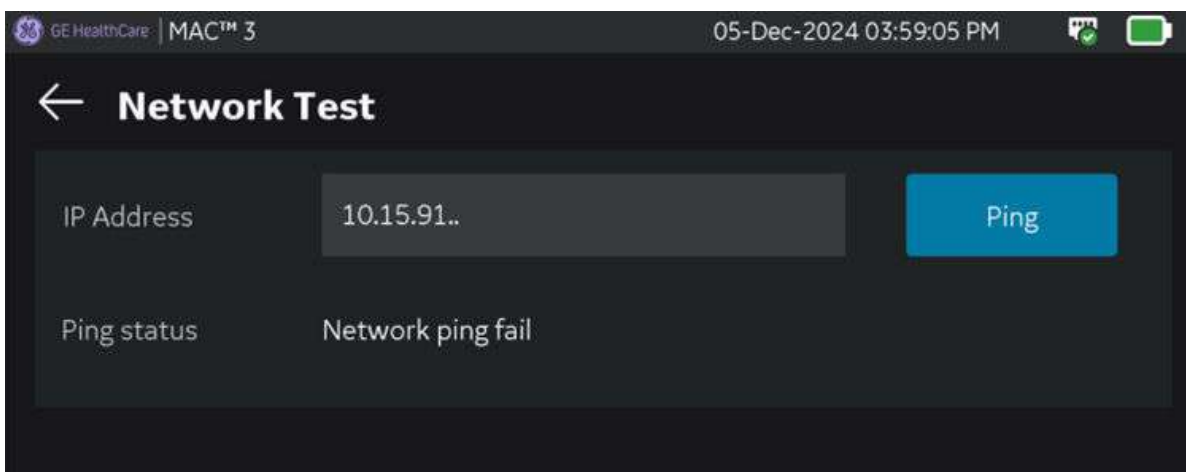
3. Enter the IP address in the **IP Address** field and tap **Ping** to verify the status.
The network ping progress screen displays.



If, no errors the ping result is a success and display on the **Ping status** of the network connection.



If you enter an invalid IP address or network error, the ping result is a failure and display on the **Ping status** of the network connection.



4. After you complete the test, close the screen.

A message displays asking you to confirm whether the test is passed.

5. Based on the test result, select **Yes** or **No**.

The **Network Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

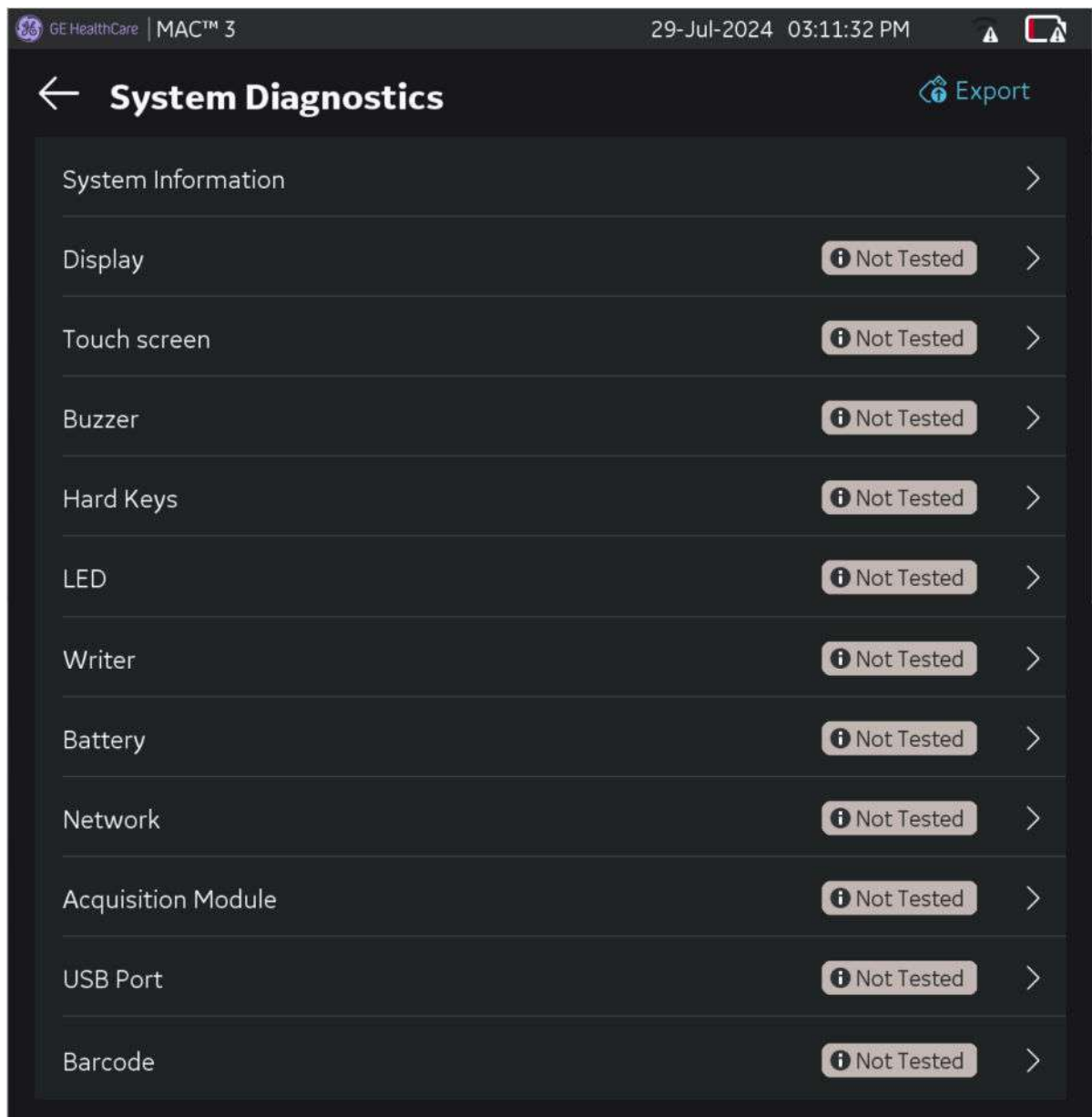
7.11 Perform the Acquisition Module diagnostics test

This test determines if all the patient cable leads operate correctly.

Make sure that you connect the patient cable to the device before you start this procedure. Also connect the leads to RL. Keep the other leads disconnect and away from all the power sources.

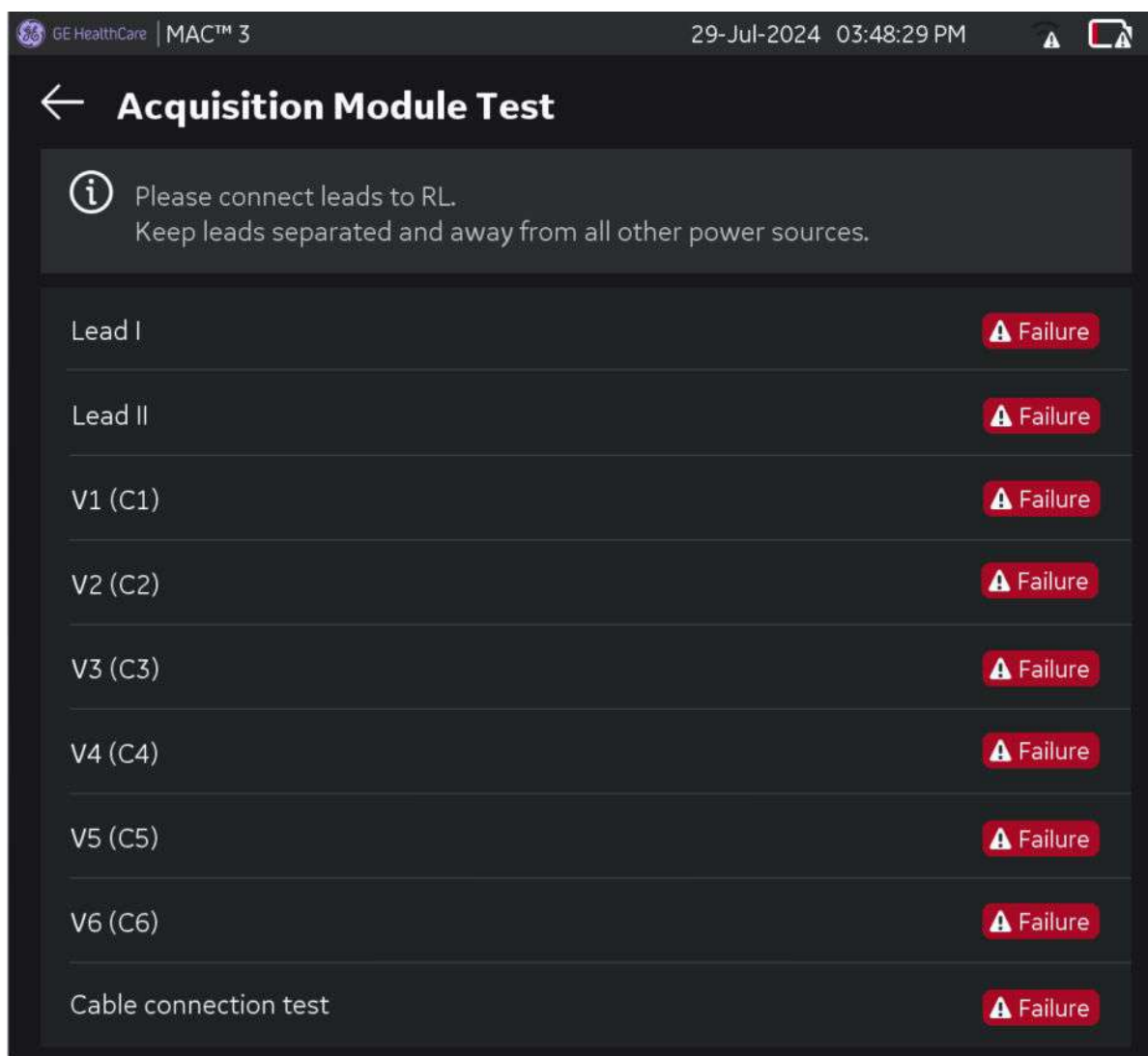
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



2. Select **Acquisition Module**.

The **Acquisition Module Test** screen displays.



3. Connect each lead individually to the ECG simulator as per the reference provided below, and verify that the status of each lead is correct.

- Lead I: Connect RA and LA
- Lead II: Connect RA and LL
- V1 (C1) : Connect V1 (C1)
- V2 (C2) : Connect V2 (C2)
- V3 (C3) : Connect V3 (C3)
- V4 (C4) : Connect V4 (C4)
- V5 (C5) : Connect V5 (C5)
- V6 (C6) : Connect V6 (C6)

Cable connection test: Disconnect the patient cable and then reconnect it.

4. Based on the test results, select one of these:
- If the test passed, the test result **Success** display on the diagnostics screen.
 - If the test failed, the test result **Failure** display on the diagnostics screen.

- When the test is complete, close the screen.

A message displays asking you to confirm whether the test is passed.

- Based on the test result, select **Yes** or **No**.

The **Acquisition Module Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

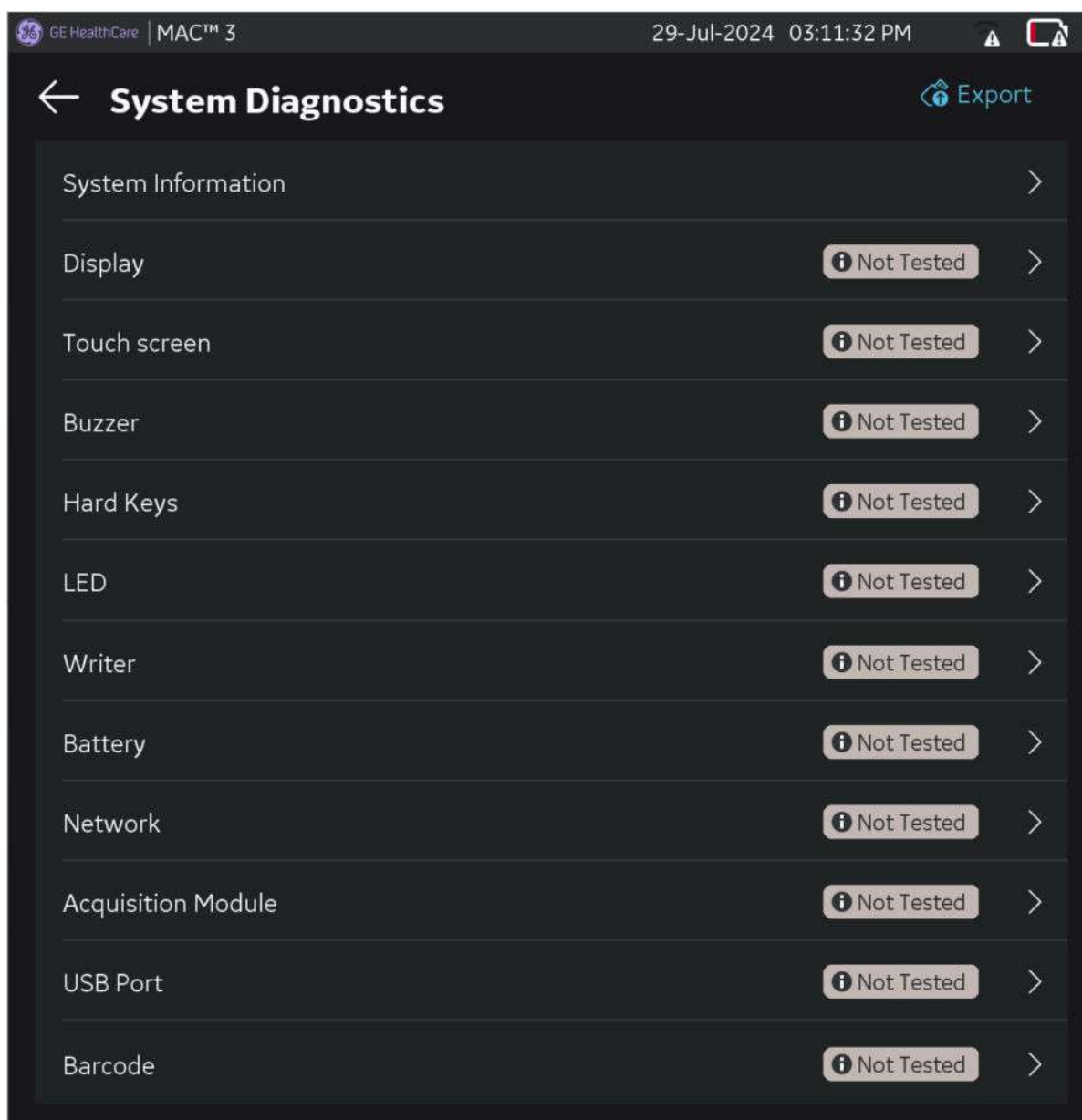
7.12 Perform USB port diagnostic test

This test determines if the USB ports operate correctly. Before you start, make sure that you enable the **USB** and **Allow USB storage** settings in **Settings > System > Hardware** screen.

To perform this test, you need to connect the USB flash drive with FAT32 file format to the USB port.

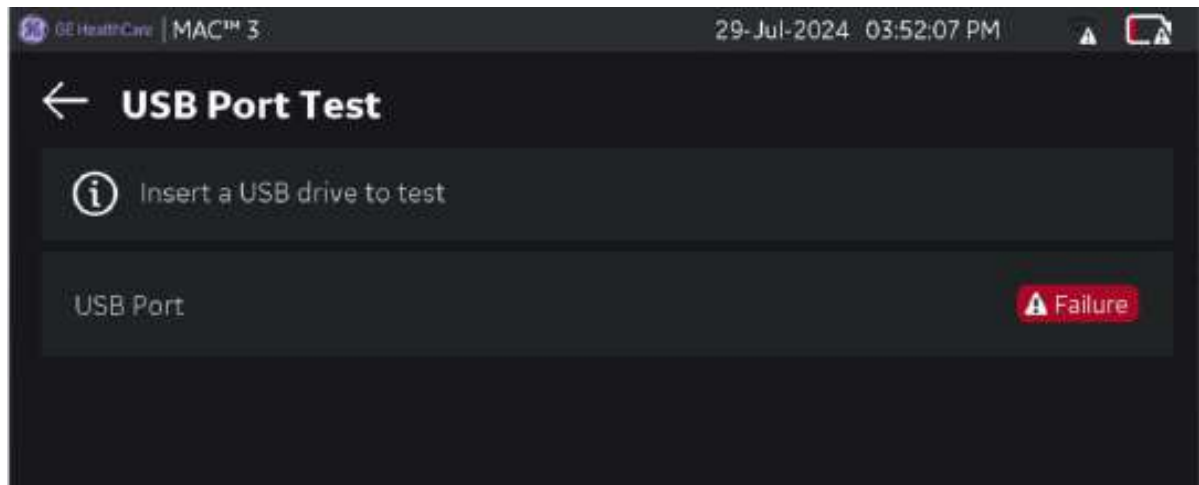
- Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



2. Select **USB Port**.

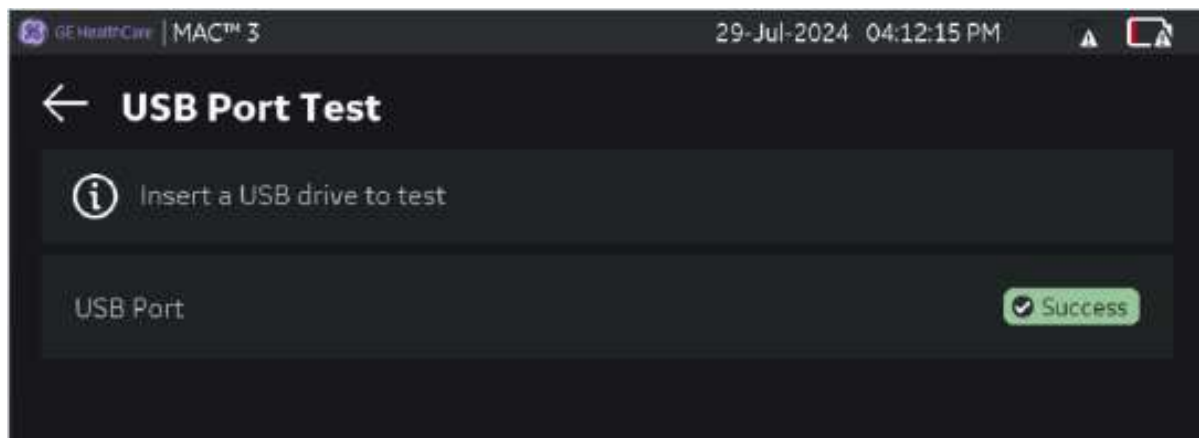
The **USB Port Test** screen displays.



If the USB flash drive is not connected to the device, the default test result show **Failure**.

3. Connect the USB flash drive to the device and perform the test.

Verify that the **USB Port** test result show **Success**.



4. When the test is complete, close the screen.

A message displays asking you to confirm whether the test is passed.

5. Based on the test result, select **Yes** or **No**.

The **USB Port Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

7.13 Perform barcode reader diagnostic test

The device is compatible with barcode readers that support the following symbologies 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

When the FRU external barcode scanner is ordered, follow these steps to set the mode of operation to USB Keyboard:

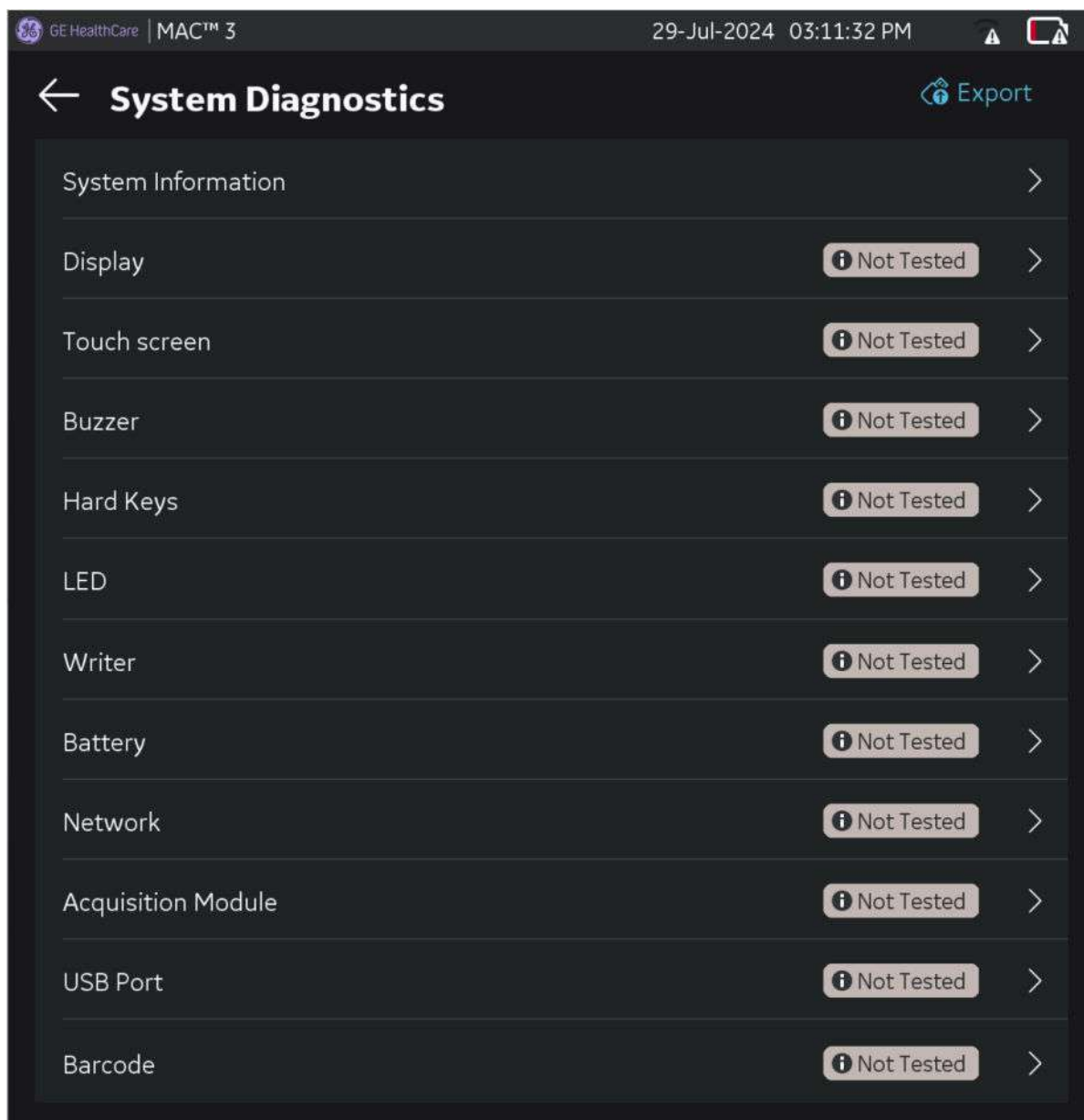
- Scan the symbology provided below to switch the scanner to USB Keyboard mode.
- Perform a power cycle by disconnecting and reconnecting the external barcode scanner before use.



Make sure that you enable the **USB** and **Allow USB storage** settings in **Settings > System > Hardware** screen. Perform the barcode diagnostic test to determine if the barcode reader operates correctly.

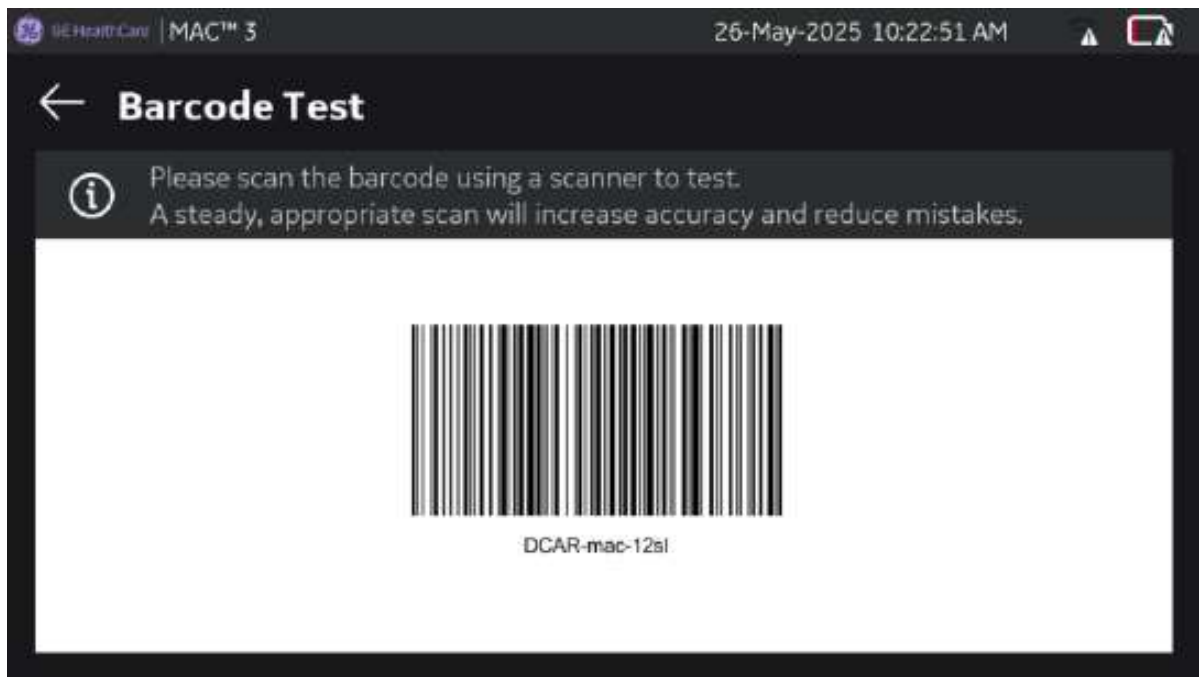
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.

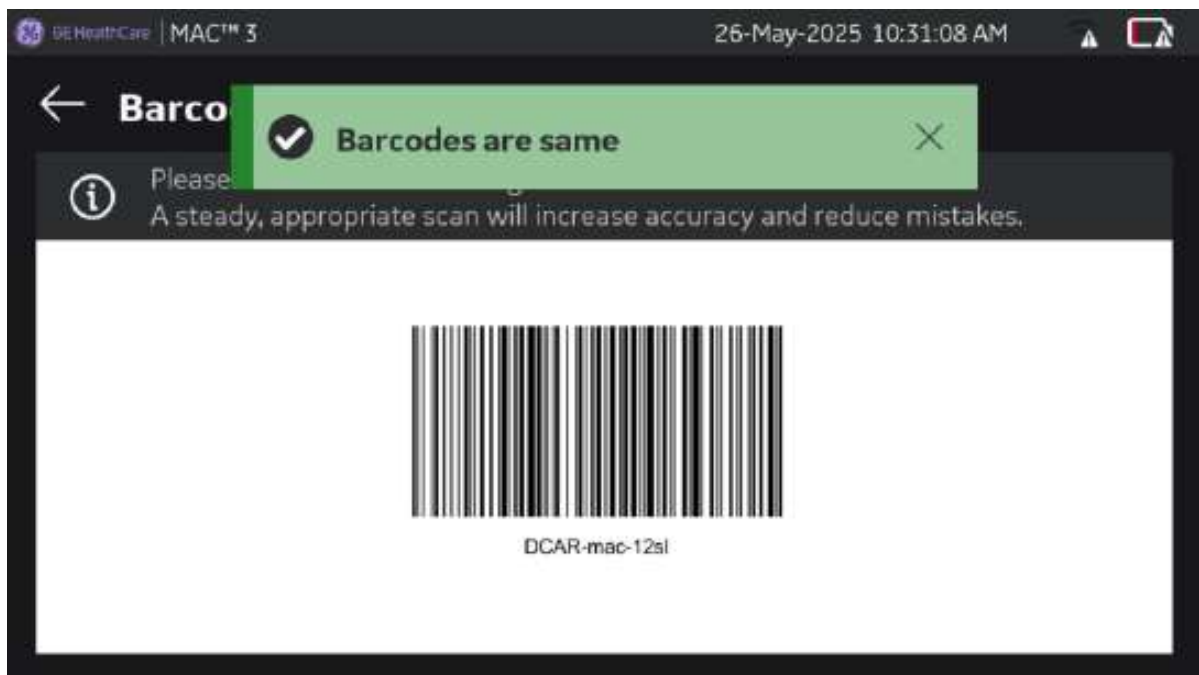


2. Select **Barcode**.

The **Barcode Test** screen displays.



3. Connect the external barcode reader to the device and scan the barcode.
If the scan barcode is same, a **Barcodes are same** message display on the diagnostic screen.



If the scan barcode is different, a failure message display on the diagnostic screen.

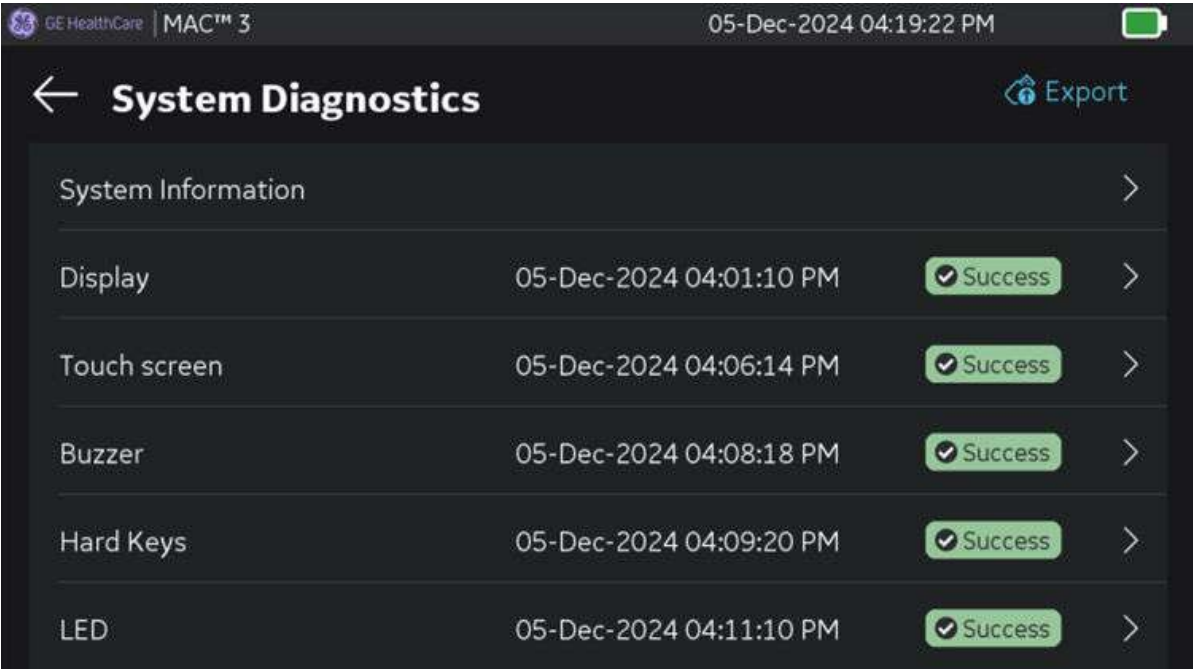
4. When the test is complete, close the screen.
A message displays asking you to confirm whether the test is passed.
5. Based on the test result, select **Yes** or **No**.
The **Barcode Test** screen closes. The **System Diagnostics** screen updates with the test result **Success** or **Failure**.

7.14 View diagnostic test results

This procedure provides you on how to review the latest status of each diagnostic test performed.

1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.



2. Scroll down the screen to see all the diagnostics test results.

The below table describes the columns on the **System Diagnostics** screen.

Table 7-1 Diagnostics test results

Column name	Description
Test name	The name of the diagnostic test. The list shows each available test.
Test status	The status of the last test. The possible status are: • Success: The diagnostic test was successful. • Failure: The diagnostic test failed. • Not Tested: The diagnostic test was not complete or you did not do the test.
Date and time	Display the date and time when you complete the test for each of the diagnostic test.

3. To export diagnostic test results to a USB flash drive, see [7.15 Export diagnostic test results to a USB flash drive on page 103](#)

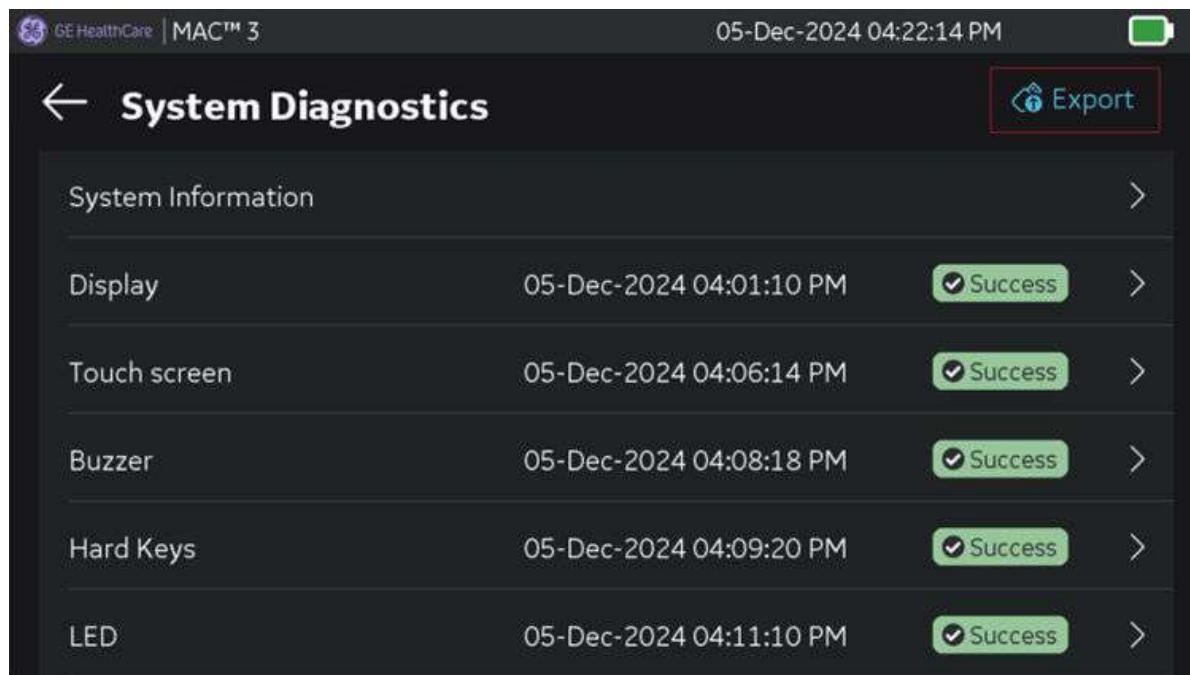
7.15 Export diagnostic test results to a USB flash drive

This procedure provides you on how to export the results of all the diagnostic tests to a USB flash drive. Before you start the procedure, make sure that you:

- Enable **USB** and **Allow USB storage** settings from **Settings > System > Hardware**.
- Use the USB flash drive with the FAT32 file system.

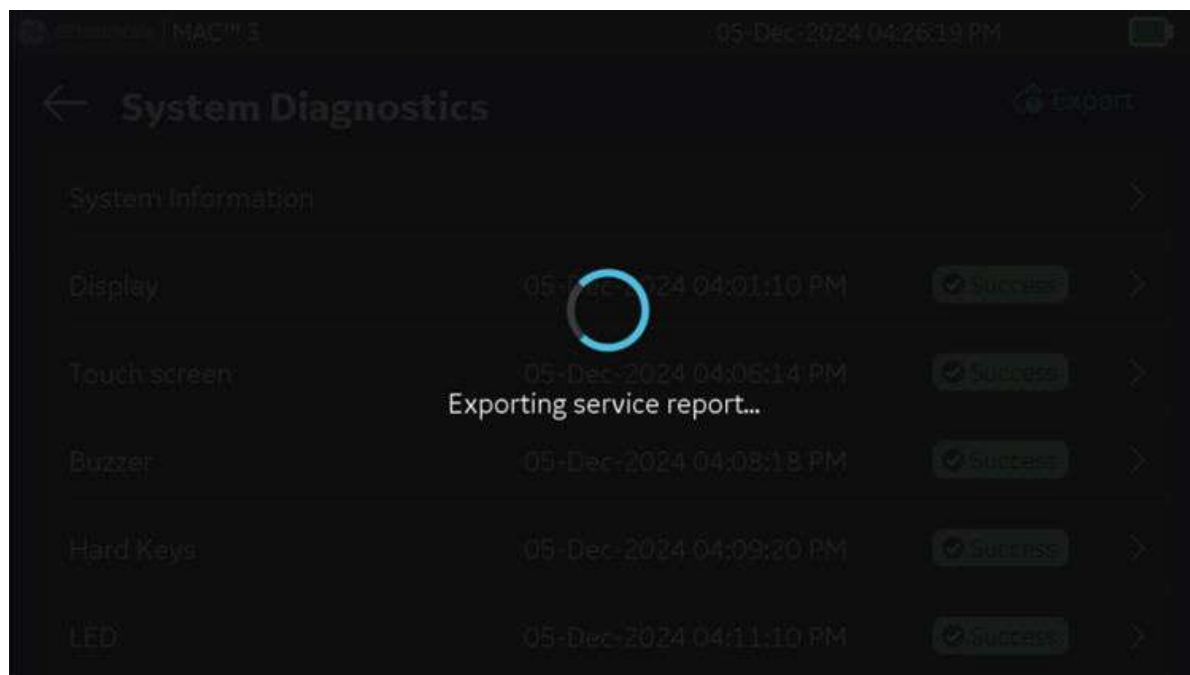
1. Select **Settings > System Diagnostics**.

The **System Diagnostics** screen displays.

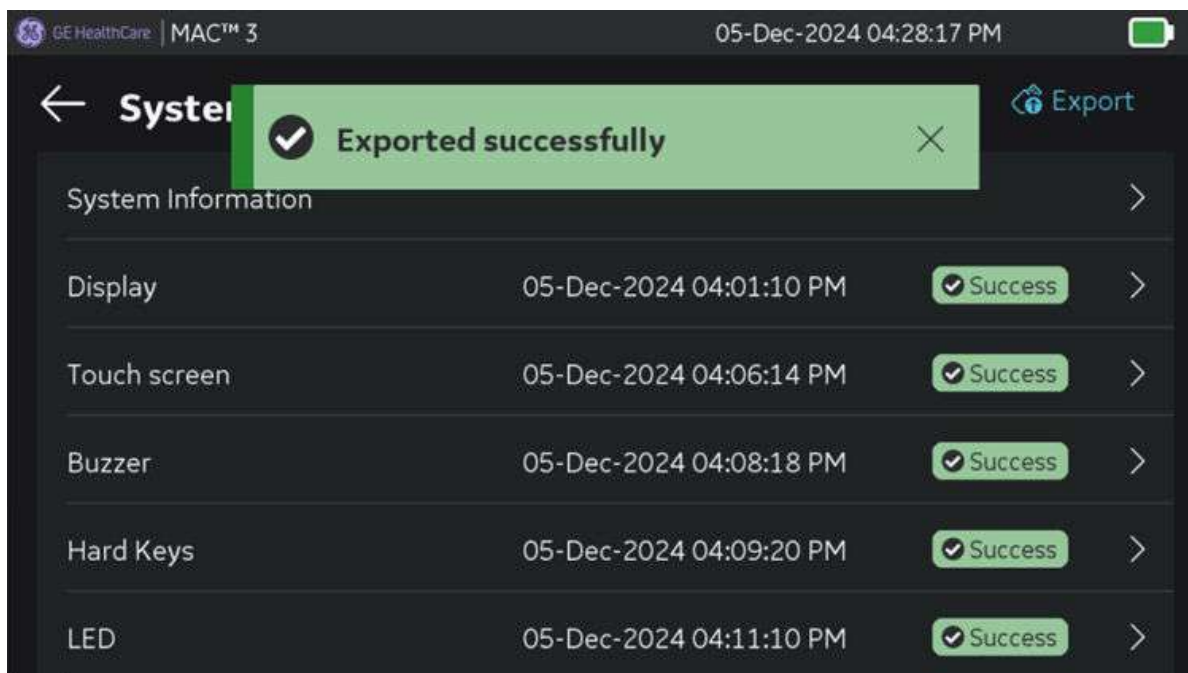


2. Connect the USB flash drive to the USB port.
3. Press the **Export** button.

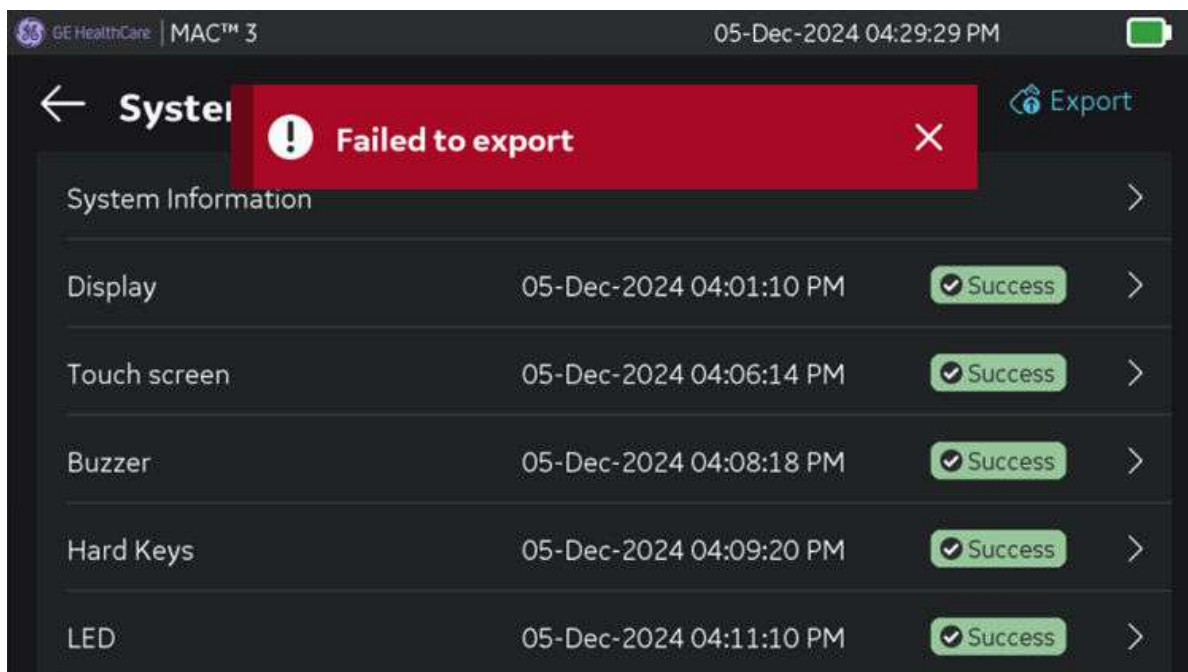
The progress window opens.



If no errors, the message **Exported successfully** displays.



If any errors occur, the failure message display.



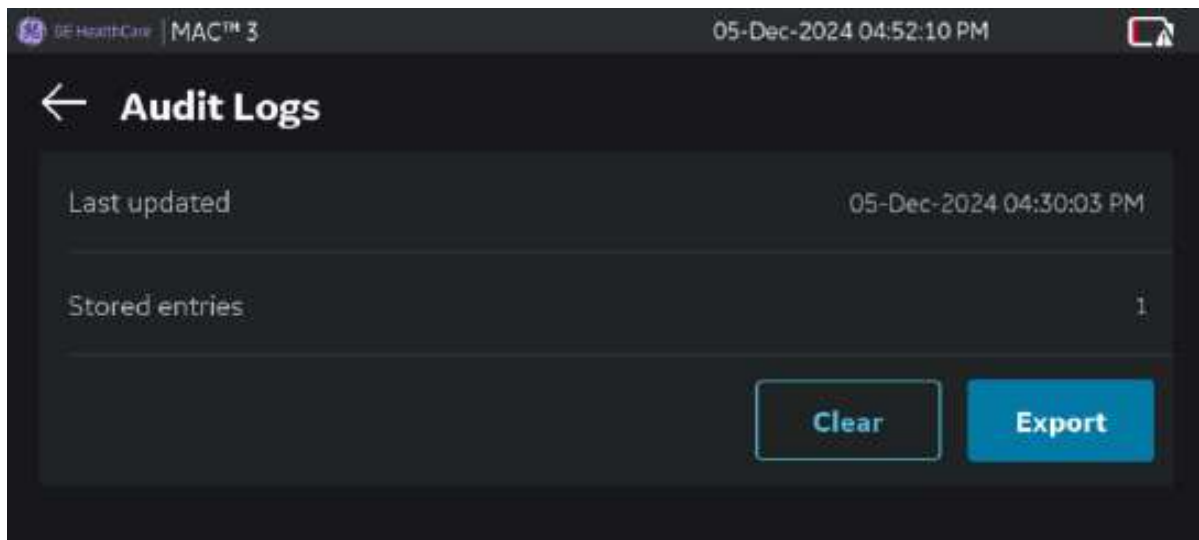
8 Working with logs

8.1 Audit logs

Audit logs are saved for two weeks for you to review. Logs older than two weeks are deleted. Implement a schedule to export the audit logs every two weeks to view logs older than two weeks. The device can have a maximum of 20 audit log files.

1. Select **Settings > System > Audit Logs**.

The **Audit Logs** screen displays.



Events in the audit log are listed in the order of date and time of occurrence of the event. The most recent event is the first entry in the audit log.

Table 8-1 Audit logs setting

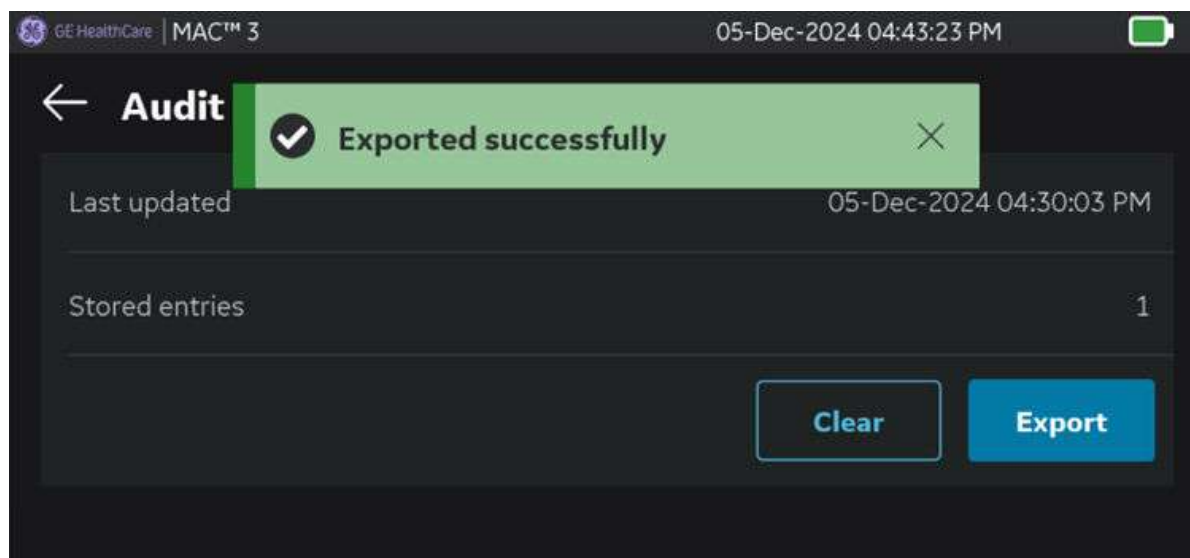
Field	Action	Description
Last updated	No action required	The date and time of the last updated action logs for Audit Log .
Stored entries	No action required	If, the size of log is more than 512 KB then the entry number increase.
Export	Select the button to export the audit logs.	Export the audit Log entries to the USB flash drive.
Clear	Select the button to clear the logs.	Clear the audit log or to reset the Stored entries field to 0.

2.  **NOTE** Before you start to export the audit log, make sure that you:

- Enable the **USB** and **Allow USB storage** settings in **Settings > System > Hardware** screen.
- Connect the USB with FAT32 file format to the USB port.

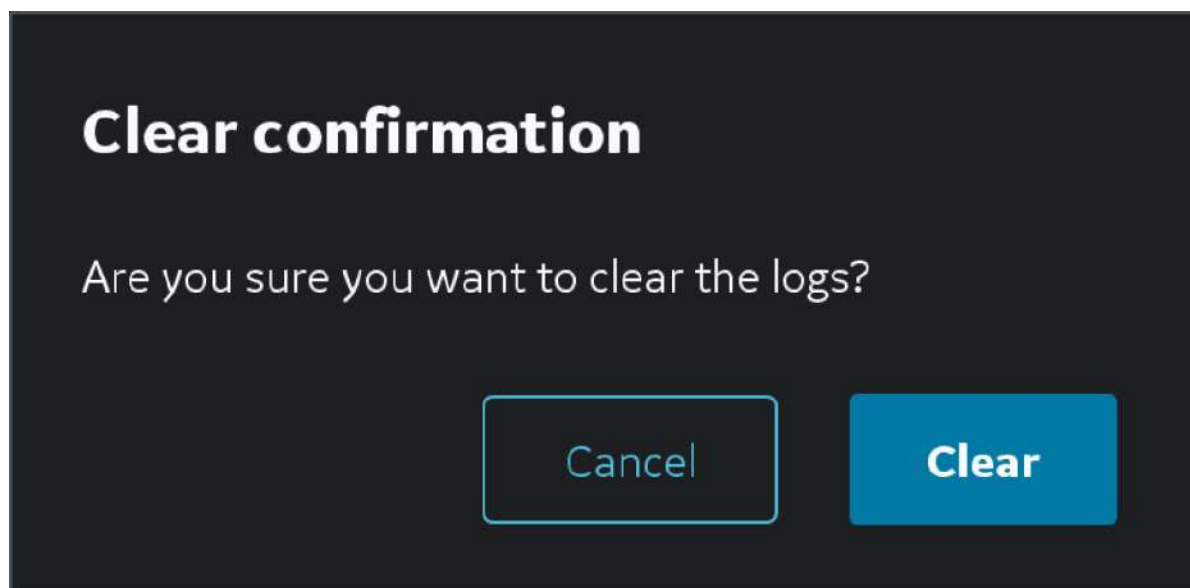
Select **Export** to export the audit log.

The **Exported successfully** message displays.



3. Select **Clear** to clear the audit log.

The **Clear confirmation** screen displays.



4. Select **Clear** to confirm and clear the audit logs.
5. Select **Cancel** to skip to clear the audit logs.

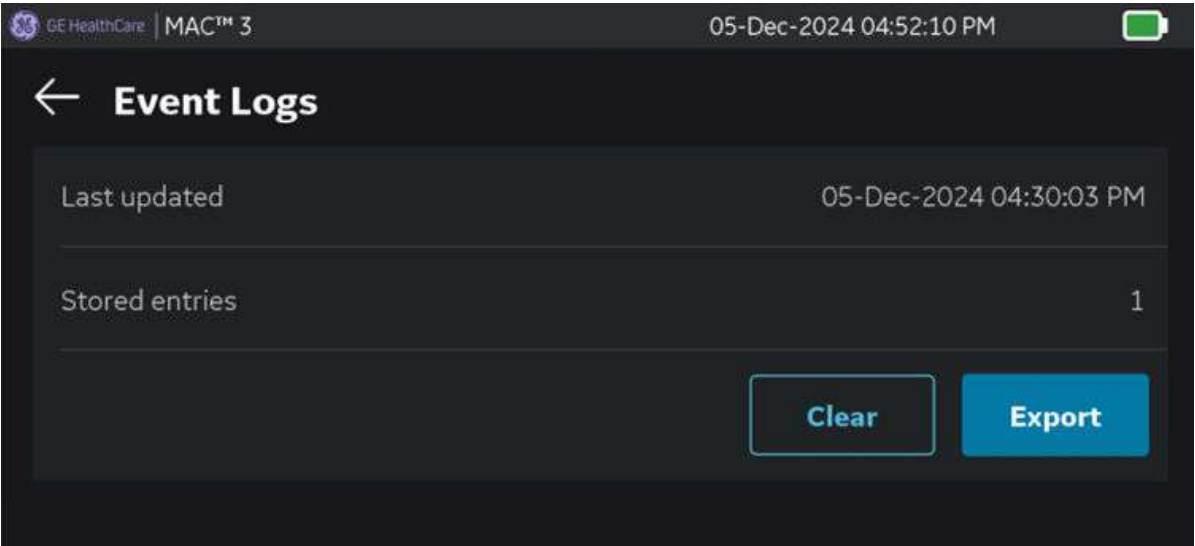
8.2 Event logs

Archived event logs are used to send troubleshooting information to GE HealthCare. The device can have a maximum of 20 event log files. The oldest event log file is deleted, and new events are written to it. The frequency with which the event log files are deleted and overwritten depends on the number of users and their level of activity.

You can export the event logs to a USB flash drive for historical reference. Export the log files on a regular basis to make sure no historical data is lost.

1. Select **Settings > System > Event Logs**.

The **Event Logs** screen displays.



Events in the event log are listed in the order of date and time of occurrence of the event. The most recent event is the first entry in the event log.

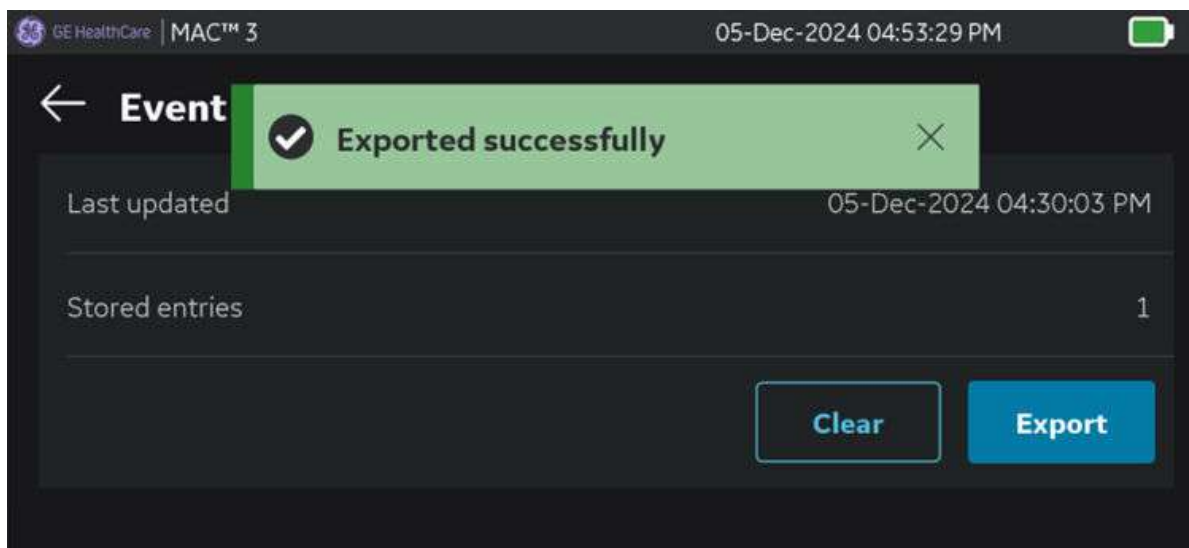
Table 8-2 Event logs setting

Field	Action	Description
Last updated	No action required	The date and time of the last updated action logs for Event Log .
Stored entries	No action required	If, the size of log is more than 512 KB then the entry number increase.
Export	Select the button to export the event logs.	Export the event Log entries to the USB flash drive.
Clear	Select the button to clear the logs.	Clear the event log or to reset the Stored entries field to 0.

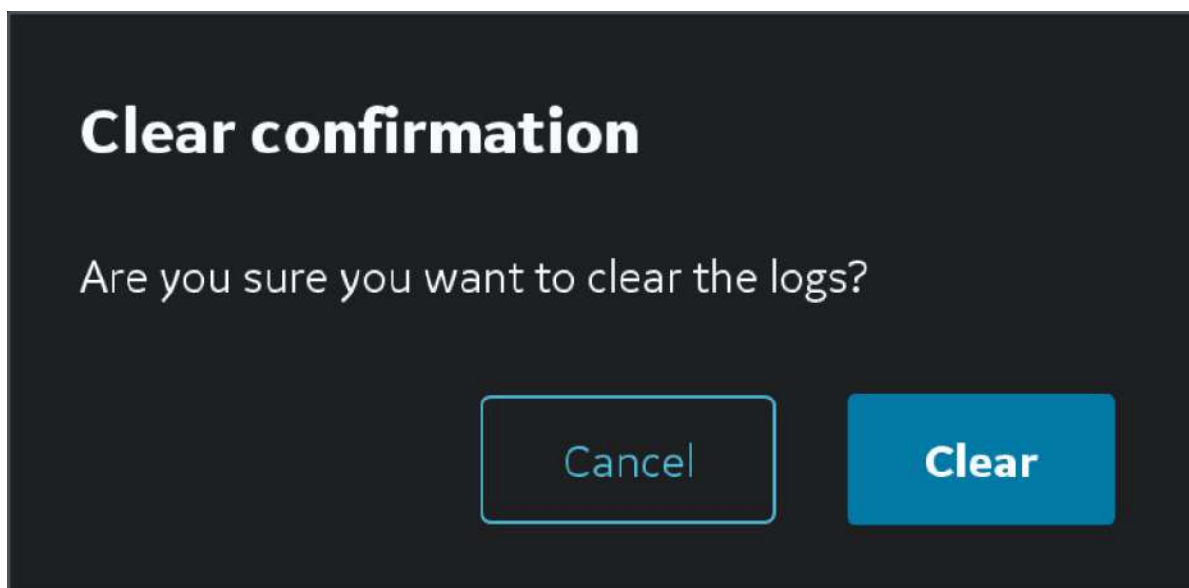
2.  **NOTE** Before you start to export the event log, make sure that you:
- Enable the **USB** and **Allow USB storage** settings in **Settings > System > Hardware** screen.
 - Connect the USB with FAT32 file format to the USB port.

Select **Export** to export the event log.

The **Exported successfully** message displays.



3. Select **Clear** to clear the event log.
The **Clear confirmation** screen displays.



4. Select **Clear** to confirm and clear the event logs.
5. Select **Cancel** to skip to clear the event logs.

9 Parts list

The Field Replaceable Unit (FRU) parts lists in this chapter supply enough detail for you to order parts for the assemblies, stand-alone FRUs, and FRU kits considered field serviceable. Only items, assemblies, and kits that have part numbers given in this chapter are available for purchase. To order parts, contact GE HealthCare Service Parts. FRUs may not be available in all regions.

This chapter is divided into two sections:

- **Part Identification**
This section helps to identify the parts associated with the device and the FRU or FRUs in which each part is available.
- **FRU Lists**
This section describes the contents of each FRU.

9.1 Part identification

This section provides the information you need to identify the parts associated with the MAC™ 3 Resting ECG Analysis System. It is intended to help you identify which FRUs to order.

The section begins with exploded diagrams calling out the individual parts of the device. That is followed by a table that identifies each part called out in the diagrams and lists the FRU or FRUs in which the part is available.

To use this section, do the following:

1. Review the diagrams until you locate the part to be identified.
2. Note the number in the callout associated with the identified part.
3. Turn to the table following the diagrams and locate the row with the same number as the callout.
4. Review the part description and the FRU or FRUs in which the part is available.
5. If necessary, review the associated FRU details in the FRU lists to determine which FRU is appropriate to order.

9.1.1 Prepare the system for FRU replacement

CAUTION



EQUIPMENT DAMAGE

Pinching, overstretching of cables, and rubbing of cables with metal surfaces can result in equipment damage.

Before you perform any of the disassembly procedures, do the below steps:



NOTE

Take precautions against Electrostatic Discharge damage while you replace the Field-Replaceable Units.

1. Store and print your device settings to restore them or manually reconfigure the system when you complete the FRU replacement.

For information on storing or printing your settings, see the *Configure Settings* of the *MAC™ 3 Resting ECG Analysis Operator's Manual*.

2. Power off the device.
3. Disconnect the device from the AC mains.
4. Disconnect the AC/DC power adapter from the rear side of the device.
5. Disconnect the below peripherals from the device, if connected:
 - External storage devices connected to the USB port
 - External barcode reader cable connected to the USB port.
 - LAN cable connected to the RJ45 port.
6. Remove any paper from the paper tray.

9.1.2 Tools

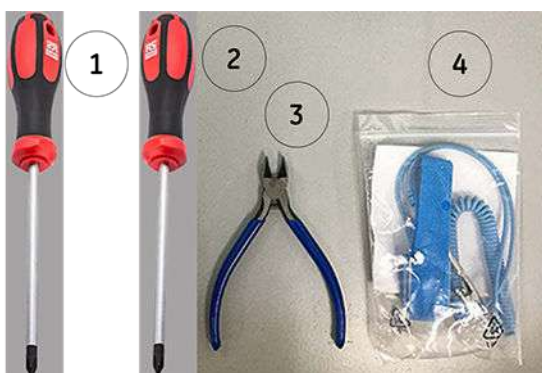
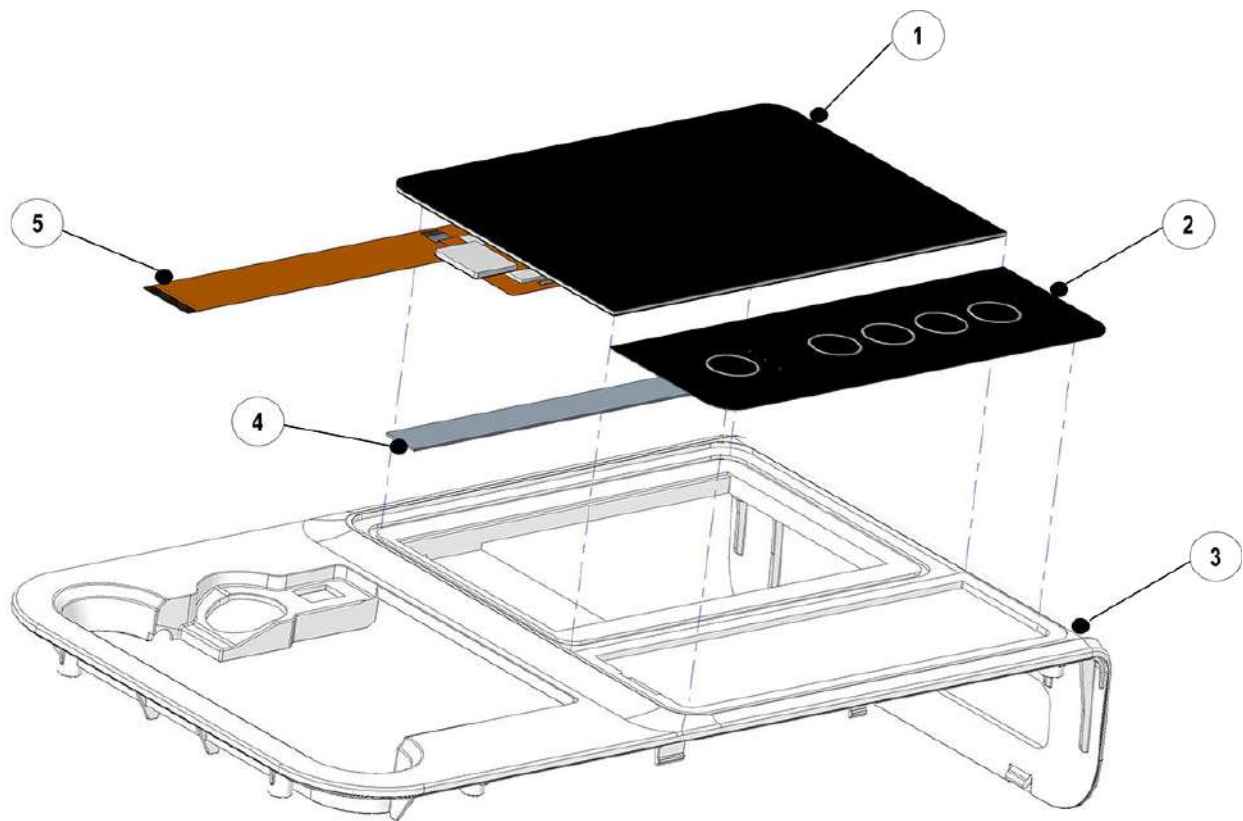


Table 9-1 Tools

Item	Description
1	PH1 Philips head screwdriver
2	PH0 Philips head screwdriver
3	Pliers
4	Anti-static bracelet

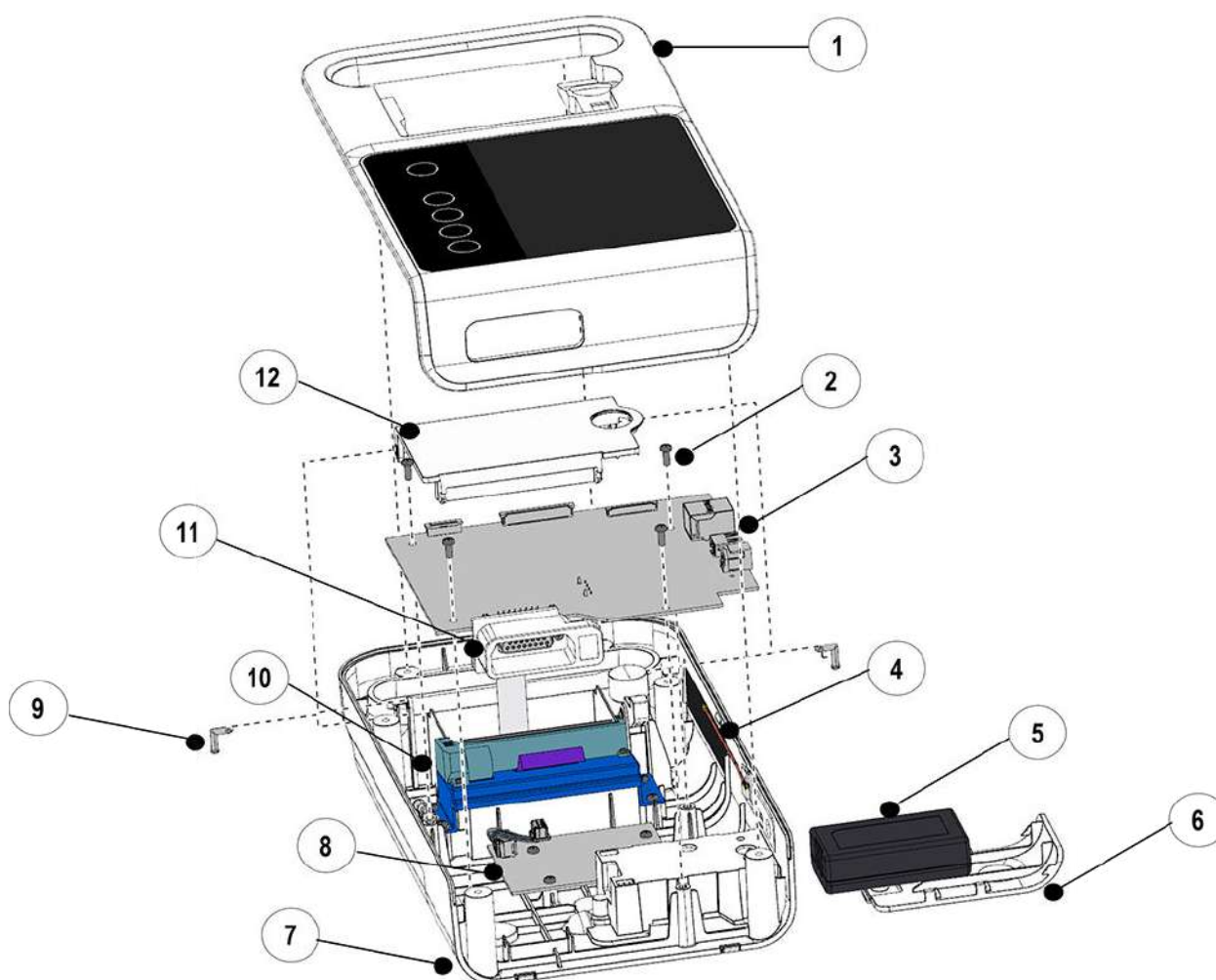
9.1.3 Field replacable parts list

9.1.3.1 Top cover assembly



Item	Part description	Available in
1	Display	MAC 3 Top Cover Assembly (5025600-102)
2	Keysheet	
3	Top cover	
4	Keysheet cable	
5	Display cable	

9.1.3.2 Bottom cover assembly



Item	Part Description	Available in
1	Top cover assembly	MAC 3 Top cover assembly (5025600-102)
2	PCB board screws	MAC 3 Mechanical kit (5025600-103)
3	PCB board	MAC 3 Main PWA (5025600-100)
4	Antenna	MAC 3 GSM PWA kit (5025600-101)
5	Battery	FRU Li-Ion battery 7.2V, 3350 MAH (2111133-001)
6	Battery door assembly	MAC 3 plastic parts kit (5025600-105)
7	Bottom cover	MAC 3 Bottom cover (5025600-107)
8	GSM PCB board	MAC 3 GSM PWA kit (5025600-101)
9	Printer door - hinge component	MAC 3 Plastic parts kit (5025600-105)
10	Printer module assembly	MAC 3 Printer module assembly (5025600-104)
11	MAC 3 Patient cable connector holder	MAC 3 Plastic parts kit (5025600-105)
12	Printer door	MAC 3 Plastic parts kit (5025600-105)

9.2 FRU list

The FRU lists are sorted by ascending part number.

Table 9-2 MAC 3 main PWA (5025600-100)

Description	Quantity	Reference
Main PWA	1 pc	

Table 9-3 MAC 3 GSM PWA kit (5025600-101)

Description	Quantity	Reference
GSM PWA and antenna assembly	1 pc	 

Continues on the next page

Table 9-3 MAC 3 GSM PWA kit (5025600-101) (Table continued)

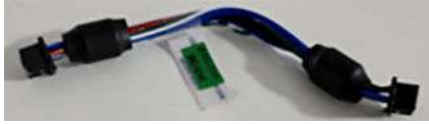
Description	Quantity	Reference
GSM cable	1 pc	
MAC series pad floppy (Red tape)	5 pcs	

Table 9-4 MAC 3 top cover assembly (5025600-102)

Description	Quantity	Reference
Top cover assembly	1 pc	
Display with cable	1 pc	
Keysheet with cable	1 pc	

Table 9-5 MAC 3 mechanical kit (5025600-103)

Description	Quantity	Reference
M3 screws	50 pcs 1 pkt	
M2 screws	20 pcs 1 pkt	
#4-40 x 1/4 inch screws	10 pcs 1 pkt	

Continues on the next page

Table 9-5 MAC 3 mechanical kit (5025600-103) (Table continued)

Description	Quantity	Reference
Bumpon	20 pcs	
Push lever hinge pin	5 pcs	
Earthing cable	2 pcs	
Circlip	10 pcs	
Paper lifting tape	5 pcs	

Table 9-6 MAC 3 printer module assembly (5025600-104)

Description	Quantity	Reference
Printer module assembly	1 pc	

Table 9-7 MAC 3 plastic parts kit (5025600-105)

Description	Quantity	Reference
Printer door	2 pcs	
Printer door - hinge component	10 pcs	
Push button lever	2 pcs	

Continues on the next page

Table 9-7 MAC 3 plastic parts kit (5025600-105) (Table continued)

Description	Quantity	Reference
Printer roller	2 pcs	
Battery door assembly	2 pcs	

Continues on the next page

Table 9-7 MAC 3 plastic parts kit (5025600-105) (Table continued)

Description	Quantity	Reference
Patient cable connector holder	2 pcs	
Warning and Defib label	4 pcs	

Table 9-8 MAC 3 power supply (5025600-106)

Description	Quantity	Reference
MAC 3 power supply	1 pc	

Table 9-9 DRU - MAC 3 bottom cover (5025600-107)

Description	Quantity	Reference
MAC 3 bottom cover	1 pc	
Bumpon	8 pcs	

Table 9-10 Li-Ion battery 7.2V, 3350MAH (2111133-001)

Description	Quantity	Reference
Li-Ion battery 7.2 V, 3350 MAH	1 pc	

Table 9-11 Honeywell barcode scanner (5844816-001-S)

Description	Quantity	Reference
Honeywell barcode scanner	1 pc	

Table 9-12 MAC 3 service accessory parts

Part number	Description
3048726-601	MAC 3 Power cord North American
3048726-602	MAC 3 Power cord Chinese
3048726-603	MAC 3 Power cord Euro
3048726-604	MAC 3 Power cord British
3048726-605	MAC 3 Power cord Italian
3048726-606	MAC 3 Power cord Israel
3048726-607	MAC 3 Power cord Swiss
3048726-608	MAC 3 Power cord Indian
3048726-609	MAC 3 Power cord Danish
3048726-610	MAC 3 Power cord Australian
3048726-611	MAC 3 Power cord American. Straight
3048726-612	MAC 3 Power cord Japan
3048726-613	MAC 3 Power cord Brazil

10 FRU replacement: Top subsystem

10.1 Battery cover FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required: No tools required.

10.1.1 Remove the battery cover

Before you start the procedure, make sure that you power off the device.

1. Carefully turn the device to view the bottom side.
2. Carefully lift the notch and move the battery cover in the direction shown on the cover to release from the battery compartment.



3. Remove the battery cover.
Removed the battery cover.



10.1.2 Replace the battery cover

Before you start the procedure, make sure that you power off the device.

1. Carefully turn the device to view the bottom side.
2. Put the new battery cover on the top of battery compartment and align it in position.



3. Move the battery cover to engage the notch.
Replaced the battery cover.



10.2 Battery FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required: No tools required.

10.2.1 Remove the battery

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
 - Disconnect the AC power cord from the device.
1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
 2. Carefully lift the the battery and move it to release from the battery compartment.



3. Remove the battery.
Removed the battery.



10.2.2 Replace the battery

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
- Disconnect the AC power cord from the device.

1. Put the new battery in the battery compartment and move it to align to the battery pins.



2. Move the battery to correctly engage the battery pins in the battery compartment.
Replaced the battery.



3. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

10.3 Remove the SIM card

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
 - Disconnect the AC power cord from the device.
1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
 2. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
 3. Carefully press the SIM card to eject it from the SIM slot.
 4. Pull the SIM card from the SIM slot.



5. Remove the SIM card.
Removed the SIM card.



10.4 Replace the SIM card

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
 - Disconnect the AC power cord from the device.
1. Put the new SIM card in the slot with gold contact towards you.



2. Move the SIM card in the direction to align to the SIM symbol on the battery compartment.

Replaced the SIM card.



3. Replace the battery, see [10.2.2 Replace the battery on page 127](#).
4. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

10.5 Top cover assembly FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required:

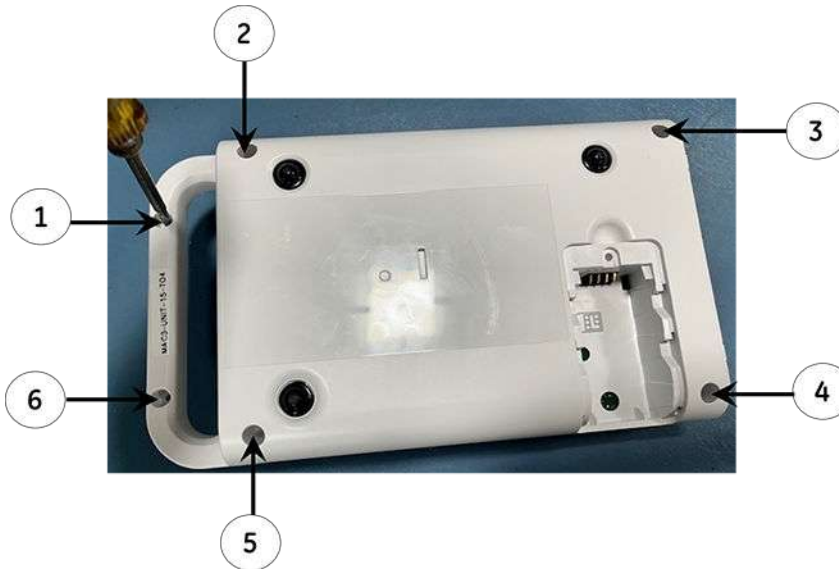
- PH1 screwdriver
- Flat head screwdriver.

10.5.1 Remove the top cover assembly

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
 - Disconnect the AC power cord from the device.
1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
 2. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
 3. Remove the SIM card, see [10.3 Remove the SIM card on page 128](#).

4. Use PH1 screwdriver and remove the 6 M3 screws from the bottom cover.



5. Press the push button lever and open the printer door and remove the paper from the paper tray.
6. Carefully remove the top cover or use a flat head screwdriver from the handle side to remove the top cover.
7. Carefully disconnect the display cable from the PWA board.



8. Carefully disconnect the keysheet cable from the PWA board.



9. Remove the top cover assembly.
Removed the top cover assembly.



10.5.2 Replace the top cover assembly

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
 - Disconnect the AC power cord from the device.
1. Replace the new top cover assembly.
 2. Carefully connect the keysheet cable from top cover assembly to the PWA board.

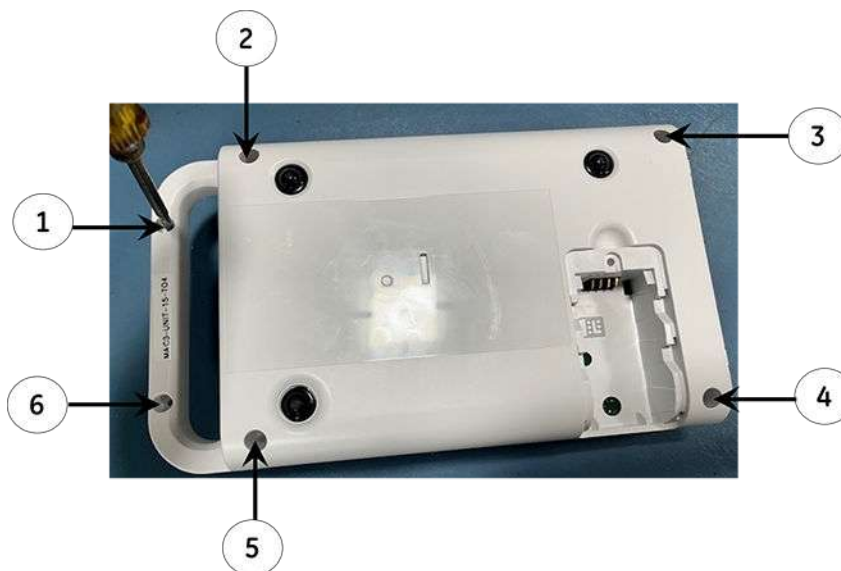


3.  **NOTE** Make sure that the display cable is not damaged when you connect it to the PWA board.

Carefully connect the display cable from the top cover assembly to the PWA board.



4. Press the push button lever and open the printer door.
5. Press the top cover assembly to attach tightly into the bottom cover slots.
6. Use PH1 screwdriver to tighten the 6 M3 screws and secure the top cover assembly to the bottom cover.



Replaced the top cover assembly.

7. Replace the SIM card, see [10.4 Replace the SIM card on page 129](#).
8. Replace the battery, see [10.2.2 Replace the battery on page 127](#).
9. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

11 FRU replacement: Bottom subsystem

11.1 Main PWA board FRU replacement

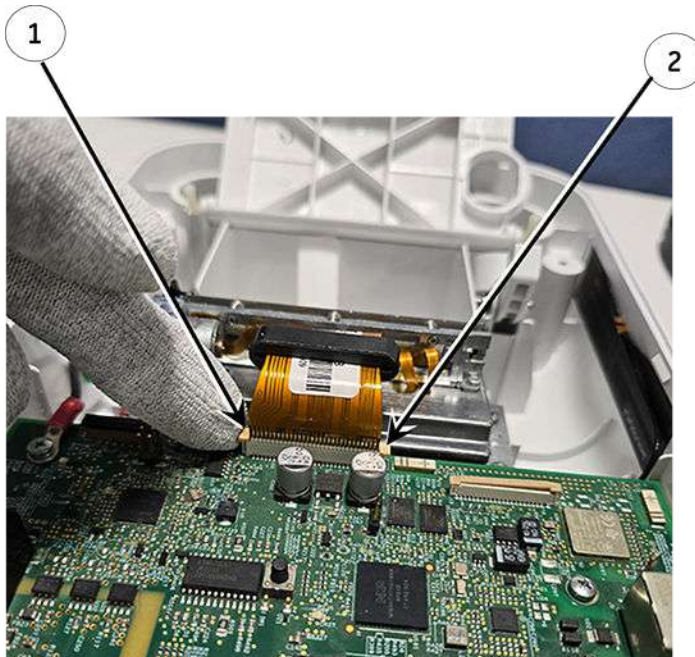
Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required: PH1 screwdriver and pliers.

11.1.1 Remove the main PWA board

Before you start this procedure make sure that you:

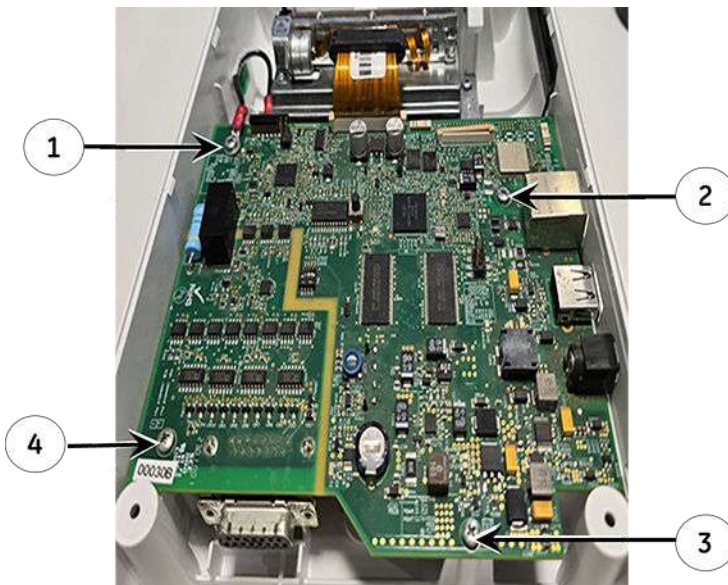
- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
 - Disconnect the AC power cord from the device.
1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
 2. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
 3. Remove the SIM card, see [10.3 Remove the SIM card on page 128](#).
 4. Remove the top cover assembly, see [10.5.1 Remove the top cover assembly on page 130](#).
 5. Carefully lift the 2 cable connector clips to unlock the printer data cable from the connector.



6. Carefully remove the printer data cable from the main PWA board.



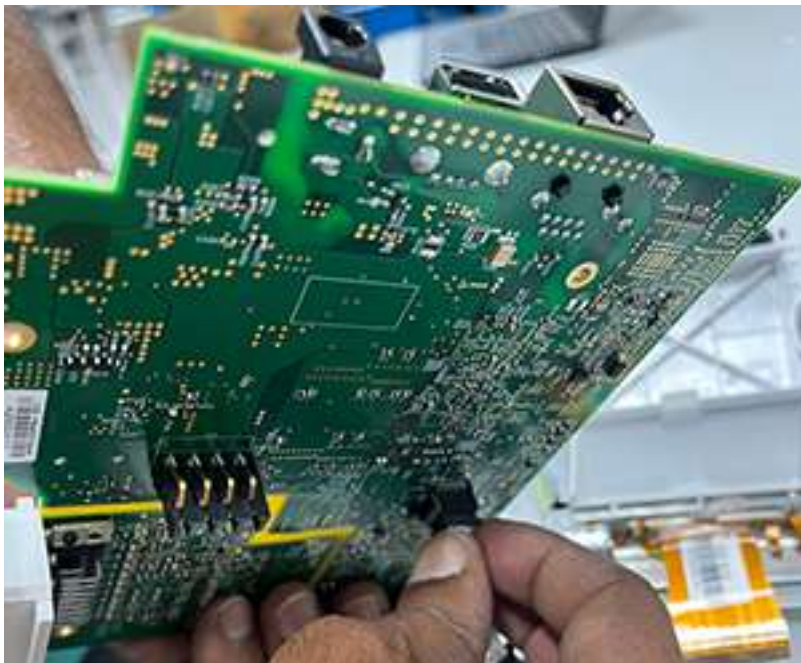
7. Use PH1 screwdriver and remove the 4 M3 screws from the main PWA board.



8. Carefully lift the PWA board and cut the tie wrap.
9. Carefully lift the main PWA board as the data cable between main PWA and GSM board is still connected.



10. Turn the main PWA board, press the side clip and disconnect the data cable from the GSM board.



11. Remove the main PWA.
Removed the main PWA board.



12. Use PH0 screwdriver and remove the #4-40X1/4" screws to remove the patient cable connector holder.

Removed the patient cable connector holder from main PWA board.



11.1.2 Replace the main PWA board

Before you start this procedure make sure that you:

- Power off the device. For more information on how to power off the device, see [4.3 Power off the device on page 44](#).
- Disconnect the AC power cord from the device.

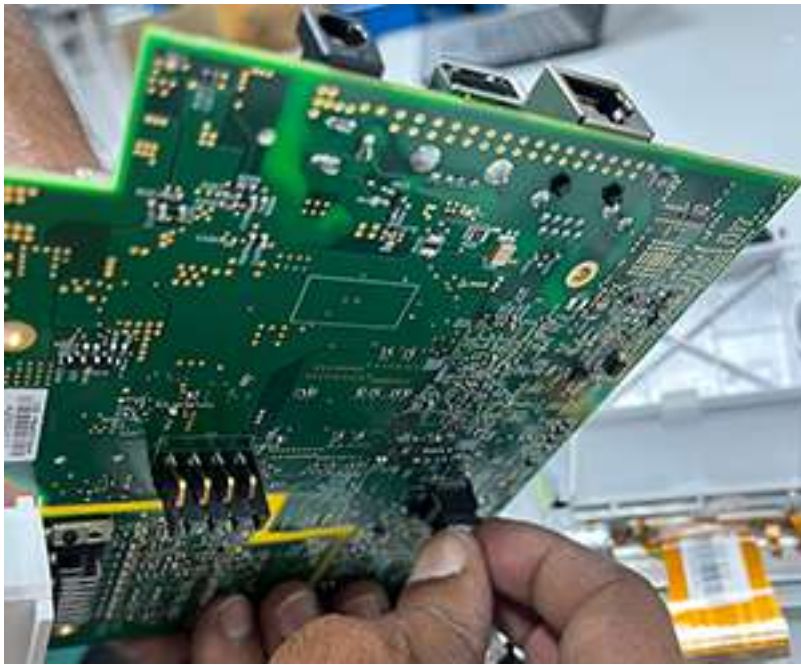
1. **NOTE**



Make sure that you apply the $0.15 \pm 5\%$ N-m Torque when you tighten the #4-40X1/4" screws.

Use PH0 screwdriver to replace the two #4-40X1/4" screws securing the patient cable connector holder to the main PWA board.

2. Connect the data cable from the GSM board.

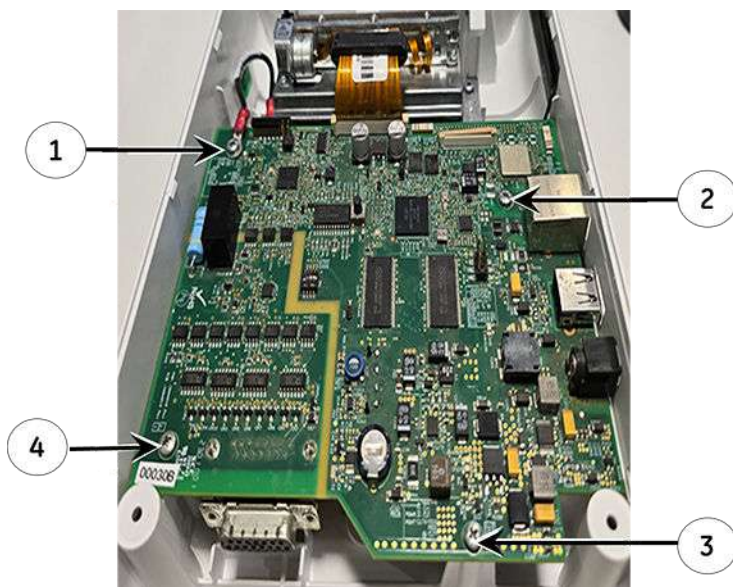


3. Carefully tie the ground cable and GSM data cable with tie wrap and put the main PWA board into position.



4.  **NOTE** Make sure that you connect the ground cable with screw (1) as shown in figure.

Use PH1 screwdriver to tighten the 4 M3 screws and secure the main PWA board to the bottom cover.



5.  **NOTE** Before, you connect the printer data cable make sure that you lift the 2 cable connector clips.

Carefully connect the printer data cable to the main PWA board and make sure that you hear a sound to lock.



6. Replace the top cover assembly, see [10.5.2 Replace the top cover assembly on page 132](#).
7. Replace the SIM card, see [10.4 Replace the SIM card on page 129](#).
8. Replace the battery, see [10.2.2 Replace the battery on page 127](#).
9. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).
10. Perform diagnostics test, see [7.1 System diagnostics overview on page 71](#).

11.2 GSM board FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required: M3 screwdriver

11.2.1 Remove the GSM board

1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
2. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
3. Remove the SIM card, see [10.3 Remove the SIM card on page 128](#).
4. Remove the top cover assembly, see [10.5.1 Remove the top cover assembly on page 130](#).
5. Remove the main PWA board, see [11.1.1 Remove the main PWA board on page 136](#).
6. Carefully disconnect the antenna cable from the GSM board.



7. Carefully disconnect the data cable from the GSM board.
8. Use PH1 screwdriver and remove the 4 M3 screws from the GSM board.



9. Remove the GSM board.
Removed the GSM board and cable.



11.2.2 Replace the GSM board

1. Replace the new GSM board.
2. Use PH1 screwdriver to tighten the 4 M3 screws and secure the GSM board to the bottom cover.



3. Carefully connect the data cable to the GSM board.
4. Carefully connect the antenna cable to the GSM board.



5. Replace the main PWA board, see [11.1.2 Replace the main PWA board on page 139](#).
6. Replace the top cover assembly, see [10.5.2 Replace the top cover assembly on page 132](#).
7. Replace the SIM card, see [10.4 Replace the SIM card on page 129](#).
8. Replace the battery, see [10.2.2 Replace the battery on page 127](#).
9. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

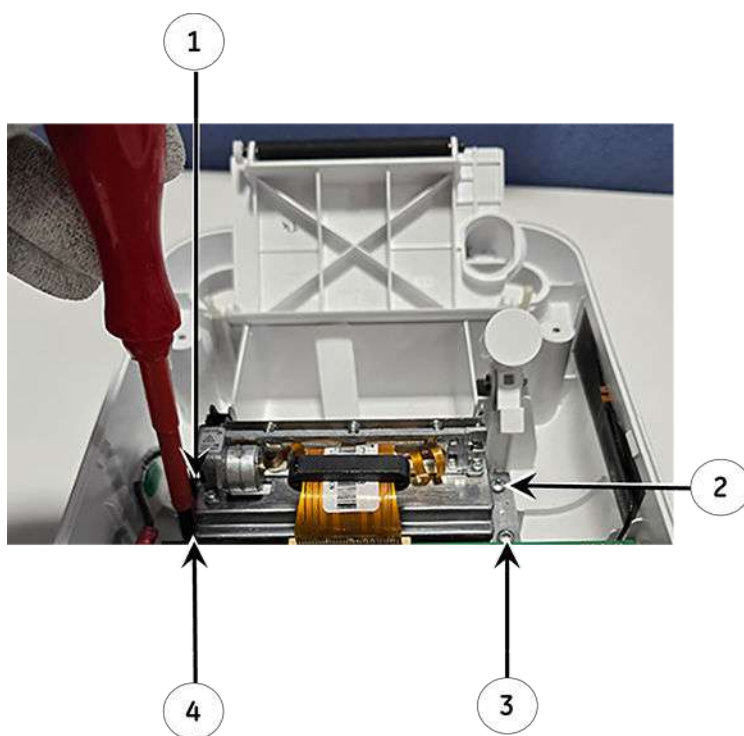
11.3 Printer module FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required: M3 screwdriver

11.3.1 Remove the printer module

1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
2. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
3. Remove the SIM card, see [10.3 Remove the SIM card on page 128](#).
4. Remove the top cover assembly, see [10.5.1 Remove the top cover assembly on page 130](#).
5. Remove the main PWA board, see [11.1.1 Remove the main PWA board on page 136](#).
6. Use PH1 screwdriver and remove the 4 M3 screws from the printer module.



7. Remove the ground cable from the printer module.



8. Lift and remove the printer module.

Removed the printer module.



11.3.2 Replace the printer module

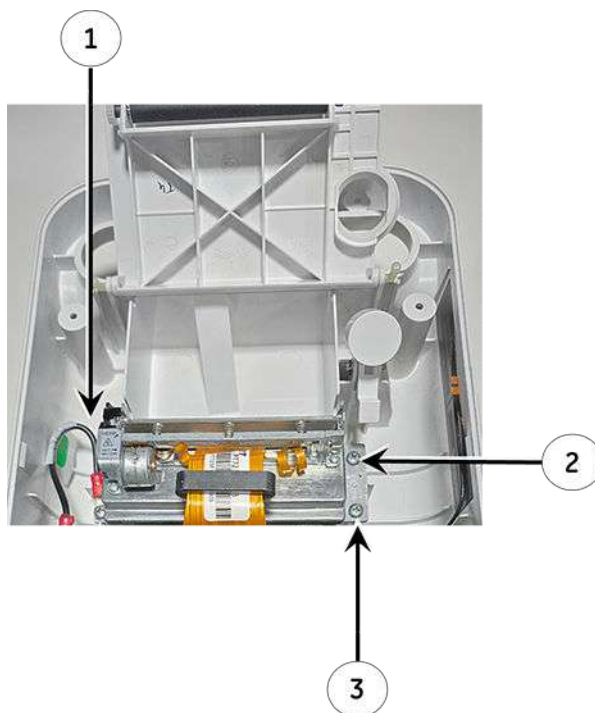
1. Put the new printer module to the bottom cover.



2. Attach the ground cable to the printer module and tighten the screw.



3. Use PH1 screwdriver to tighten the remaining 3 M3 screws and secure the printer module to the bottom cover.



4. Replace the main PWA board, see [11.1.2 Replace the main PWA board on page 139](#).
5. Replace the top cover assembly, see [10.5.2 Replace the top cover assembly on page 132](#).
6. Replace the SIM card, see [10.4 Replace the SIM card on page 129](#).
7. Replace the battery, see [10.2.2 Replace the battery on page 127](#).
8. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

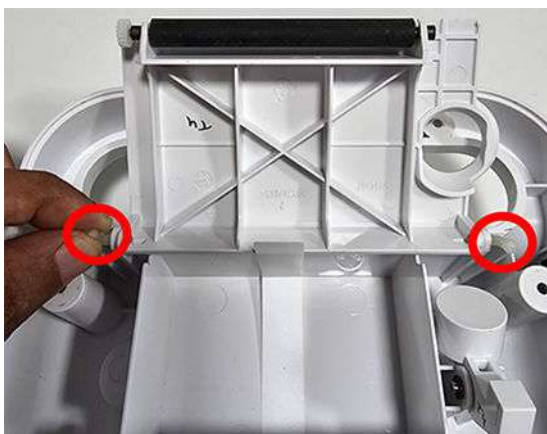
11.4 Printer door FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required: pliers

11.4.1 Remove the printer door assembly

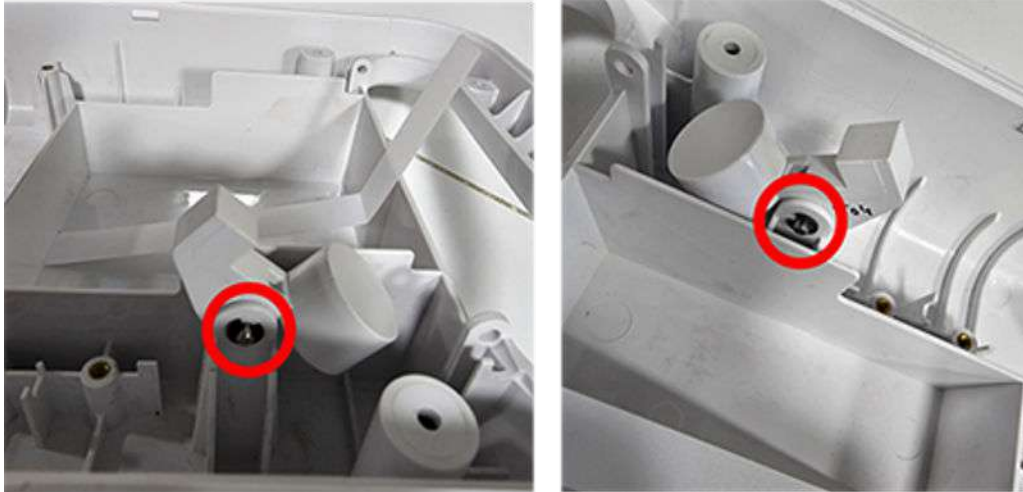
1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
2. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
3. Remove the SIM card, see [10.3 Remove the SIM card on page 128](#).
4. Remove the top cover assembly, see [10.5.1 Remove the top cover assembly on page 130](#).
5. Remove the main PWA board, see [11.1.1 Remove the main PWA board on page 136](#).
6. Remove the GSM board, see [11.2.1 Remove the GSM board on page 142](#).
7. Remove the printer module, see [11.3.1 Remove the printer module on page 145](#).
8. Remove two plastic hinges on both the ends of the printer door assembly.



9. Move the roller up and remove it from the printer door assembly.
10. Push the paper lifting tape outside and remove.



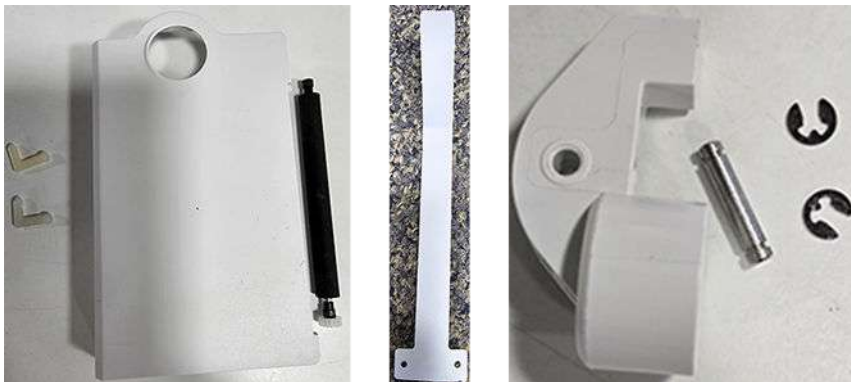
11. Use the pliers and remove two circlips.



12. Push the steel bar from one of the side and remove.

13. Remove the push button.

The printer door assembly is removed.

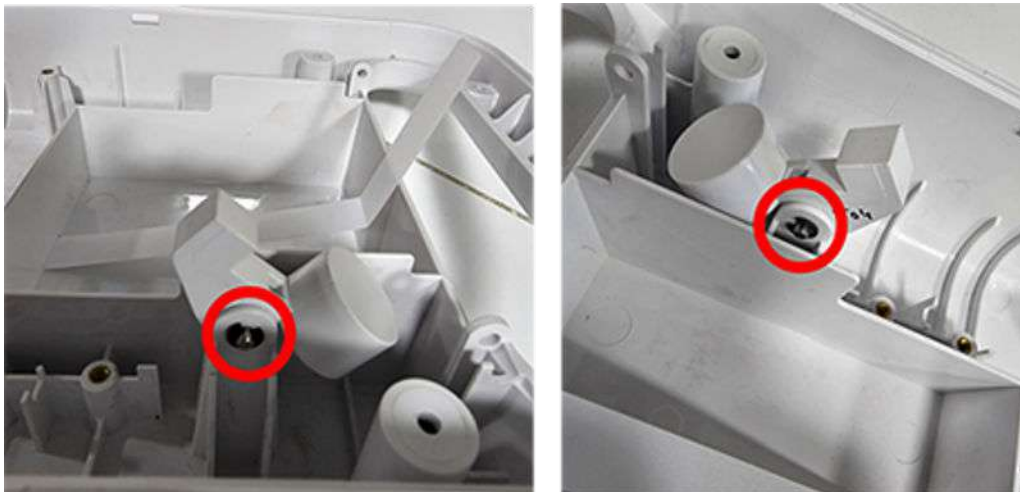


11.4.2 Replace the printer door assembly

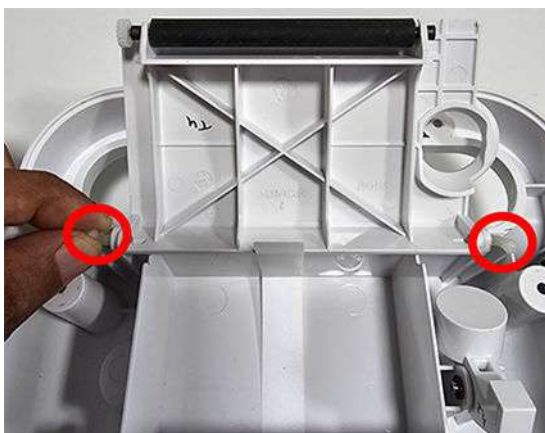
Make sure that you have the new printer door assembly to replace.

1. Keep the push button and move the steel bar from one side of the groove.

2. Use the pliers to attach the circlips and secure the push button.



3. Push the paper lifting tape inside to replace.
4. Move the roller down and replace it to the printer door assembly.
5. Attach the two plastic hinges on both the ends of the printer door assembly.



6. Replace the printer module, see [11.3.2 Replace the printer module on page 146](#).
7. Replace the GSM board, see [11.2.2 Replace the GSM board on page 143](#).
8. Replace the main PWA board, see [11.1.2 Replace the main PWA board on page 139](#).
9. Replace the top cover assembly, see [10.5.2 Replace the top cover assembly on page 132](#).
10. Replace the SIM card, see [10.4 Replace the SIM card on page 129](#).
11. Replace the battery, see [10.2.2 Replace the battery on page 127](#).
12. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

11.5 Antenna assembly FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

11.5.1 Remove the antenna assembly

1. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
2. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
3. Remove the SIM card, see [10.3 Remove the SIM card on page 128](#).
4. Remove the top cover assembly, see [10.5.1 Remove the top cover assembly on page 130](#).
5. Remove the main PWA board, see [11.1.1 Remove the main PWA board on page 136](#).
6. Remove the antenna cable from the GSM board.
7. Carefully peel the tape along with the antenna assembly to remove from the bottom cover.

The antenna assembly is removed.



11.5.2 Replace the antenna assembly

1. Carefully attach the tape along with the antenna assembly to replace to the bottom cover.

The antenna assembly is replaced to the bottom cover.



2. Connect the antenna cable to the GSM board.
3. Replace the main PWA board, see [11.1.2 Replace the main PWA board on page 139](#).
4. Replace the top cover assembly, see [10.5.2 Replace the top cover assembly on page 132](#).
5. Replace the SIM card, see [10.4 Replace the SIM card on page 129](#).

6. Replace the battery, see [10.2.2 Replace the battery on page 127](#).
7. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

11.6 Bottom cover FRU replacement

Before you begin the FRU replacement procedure, make sure that you complete the steps in [9.1.1 Prepare the system for FRU replacement on page 110](#).

Tools required: M3 screwdriver

11.6.1 Remove the bottom cover

1. Carefully turn the device to view the bottom side.
2. Remove the battery cover, see [10.1.1 Remove the battery cover on page 123](#).
3. Remove the battery, see [10.2.1 Remove the battery on page 126](#).
4. Remove the SIM card, see [10.3 Remove the SIM card on page 128](#).
5. Remove the top cover assembly, see [10.5.1 Remove the top cover assembly on page 130](#).
6. Remove the main PWA board, see [11.1.1 Remove the main PWA board on page 136](#).
7. Remove the GSM board, see [11.2.1 Remove the GSM board on page 142](#).
8. Remove the printer module, see [11.3.1 Remove the printer module on page 145](#).
9. Remove the printer door assembly, see [11.4.1 Remove the printer door assembly on page 148](#).
10. Remove the antenna assembly, see [11.5.1 Remove the antenna assembly on page 151](#).

Removed the bottom cover.



11.6.2 Replace the bottom cover

1. Replace the new bottom cover.



2. Replace the antenna assembly, see [11.5.2 Replace the antenna assembly on page 151](#).
3. Replace the printer door assembly, see [11.4.2 Replace the printer door assembly on page 149](#).
4. Replace the printer module, see [11.3.2 Replace the printer module on page 146](#).
5. Replace the GSM board, see [11.2.2 Replace the GSM board on page 143](#).
6. Replace the main PWA board, see [11.1.2 Replace the main PWA board on page 139](#).
7. Replace the top cover assembly, see [10.5.2 Replace the top cover assembly on page 132](#).
8. Replace the SIM card, see [10.4 Replace the SIM card on page 129](#).
9. Replace the battery, see [10.2.2 Replace the battery on page 127](#).

10. Replace the battery cover, see [10.1.2 Replace the battery cover on page 124](#).

12 Functional checkout

12.1 Recommended maintenance

Regular yearly maintenance, irrespective of usage, is essential to ensure that the equipment is always functional when required.

For non-FRU repairs and their associated visual inspections and functional checkout procedures, see [12.4 Non-FRU repairs on page 157](#).

Refer to *MAC™ 3 Resting ECG Analysis System Operator's Manual* for cleaning procedures. The system does not require any calibration procedures.

CAUTION



PREVENTIVE MAINTENANCE

The manufacturer does not in any manner assume the responsibility for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists.

12.2 Functional checkout workflow

This procedure shows you the workflow to perform a functional checkout of the device.

This section identifies the workflow of the visual inspections and functional checkout procedures that you must perform when you replace a FRU. All inspection and checkout procedures identified for a FRU also apply to the FRU's internal expansion boards and components.

1. Locate the appropriate FRU or non-FRU repair in one of the following tables:
 - [Table 12-2 Optional system FRU repairs on page 157](#)
 - [Table 12-3 Non-FRU repairs on page 158](#)
2. To perform the visual inspections required for the repair, do the following:
 - a. Record the numbers in the repair's corresponding Visual Inspections column.
 - b. Refer to [12.5 Visual Inspection as per IEC62353:2014 \(subsection 5.2\) requirement on page 158](#).
 - c. Locate and perform the inspections associated with the numbers in the repair's corresponding **Visual Inspections** column.
3. To perform the functional checkouts required for the repair, do the following:
 - a. Record the numbers in the repair's corresponding **Functional Checkouts** column.
 - b. Refer to [12.7 Functional checkout procedures on page 161](#).
 - c. Record the numbers in the repair's corresponding **Functional Checkouts** column.

12.3 FRU repairs

This section provides an overview of the types of FRU repairs and their associated visual inspections and functional checkout procedures.

FRU repairs can be categorized into two types:

- [Table 12-1 Basic system FRU repairs on page 157](#)
- [Table 12-2 Optional system FRU repairs on page 157](#)

Table 12-1 Basic system FRU repairs

FRU	Visual inspections	Functional checkouts		
		Operational checks	Diagnostic checks	Electrical safety checks
Printer module	1, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13	1, 2	1, 3, 7	Yes
Battery	1, 7	-	3	-
Top cover assembly	1, 2, 3, 4, 5, 6, 9, 11, 12, 13	-	1, 2, 4, 5, 8, 11	Yes
Main PWA	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13	1, 2, 3, 4, 5	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	Yes
GSM PWA	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13	4	5, 8	Yes
Power supply	1, 6	-	9	-
Hardware/Mechanical kit	1, 2, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13	1	-	Yes
Harness/Cables	1, 2, 6, 8, 9, 10, 12, 13	1, 2	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	Yes

Table 12-2 Optional system FRU repairs

FRU	Visual inspections	Functional checkouts		
		Operational checks	Diagnostic checks	Electrical safety checks
Barcode Reader	1, 2	1, 2, 5	4	-

12.4 Non-FRU repairs

This section provides an overview of the types of non-FRU repairs and their associated visual inspections and functional checkout procedures.

Table 12-3 Non-FRU repairs

Type of repair	Visual inspection	Functional checkouts		
		Operational checks	Diagnostic checks	Electrical safety checks
No parts replaced	7, 9, 10, 11	1, 2, 3, 4, 5	-	Yes (If the device is opened)
Installation	7, 9, 10, 11	1, 2, 3, 4, 5	-	Yes (If the device is opened)
Software Update	-	1, 2, 3, 4, 5	-	-
Hardware Upgrade	9, 10, 11, 12, 13	1, 2, 3, 4, 5	-	Yes (If the device is opened)
Annual Electrical Safety Checkout	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11	Yes

12.5 Visual Inspection as per IEC62353:2014 (subsection 5.2) requirement

Visual Inspections are performed to make sure that the repair procedure is successful. A thorough visual inspection of the equipment can save time. Disconnected cables, foreign debris on expansion boards, missing hardware, or loose components can frequently cause symptoms and equipment failures that may seem to be unrelated and difficult to track.

WARNING



ELECTRICAL HAZARD

Improper handling during visual inspection could result in electrical shock.

To avoid potential shock, observe the below guideline at all times: Before inspecting or cleaning the device, turn it off, unplug it from AC power, and remove the battery.

1. Verify the device surface is free of cracks, dust collection, or other damages.
2. Inspect the patient cable, lead wires, and electrodes and verify they do not show one of the below problems:
 - Defects or damages
 - Metal part corrosion
 - Discoloration
 - Brittle wires and connectors
 - Expiration
3. Verify the keysheet does not show one of the below problems:
 - Cuts or cracks in the keysheet membrane
 - Illegible labels on the keys
4. Verify the touchscreen display does not show one of the below problems:
 - Scratches or cracks
 - An opaque display filter (transparent part of the keysheet bezel) that impair viewing

5. Verify the power source does not show one of the below problems:

- Faulty wiring, especially the AC outlet
- Circuit not dedicated to the system



NOTE

Power source problems can cause static discharge, resetting problems, and noise.

6. Verify the I/O connectors, cables, and AC power cord do not show one of the below problems:

- Fraying or other damage
- Bent prongs or pins
- Cracked housing
- Loose screws in the plugs

7. Verify the battery pack does not show one of the below problems:

- Cracked, swollen, or leaky battery pack enclosure
- Debris on the battery pack electrical contacts

8. Verify the wireless antenna does not show one of the below problems:

- Loose connection
- Dirt, scratches, or debris on the contacts

9. Verify all harnesses do not show one of the below problems:

- Excessive tension or wear
- Loose connection
- Strain reliefs out of place

10. Verify all ground wires/wiring does not show one of the below problems:

- Loose wires or ground strap connections
- Faulty wiring
- Wires pinched or in a vulnerable position

11. Verify all mounting hardware/fasteners have been replaced and secured.

Check for loose or missing screws or other hardware, specially fasteners used as connections to ground planes on expansion boards.

12. Verify the circuit boards do not show one of the below problems:

- Moisture, dust, or debris (top and bottom)
- Loose or missing components
- Burn damage or the smell of over-heated components
- Socketed components not firmly seated
- Expansion board not seated properly in edge connectors
- Solder problems: cracks, splashes on board, incomplete feedthrough, prior modifications or repairs.

13. Verify the safety related marking, labels and labelling on the product are legible and complete.

12.6 Electrical safety checks

1. Perform the current leakage test and ground continuity tests and verify the test results meet requirements.

Table 12-4 Electrical safety checklist

Step	Test	Condition	UUT - ON	Result	Leakage Current Limits
Measuring of Protective Earth Resistance [As per IEC 62353:2014 (subsection 5.3.2) requirement]					
1	AC mains power cord ground prong to exposed metal surface (ground lug) 	NA	_____ Ohm	Pass/Fail	$\leq 100 \text{ m}\Omega$
Equipment Leakage Current [As per IEC 62353:2014 (subsection 5.3.4.2) requirement]					
1	Forward Polarity	NC	_____ uA	Pass/Fail	$\leq 500 \text{ uA}$
2	Neutral open, Forward Polarity	SFC	_____ uA	Pass/Fail	$\leq 1000 \text{ uA}$
3	Neutral open, Reverse Polarity	SFC	_____ uA	Pass/Fail	$\leq 1000 \text{ uA}$
4	Reverse Polarity	NC	_____ uA	Pass/Fail	$\leq 500 \text{ uA}$
Touch Current (Not Mandatory for IEC 62353 Standard)					
1	Forward Polarity	NC	_____ uA	Pass/Fail	$\leq 100 \text{ uA}$
2	Neutral open, Forward Polarity	SFC	_____ uA	Pass/Fail	$\leq 500 \text{ uA}$
3	Ground open, Forward Polarity	SFC	_____ uA	Pass/Fail	$\leq 500 \text{ uA}$
4	Ground open, Reverse Polarity	SFC	_____ uA	Pass/Fail	$\leq 500 \text{ uA}$
5	Neutral open, Reverse Polarity	SFC	_____ uA	Pass/Fail	$\leq 500 \text{ uA}$
6	Reverse Polarity	NC	_____ uA	Pass/Fail	$\leq 100 \text{ uA}$
Patient Leakage Current (Not Mandatory for IEC 62353 Standard)					
1	Forward Polarity	NC	_____ uA	Pass/Fail	$\leq 10 \text{ uA}$
2	Neutral open, Forward Polarity	SFC	_____ uA	Pass/Fail	$\leq 50 \text{ uA}$

Continues on the next page

Table 12-4 Electrical safety checklist (Table continued)

Step	Test	Condition	UUT - ON	Result	Leakage Current Limits
3	Ground open, Forward Polarity	SFC	_____ uA	Pass/Fail	<=50 uA
4	Ground open, Reverse Polarity	SFC	_____ uA	Pass/Fail	<=50 uA
5	Neutral open, Reverse Polarity	SFC	_____ uA	Pass/Fail	<=50 uA
6	Reverse Polarity	NC	_____ uA	Pass/Fail	<=10 uA
Applied Part leakage current [As per IEC 62353:2014 (subsection 5.3.4.3) requirement]					
1	Forward Polarity Neutral / Ground Closed	SFC	_____ uA	Pass/Fail	<=50 uA
2	Reverse Polarity Neutral / Ground Closed	SFC	_____ uA	Pass/Fail	<=50 uA

Key to Condition Abbreviations

- NC = Normal Condition
- SFC = Single Fault Condition
- NA = Not Applicable
- UUT = Unit Under Test
- All SIPs/SOPs grounded.

12.7 Functional checkout procedures

This procedure shows you how to perform a functional checkout of the device.

Make sure that you have performed a visual inspection of the replaced FRU.

Functional checkouts are performed to verify that the repair procedure is successful. There are two types of functional checkout procedures.

- [Operational Checks on page 161](#)
- [Diagnostic checks on page 162](#)

Operational Checks

**NOTE**

For more information on each check, refer the *MAC™ 3 Resting ECG Analysis System Operator's Manual*.

1. Record a rhythm strip of simulated ECG data and verify it recorded successfully.
2. Record a 3-lead or 12-lead ECG and verify it is analyzed and recorded successfully. Use an ECG simulator set with Normal Sinus Rhythm (NSR), a known heart rate, and a known gain, for example, NSR @ 80bpm, 1 mV R-wave.
3. Store a simulated ECG and verify it stored successfully.
4. Transmit a simulated ECG and verify the data was successfully received.
5. Scan a barcode using the barcode reader connected to the device and verify the barcode reader communicates successfully with the device.

Diagnostic checks

1. Perform the hard keys diagnostics and verify the test passed successfully.
See [7.6 Perform the hard keys diagnostic test on page 80](#).
2. Perform the touchscreen diagnostics and verify the test passed successfully.
See [7.4 Perform touchscreen diagnostic test on page 76](#).
3. Perform the battery status test and verify the test passed successfully.
See [7.9 Perform battery test on page 91](#).
4. Perform the barcode reader diagnostics and verify the test passed successfully.
See [7.13 Perform barcode reader diagnostic test on page 99](#).
5. Perform the display diagnostics and verify the test passed successfully.
See [7.3 Perform the display test on page 73](#).
6. Perform the buzzer diagnostics and verify the test passed successfully.
See [7.5 Perform buzzer diagnostic test on page 79](#).
7. Perform the writer diagnostics and verify the test passed successfully.
See [7.8 Perform writer diagnostic test on page 86](#).
8. Perform the network diagnostics and verify the test passed successfully.
See [7.10 Perform network diagnostics test on page 92](#).
9. Perform the LED diagnostics and verify the test passed successfully.
See [7.7 Perform LED diagnostic test on page 84](#).
10. Perform the Acquisition Module Diagnostics and verify the test passed successfully.
See [7.11 Perform the Acquisition Module diagnostics test on page 95](#).
11. Perform the USB port diagnostics and verify the test passed successfully.
See [7.12 Perform USB port diagnostic test on page 98](#).

13 Troubleshooting

13.1 Self registration errors

Table 13-1 Self registration errors

Error message	Cause	How to troubleshoot
Invalid Email	You entered an incorrect email address in the Email (owner / contact) field.	Make sure that you enter a correct email address in the Email (owner / contact) field.
Invalid One Time Passcode (OTP)	You entered an incorrect OTP in the Email Verification Code field.	Make sure that you enter the correct OTP that you receive via email in the Email Verification Code field.
Invalid Serial Number and Security Code	You entered an incorrect Serial Number and Security Code .	Make sure that you enter the correct Serial Number and Security Code .
Activation Failure	The OAC system fails to register the device.	Contact the GE HealthCare Contact Center.

13.2 ECG data noise

The unwanted noise levels on ECGs can cause because of:

- **Environment**
Interference from electromagnetic equipment (such as radios, cell phones, or other medical equipment) can cause in unwanted noise. Verify that the environment in which you use the device meets the minimum EMC requirements. For more information, refer to *MAC™ 3 Operator Manual*.
- **Inadequate patient preparation**
Incorrect patient preparation or electrode placement can cause in unwanted noise on ECGs.
 - Verify that you have prepare the patient skin correctly and put the electrodes correctly.
 - Verify the patient position. The patient does not be in movement when you acquire the resting ECG.

For more information, refer to *MAC™ 3 Operator Manual*.

- **Leadwire, cable, and electrode failure**
Do the following:
 - Check for defective, broken, or disconnected leadwires.
 - Check for defective or expired electrodes.

You can use the Hookup Advisor to monitor the ECG signal quality. It can help you to point if the noise is because of the leadwire failure, baseline shift, muscle artifacts, power line interference, baseline wander, or electrode noise. This can point you to the correct areas for more troubleshooting. For more information, refer to *MAC™ 3 Operator Manual*.

**NOTE**

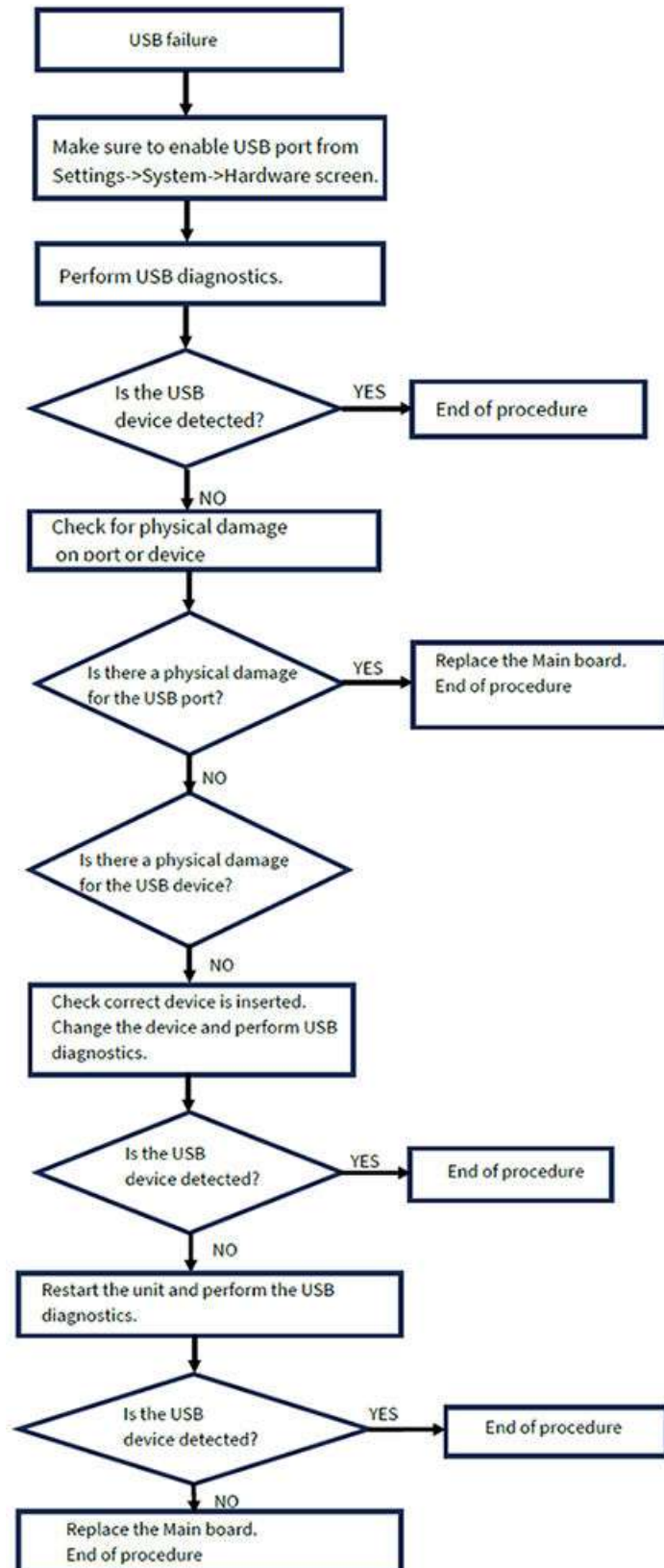
Make sure that you use only electrodes and the contact agents recommended by GE HealthCare. The signal quality on the lead check screen will not show until you apply the RL/N electrode. When you disconnect the RA/R lead, the Limb Lead Disconnected displays on the device.

13.3 Software update errors

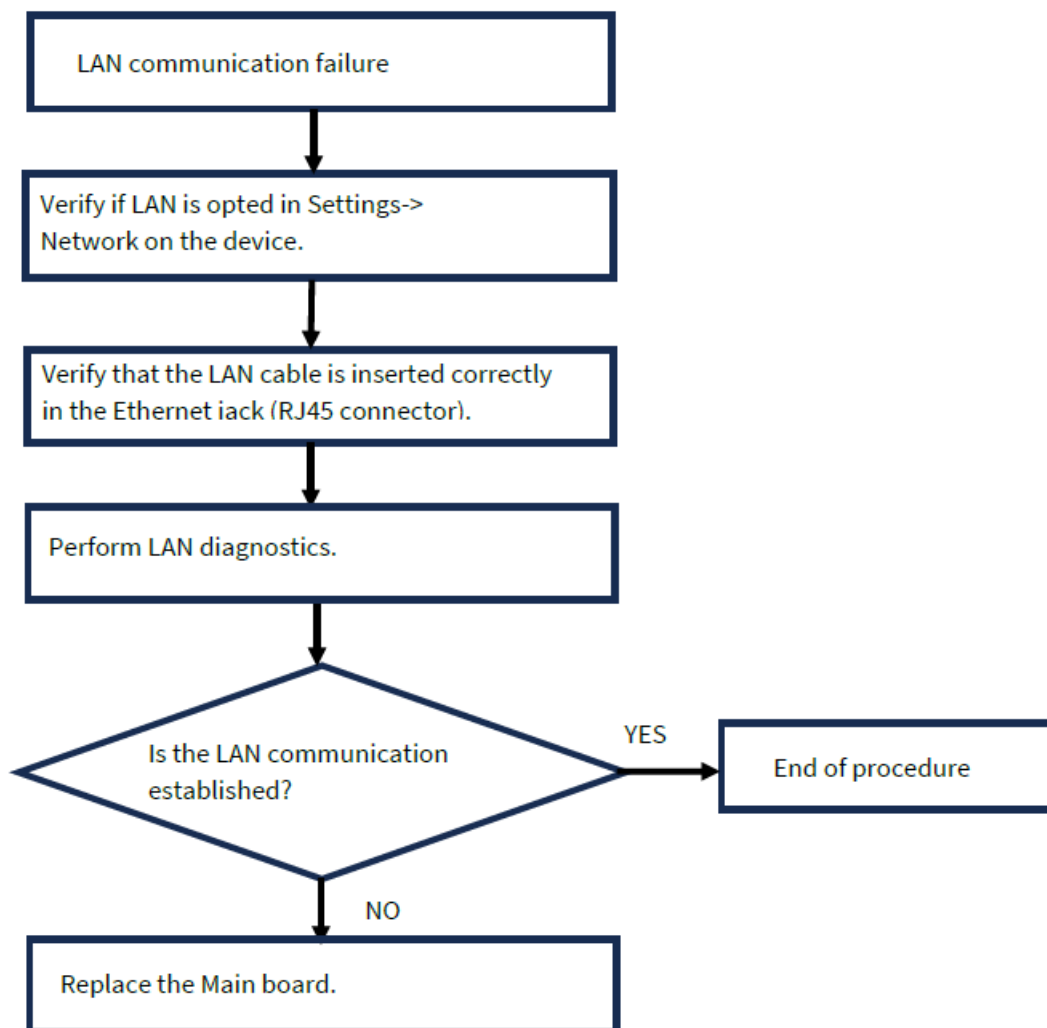
Table 13-2 Software update errors - via USB

Error message	Cause	How to troubleshoot
Connect a USB drive to update the software.	USB is disconnected.	Make sure that you connect a USB.
No software package is available/Invalid package.	No software image found or invalid software image.	Make sure that the USB flash drive contains the correct version of the digitally signed software image. Copy the image again.
Verify that the battery is charged up-to 50% and connect the device to AC power.	Low battery charge and/or AC power is disconnected.	Make sure that you: • Charge the battery. • Connect the AC adapter to the device.
Software update failed. Retry or contact GE service if the problem persists.	Unknown.	1. Retry the software update. 2. If the error is not resolved, power off and power on the device. 3. If the error continues and not resolved, contact your GE HealthCare Service Support representative.

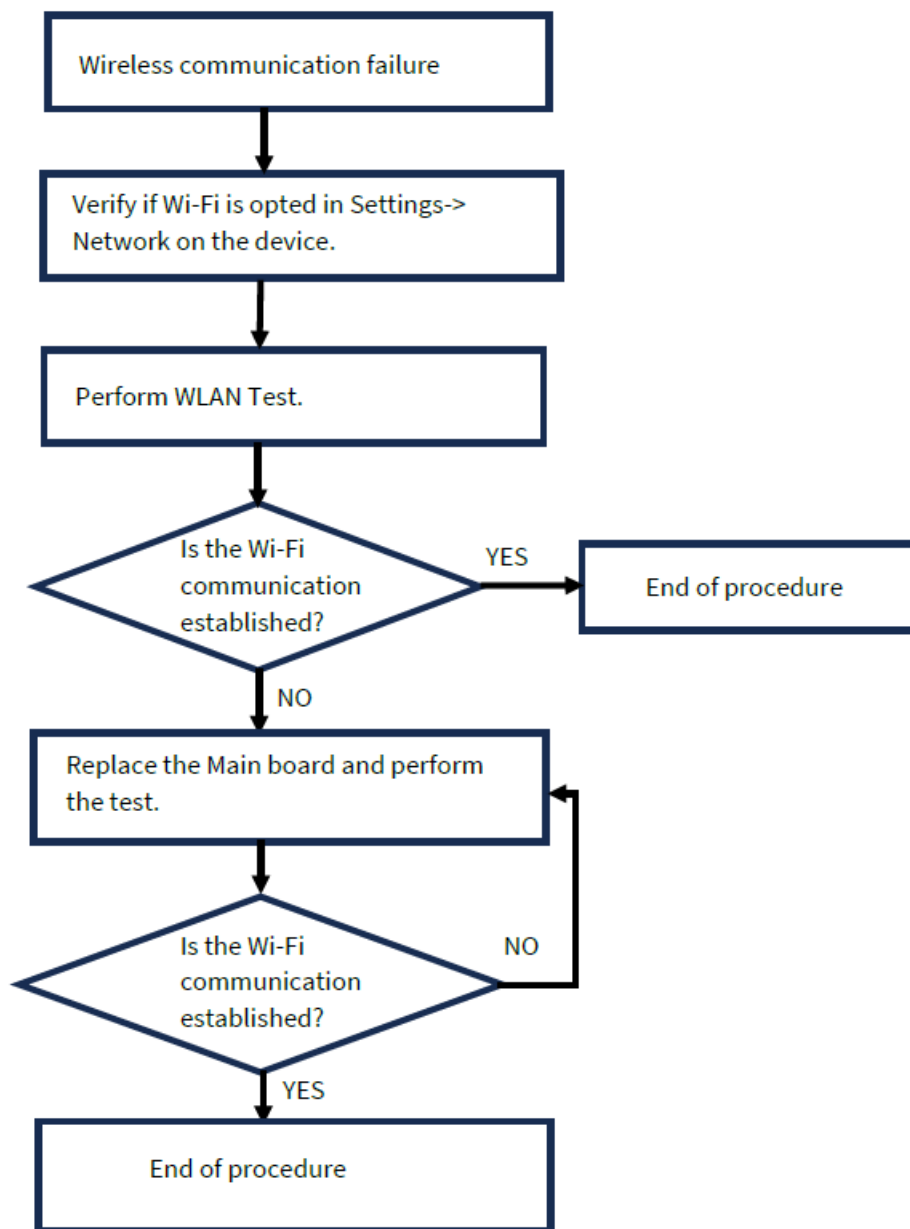
13.4 Troubleshooting USB failure



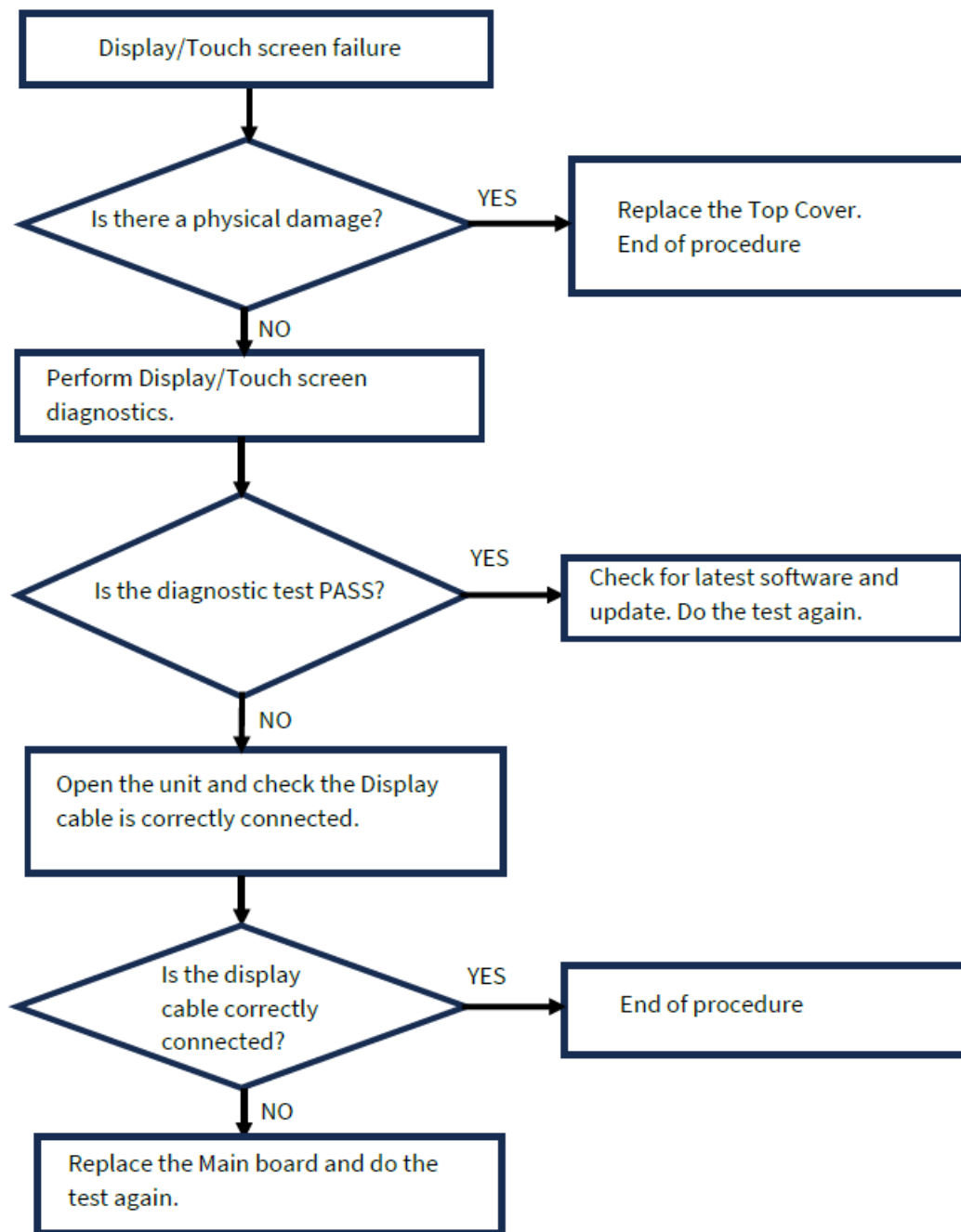
13.5 Troubleshooting LAN communication failure



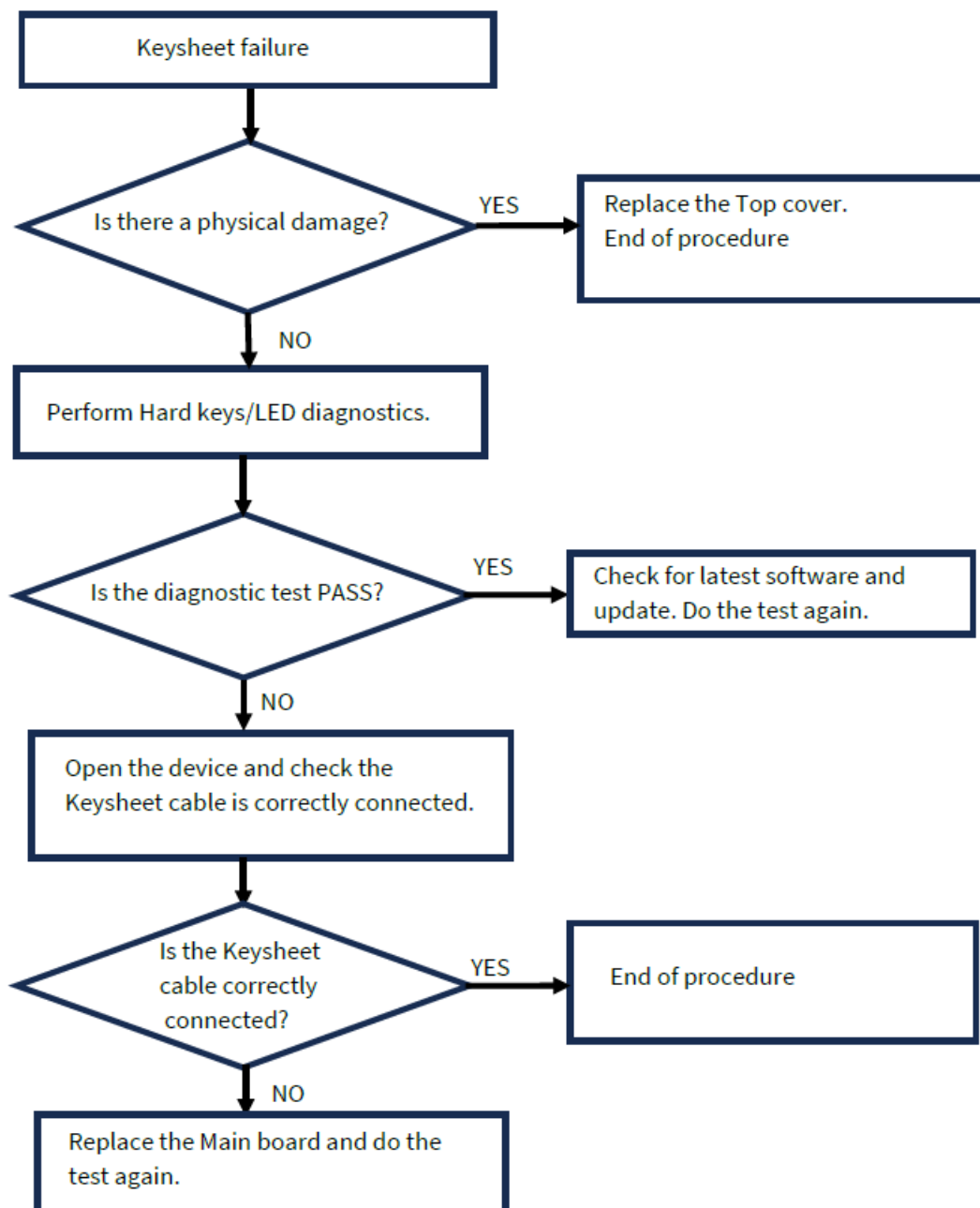
13.6 Troubleshooting wireless communication failure



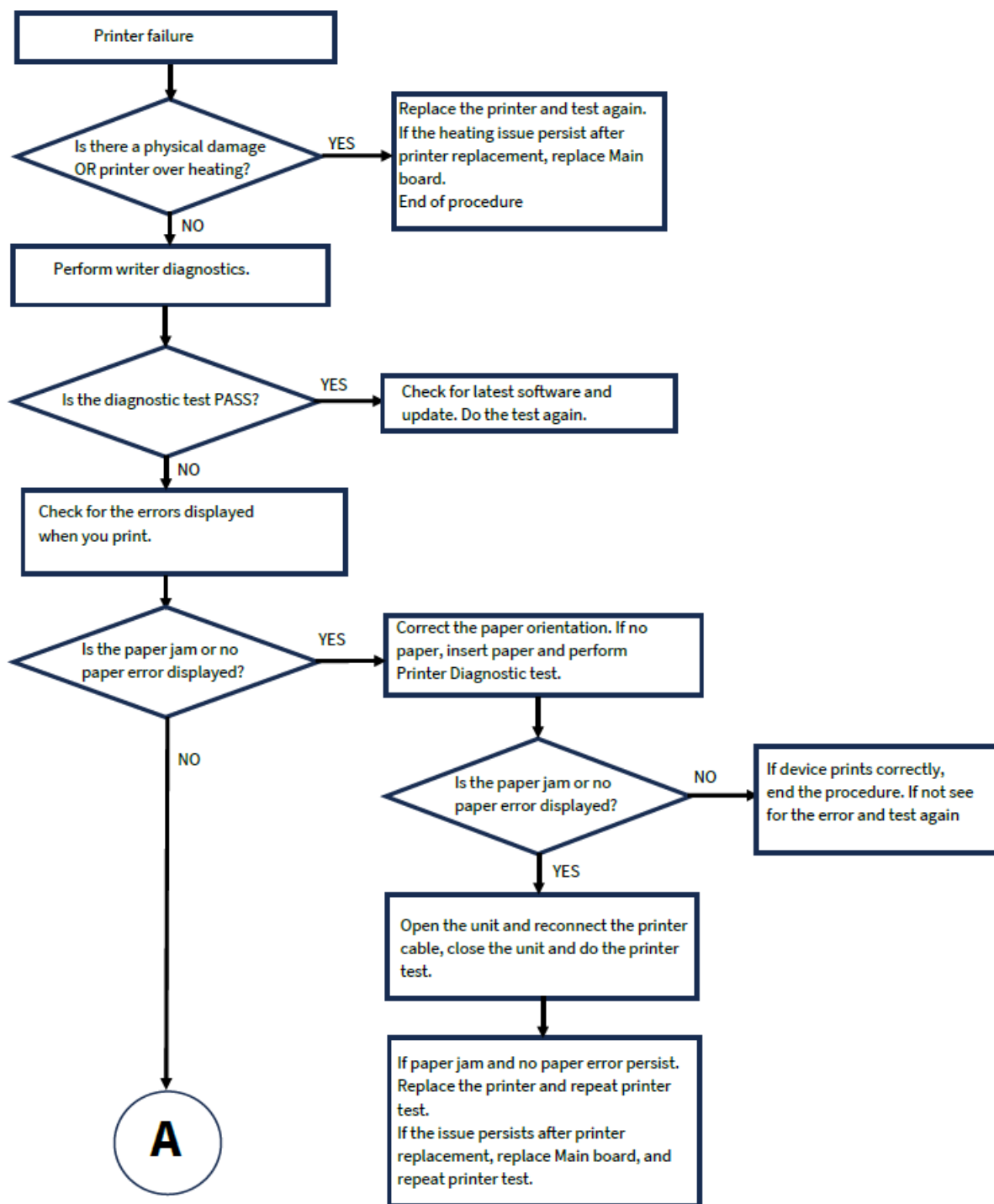
13.7 Troubleshooting display/touchscreen failure

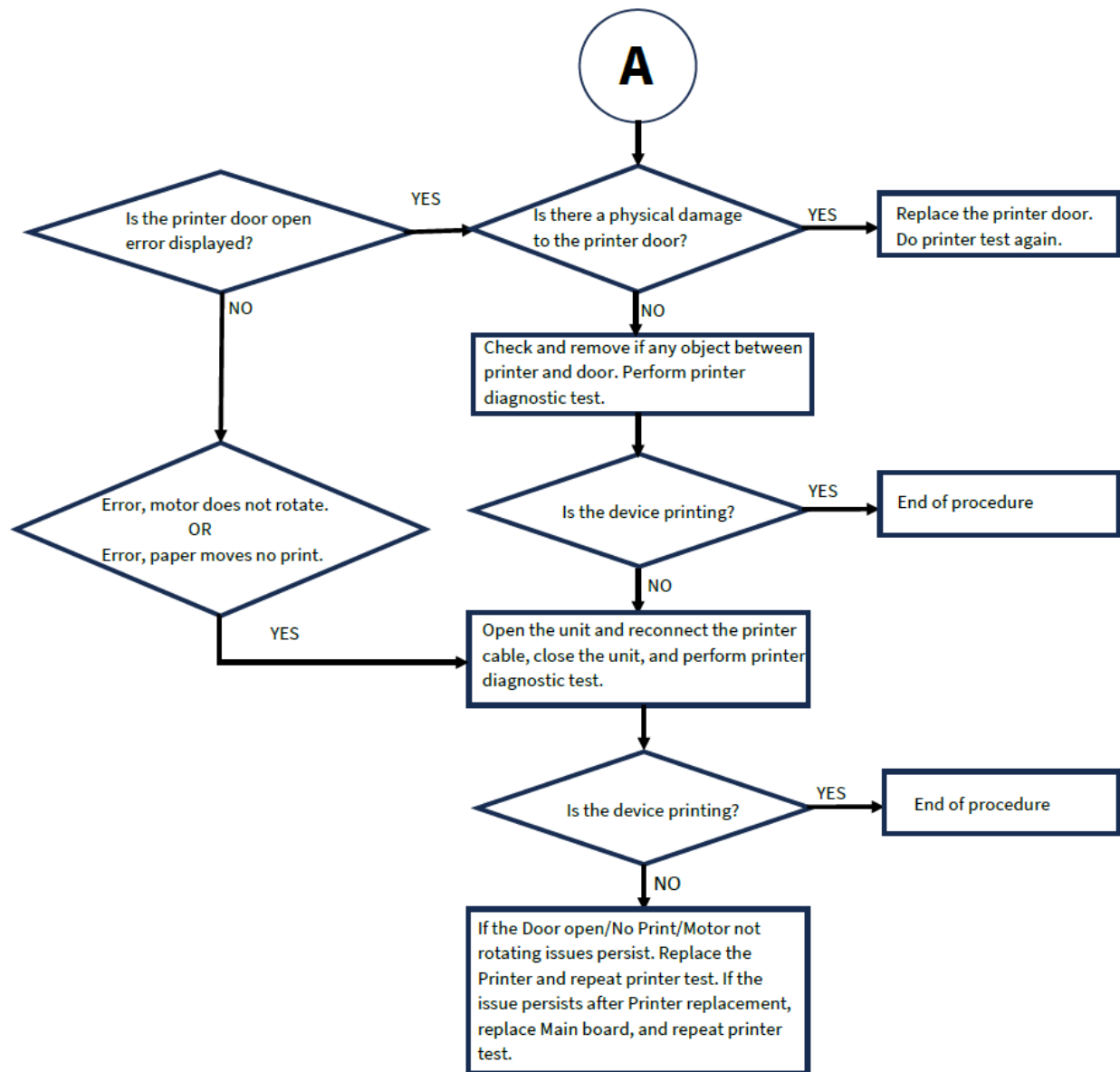


13.8 Troubleshooting keysheet failure

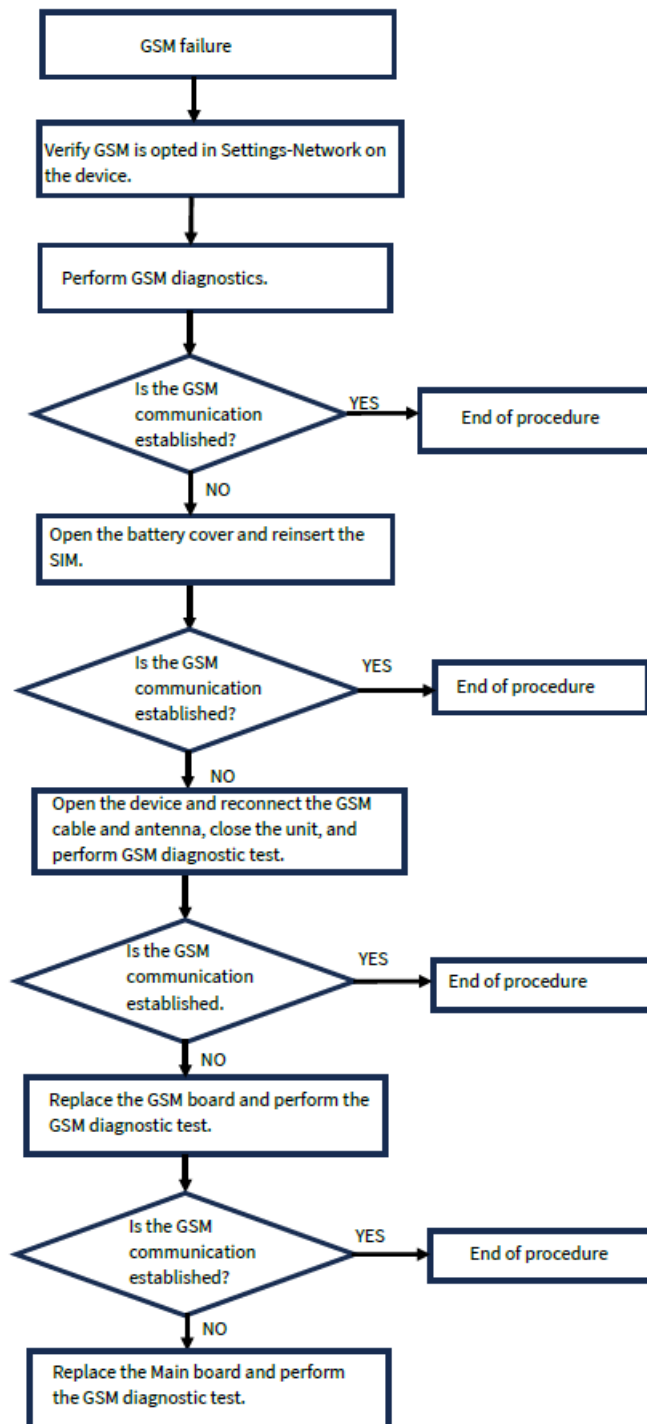


13.9 Troubleshooting printer failure

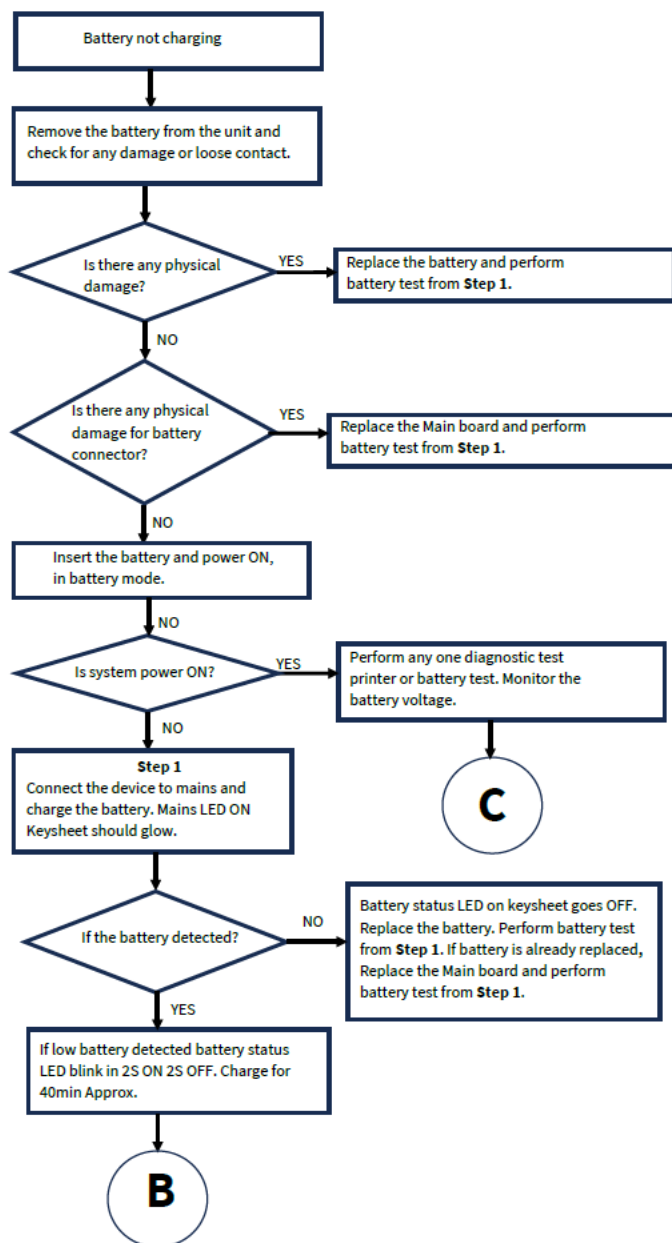


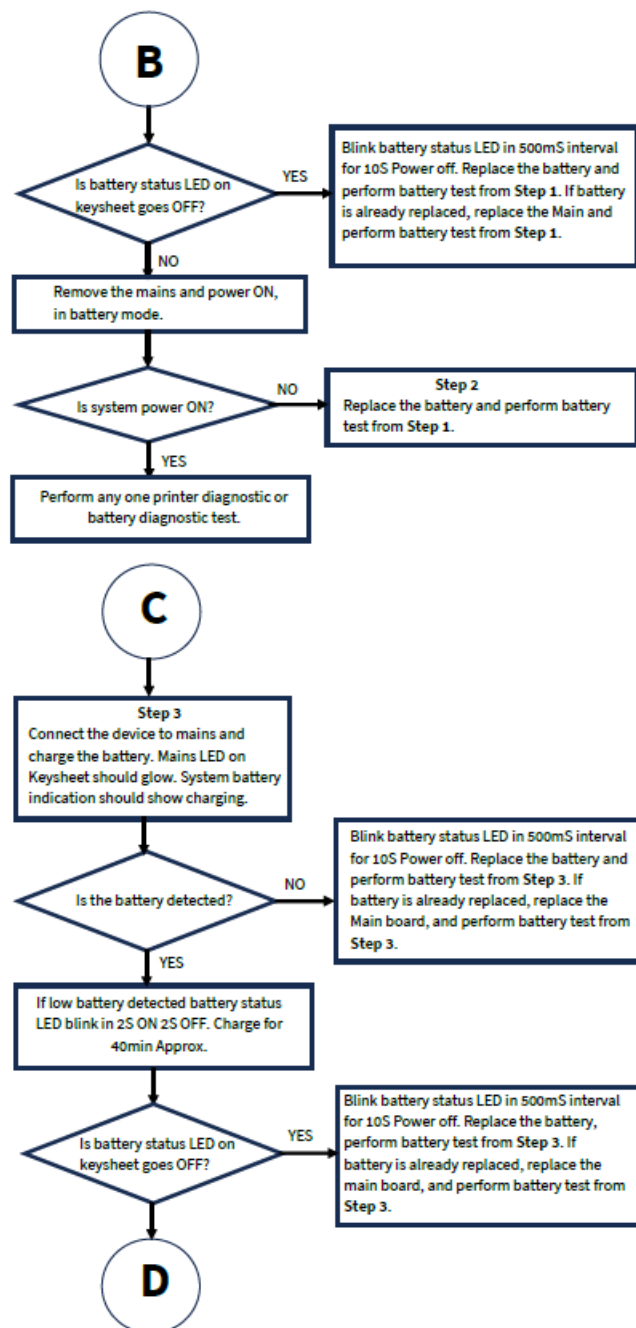


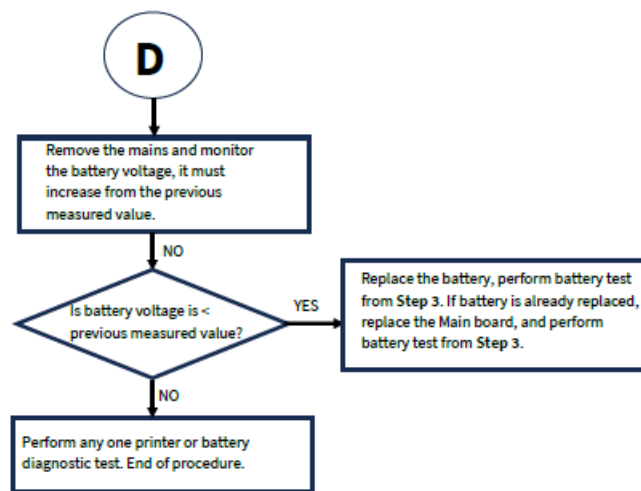
13.10 Troubleshooting GSM failure



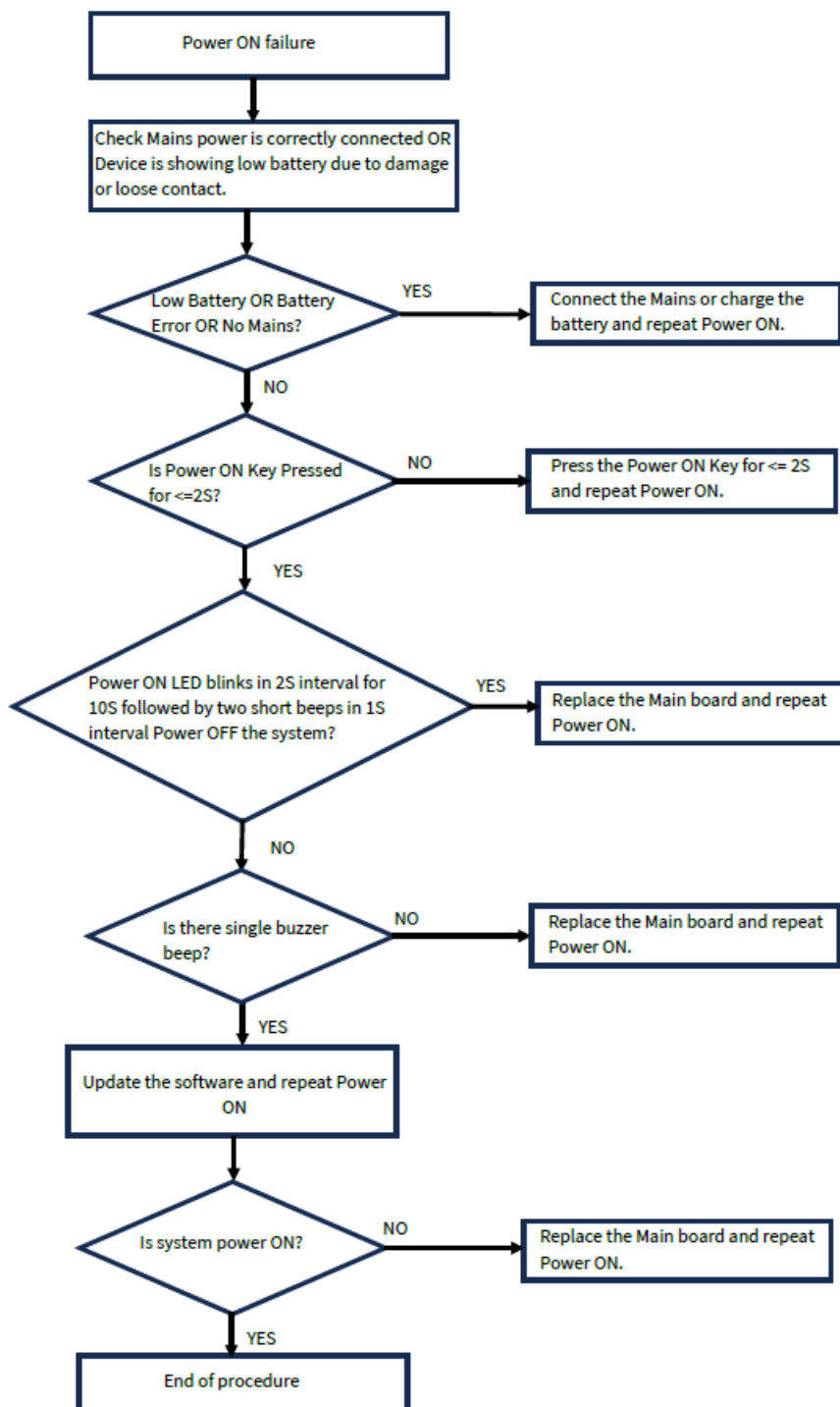
13.11 Troubleshooting battery failure



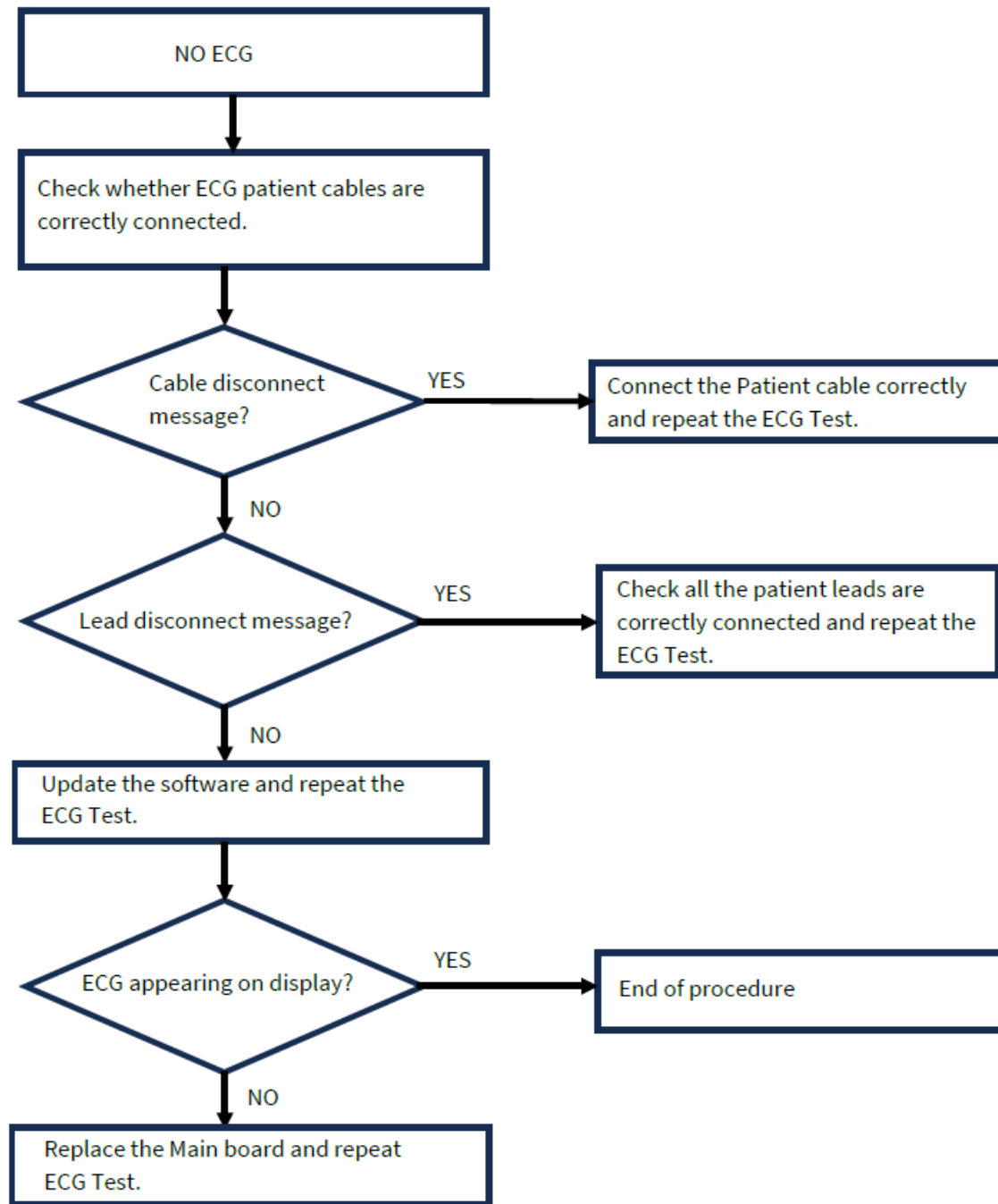




13.12 Troubleshooting power on failure

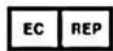


13.13 Troubleshooting ECG failure





GE Medical Systems
Information Technologies, Inc.
3114 N Grandview Blvd
Waukesha, WI 53188 USA



GE Medical Systems S.C.S.
283 rue de la Minière
Buc 78530 France

GE Medical Systems Information Technologies, Inc., doing business as GE HealthCare.



GE HealthCare

www.gehealthcare.com