Anexa A

la Termenii si Condițiile de Livrare

Detalii specifice și standarde tehnice

Lotul nr.2 Electrocardiograf cu 12 canale, cu bandă lată de imprimare

Nr.	Denumire produs	Specificații (minime obligatorii) solicitate			Specificații tehnice oferite
1.	**Electrocardiograf cu 12 canale, cu bandă lată de imprimare COD - 260270**	**Descriere**	**Electrocardiograf cu 12 canale, cu bandă lată de imprimare**		
		Parametru	**Specificația**		
		Tip pacient	adult, pediatric		Da
		Numărul de canale de procesare	12		Da 12
		Configurația	**Portabil**	da	Da
			Suport pe rotile	da	Da
		Derivațiile	**Tip înregistrare**	auto și manual	Da
			Sensivitatea	2.5, 5, 10, 20 mm/mv	Da
			Semnal de calibrare	da	Da
		Gama de frecvență	**De diagnostic**	0.67-150 Hz	Da 0.04 to 150 Hz
			De filtrare	musculare	Da
				de frecvență înaltă	0.04 Hz (ADS off), 0.56 Hz (ADS On)
				de frecvență joasă	0.04 Hz (ADS off), 0.56 Hz (ADS On)
				de rețea 50 Hz	Da
		Impendanța de intrare	≥2.5 M Ohm		>135 dB (with 50/60 Hz filter ON)
		Gama de rejecție a modului comun la 50 Hz	>86 dB		

		Indicator deconectare electrod acustic sau vizual	da		
		Imprimantă	**Termică**	încorporată	Da
			Lățimea hîrtiei	≥ 110 mm	Da 8.46 in x 11 in (215 mm × 280 mm) Letter • 8.27 in × 11.69 in (210 mm x 295 mm) A4 • 8.43 in x 11 in (214.2 mm x 279.4 mm) Modified Letter
			Să se indice numele derivației printate	da	Da
			Viteza de înscriere	25, 50 mm/s	Da 5, 12.5, 25, and 50 mm/s
			Derivațiile înscrise	minim 12	Da
			Numărul de derivații înscrise simultan	3, 6, 12	Da
		Display	**Grafic**	da	Da
			Numărul de derivații afișate simultan	12	Da
		Posibilitatea transmiterii datelor la un sistem de management al datelor ECG	prin fir (să se indice interfața de transmitere) USB, RS-232, etc		Da
		Date pacient	Nume, ID, vîrsta, sex, greutate, înălțimea		Da Supported patient Patient ID, secondary patient ID, visit ID, information last name, first name, height, weight, gender, race, pacemaker patient, systolic BP, diastolic BP, location number, room, order number, phone number, medication, ordering physician, referring physician, attending physician, technician, test indication
		Măsurări	PR, PQ, QT, QTC, P, QRS, T, HR;		Da
		Identificarea aritmiei	da		Da Marquette™ 12SL™ ECG Analysis Program for Adults and Pediatrics
		Interpretarea	da		Da Marquette™ 12SL™ ECG Analysis Program for Adults and Pediatrics

			Timpul interpretării	minim 10 s	Da
		Alimentarea		220 V, 50 Hz	Da
		Baterie internă	**reîncărcabilă**	da	Da
		Timp operare autonomă		≥2,5 h	Da 14.54V nominal voltage @ 3.5 AH – 10% 150 single-page resting ECG recordings or 6 Hours (typical) of continuous monitoring without printing, at a minimum.
		Indicatori vizuali	contact slab sau lipsă de contact		Da
			statut al sistemului		Da
			deconectare alimentare rețea		Da
			baterie descărcată		Da
		Acesorii standard	**Cablu pacient cu set de electrozi pectorali de tip pară (6 buc.) și membranari de tip clește (4 buc.)**	2 unități	Da
			Hîrtie termică	5 bucăți	Da
			Gel de contact	1 litru	Da
			Suport pe rotile	1 unit.	Da, Versa trolley Astar
			Geantă pentru transportare	1 unit.	Nu e necesar, e un dispozitiv cu troleu
Garanția			Min. 12 luni Prezența certificatului de garanție obligatorie		Da, va fi prezentat la instalare
CERTIFICĂRI			Se vor accepta doar dispozitive marcate CE certificate conform directivei 93/42 sau a Regulamentului 2017/745 și incluse în Registrul de Stat al Dispozitivelor Medicale; 1. Certificat de conformitate CE emis de către un organism de evaluare a conofmrității inclus în lista NANDO - https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=notifiedbody.main 2. Declarația de conformitate CE emisă în baza directivei 93/42 EEC sau a Regulamentului 2017/745 care face trimitere la certificatul de conofmritate CE prin număr sau prin codul NOTIFY BODY. 3. ISO 13485/9001 - Sistemul de management al Calității 4. Raportul din documentația tehnică „ESSENTIAL REQUIEREMENT”		1. Da 2. Da 3.Da 4. Extras cu toate standardele este indicat în documentul cu specificațiile tehnice

ETICHETA/MANUAL DE UTILIZARE	1. ETICHETA se prezintă în limba de stat și în una din limbile de circulație internațională conform H.G. 702 „pentru aprobarea Regulamentului privind condiţiile de introducere pe piaţă a dispozitivelor medicale" Secţiunea a 7-a. „Informaţii furnizate de producător" și anume pct. 48. 2. INSTRUCȚIUNEA DE UTILZARE - se prezintă în limba de stat și în una din limbile de circulație internațională conform H.G. 702 „pentru aprobarea Regulamentului privind condiţiile de introducere pe piaţă a dispozitivelor medicale" Secţiunea a 7-a. „Informaţii furnizate de producător" și anume pct. 51	1. Da 2. Da

Furnizor: **"GBG-MLD"SRL**
Adresa Furnizorului: mun. Chișinău, str. Albișoara 64/2
Tel: 022 54-91-21 Fax: 022 54-73-73
E-mail: info@gbg.md
Semnătura autorizată: **Ceaicovschi Tudor**

Numele si funcția semnatarului: Director general

Data: _____ L.Ş.

14 June 2022

MAC 2000 ECG Analysis System

Simple is better

Simple is Smart

Introducing the MAC™ 2000 ECG Analysis System

The support you want in a connected system that's intuitive and easy to use.

Really, really smart.

Simple is Smart

Introducing the MAC™ 2000 ECG Analysis System

The support you want in a connected system that's intuitive and easy to use.

Really, really smart.

Simple is Smart

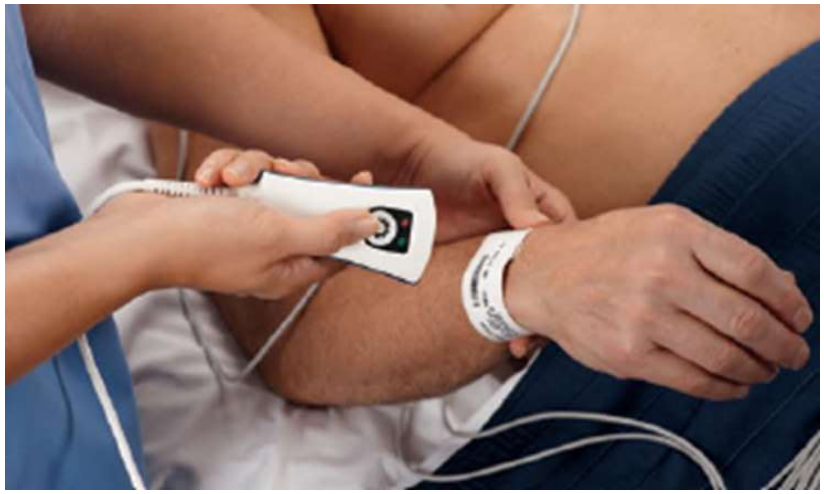
Simple

Connected

Advanced Technology

Simple

Simple is Productive



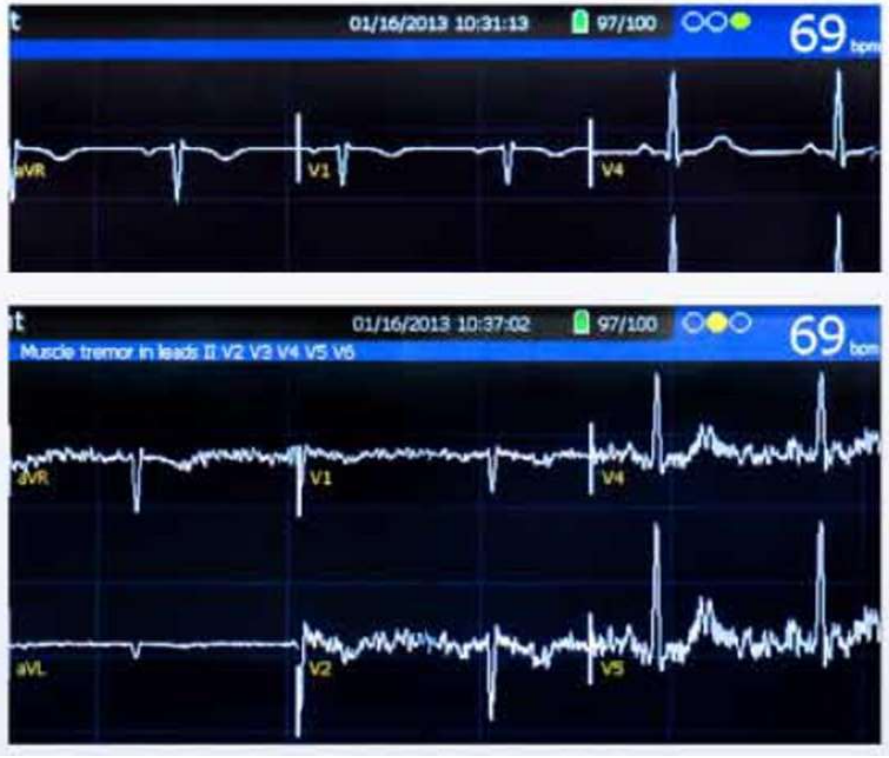
Tools to simplify your ECG workflow

- Hookup Advisor™ program helps clinicians identify a quality signal prior to acquisition
- On-screen 12 lead results help streamline ECG review and analysis
- Convenient computer-based training tools to bring your team up to speed quickly
- Available in exercise testing configuration

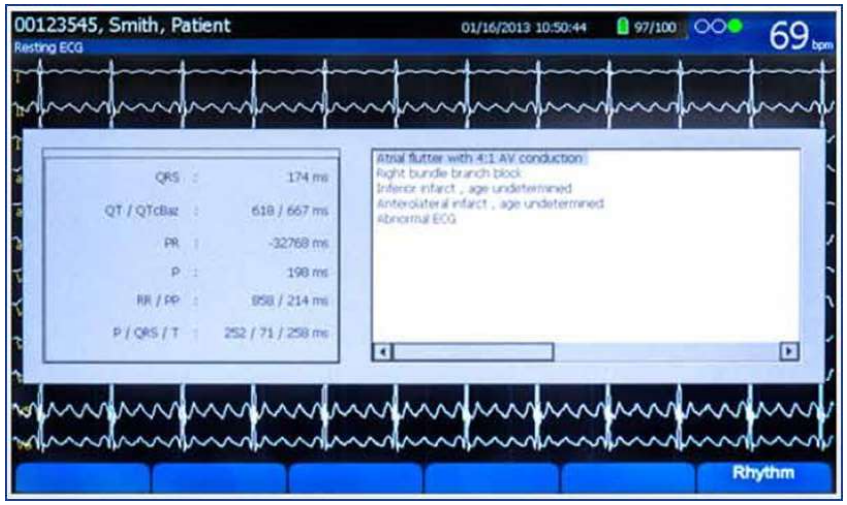
Simple is Productive

Hookup Advisor program

- Hookup Advisor program helps clinicians identify a quality signal prior to acquisition
- Identifies the type of noise & leads affected
- Helps clinicians avoid costly repeat ECGs



Simple is Productive



On-screen 12-lead results

- Help to streamline ECG review and analysis
- 12-lead waveforms, measurements, and computerized Marquette™ 12SL™ interpretation available as soon as ECG is recorded

Simple is Productive

Computer-based training

- Provides a thorough look at the features and functionality of the MAC 2000 system
- Modular design of the training encourages user interaction
- Move through basic system overview, acquiring an ECG, acquiring an arrhythmia report, completing a stress ECG test, and managing patient data
- Facilitates on-demand initial and refresher training

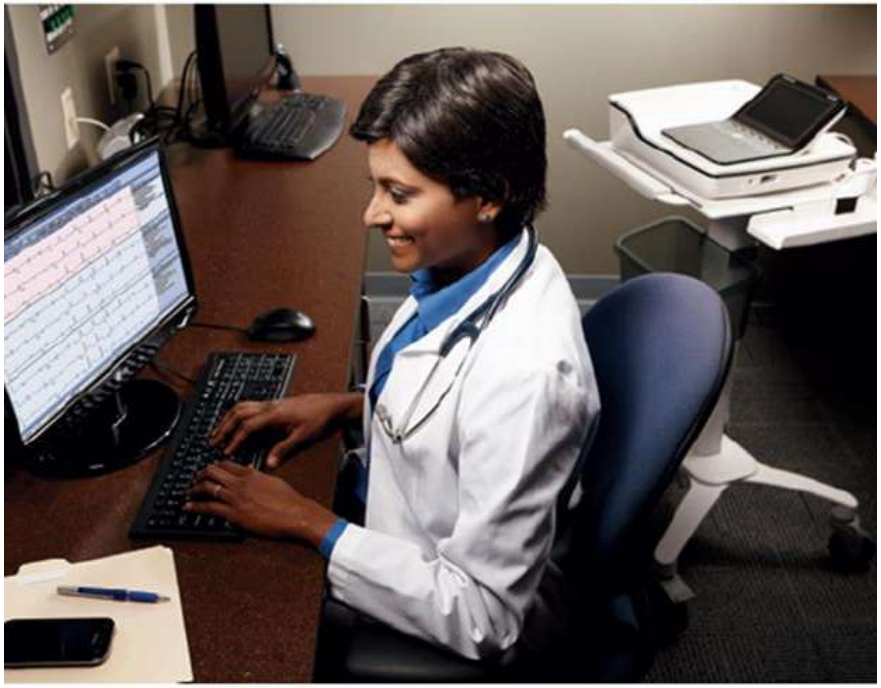
Simple is Productive

Stress testing configuration

- Expanded capability to help you make the most of your device investment
- Available for use with GE brand ergometers and treadmills

Connected

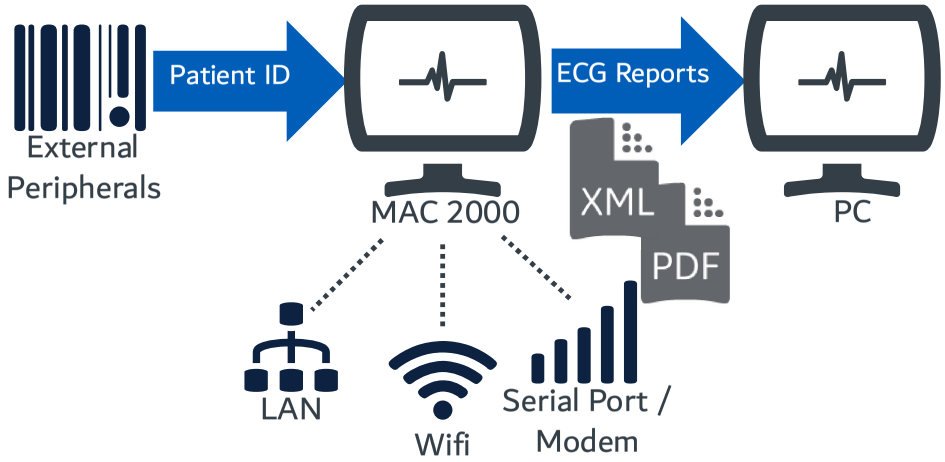
Simple is connected



Your link to ECG data connectivity

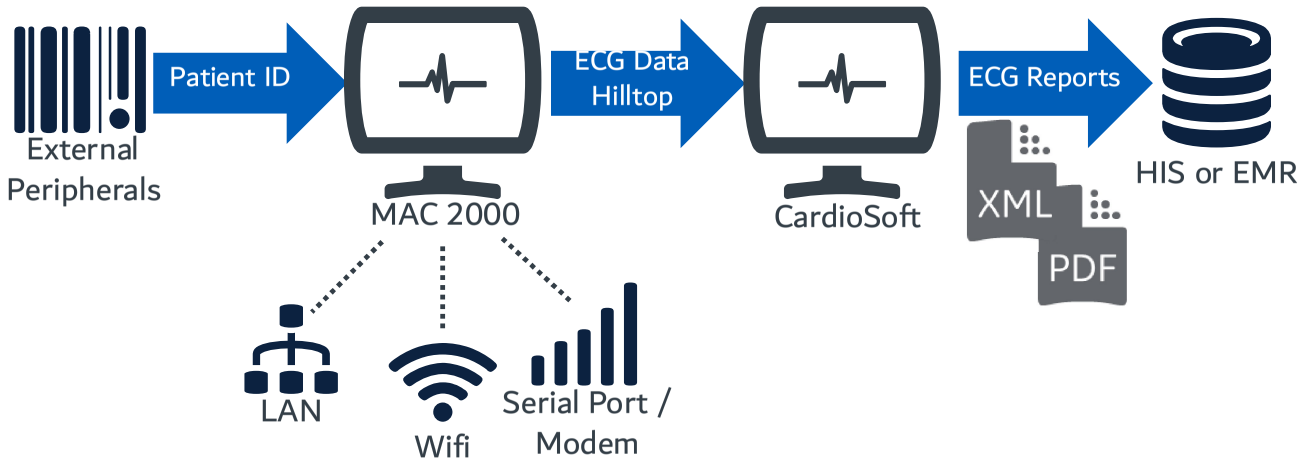
- Seamless connectivity with the MUSE™ cardiology system and the CardioSoft™ program
- Transfer data via Wi-Fi, LAN, SD cards, modem, and serial ports
- PDF and XML export capabilities

MAC 2000 workflow with shared directory/PC workstation



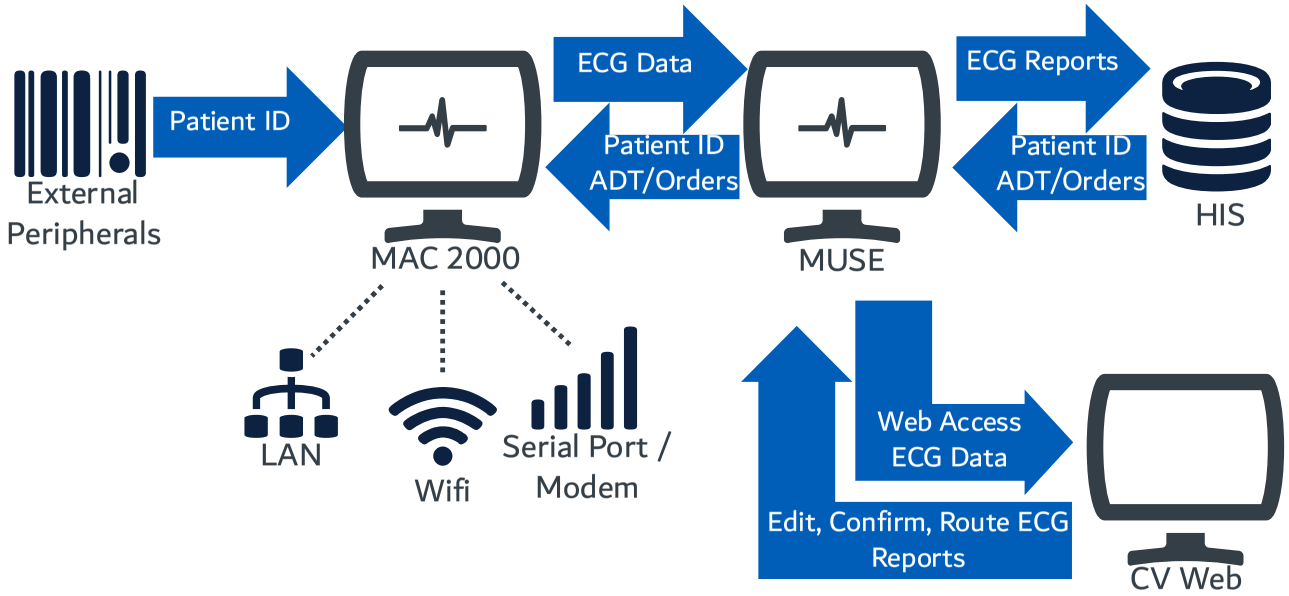
- Paperless workflow
- PDF out
- Wi-Fi connection
- Built-in storage of up to 200 ECGs

MAC 2000 workflow with CardioSoft Diagnostic Program



- Paperless workflow
- ECG measurement and editing
- PDF out
- Wi-Fi connection
- Built-in storage of up to 200 ECGs

MAC 2000 workflow with MUSE Cardiology Information System

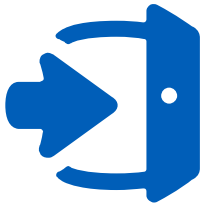


- Bi-directional communication with HIS system
- Orders and ADT query capabilities
- Web-enabled ECG report access and editing possible with CV Web 3.0
- Fast communication with DCP protocol
- Optional barcode reader functionality

Secure

Simple is Secure

Patient data encryption



Automatic, time configurable log-off

Username and password authentication

Site and location support

Audit trail, activity log

Automatic patient data deletion after transmission

Just a few ways this approach is manifested in MAC 2000

We encrypt all patient information stored on the MAC 2000 using 128 bit encryption software.

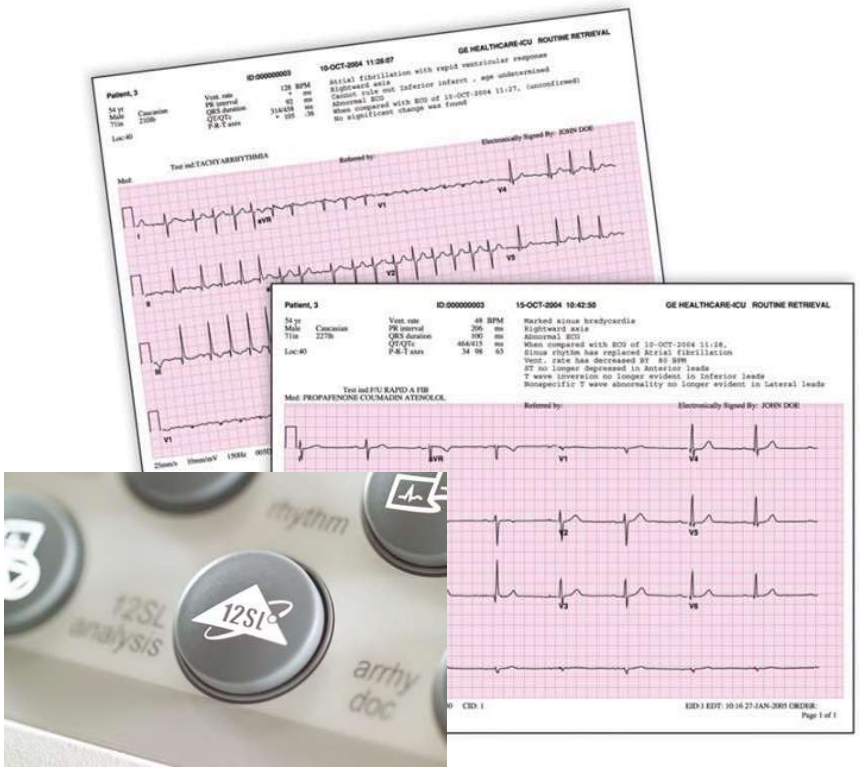
As an added layer of security, the MAC 2000 offers the option to create usernames and passwords.

To keep the system safe MAC 2000 can only receive inbound traffic from GE's MUSE, Gateways and FTP servers with a designated port.

The MAC 2000 can monitor and record security-related activities, such as logins and network connections, for audit.

Advanced Technology

Marquette™ 12SL™



- Over 30 years of innovation and development
- Over 150 scientific references[1]
- Validated against clinically-correlated databases for accuracy[1]
- ACI-TIPI option calculates probability of the presence of Acute Cardiac Ischemia
- Gender-specific interpretation has been shown to provide a 25% relative improvement in detection of Acute Inferior MI in women under 60 years of age[2]

[1]for more details please refer to the GE 12SL statement of validation and accuracy
[2]Xue, J. et al. "A New Method to Incorporate Age and Gender into the Criteria for the Detection of Acute Inferior Myocardial Infarction." J Electrocardiol. 34(4) (Part 2) (Oct 2001):229-234

MAC 2000 Solution for Pharma Clinical Trials

- Hookup Advisor helps the clinician to identify a quality signal prior to acquisition. Less noise means reduced QT measurement variability[3]
- CT Data Guard helps in capturing clinical trial details, and records the same in the ECG report
- CFR Audit Trail supports 21 CFR Part 11 compliance requirements

[3] Farrell, R.M and Rowlandson, G.I., "The Effects of Noise on Computerized Electrocardiogram measurements." J Electrocardiol, 2006, 39(4 Suppl): p.S165-73.

KISS Suction Electrode Application System

- Provide consistent connection to patients
- Fast and easy electrode applications in the cardiology department
- Operates with a slight suction regulated by the electronically controlled suction pump via high sensitive sensors

MAC 2000 ECG Analysis System

Simple is here

Building a world that works

JB20046XE(4)

GE Healthcare

MAC® 2000 ECG Analysis System

Quick Reference Guide

Global Customer Education

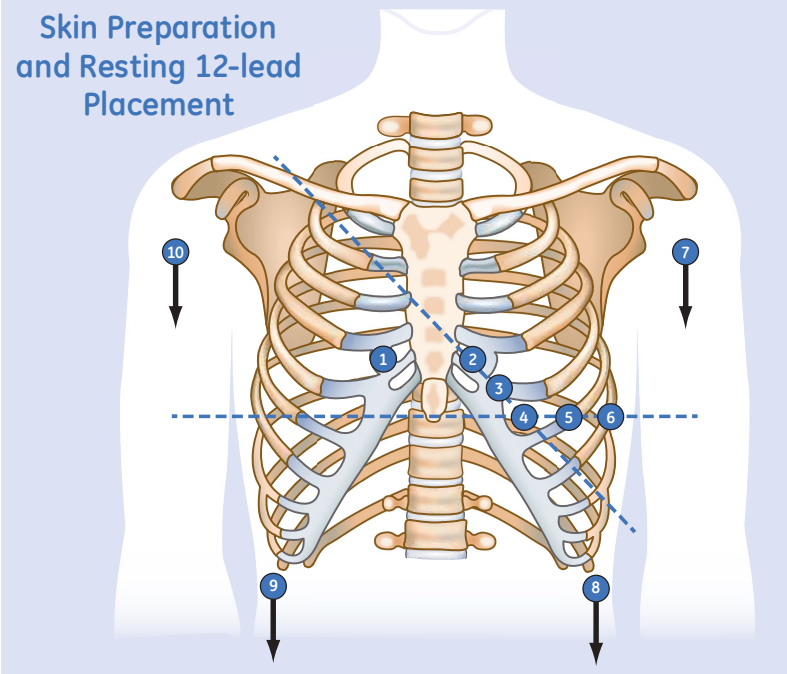
2053535-065 Rev E

Notice

The materials contained in this document are intended for educational purposes only. This document does not establish specifications, operating procedures or maintenance methods for any of the products referenced. Always refer to the official written materials (labeling) provided with the product for specifications, operating procedures and maintenance requirements.

Contents

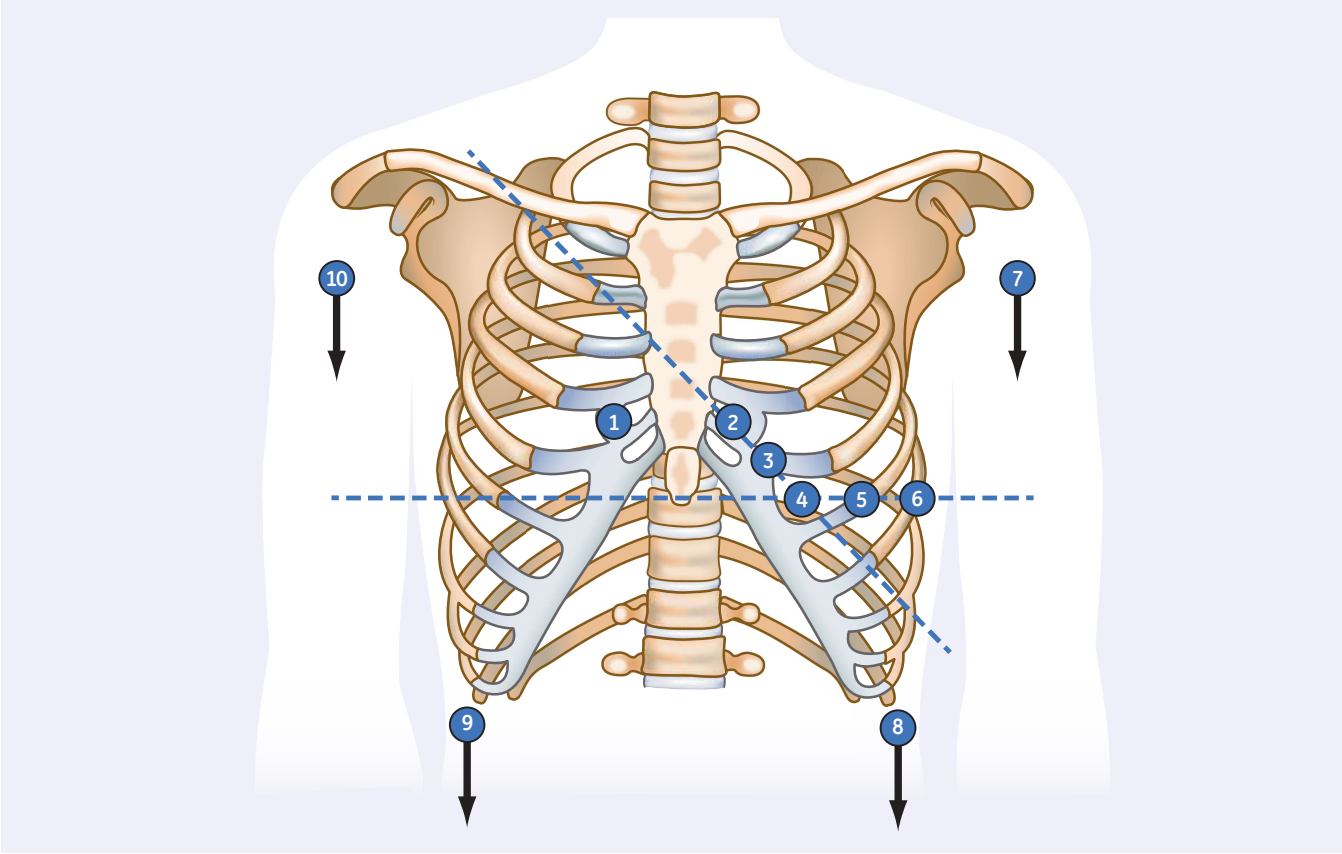
Skin Preparation and Resting 12-lead Placement



The quality of your ECG tracing is a direct result of skin prep and lead placement.

1. Ensure that skin is dry, clean and remove excessive hair.
2. Mark each electrode site with a felt tip pen.
3. Degrease each site with a skin preparation cream.
4. Use a mild abrasion to remove the mark left by the felt tip pen.
5. Apply the electrodes to the prepared sites.
6. Look at the hook-up advisor and on-screen messages for indication of lead problems.

Lead	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 purple	C6 purple	Mid-axillary line on the same horizontal level as 4 and 5
7	LA black	L yellow	Left wrist
8	LL	F green	Above left ankle (Alternate placement, upper leg as close to torso as possible)
9	RL green	N black	Above right ankle (Alternate placement, upper leg as close to torso as possible)
10	RA white	R red	Right wrist



Skin Preparation and Stress ECG Lead Placement

Preparing the patient correctly of their ECG is a critical part of making sure that the reading is accurate and free of noise. Here is what is suggested for a proper patient prep.

1. Ensure that skin is dry, clean and remove excessive hair.
2. Mark each electrode site with a felt tip pen.
3. Degrease each site with a skin preparation cream.
4. Use a mild abrasion to remove the mark left by the felt tip pen.
5. Apply the electrodes to the prepared sites.
6. Look at the hook-up advisor and on-screen messages for indication of lead problems.

Lead	Electrode Placement
1	Fourth intercostal space at the right sternal border
2	Fourth intercostal space at the left sternal border
3	Midway between 2 and 4
4	Mid-clavicular line in the fifth intercostal space
5	Anterior axillary line on the same horizontal level as 4
6	Mid-axillary line on the same horizontal level as 4 and 5
10	Recommend placing in the soft fleshy area just below the right clavicle
7	Recommend placing in the soft fleshy area just below the left clavicle
9	Recommend placing on the corresponding right side of the thorax at the lower edge of the rib cage, or at the lower level of umbilicus at the right mid-clavicular line.
8	Recommend placing on the corresponding left side of the thorax at the lower edge of the rib cage, or at the lower level of umbilicus at the left mid-clavicular line.

Patient Data (ADT)

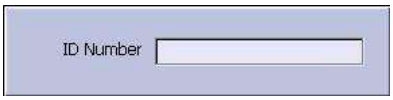
The MAC 2000 allows you to download patient demographics via an ADT interface. You can download patient demographics using internal or external keyboard, or barcode reader. Use the following procedures to query the database and select patient demographic for each.

Database Query Using Barcode Reader

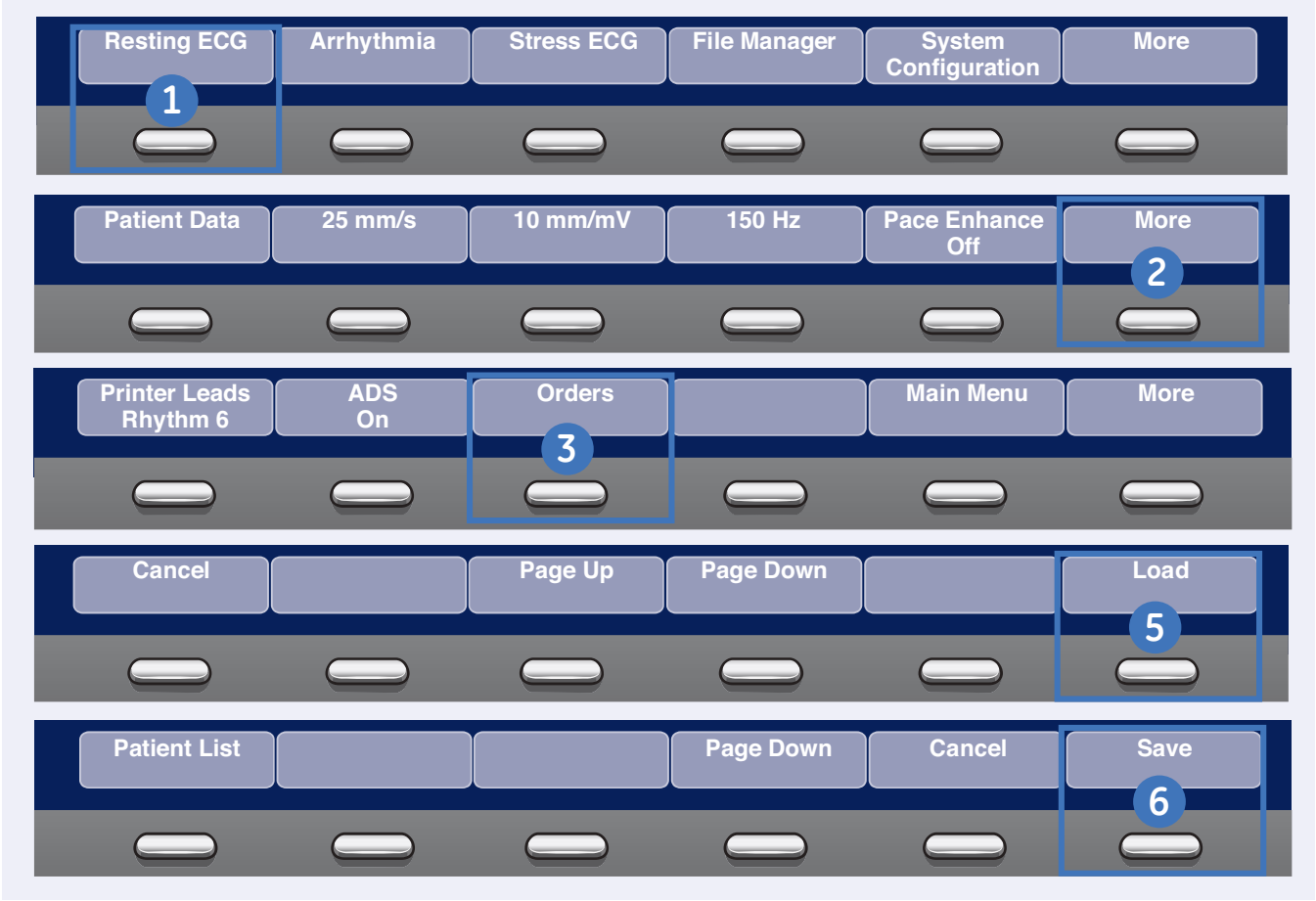
1. Select ***Resting ECG***.
2. Select the ***Patient Data***.
3. Scan the patient barcode using the barcode reader. A dialog box opens with the scanned Patient ID.
4. Click ***OK*** to accept the selection.
5. The patient demographic data is populated. Modify any fields as necessary.
6. Select ***Save***.

Database Query Using Internal or External Keyboard

1. Select ***Resting ECG***.
2. Select the ***Patient Data***. A dialog box opens instructing you to enter the Patient ID.



3. Enter the Patient ID using the internal keypad or external keyboard. A dialog box opens with the Patient ID you entered.
4. Click ***OK*** to accept the selection.
5. The patient demographic data populated. Modify any fields as necessary.
6. Select ***Save***.



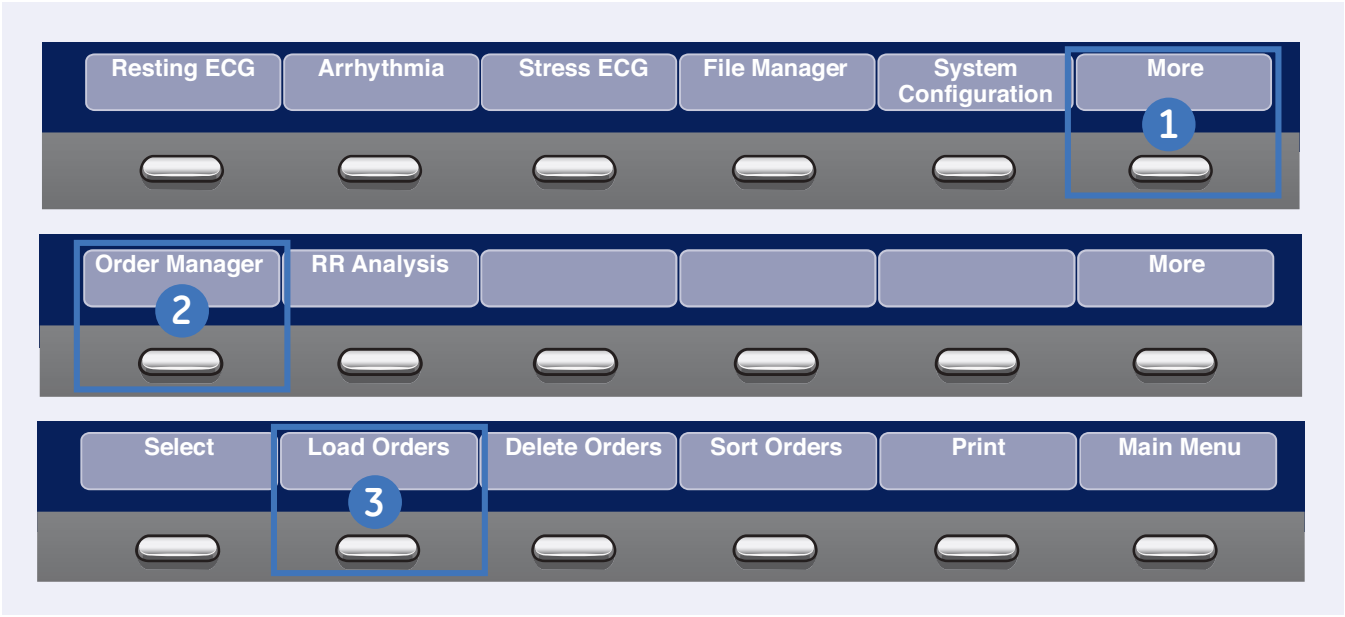
Simple Orders

Simple Orders provides an interface to quickly download and execute one order at a time. Use the following steps to execute a simple order.

1. Select ***Resting ECG***
2. Select ***More.***
3. Select ***Orders.***

Note! *If Auto Execute Single Order setting is enabled in Resting ECG Setup and only one open order for that given location is present the system will automatically download that single order and populate the Patient Information screen.*

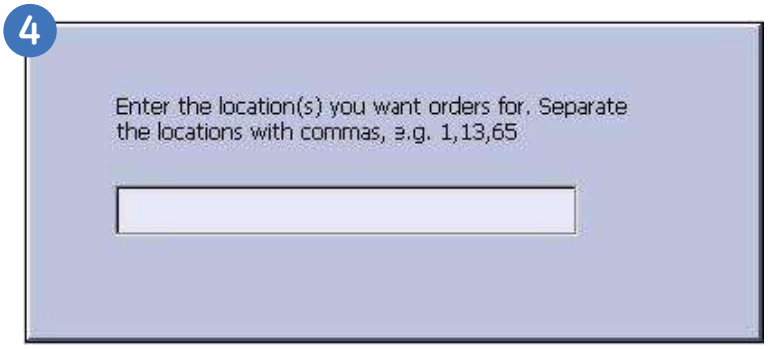
4. Select an order from the list.
5. Select ***Load.***
6. The order will download and populate the Patient Data screen. Modify as patient data as necessary.
7. Select ***Save.***



Advanced Order Manager

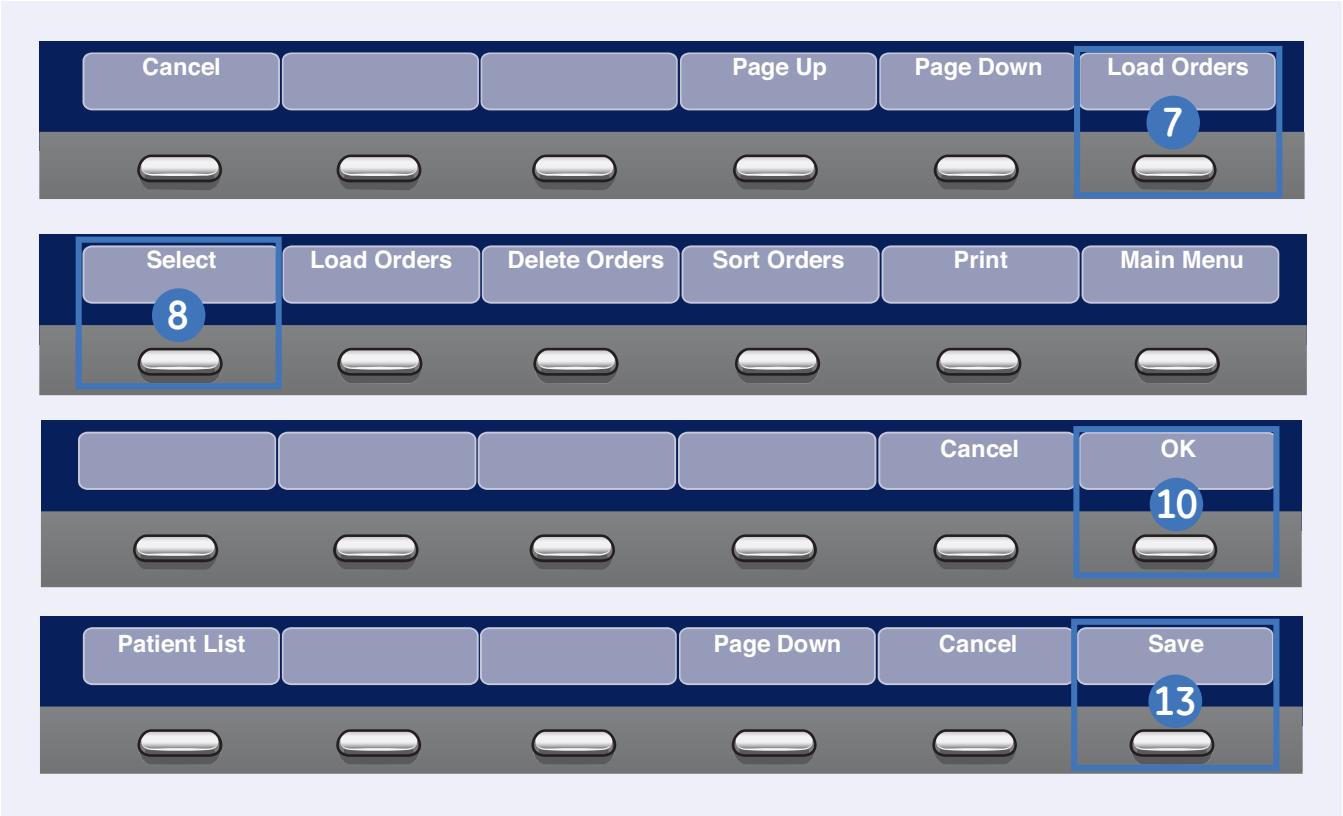
Advanced Order Manager provides an interface to download and store multiple orders on the system and execute them later. Use the following procedure to execute an advanced order.

1. From the Main Menu, select ***More***.
2. Select ***Order Manager***.
3. Select ***Load Orders.***
4. Enter the location(s).

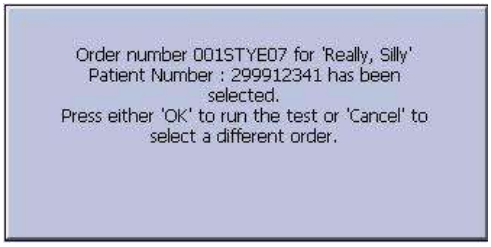


Note! *To query multiple locations, add a comma between each location number e.g. 1,2,5,7.*

5. Select ***Ok***.



6. Select the order(s) from the list.
7. Select ***Load Orders.***
8. Select ***Select***.
9. Select an order.
10. Select ***Ok*** to confirm the order selection.

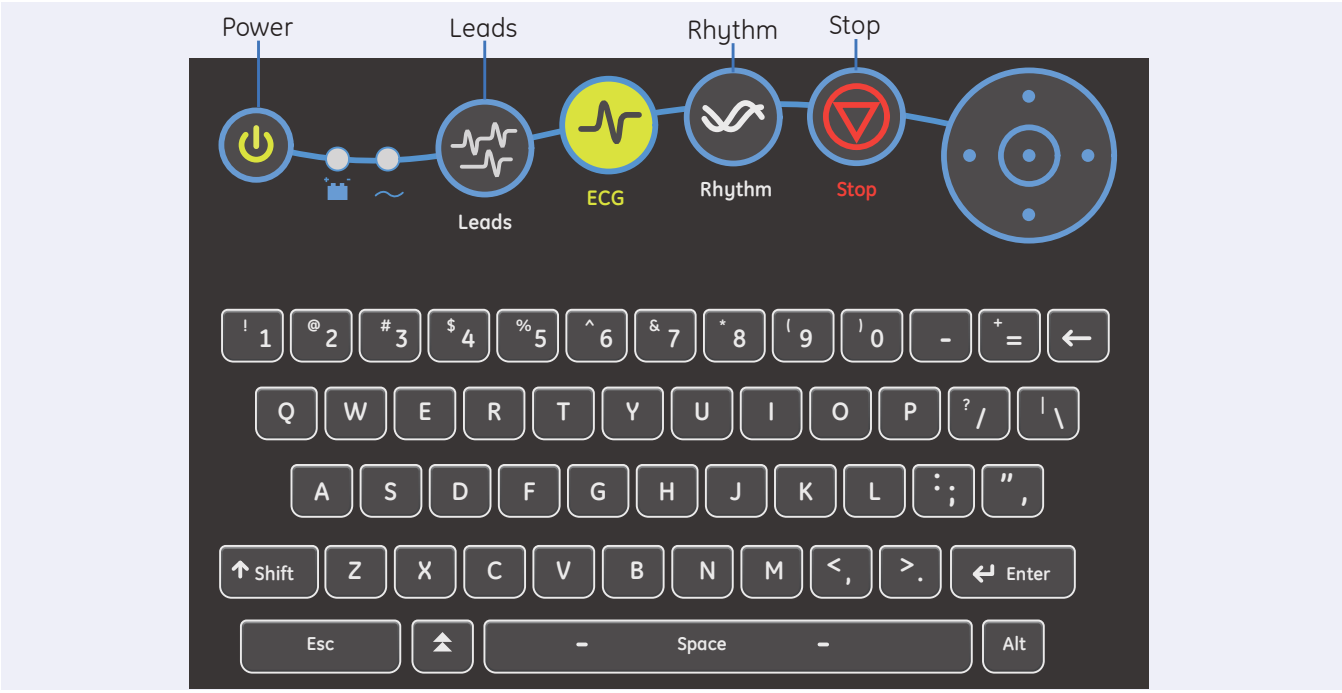


11. Select ***Patient Data*** to open with the patient information screen which will be populated from the selected order.
12. Modify the patient and test data as necessary.
13. Select ***Save***.

Acquire an ECG

1. **Prepare the patient.**
2. Open the Resting ECG function in one of two ways:
   - Power on the unit or
   - From ***Main Menu*** select ***Resting ECG***.
3. Verify waveform quality by:
   - Checking ***Hook-up Advisor***. Green indicates a good quality waveform.
   - Cycle through the lead groups to visually verify lead quality by selecting the ***Leads*** key on the keyboard.
4. Use the appropriate keys to make adjustments to (if necessary):
   - ***Speed***
   - ***Gain***
   - ***Filter***
5. **Select *Patient Data* to enter the patient information.**
6. Select ***Page Down*** to access other Test Information windows.
7. Select ***Save*** to save and close the Patient Data window.
8. **Select the *ECG* key on the keyboard to record and print an ECG.**
9. If you have your system set to ***Preview before Analysis***, select ***Continue*** to proceed to analyze and print an ECG or ***Cancel*** to cancel the analysis.
10. If finished, continue with step 11, or continue with these options:
    - Select ***Print*** to print another copy
    - Select ***Save*** if the unit is not set to save the ECG automatically.
    - Select ***Transmit*** to transmit that single record to the default transmit location.
    - Select ***Next Patient*** to start a new patient or Select the ***ECG key*** to take another ECG on the same patient.
11. When finished, do one of two things:
    - Proceed to ***File Manager*** to transmit records. **(See Transmit Stored Records.)**
    - Turn the unit off and plug it into AC power.

Note! ***Steps 1, 5 and 8 are the minimal basic steps for acquiring an ECG. All other steps are only used as required depending on options and features turned on.***



Print Continuous Rhythm

1. Prepare the Patient.
2. Open the Resting ECG function in one of two ways:
   - If the select default power on option is Resting ECG, simply power on the unit or
   - From ***Main Menu*** select ***Resting ECG***
3. Verify waveform quality by:
   - Checking ***Hook-up Advisor***. Green indicates a good quality waveform.
   - Cycle through the lead groups to visually verify lead quality by selecting the ***Leads*** key on the Keyboard.
4. Use the keys to make adjustments to (if necessary):
   - ***Speed***
   - ***Gain***
   - ***Filter***
5. Select ***Patient Data*** to enter patient information.
6. Select ***Page Down*** to access other Test Information windows
7. Select ***Save*** to save and close the Patient Data window.
8. Select the ***Rhythm*** key on the keyboard to print a continuous rhythm.
9. Select the ***Stop*** button to stop printing.

Note! *Rhythm reports are not stored to File Manager.*

Printing an RR Analysis Report (not sold in all countries)

Use the following steps to generate an RR Analysis report.

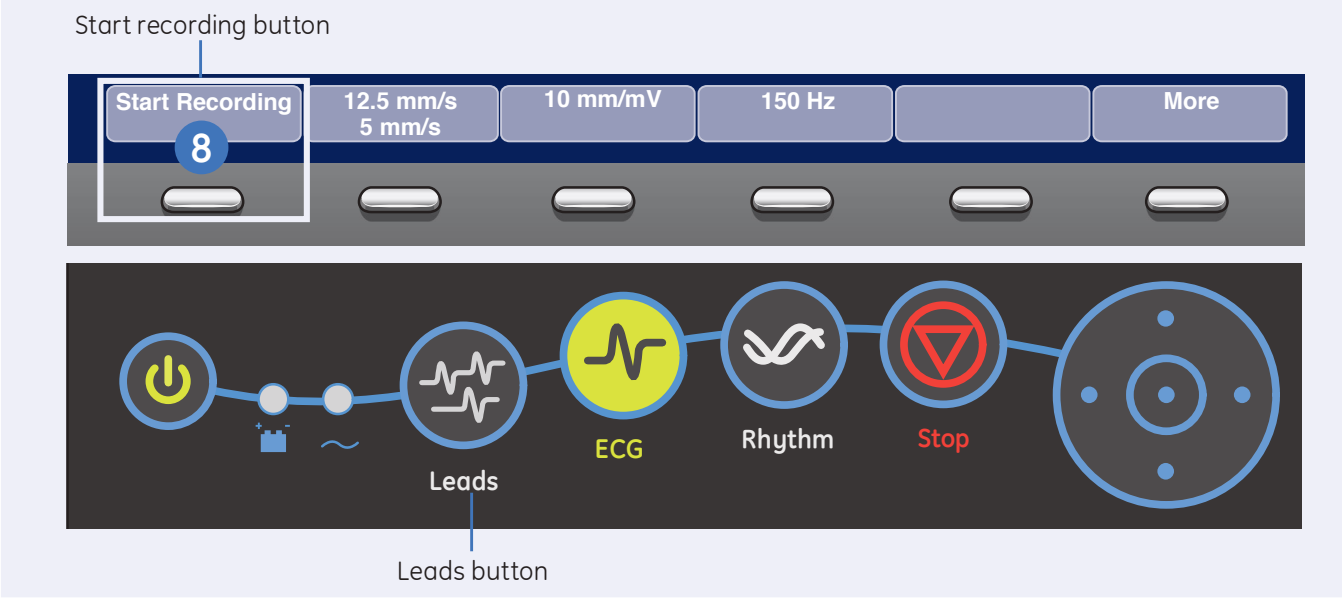
1. **Prepare the patient.**
2. From the Main Menu select ***More***.
3. Select ***RR Analysis***. You can also access RR Analysis from the Resting ECG mode after an ECG has been acquired.
4. **Select *Patient Data* and enter the patient data.**
5. Adjust the setup options (target, record lead, gain, speed, filter, pacemaker detection, rhythm record, and RR table) as necessary by selecting ***RR Analysis Setup.***
6. **Select *Start Test* to start the test.**

   When the target is achieved, a preview of the summary results, histogram, and trendgram are shown on the display.

   Note! *You may select* ***Stop Test*** *to stop the test prior to the reaching the target.*
7. While reviewing the preview, do any of the following:

   - To discard the reading and begin over, select ***Return.*** and repeat from Step 5.
   - To discard the reading and return to the Main Menu, select ***Main Menu.***
   - To accept the reading and print the report on the thermal printer, select ***Print***
   - To accept the reading and export the results as a PDF file, select ***PDF Export.***

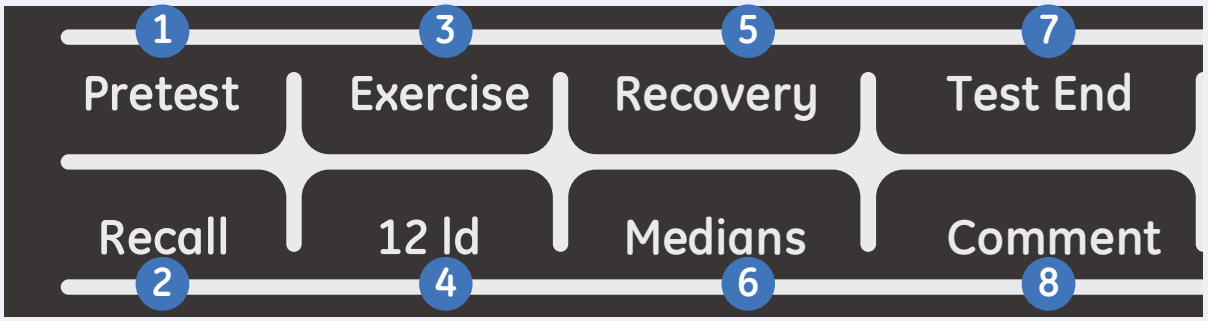
Note! Steps 1, 4 and 6 are the minimal basic steps for acquiring RR Analysis.



Acquire an Arrhythmia

1. **Prepare the Patient.**
2. Open the Arrhythmia function in one of two ways:
   - If the select default power on option is Arrhythmia, simply power on the unit or
   - From ***Main Menu*** select ***Arrhythmia***
3. **The *Patient Data* window automatically opens. Enter the desired information.**
4. Select ***Page Down*** to access other Test Information windows.
5. Select ***Save*** to save and close the Patient Data window.
6. Verify waveform quality by:
   - Checking ***Hook-up Advisor.*** Green indicates a good quality waveform.
   - Cycle through the lead groups to visually verify lead quality by selecting the ***Leads*** key on the Keyboard.
7. Make adjustments to (if necessary):
   - ***Speed***
   - ***Gain***
   - ***Filter***
8. **Select *Start Recording*.**
9. Select ***Stop Recording***.
10. Select **Confirm Stop** to stop the recording or ***Continue Recording*** to continue to collect information.
11. After the recording is stopped, select the type of Arrhythmia report you wish the printout to include: Summary Report, Table Report, or Episode Report.
12. Select ***Main Menu.***

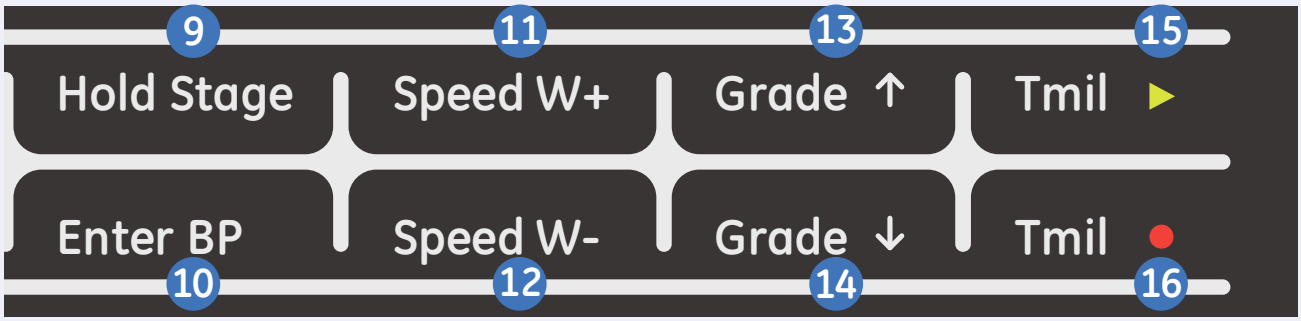
Note! Steps 1, 3 and 8 are the minimal basic steps for acquiring an ECG.



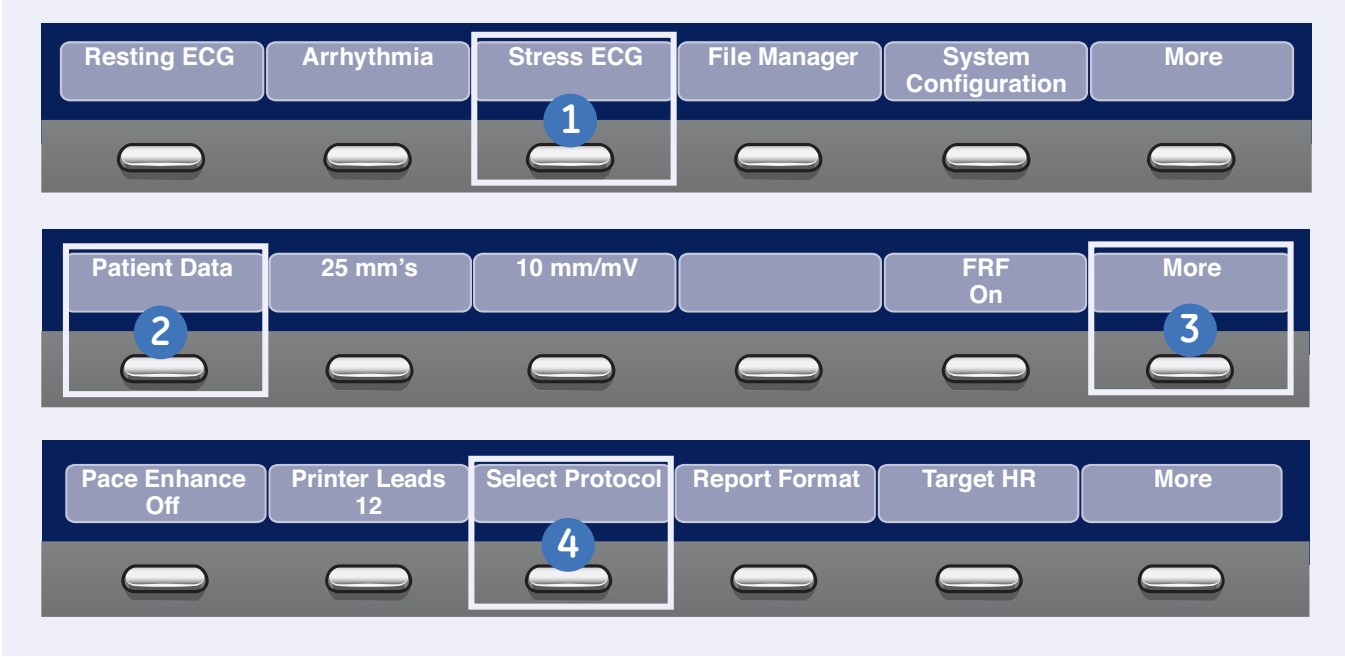
Stress ECG Testing Keyboard

The Stress ECG test keys are located at the top of the stress test keyboard. These keys are used to control the functions of the stress test as well as the connected stress device.

1. **Pretest:** Advanced the test to the Pretest Phase or while in the Pretest Phase if selected will advance to the next stage in that phase.
2. **Recall:** Prints a one-page rhythm strip report using the previous 10 secs of data from the point from which you select the Recall key
3. **Exercise:** Advanced the test to the Exercise Phase or while in the Exercise Phase if selected will advance to the next stage in that phase.
4. **12 Ld:** Prints a 12 lead report.
5. **Recovery:** Advances to the Recovery phase or while in the Recovery Phase if selected will advance to the next stage.
6. **Medians:** Prints a median report. Set the type of median report you wish to print in the Stress Setup window under In-test Reports.
7. **Test End:** Ends the current test. When a confirmation message appears on the screen, select the desired function key.
8. **Comment:** Allows you to enter comments about the test. Comments are printed on the Tabular Summary Report. You can enter up to 100 characters.



9. **Hold Stage:** Maintains the current test stage and doesn't allow the protocol to go to next stage. Select again to remove the stage hold and to go back to programmed protocol staging.
10. **Enter BP:** Allows you to enter a Blood Pressure reading manually or triggers a reading for a supported external device.
11. **Speed W+:** Increase treadmill speed or ergometer load. Selecting this button will result in the system no longer following the selected protocol and places the system in manual mode.
12. **Speed W- :** Decreases treadmill speed or ergometer load. Selecting this button will result in the system no longer following the selected protocol and places the system in manual mode.
13. **Grade↑:** Increase treadmill incline. Selecting this button will result in the system no longer following the selected protocol and places the system in manual mode.
14 **Grade↓:** Decrease treadmill incline. Selecting this button will result in the system no longer following the selected protocol and places the system in manual mode.
15. **Tmil >:** Starts the Treadmill
16. **Tmil•:** Stops the Treadmill



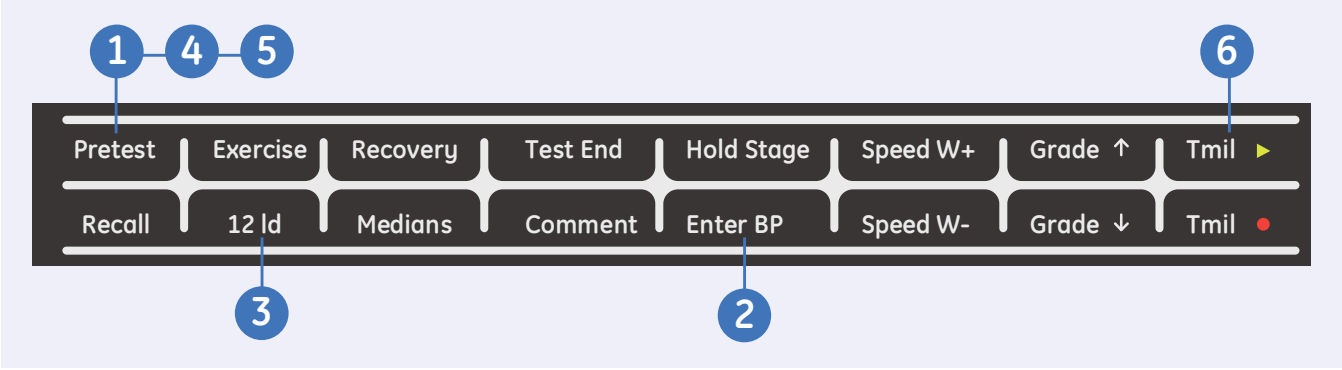
Accessing Stress ECG Mode

The Stress ECG mode is a purchasable option and allows you to conduct a Stress ECG test with a direct connection to treadmill or ergometer. Regardless of the devices the basic procedure for conducting a Stress ECG test is the same. Now let's access the Stress ECG menu.

1. Select ***Stress ECG*** from the Main Menu.
2. Select ***Patient Data*** and enter the appropriate data.
3. Select ***More***.

4. Select ***Protocol*** to choose desired protocol. The default protocol will be chosen, however you can select another protocol from the list. If you do select a new protocol, select ***Save***.
5. You can also turn Pace Enhance On or Off, select the Printer Leads, select Report Formats or change the Target HR.

Note! In setups you can automatically set the Target HR % that you wish to achieve. This number is calculated against the patient's age.

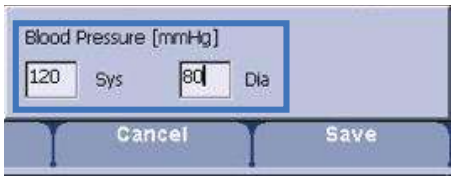


Pretest Phase

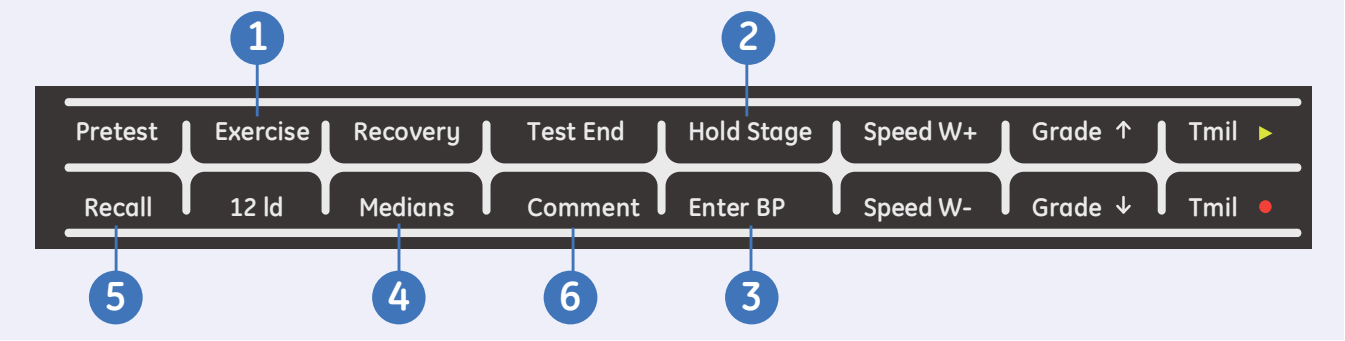
A Stress ECG protocol typically is composed of 4 phases. These include Pretest, Exercise Recovery and Test End.

Pretest allows the user to take ECG and blood pressure measurements in a variety of patient positions. Depending on the protocol, it is also a phase that could be used to allow the patient to warm-up before the Exercise portion of the Stress ECG test.

1. Select the ***Pretest*** button on the keyboard to enter the Pretest Phase.
2. Select the ***BP*** button on the keyboard and enter patient's blood pressure.



3. Select the ***12 ld*** button on the keyboard to take a 12-lead ECG
4. Select the **Pretest** button to advance through the Standing and Hypervent stages a BP and 12-lead as required.
5. Select the ***Pretest*** button to advance to Warm-up.
6. Select the ***Tmil>*** button to start the treadmill.
7. Have the patient start to walk at speed based on the selected protocol.



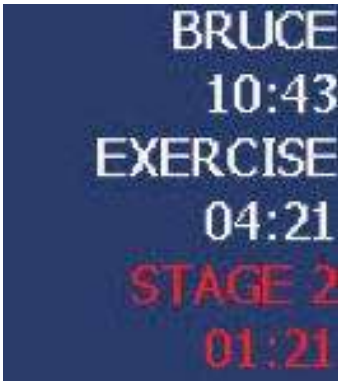
Exercise Phase

Once the patient is comfortable walking on the treadmill or peddling on the ergometer, select the Exercise key on the keyboard to start the Exercise Phase. The phase will now indicate Exercise and the stage time and workload will be dictated by the protocol.

1. Select the ***Exercise*** button on the keyboard. The system will now enter the exercise phase and follow the selected protocol. Select the ***Exercise*** button a second time will advance the protocol to the next stage.

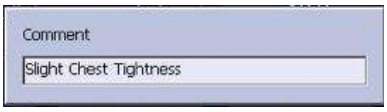
Note! Selecting the Speed or Grade controls for the treadmill or ergometer will result in the system dropping out of the protocol. At this point the user must manually control the treadmill or ergometer's workload.

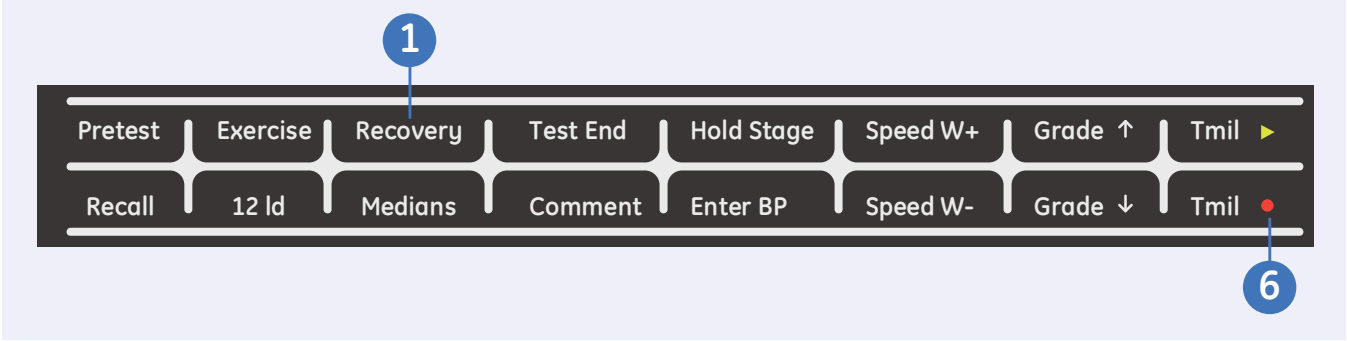
2. Select the ***Hold Stage*** button will result in the stage being held at that workload for as long as the stage is held. Select ***Hold Stage*** a second time to release the stage to follow the selected protocol.



Note! The stage time will turn red when the stage is in hold.

3. A blood pressure will be automatically prompted for based on the protocol or you can select the ***Enter BP*** button on the keyboard to enter a BP.
4. A 12 lead will be automatically taken by the system based on the protocol or you can select the ***12 ld*** button on the keyboard to take a 12 lead. You may also take a median report at any time by selecting ***Medians***.
5. Select the ***Recall*** button to capture the previous 10 sec of ECG that just pasted on the screen.
6. Select ***Comment*** on the keyboard to enter a patient related comment.

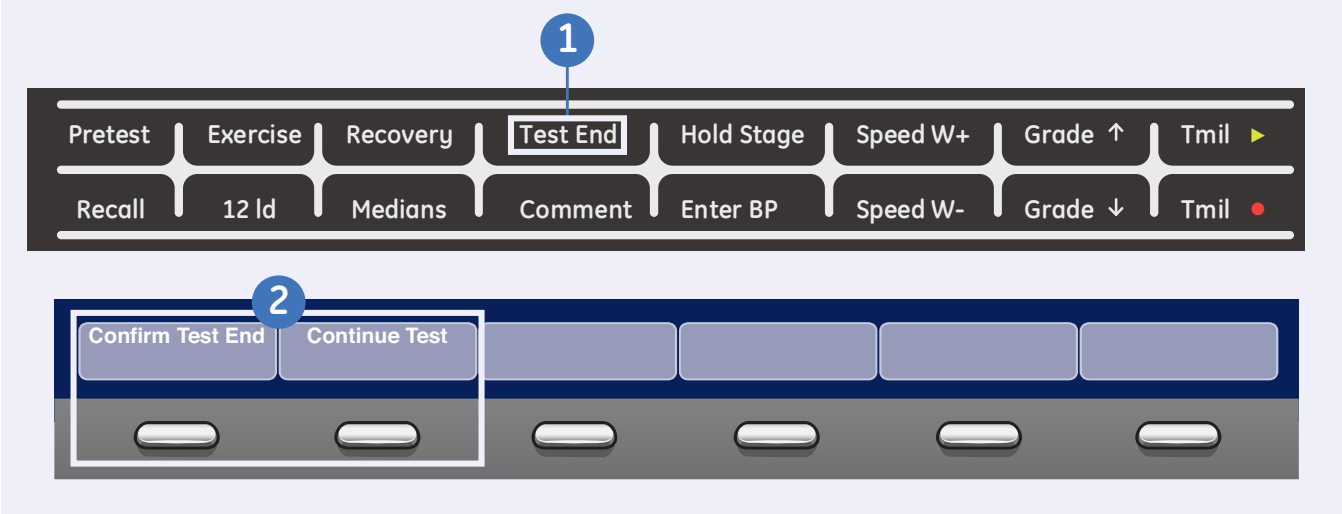




Recovery Phase

Once it is determined that the Exercise portion of the stress test has been completed, you will now select the Recovery button and enter into the recovery phase. The Recovery phase is opportunity to continue to monitor the patient to make sure their blood pressure, heart rate, symptoms and ECG return to their pre- test values. The length of the Recovery Phase will depend on your clinician protocol.

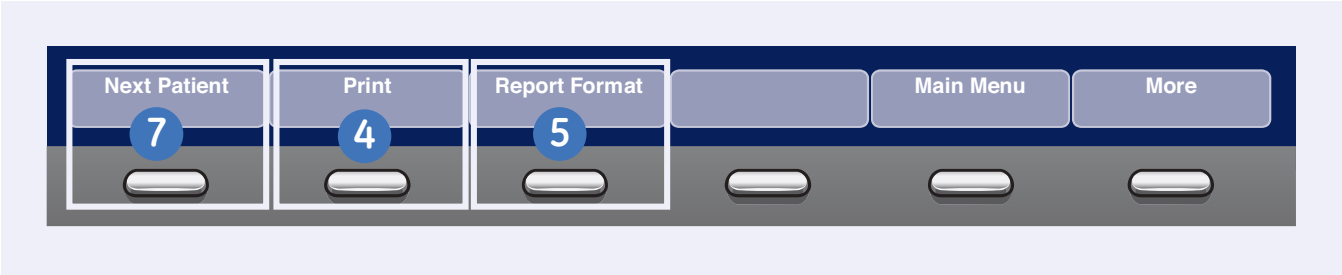
1. Select the ***Recovery*** key on the function keyboard when the patient has reached peak exercise, or when you are ready to advance to the Recovery Phase.
2. On supported treadmills the speed and grade of the treadmill will gradually decrease according to the protocol.
3. The system will automatically print a peak 12-lead or median report according to the protocol.
4. BP will automatically be prompted based on the protocol.
5. Enter comments or take extra 12 leads or medians as needed.
6. Select ***Tmil•*** on the keyboard to stop the belt. If using an ergometer, have the patient stop peddling.



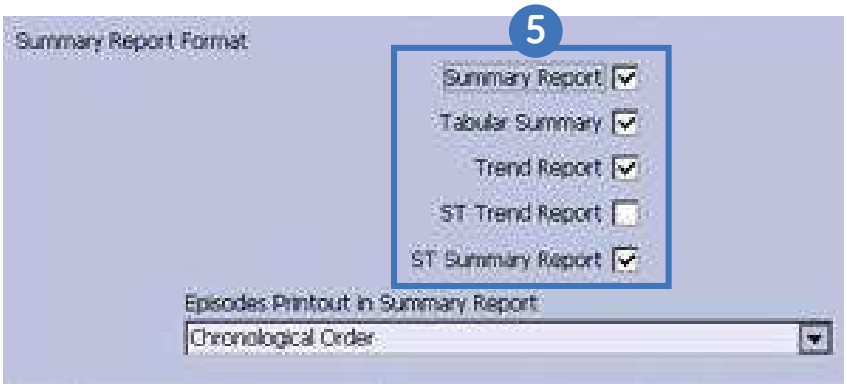
Test End

Once the Recovery phase is completed you can select Test End on the keyboard and disconnect the leads from the patient.

1. Select the ***Test End*** key on the keyboard when ready to end the test.
2. Confirmation of ending the test appears. Select ***Confirm Test End*** to end test or select ***Continue Test*** to continue collecting data for the current patient.
3. Once you have selected ***Confirm Test End*** the following menu selections appear.



4. Select ***Print*** to print the default Summary Report Format.
5. If you desire to select different Summary Report components then originally chosen in the Stress Testing Setup, select ***Report Format*** to override those default selections. The following screen appears to allow you to select the different components.



6. Select ***Save*** to save your changes and select ***Print*** to print that Summary report.
7. Select ***Next Patient*** to conduct a Stress ECG test on the next patient. The system will verify that ***The previous test data will be lost. Do you wish to continue with the Next Patient?***

   Select ***Yes*** to continue

Note! Stress ECG test are not saved to the File Manager. Once you select to do you next patient all test data will be lost.

To Select Records:

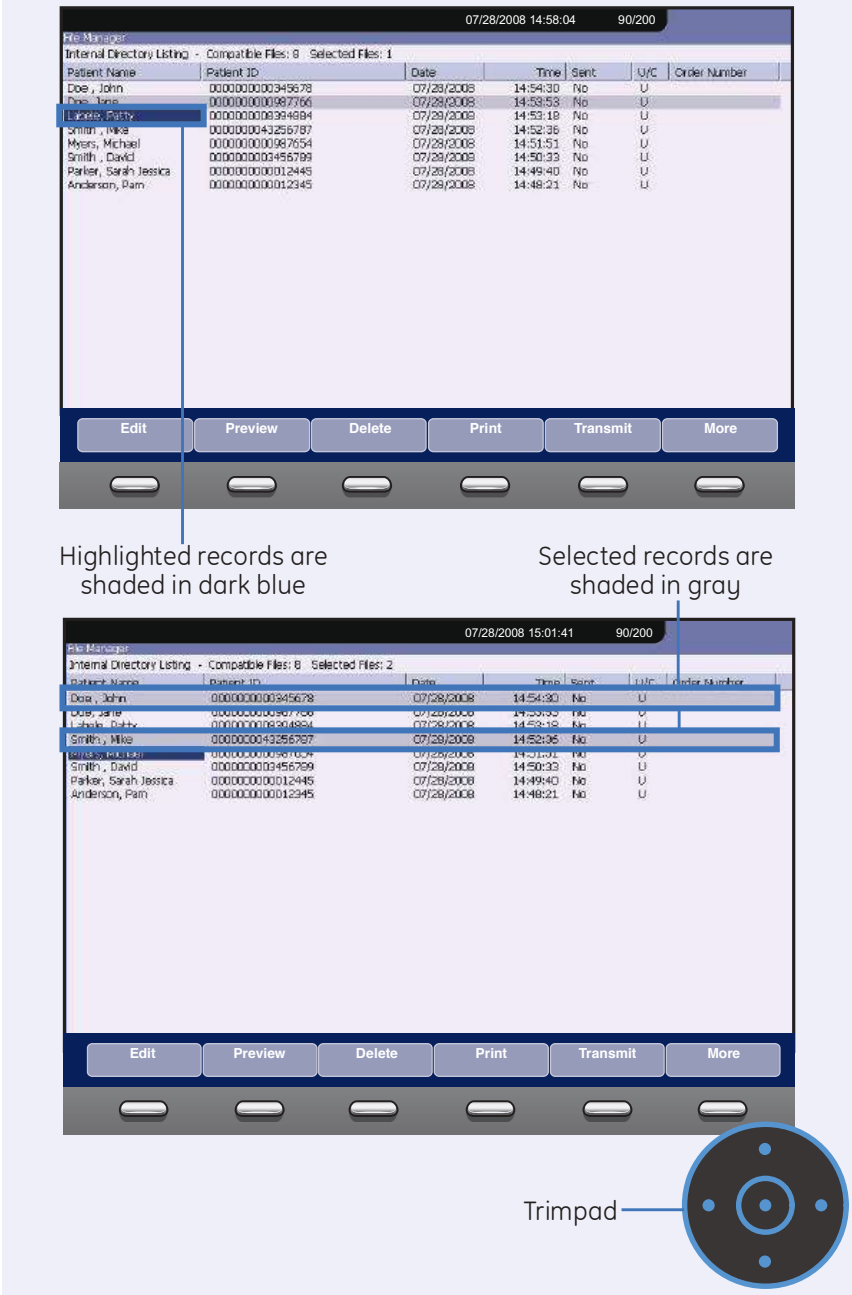
1. From ***Main Menu*** select ***File Manager***.
2. From File Manager you can select records to:
   - Edit
   - Preview
   - Delete
   - Print
   - Transmit
   - Import
   - Export

To Select All:

1. Select ***Select All.*** All records are selected.
2. Select the menu key of the desired function, such as ***Print.***

To Select Individual Records:

1. Select ***Select***.
2. Use the circles on the trimpad to highlight the record. Highlighted records are shaded in dark blue.
3. Select the middle of the trimpad to select the records. Selected records are then shaded in gray.
5. If needed, continue to select other records.
6. Select the menu key of the desired function, such as ***Print.***

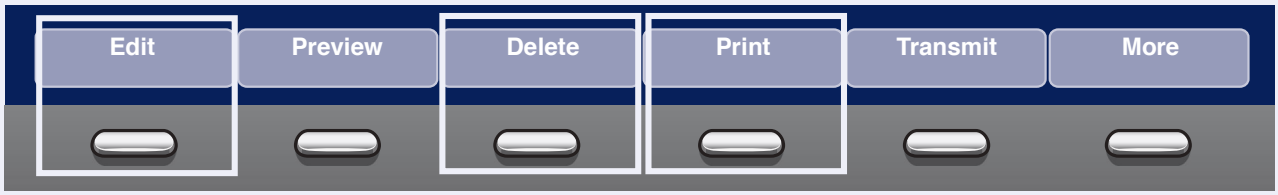


Tier 1 F Keys for File Manager

Select individual records

Select all records

Tier 2 F Keys for File Manager



Edit a record

Delete a record

Print the selected record(s)

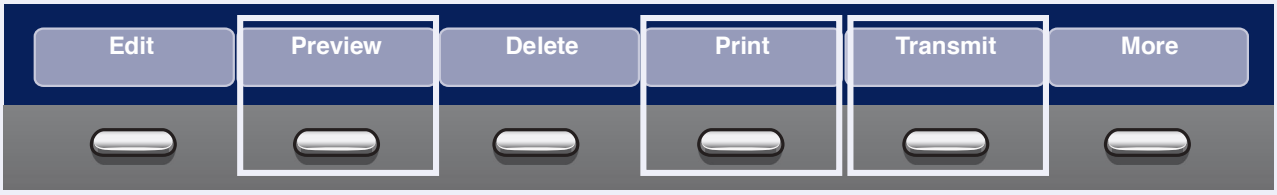
Edit Stored ECG Records

1. From Main Menu select ***File Manager***.
2. Select ***Select*** to highlight the individual record to edit. You may only select one record to edit at a time.
3. Select ***Edit*** to edit the selected record.
4. Use the keys on the Trimpad to select the Patient Information to be edited.
5. Edit the data as required.
6. Select ***Page Down*** to access other Test Information Windows
7. Edit the data as required.
8. Select ***Save*** to save edited fields and close the data window.
9. Highlight the record using the Trimpad and select ***Print*** to print the edited record.

Delete Stored ECG Records

1. From Main Menu select ***File Manager.***
2. Select ***Select*** to select individual records to delete. ***Select All*** to select all records.
3. Select ***Delete***.
4. A message will appear verifying whether you want to delete the selected record(s).
5. Select ***Yes*** to delete the record(s). Select ***No*** to cancel the delete function.

Tier 3 F Keys for File Manager



Print Stored ECG Records

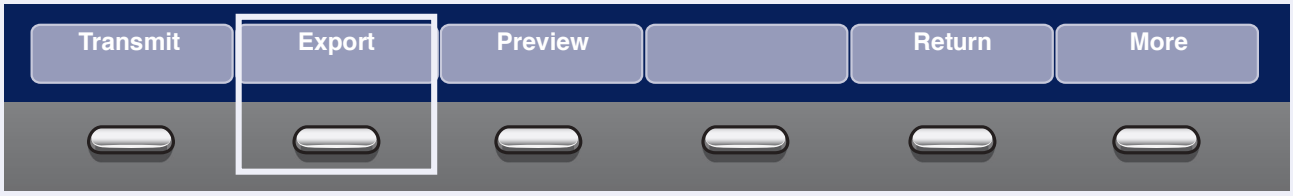
1. From Main Menu select the key for ***File Manager***.
2. Select ***Select*** to highlight an individual records to print. ***Select All*** to select all records.
3. Select ***Print*** to print the selected record(s) to the thermal printer.

Transmit Stored Records

1. From ***Main Menu*** select the key for ***File Manager.***
2. Select ***Print Directory*** to print a list of stored files
3. Select ***Select All*** to select all records to transmit or select ***Select t***o select individual records.
4. Select ***Transmit*** to transmit selected records.
5. One of two things will happen:
   - If only one location is defined, the file(s) will be transmitted to the default location.
   - If multiple locations are defined, select the desired location and select ***Ok.***

Preview Stored ECG Records

1. From the Main Menu select the key for ***File Manager***.
2. Select ***Select*** to highlight the record to preview.
3. Select ***Preview.***
4. The 12 lead display of the ECG record will be displayed.
5. Select ***Return*** to return to the File Manager main screen.

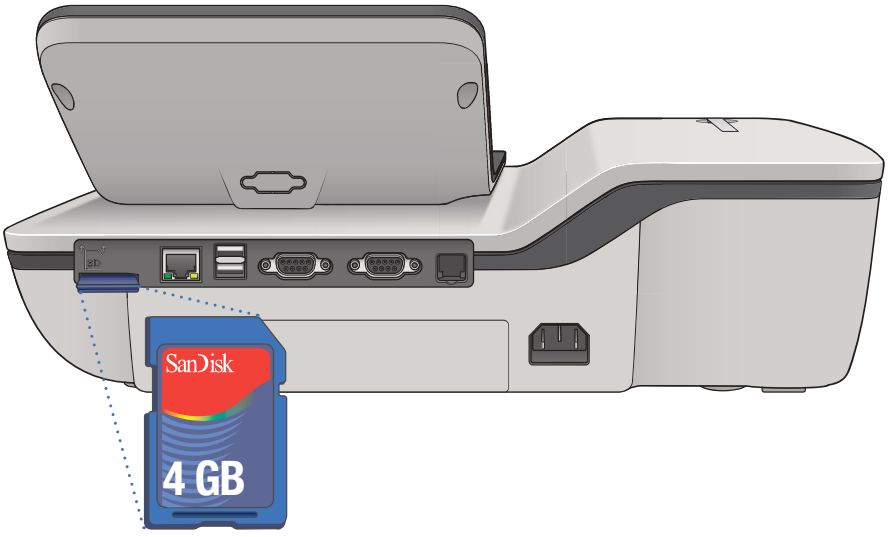


Export record(s)

Exporting to SD Card

1. Select ***Select*** to highlight individual records to export. ***Select All*** to select all records.

2. If you are exporting to an SD card, insert the card into the MAC 2000 SD Card Slot. Make sure the card has sufficient free space for the selected records and that it is not write protected. If there is no sufficient space on the SD card a message will appear indicating that.
3. Select **More**.
4. Select ***Export.*** The F keys change to allow you to select the format in which to export the data.
   - To export the data in XML, skip to step 5.
   - To export the data in PDF, proceed to step **8.**
5. To export the data in XML, select ***Hilltop XML***. One of two things happens:
   - If a shared directory was defined, a window opens for you to select the destination.



Skip to step **6.**

- If a shared directory was not defined, the selected records are exported to the SD card.

  A window opens to inform you of the export's progress. The window closes when the export is complete.

6. Do one of the following:
   - To export to the SD card, select SD Card in the window.
   - To export to the shared directory, select Shared Directory in the window.
7. Select ***OK.*** The selected records are exported to the selected destination. A window opens to inform you of the export's progress. The window closes when the export is complete.

Note! *When exporting to a shared directory, the MAC 2000 device logs on to the directory with the user name and password defined on the* ***Communications Setup*** *window. If either of those values are incorrect, you will receive an error message. Correct the user name and password on the* ***Communication Setup*** *window and repeat the export process.*

8. To export the data as a PDF, select ***PDF***.
9. Follow steps 6 through 7.

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2053535-065 Rev F

MAC™ 2000

Specification Sheet

Instrument type

Microprocessor augmented automatic electrocardiograph; 10-leadwire, 12-lead simultaneous acquisition with programmable lead configuration.

.Processing

ECG Interpretation	Marquette™ 12SL™ ECG Analysis Program for Adults and Pediatrics
Computerized measurements	12-lead analysis
ECG analysis frequency	500 or 1000 samples/second/channel
Digital sampling rate	16000 samples/second/channel for normal data acquisition
Pace sampling rate	75K samples/second/channel
ECG on-screen preview	On-screen preview of acquired 10 second ECG waveform
Acquisition mode	Provides 10 seconds of instantaneous ECG acquisition
Dynamic range	AC Differential ±5 mV, DC offset ±300 mV
Resolution	4.88 µV +/-1% per LSB @ 500 SPS
Frequency range	0.04 to 150 Hz
Low cut off frequency	0.04 Hz (ADS off), 0.56 Hz (ADS On)
High cut off frequency	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz
Common mode rejection	>135 dB (with 50/60 Hz filter ON)
Input impedance	>10MΩ @ 10 Hz
Patient leakage	<10µA (Normal Condition), <50µA (Single Fault Condition)
Lead detection	All disconnected lead detection except RL and RA
Heart rate meter	30 to 300 BPM
Operating system	Microsoft® Windows® Embedded Compact 7
Start-up time	Less than 30 seconds

Patient information

Supported patient information	Patient ID, secondary patient ID, visit ID, last name, first name, height, weight, gender, race, pacemaker patient, systolic BP, diastolic BP, location number, room, order number, phone number, medication, ordering physician, referring physician, attending physician, technician, test indication

Display

Display type	7 in. color TFT display with support of minimum 32K colors
Display resolution	WVGA resolution – 800 x 480
Display data	Heart rate, patient ID, clock, battery power indicator, waveforms, lead lables, speed, gain and filter settings, warning messages, prompts, help messages, and 12-lead display

Writer

Writer technology	Thermal dot array
Writer speed`	5, 12.5, 25, and 50 mm/s
Number of traces	Up to 12 ECG traces
Writer sensitivity/gain	2.5, 5, 10, 20, 40 mm/mV
Writer speed accuracy	5, 12.5 mm/s @ ±5% and 25, 50 mm/s @ ±2%
Writer amplitude accuracy	+/-5%

Writer resolution	Horizontal 40 dots/mm @ 25 mm/s, 8 dots/mm vertical
Paper type	Z-fold Thermal Paper with pre-printed grid and perforation with Queue mark or Queue hole
Paper size	8.46 in x 11 in (215 mm × 280 mm) Letter 8.27 in × 11.69 in (10 mm x 295 mm) A4 8.43 in x 11 in (214.2 mm x 279.4 mm) Modified Letter

Keyboard

Type	Membrane keyboard with tactile feedback – Soft function keys, alphanumeric keys (Qwerty key set), writer controls and Trim Pad cursor controls

Operating modes and additional features

Resting ECG mode	Records and prints 12-lead resting ECGs with 10 seconds duration as a standard feature
Arrhythmia mode	Continuously monitors ECG and prints report when arrhythmia events of the user-selected class occur
Exercise mode	Exercise mode for exercise stress testing
RR Analysis mode*	RR analysis for RR intervals analysis
Full Disclosure mode	Store upto 5 minutes of 1 lead data in PDF format
Hookup advisor	Provides visual indication of signal quality
Multi-language support	Supports 19 languages in User Interface and 31 languages in User Manual
Order manager	Provides an interface for managing orders
ADT and Order Query	Provides an interface for querying patient demographics and orders
File manager	Provides an interface for managing ECG Records
System setup	Provides an interface for managing Device Configuration

Stress/Pharma application options

Stress testing application	Ergometers supported include: eBike Treadmills supported include: T2100, T2000 Master's Step device without interface (acoustic signal only) *Note: Ergometer, Master Step, and Treadmill sold separately*
Pharma application options	• Date & Time Prompt upon log in • Auto Save and export to SD Card of Patient test record after acquisition • Audit trail export • CT Data Guard™ • High security login protection

External peripherals

Keyboard	Standard USB English Keyboard
Barcode reader	Jadak-1799
Barcode Symbologies	Code 39, Code 39EX, Code 128, PDF-417, Interleaved Code 2 of 5, Data Matrix
Special Characters	In Italian, French, German, English and Spanish Languages

Communication

- Secured Digital card, Serial, LAN, and WIFI communicates outbound to MUSE™ and CardioSoft™
- LAN, and WIFI communicates inbound to MUSE
- MUSE Cardiology Information System and CardioSoft® compatible
- Bi-directional communication enabled with integration capabilities to MUSE, EMR, DICOM and DICOM modality work list systems workflow

RS232 serial cable Protocol	ECG Transmission with A5 and CSI
Supported MUSE/CardioSoft	Compatible with MUSE V 7.1.1, v8.0.1, v9.0.0 and NX CardioSoft/CS V6.51, V6.61, V6.71, V6.73 and V7
RJ45 Wired LAN	ECG Transmission with CSI, DCP Protocol, FTPS and Shared Directory‡
Wireless LAN (WIFI)	ECG Transmission with CSI, DCP Protocol, FTPS and Shared Directory‡

WiFi Authentication Protocols

Wireless Bridge Option:	Open, Shared, WPA2 with pre-shared key, WPA/WPA2 Mixed Mode with pre-shared key, WPA2 with PEAP, WPA/WPA2 Mixed Mode with PEAP, WPA2 with EAP-TLS, WPA/WPA2 Mixed Mode with EAP-TLS, WPA2 with EAP-TTLS, WPA/WPA2 Mixed Mode with EAP-TTLS, WPA2 with EAP-FAST, WPA/WPA2 Mixed Mode with EAP-FAST, WPA2 with LEAP, WPA/WPA2 Mixed Mode with LEAP
Embedded Wireless Module:	• Open • Shared • WPA – PSK* • WPA2-PSK* • WPA/WPA2 with PEAP • WPA/WPA2 with TLS • WPA/WPA2 with TTLS

Certain network settings are required for WIFI authentication. To determine whether your network is compatible, please refer to the MAC2000 site survey document DOC2368090.

*Not available in some countries.

‡Shared Directory require WINS

WiFi Encryption

Wireless Bridge Options:	Disabled (for Open authentication), WEP (for Shared and Open authentications) TKIP (for WPA/WPA2 Mixed Mode authentications), AES (for WPA & WPA2 authentications)
Embedded Wireless Module:	• Disabled (For Open authentication) • WEP (For Shared and Open authentications) • TKIP (for WPA-PSK1, WPA2-PSK1, WPA2 authentications) • AES (for WPA-PSK1, WPA2-PSK1, WPA2 & WPA22 authentications)

Storage

ECG Storage Format	XML format, Hilltop format, PDF storage format
Storage Capacity	Internal storage of 100 or 200 ECGs

Accessories

ECG Cables/Leadwires	IEC/AHA Value 10LD Patient Cable/Leadwire 10-lead IEC/AHA Patient trunk cable IEC/AHA Leadwire set (ECG 10-L w/resist, Banana) IEC/AHA Set of leadwires (4mm connector, 10 leads, defibrillator proof)
ECG Adapter	IEC/AHA Kit Adapter, 10 set Banana Electrode Prep Pads, CLIP Universal GE 10/Pkg
Electrodes	ECG Electrode Clamp (Large, 4/set) ECG Electrode Bulb (6/set) Baby MAC electrodes Silver Mactrode Plus 1000/CASE Electrode Application System KISS 10-lead
Other accessories	Country specific power cords Z-fold Thermal Paper with pre-printed grid and perforation with Queue mark or Queue hole of size: • 8.46 in x 11 in (215 mm × 280 mm) Letter • 8.27 in × 11.69 in (210 mm x 295 mm) A4 • 8.43 in x 11 in (214.2 mm x 279.4 mm) Modified Letter • 150 sheets/pack, 1500 sheets/case USB data matrix barcode scanner Secure Digital High Capacity Card – 2GB/4GB/8GB/16GB/32GB

Electrical

Power supply	Internal AC/DC or battery operation

AC/DC operation specifications

Input voltage:	100 to 240 VAC ±10%
Input current:	Maximum 1.5A in voltage range 115 V to 230 V AC
Input frequency:	47 to 63 Hz

Battery specifications

Battery type:	Replaceable and rechargeable, Lithium Ion
Battery capacity:	14.54V nominal voltage @ 3.5 AH – 10% 150 single page resting ECG recordings or 6 Hours (typical) of continuous monitoring without printing, at a minimum.
Battery charge time:	Approximately 3.5 hours after low battery shut down (with device off) to 90% full capacity

Physical specification

Height	7.87 inches (200 mm)
Width	15.35 inches (390 mm)
Depth	Depth 12.99 inches (330 mm)
Weight	Approx. 11.02 lbs (5 kg) including battery, without paper

Environmental specification

Temperature	Operating: 50°F to 104°F (10°C to 40°C) Transport/storage: -104°F to 158°F (-40°C to 70°C)
Humidity	Operating: 20% to 95% RH non-condensing Transport/storage: 15% to 95% RH non-condensing
Pressure	Operating: 700 to 1060 hPA (Altitude range: 3010.9 to -381.9 meters Transport/storage: 500 to 1060 hPA (Altitude range: 5570 to -380 meters)

Safety and regulatory

- CE marking for Council Directive 93/42/EEC concerning medical devices
- EN 60601-1 (IEC 60601-1) Medical electrical equipment – Part 1: General Requirements for Safety
- IEC 60601-1-2 General Requirements for Safety Electromagnetic Compatibility
- IEC 60601-2-25 Safety of Electrocardiographs
- UL 60601-1: 2006 UL Standard for Safety Medical Electrical Equipment, Part 1: General Requirements for Safety
- CAN/CSA C22.2 No. 601.1 M90
- IEC 60601-1-6 General Requirements for Safety – Usability

[1] WPA-PSK and WPA2-PSK are personal authentication frameworks.

[2] WPA and WPA2 are enterprise authentication frameworks.

GE Healthcare
9900 Innovation Drive
Wauwatosa, WI 53226
U.S.A.

www.gehealthcare.com

MAC 2000 V1.1 SP7 onwards
DOC1303761 Rev 9

ATTESTATION / *CERTIFICATE* **N° 7550 rev. 22**
Délivrée à Paris le 17 mai 2021
Issued in Paris on May 17th, 2021

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité */ Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 DIRECTIVE 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Catégorie du(des) dispositif(s) */ Device(s) category*

Equipements de cardiologie et systèmes de surveillance de patients
Systèmes de surveillance clinique et systèmes de télémétrie médicale
Baie de cathétérisme et/ou d'électrophysiologie
Moniteurs cardiaques et leurs accessoires
Moniteurs de surveillance patient
Systèmes d'électrocardiographie et de surveillance de patients

Cardiology equipment and patient monitoring systems
Clinical Monitoring Systems and Medical Telemetry Systems
Catheterization and/or Electrophysiology lab System
Cardiology monitors and accessories
Patient monitors
Electrocardiographs and patient monitoring systems

Voir document complémentaire GMED */ See GMED additional document*
n° 38313

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P602818, P601202, le système d'assurance qualité – pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P602818, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification.

Début de validité / *Effective date :* **June 8th, 2021 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

GMED_b2p3_new2020-V0-04

GMED – 7550 rev. 22
Renouvelle le certificat 7550-21

Ce document complémentaire GMED n° 38313 rev. 1 atteste de la validité du certificat CE N° 7550 rev. 22 au regard des informations listées ci-dessous.

This GMED additional document n° 38313 rev. 1 attests to the validity of EC certificate N° 7550 rev. 22 with regard to the information listed below.

Fabricant / *Manufacturer:*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Patient monitor, Central unit	Central Station (CSCS)	IIb
Patient monitor module, multiparameter	Patient Data Module (PDM)	IIb
Patient monitor, multiparameter	B20	IIb
Patient monitor, multiparameter	B40	IIb
Patient Monitor, multiparameter	B105	IIb
Patient Monitor, multiparameter	B125	IIb
Patient Monitor, multiparameter	CARESCAPE ONE	IIb
Transportable physiologic monitoring system	V100	IIb
Telemetry system, electrocardiograph	ApexPro Telemetry System	IIb
Clinical monitoring systems	Unity Network ID	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	MacLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	CardioLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	ComboLab	IIb

GMED SAS GMED SAS
DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

GMED	0459

GMED - 38313 rev. 1
Renouvelle le document n° 38313 rev. 0

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	**Réf commerciale du dispositif ou code article** *Device commercial reference or article code*	**Classe du DM** *MD class*
Electrocardiograph, Holter analyzer	**Mars**	**IIa**
Electrocardiograph, Holter analyzer	**Mars SP4**	**IIa**
Information system software, application program, cardiology	**MUSE – SW Only**	**IIa**
Information system software, application program, cardiology	**CV Web**	**IIa**
ECG Acquisition module	**CAM 14V2**	**IIa**
ECG Acquisition module	**CAM HD**	**IIa**
Interpretive multichannel electrocardiograph	**MAC 2000**	**IIa**
Interpretive multichannel electrocardiograph	**MAC 600**	**IIa**
Interpretive multichannel electrocardiograph	**MAC VU360**	**IIa**
Stress exercise monitoring system, cardiac	**Case**	**IIa**
Stress exercise monitoring system, cardiac	**Cardiosoft / CS**	**IIa**
Stress exercise monitoring system, cardiac	**Cardiosoft / CS WIN8**	**IIa**
Electrocardiograph, Electrodes	**KISS**	**IIa**

Site couvert et Activités / *Location and Activities*

Site / *Location*	**Activités** / *Activities*
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC **8200 WEST TOWER AVENUE** **MILWAUKEE, WISCONSIN 53223 - USA**	**Siège social – responsable de la mise sur le marché** **Conception, fabrication et contrôle final** *Headquarters – legal manufacturer* *Design, manufacture and final control*

GMED 0459

GMED - 38313 rev. 1
Renouvelle le document n° 38313 rev. 0

DocuSigned by:
Lionel DREUX
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Lionel DREUX
Certification Director

Versa trolley

Biostimulation laser therapy
Electrotherapy
High power laser therapy
Magnetotherapy
Shockwave therapy
Ultrasound therapy

Features

product code	A-AM-AST-VSA
compatibility with ASTAR units / accessories	✓
running system with brakes	✓
shelves height adjustment (second, third and for CPEP applicators)	✓

General technical parameters

upper shelf load capacity	max 10 kg
total load capacity of the bottom shelf (with drawer and contents)	max 7 kg
bottom shelf adjustment range	approx. 60 cm
external dimension of the upper shelf (WxD)	58,0 x 34,0 cm
internal dimension of the upper shelf (WxD)	39,5 x 30,0 cm
external dimension of the bottom shelf (WxD)	40,0 x 26,0 cm
external dimension of the drawer (WxDxH)	39,0 x 33,0 x 9,0 cm
internal size of the drawer (WxDxH)	28,5 x 18,5 x 8,0 cm
trolley size (WxDxH)	58,0 x 49,0 x 87,5 cm
weight	13,9 kg

Dedicated for

Sonaris M	✓
Sonaris S	✓
Polaris 2	✓
Etius U	✓
Etius LM	✓
Etius ULM	✓
Polaris HP S	✓
Polaris HP M	✓
PHG 100A	✓
PHG 200A	✓

PHG 300A	✓
PHG 400C	✓
PHG 500I	✓
PHG 601C	✓
PHG 701C	✓
PHG 701I	✓
PhysioGo.Lite LASER	✓

EC DECLARATION OF CONFORMITY

TF – DOC1430163 (CE-M-201)

Following the provisions of the medical devices directive 93/42/EEC, ROHS directive 2011/65/EU and Radio Equipment Directive 2014/53/EU

EG-KONFORMITÄTSERKLÄRUNG

Entspreched der Anforderung der Medizin Produkte Richtlinie 93/42/EEC, der Richtlinie 2011/65/EU und radio - richtlinie richtlinie 2014/53/EU

We/ *Wir*

Manufacturer
Hersteller

GE Medical Systems
Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223, USA

EU Authorized Representative
Autorisierter EU-Vertreter

GE Medical Systems
Information Technologies GmbH
Munzingerstrasse 5
79111 Freiburg, Germany

Manufacturing site (if different from manufacturer)
Fertigungsstätte (falls anders als Hersteller)

Wipro GE Healthcare Private Limited
No. 4, Kadugodi Industrial Area
Bangalore 560067, Karnataka, India

GE Healthcare Finland OY
Kuortaneenkatu 2
Helsinki, FIN-00510, Finland

Critikon de Mexico S. de R.L. de C.V.
Calle valle del cedro 1551 Juarez Mexico 32575

Declare under our sole responsibility that the class **IIa** medical device:
*Erklären unter alleiniger Verantwortung, dass das Medizinprodukt der Klasse **IIa**:*

MAC 2000 ECG Analysis System

Ref. : see addendum/ *oder siehe Anhang*

GMDN Code: 16231

UMDNS Code: 11411

Classification rule (93/42/EC Annex IX) / *Klassifizierungsregel (93/42/EG Anhang IX)*: **Rule 10**

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
Auf das sich diese Erklärung bezieht, den Anforderungen der Richtlinie 93/42/EWG über Medizinprodukte, die für das Produkt gelten, und den Anforderungen der Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten entspricht.

This medical device conformity is based on the following elements:
Diese Medizinprodukte Konformität basiert auf den folgenden Elementen:

- Information included in the documents:
  Technical Documentation/DHF Ref./ réf: **DOC0851945**, of the product to which this declaration relates.
  Informationen, die in den Dokumenten enthalten sind:
  Technische Dokumentation/DHF-Ref./réf: **DOC0851945** des Produkts, auf das sich diese Erklärung bezieht.
- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by LNE/G-MED France, (NB #0459) / Certificate No. 7550.

  The medical device bears the mark

CE
0459

- *EG-Zertifikat:* Genehmigung *des kompletten Qualitätssicherungssystems (Anhang II der Richtlinie 93/42/EWG über Medizinprodukte), ausgestellt von G-MED France,* NB #0459 */ Zertifikat Nr.* 7550.

- List of harmonized standards applied for CE marking as in Appendix 1
  Liste der harmonisierten Normen, die für die CE-Kennzeichnung angewendet wurden in anhang 1.

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

We, manufacturer, declare under our sole responsibility that:

Wir. Hersteller, Erklären unter unserer alleinigen Verantwortung

MAC 2000 embedded with MSD45N WLAN module

To which this declaration relates is in conformity with the requirements of the Radio Equipment Directive 2014/53/EU which applies to it.
die erklärung bezieht, in übereinstimmung mit den anforderungen der funkgeräte richtlinie 2014/53/EU

This conformity is based on the following elements:
Diese Konformität basiert auf den folgenden Elementen:

- The device conforms to the Directive 2014/53/EU through Annex II-Internal Production Control.
  das gerät mit der richtlinie 2014 / 53 / eu über anhang ii- interne fertigungskontrolle
- List of standards applied for CE marking as in Appendix 2.
  Liste der Normen, die für die CE-Kennzeichnung angewendet wurden in anhang 2.

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Appendix 1/ *Anhang 1*

Relevant Standards*/ relevante normen*
EN 60601-1:2006/A1:2013 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2:2015 Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-2-25:2015 Medical Electrical Equipment - Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
EN 60601-1-6:2010+A1:2015 Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 62366-1:2015 Medical devices - Application of usability engineering to medical devices
EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes
EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN 1041:2008+A1:2013 Information supplied by the manufacturer with medical devices

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Appendix 2/ *Anhang 2*

Relevant Standards/ *relevante normen*
EN 300 328 V2.2.2 Wideband transmission systems;Data transmission equipment operating in the 2.4GHz ISM band and using wideband modulation techniques;Harmonised Standaed covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 893 V2.1.1 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
EN 301 489-1 V2.2.3 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
EN 301 489-17 V3.2.2 ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
EN 62311:2008 Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)
EN 60601-1-2:2007 Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
EN 60601-1:2006/A1:2013 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance

This EC declaration of conformity supersedes the previous declaration dated 28 October 2020

Diese EG-Konformitätserklärung ersetzt die vorherige Erklärung mit Datum vom 28 October 2020

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

ADDENDUM TO THE EC DECLARATION OF CONFORMITY
ERGÄNZUNG ZUR KONFORMITÄTSERKLÄRUNG

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
MAC 2000	2063587-001
Unit Options	
MAC 2000 UNIT	2063587-017
MAC 2000 KISS UNIT	2063587-018
MAC 2000 ECG Pharma	2063587-171
MAC 2000 UNIT with embedded wifi	2063587-223
MAC 2000 STRESS OPTION	
MAC 2000 STRESS	2063587-140
STARTER KIT SELECTION	
MAC 2000 STARTER KIT AHA VALUE REUSABLE	2063587-500
MAC 2000 STARTERKIT AHA MULTILINK WITH ECG CLIP	2063587-501
MAC 2000 STARTER KIT AHA MULTILINK WITH ADAPTER	2063587-503
MAC 2000 STARTER KIT IEC VALUE REUSABLE	2063587-504
MAC 2000 STARTER KIT IEC MULTILINK REUSABLE	2063587-505
MAC 2000 STARTER KIT IEC MULTILINK WITH ECG CLIP	2063587-506
MAC 2000 STARTER KIT IEC MULTILINK WITH ADAPTER	2063587-508
MAC 2000 STARTER KIT IEC MULTILINK REUSABLE	2063587-509
MAC 2000 STARTER KIT AHA VALUE WITH CLIP	2063587-510
MAC 2000 STARTER KIT IEC VALUE WITH CLIP	2063587-511
Language Options	
MAC 2000 ENG LANGUAGE NON-STRESS	2063587-019
MAC 2000 GER LANGUAGE NON-STRESS	2063587-020
MAC 2000 FRE LANGUAGE NON-STRESS	2063587-021
MAC 2000 SPA LANGUAGE NON-STRESS	2063587-022
MAC 2000 ITA LANGUAGE NON-STRESS	2063587-023
MAC 2000 JAP LANGUAGE NON-STRESS	2063587-024
MAC 2000 SWE LANGUAGE NON-STRESS	2063587-025
MAC 2000 DUT LANGUAGE NON-STRESS	2063587-026
MAC 2000 HUN LANGUAGE NON-STRESS	2063587-027
MAC 2000 RUS LANGUAGE NON-STRESS	2063587-028
MAC 2000 FIN LANGUAGE NON-STRESS	2063587-029
MAC 2000 CHI LANGUAGE NON-STRESS	2063587-030
MAC 2000 CZECH LANGUAGE NON-STRESS	2063587-031

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
Language Options (Continued)	
MAC 2000 POL LANGUAGE NON-STRESS	2063587-032
MAC 2000 NOR LANGUAGE NON-STRESS	2063587-033
MAC 2000 SLO LANGUAGE NON-STRESS	2063587-034
MAC 2000 BRA POR LANGUAGE NON-STRESS	2063587-035
MAC 2000 DAN LANGUAGE NON-STRESS	2063587-036
MAC 2000 KOR LANGUAGE NON-STRESS	2063587-037
MAC 2000 EURO POR LANGUAGE NON-STRESS	2063587-038
MAC 2000 CRO LANGUAGE NON-STRESS	2063587-039
MAC 2000 GRE LANGUAGE NON-STRESS	2063587-040
MAC 2000 TUR LANGUAGE NON-STRESS	2063587-041
MAC 2000 EST LANGUAGE NON-STRESS	2063587-042
MAC 2000 LIT LANGUAGE NON-STRESS	2063587-043
MAC 2000 ROM LANGUAGE NON-STRESS	2063587-044
MAC 2000 BUL LANGUAGE NON-STRESS	2063587-045
MAC 2000 SER LANGUAGE NON-STRESS	2063587-046
MAC 2000 EGYPT LANGUAGE NON-STRESS	2063587-141
MAC 2000 VENEZUELA-SPA LANGUAGE NON-STRESS	2063587-142
MAC 2000 MEXICO-SPA LANGUAGE NON-STRESS	2063587-143
MAC 2000 INDONESIA LANGUAGE NON-STRESS	2063587-144
MAC 2000 ARG-SPA LANGUAGE NON-STRESS	2063587-166
MAC 2000 VIT LANGUAGE NON-STRESS	2063587-177
MAC 2000 LATVIAN LANGUAGE NON-STRESS	2063587-179
MAC 2000 KAZAKH LANGUAGE NON-STRESS	2063587-182
MAC 2000 TAIWAN LANGUAGE NON-STRESS	2063587-184
MAC 2000 MALAYSIA LANGUAGE NON-STRESS	2063587-190
MAC 2000 Pharma Japan	2063587-172
MAC 2000 ENG LANGUAGE W/STRESS	2063587-047
MAC 2000 GER LANGUAGE W/STRESS	2063587-048
MAC 2000 FRE LANGUAGE W/STRESS	2063587-049
MAC 2000 SPA LANGUAGE W/STRESS	2063587-050
MAC 2000 ITA LANGUAGE W/STRESS	2063587-051
MAC 2000 JAP LANGUAGE W/STRESS	2063587-052
MAC 2000 SWE LANGUAGE W/STRESS	2063587-053
MAC 2000 DUT LANGUAGE W/STRESS	2063587-054
MAC 2000 HUN LANGUAGE W/STRESS	2063587-055
MAC 2000 RUS LANGUAGE W/STRESS	2063587-056
MAC 2000 FIN LANGUAGE W/STRESS	2063587-057
MAC 2000 CHI LANGUAGE W/STRESS	2063587-058
MAC 2000 CZECH LANGUAGE W/STRESS	2063587-059
MAC 2000 POL LANGUAGE W/STRESS	2063587-060

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
Language Options (Continued)	
MAC 2000 NOR LANGUAGE W/STRESS	2063587-061
MAC 2000 SLO LANGUAGE W/STRESS	2063587-062
MAC 2000 BRA POR LANGUAGE W/STRESS	2063587-063
MAC 2000 DAN LANGUAGE W/STRESS	2063587-064
MAC 2000 KOR LANGUAGE W/STRESS	2063587-065
MAC 2000 EURO POR LANGUAGE W/STRESS	2063587-066
MAC 2000 CRO LANGUAGE W/STRESS	2063587-067
MAC 2000 GRE LANGUAGE W/STRESS	2063587-068
MAC 2000 TUR LANGUAGE W/STRESS	2063587-069
MAC 2000 EST LANGUAGE W/STRESS	2063587-070
MAC 2000 LIT LANGUAGE W/STRESS	2063587-071
MAC 2000 ROM LANGUAGE W/STRESS	2063587-072
MAC 2000 BUL LANGUAGE W/STRESS	2063587-073
MAC 2000 SER LANGUAGE W/STRESS	2063587-074
MAC 2000 EGYPT LANGUAGE W/STRESS	2063587-145
MAC 2000 VENEZUELA-SPA LANGUAGE W/STRESS	2063587-146
MAC 2000 MEXICO-SPA LANGUAGE W/STRESS	2063587-147
MAC 2000 INDONESIA LANGUAGE W/STRESS	2063587-148
MAC 2000 ARG-SPA LANGUAGE W/STRESS	2063587-167
MAC 2000 VIT LANGUAGE W/STRESS	2063587-176
MAC 2000 LATVIAN LANGUAGE W/STRESS	2063587-178
MAC 2000 KAZAKH LANGUAGE W/STRESS	2063587-181
MAC 2000 TAIWAN LANGUAGE W/STRESS	2063587-183
MAC 2000 MALAYSIA LANGUAGE W/STRESS	2063587-191
Power Cord Selection	
MAC 2000 N AMERICAN POWERCORD	2063587-085
MAC 2000 EURO POWERCORD	2063587-086
MAC 2000 BRITISH POWER CORD	2063587-087
MAC 2000 ITALIAN POWER CORD	2063587-088
MAC 2000 AUSTRALIAN POWER CORD	2063587-089
MAC 2000 ISRAELI POWER CORD	2063587-090
MAC 2000 SWISS POWER CORD	2063587-091
MAC 2000 INDIAN POWER CORD	2063587-092
MAC 2000 CHINESE POWER CORD	2063587-093
MAC 2000 JAPANESE POWER CORED	2063587-094
MAC 2000 BRAZIL POWER CORD	2063587-095

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
Analysis Options	
MAC 2000 MEASUREMENT BY 12SL	2063587-096
MAC 2000 MEASUREMENT INTERPRETATION BY 12SL	2063587-097
MAC 2000 MEASUREMENT IINTERPRETATION ACITIPI BY 12SL	2063587-098
MAC 2000 MEASUREMENT BY HEART	2063587-099
MAC 2000 MEASUREMENT INTERP BY HEART	2063587-100
Storage And Export Options	
MAC 2000 INT STOR 100 – SDCD PDF/XML/HT	2063587-101
MAC 2000 INT STOR 200 – SDCD PDF/XML/HT	2063587-102
MAC 2000 INT STOR 100 – SDCD XML/HT	2063587-103
MAC 2000 INT STOR 200 – SDCD XML/HT	2063587-104
Workflow Executive Packages Options	
MAC2000 ADT – MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-150
MAC2000 ADT SIMP ORDRS – MUSE LAN SERL CONN – INT STOR 200 -SDCD PDF/XML/HT	2063587-151
MAC2000 ADT ADV ORDRS – MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-152
MAC2000 CARDIOSOFT LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-153
MAC2000 PC LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-154
MAC2000 MUSE LAN SERL CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-155
MAC2000 ADT – NON-MUSE LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-157
MAC2000 ADT SIMP ORDRS – NON-MUSE LAN CONN – INT STOR 200-SDCD PDF/XML/HT	2063587-158
MAC2000 ADT ADV ORDRS – NON-MUSE LAN CONN – INT STOR 200 – SDCD PDF/XML/HT	2063587-159
MAC2000 SIMP ORDRS - MUSE LAN SERL CONN - INT STOR 200-SDCD /XML/HT	2063587-160
MAC2000 SIMP ORDRS - MUSE LAN SERL CONN - INT STOR 100-SDCD /XML/HT	2063587-161
MAC2000 CARDIOSOFT LAN SERL CONN - INT STOR 200 - SDCD XML/HT	2063587-162
MAC2000 CARDIOSOFT LAN SERL CONN - INT STOR 100- SDCD XML/HT	2063587-163
MAC2000 MUSE LAN SERL CONN - INT STOR 200 - SDCD XML/HT	2063587-164
MAC2000 MUSE LAN SERL CONN - INT STOR 100- SDCD XML/HT	2063587-165
Pharma Workflow Option Pack	2063587-222
Pharma Workflow Option Pack 1 - Japan	2063587-221
WIFI CHNL 11 /Modem Option	
MAC 2000 WIFI BRIDGE CHANNEL 11	2063587-169

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

DOC1430161

Product Description ***Produktbezeichnung***	**Catalog Designation** ***Katalogbezeichnung***
WIFI CHNL 13 /Modem Option	
MAC 2000 MODEM	2063587-112
MAC 2000 WIFI BRIDGE CHANNEL 13	2063587-170
Pharma Options	
MAC 2000 AUDIT TRAIL EXPORT	2063587-122
MAC 2000 CT DATA GUARD	2063587-123
MAC 2000 PHARMA PKG	2063587-168
Barcode Options	
MAC 2000 ENG BARCODE	2063587-124
MAC 2000 GER BARCODE	2063587-125
MAC 2000 FRE BARCODE	2063587-126
MAC 2000 SPA BARCODE	2063587-127
MAC 2000 ITA BARCODE	2063587-128
MAC 2000 SWE BARCODE	2063587-129
MAC 2000 DUT BARCODE	2063587-130
MAC 2000 HUN BARCODE	2063587-131
MAC 2000 RUS BARCODE	2063587-132
MAC 2000 FIN BARCODE	2063587-133
MAC 2000 CZE BARCODE	2063587-134
MAC 2000 NOR BARCODE	2063587-135
MAC 2000 SLO BARCODE	2063587-136
MAC 2000 POR BARCODE	2063587-137
MAC 2000 DAN BARCODE	2063587-138
MAC 2000 BARCODE SW only	2063587-185
RR OPTION	
MAC 2000 RR ANALYSIS	2063587-106
FULL DISCLOSURE OPTION Optional	
MAC 2000 FULL DISCLOSURE	2063587-201
EMBEDDED WIRELESS OC	
MAC2000 EMBEDDED WIRELESS	2063587-174
MAC 2000 SW OPTION for EMBEDDED WIRELESS	2063587-224

March 15, 2021

Lee, Bush
Director, Regulatory Affairs, LCS MIC & DCAR

CERTIFICAT

CERTIFICATE OF REGISTRATION

N° 19645 rev. 13

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES - CRITIKON DE MEXICO S. de R.L. de C.V., Calle Valle del Cedro 1551, Juarez 32575 CHIHUAHUA MEXICO

pour les activités

for the activities

Fabrication et distribution de systèmes de monitorage patients, de systèmes de monitorage cardiaque, de systèmes d'enregistrement ECG d'effort, de manchettes pour mesure de pression sanguine et accessoires associés. Fabrication de systèmes de diagnostic par ultrasons. Remise à neuf de moniteurs de surveillance de patients et de système de cardiologie. (Voir addendum)

Manufacture and distribution of patient monitors, of cardiac monitoring devices, of stress cardiology ECG recording systems, of blood pressure cuffs and associated accessories. Manufacturing of ultrasound diagnostic systems. Remanufacturing of patient monitors and cardiology systems. (See addendum)

réalisées sur le(s) site(s) de

performed on the location(s) of

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES - CRITIKON DE MEXICO S. de R.L. de C.V.
Calle Valle del Cedro 1551 - Juarez - 32575 CHIHUAHUA - MEX
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES
465 Pan American Drive - Suite 11 - EL PASO, TEXAS 79907 - USA
GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES – CRITIKON DE MEXICO S. de R.L. de C.V.
Calle Valle del Cedro 1310 - Parque Industrial Intermex - Juarez - 32575 CHIHUAHUA - MEX

est conforme aux exigences des normes internationales

complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité */ Effective date :* **November 30th, 2020 (included)**
Valable jusqu'au */ Expiry date :* **November 29th, 2023 (included)**
Etabli le */ Issued on :* **November 19th, 2020**

DocuSigned by:
Lionel DREUX
A1080E08C60D47A...

Lionel DREUX
Certification Director

GMED N° 19645–13
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

Renouvelle le certificat 19645-12

GMED_SQ-F-V0-07-2018

Résumé des activités couvertes par le certificat
Summary of activities covered by the certificate

French version :
Fabrication, assemblage et distribution de systèmes de monitorage de patients, de systèmes d'acquisition, d'oxymètres de pouls, et de câbles et capteurs d'oxymétrie incluant : les accessoires pour l'ensemble des équipements.
Fabrication et distribution de manchettes utilisées pour la mesure de la pression sanguine, des tubulures, accessoires et kits.
Fabrication et configuration finale de systèmes de monitorage cardiaque, d'équipements de cardiologie invasive, de systèmes d'enregistrement ECG d'effort, de tapis roulant d'épreuve d'effort et d'accessoires.
Fabrication d'appareils ou systèmes de diagnostic par ultrasons.
Remise à neuf de moniteurs de surveillance de patients et de système de cardiologie.
Entreposage, distribution de systèmes de monitorage de patients, d'oxymètres de pouls, de systèmes d'enregistrement ECG d'effort, de tapis roulant d'épreuve d'effort et d'accessoires.
Fabrication de logiciels et kits de diagnostic pour la cardiologie et cardiologie invasive.
Entreposage, distribution de manchettes utilisées pour la mesure de la pression sanguine.

English version :
Manufacture, assembly and distribution of patient monitors, acquisition devices, oximetry monitors, and pulse oximetry cables and sensors including : accessories for all devices.
Manufacturing and distribution of blood pressure cuffs, hoses, accessories and kits.
Manufacturing and final configuration of cardiac monitoring, invasive cardiology devices, stress cardiology ECG recording systems, treadmills and accessories.
Manufacturing of ultrasound diagnostic devices or systems.
Remanufacturing of patient monitors and cardiology systems.
Warehousing, distribution of patient monitors, oximetry monitors, stress cardiology ECG recording systems, treadmills and accessories.
Manufacturing of Diagnostic Cardiology and Invasive Cardiology Software and Kits.
Warehousing, distribution of blood pressure cuffs.

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

Ce certificat couvre les activités et les sites suivants :
This certificate covers the following activities and sites :

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES – CRITIKON DE MEXICO S. de R.L. de C.V.
Calle Valle del Cedro 1551
Juarez
32575 CHIHUAHUA - MEXICO

French version :
Fabrication, assemblage et distribution de systèmes de monitorage de patients, de systèmes d'acquisition, d'oxymètres de pouls, et de câbles et capteurs d'oxymétrie incluant : les accessoires pour l'ensemble des équipements.
Fabrication et distribution de manchettes utilisées pour la mesure de la pression sanguine, des tubulures, accessoires et kits.
Fabrication et configuration finale de systèmes de monitorage cardiaque, d'équipements de cardiologie invasive, de systèmes d'enregistrement ECG d'effort, de tapis roulant d'épreuve d'effort et d'accessoires.
Fabrication d'appareils ou systèmes de diagnostic par ultrasons.
Remise à neuf de moniteurs de surveillance de patients et de système de cardiologie.

English version :
Manufacture, assembly and distribution of patient monitors, acquisition devices, oximetry monitors, and pulse oximetry cables and sensors including : accessories for all devices.
Manufacturing and distribution of blood pressure cuffs, hoses, accessories and kits.
Manufacturing and final configuration of cardiac monitoring, invasive cardiology devices, stress cardiology ECG recording systems, treadmills and accessories.
Manufacturing of ultrasound diagnostic devices or systems.
Remanufacturing of patient monitors and cardiology systems.

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES
465 Pan American Drive
Suite 11
EL PASO, TEXAS 79907 - USA

French version :
Entreposage, distribution de systèmes de monitorage de patients, d'oxymètres de pouls, de systèmes d'enregistrement ECG d'effort, de tapis roulant d'épreuve d'effort et d'accessoires.
Fabrication de logiciels et kits de diagnostic pour la cardiologie et cardiologie invasive.

English version :
Warehousing, distribution of patient monitors, oximetry monitors, stress cardiology ECG recording systems, treadmills and accessories.
Manufacturing of Diagnostic Cardiology and Invasive Cardiology Software and Kits.

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES – CRITIKON DE MEXICO S. de R.L. de C.V.
Calle Valle del Cedro 1310
Parque Industrial Intermex
Juarez
32575 CHIHUAHUA - MEXICO

French version *:*
Entreposage, distribution de manchettes utilisées pour la mesure de la pression sanguine.

English version :
Warehousing, distribution of blood pressure cuffs.

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

Electronic Signature Information

Name	DOC0279260
Revision	23
Type	Controlled Document
Title	Tower Avenue_EC Certificate
Reason For Change	Updated certificate
Originator	212028045_shari__hess
Release Date	03/12/2020 07:06:56 PM
Obsolete Date	

File Name	File Description	File Size (Bytes)
MMA MGR BLY 845 20.pdf	MMA MGR BLY 845 20	135621
7550-20 signe.pdf	7550-20 signe	40416

Route	Signer	Function	Status	Comments	Completion Date
R-9693838	212007407_robert__triscari		Approve		12 Mar 2020 19:06:55 GMT
R-9693838	212028045_shari__hess		Approve	Approved Without Comments	12 Mar 2020 18:36:41 GMT

Periodic Review

There are no signatures or routes related to this business object.

Obsolesence Approval

There are no signatures or routes related to this business object.

* Printed versions are For Reference Only *
+ Indicates a task was reassigned from an original assignee

Released

GMED
GROUPE LNE

ATTESTATION / *CERTIFICATE* **N° 7550 rev. 20**
Délivrée à Paris le 6 mars 2020
Issued in Paris on March 6th, 2020

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système Complet d'Assurance Qualité / *Approval of full Quality Assurance System*
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 DIRECTIVE 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / *Manufacturer*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 West Tower Avenue
MILWAUKEE, WISCONSIN 53223 UNITED STATES

Catégorie du(des) dispositif(s) / *Device(s) category*

Equipements de cardiologie et systèmes de surveillance de patients
Systèmes de surveillance clinique et systèmes de télémétrie médicale
Baie de cathétérisme et/ou d'électrophysiologie
Moniteurs cardiaques et leurs accessoires
Moniteurs de surveillance patient
Systèmes d'électrocardiographie et de surveillance de patients

Cardiology equipment and patient monitoring systems
Clinical Monitoring Systems and Medical Telemetry Systems
Catheterization and/or Electrophysiology lab System
Cardiology monitors and accessories
Patient monitors
Electrocardiographs and patient monitoring systems

Voir détails sur addendum / *See attachment for additional information*

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P178961, P601202, le système d'assurance qualité – pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P178961, P601202, the quality system - for design, manufacturing and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4.

La validité du présent certificat est soumise à une vérification périodique ou imprévue.
The validity of the certificate is subject to periodic or unexpected verification.

Début de validité / *Effective date :* **January 7th, 2020 (included)**
Valable jusqu'au / *Expiry date :* **May 26th, 2024 (included)**

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED – 7550 rev 20
Annule et remplace le certificat 7550-19

GMED_1d23-F- V0-07-2018

GMED GROUPE LNE

Addendum à l'attestation N° 7550 rev. 20 page 1 / 2
Addendum of the certificate N° 7550 rev. 20
Dossier / *File* N° P178961, P601202

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Produit *Product* Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Patient monitor, Central unit	Central Station (CSCS)	IIb
Patient monitor module, multiparameter	Patient Data Module (PDM)	IIb
Patient monitor, multiparameter	B20	IIb
Patient monitor, multiparameter	B40	IIb
Patient Monitor, multiparameter	B105	IIb
Patient Monitor, multiparameter	B125	IIb
Patient Monitor, multiparameter	CARESCAPE ONE	IIb
Transportable physiologic monitoring system	V100	IIb
Telemetry system, electrocardiograph	ApexPro Telemetry System	IIb
Clinical monitoring systems	Unity Network ID	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	MacLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	CardioLab	IIb
Cardiac Catheterization monitoring system, Cardiac electrophysiology analysis system	ComboLab	IIb

GMED 0459

On behalf of the President
Béatrice LYS
Technical Director

GMED GROUPE LNE

Addendum à l'attestation N° 7550 rev. 20 **page 2 / 2**
Addendum of the certificate N° 7550 rev. 20
Dossier / *File* N° P178961, P601202

Identification des dispositifs / *Identification of devices*

Désignation du dispositif / Accessoires marqués CE *Device designation / CE marked accessories*	Produit *Product* Réf commerciale du dispositif ou code article *Device commercial reference or article code*	Classe du DM *MD class*
Electrocardiograph, Holter analyzer	Mars	IIa
Electrocardiograph, Holter analyzer	Mars SP4	IIa
Information system software, application program, cardiology	MUSE – SW Only	IIa
Information system software, application program, cardiology	CV Web	IIa
ECG Acquisition module	CAM 14V2	IIa
ECG Acquisition module	CAM HD	IIa
Interpretive multichannel electrocardiograph	MAC 2000	IIa
Interpretive multichannel electrocardiograph	MAC 600	IIa
Interpretive multichannel electrocardiograph	MAC VU360	IIa
Stress exercise monitoring system, cardiac	Case	IIa
Stress exercise monitoring system, cardiac	Cardiosoft / CS	IIa
Stress exercise monitoring system, cardiac	Cardiosoft /CS WIN8	IIa
Electrocardiograph, Electrodes	KISS	IIa

Identification du site couvert et des activités / *Identification of location and activities*

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC - 8200 WEST TOWER AVENUE - MILWAUKEE, WISCONSIN 53223 - USA
Siège social – responsable de la mise sur le marché
Conception, fabrication et contrôle final
Headquarters – legal manufacturer
Design, manufacture and final control

GMED 0459

On behalf of the President
Béatrice LYS
Technical Director

GMED
LNE GROUP

GE HMEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223
USA

To the attention of Mr Bob TRISCARI

Paris, March 6th, 2020

Registered Mail with Return Receipt

Certification Project Manager : Michel GREC
Tel. : + 33 1 40 43 39 35
Fax : + 33 1 40 43 37 37
E-mail: michel.grec@lne-gmed.com

Re : EC certificate
Ref. : MMA/MGR/BLY/845/2020

Dear Mr TRISCARI,

After receipt of our letter referenced MMA/MGR/BLY/049/2020 dated January 7th, 2020, further to your e-mails of March 3rd, 2020 and according to your request to restore only the CE marking of the product "B20" with GMED SAS due to a miss communication by your company, we notify you the continuation of the product B20 on your EC certificate N° 7550 according to the annex II excluding section 4 of the directive 93/42/EEC.

You will find attached the EC certificate N° 7550 rev 20 duly modified.

Furthermore, we remind you that following the "Code de la Santé Publique" – articles R 5211-12 and R5211-17 - which transposes the European Directives into French law, it is your responsibility to assure that only medical devices which are in compliance with requirements specified in these articles can bear the CE mark and can be put on the European market.

Yours sincerely,

Béatrice LYS
Technical Director

Encs. : 1 EC certificate N° 7550 rev. 20 and its addendum (2 pages)

Electronic Signature Information

Name	DOC0271556
Revision	18
Type	Controlled Document
Title	Tower Avenue_ISO 13485 2016
Reason For Change	Issued ISO 13485 2016
Originator	212028045_shari__hess
Release Date	06/08/2021 12:38:02 PM
Obsolete Date	

File Name	File Description	File Size (Bytes)
ISO 13485 34389-2.pdf	ISO 13485 34389-2	1398809

Route	Signer	Function	Status	Comments	Completion Date
R-10124910	212028045_shari__hess		Approve	Approved as a Task Assignee	8 Jun 2021 12:38:00 GMT

Periodic Review

There are no signatures or routes related to this business object.

Obsolesence Approval

There are no signatures or routes related to this business object.

* Printed versions are For Reference Only *
+ Indicates a task was reassigned from an original assignee

Released

CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 34389 rev. 2

GMED certifie que le système de management de la qualité développé par

GMED certifies that the quality management system developed by

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC

8200 WEST TOWER AVENUE
MILWAUKEE, WISCONSIN 53223 UNITED STATES

pour les activités
for the activities

Conception et fabrication de systèmes de surveillance de patients, de brassards pour la mesure de la pression sanguine, d'électrodes et d'équipements d'enregistrement de l'ECG et d'analyse.

Design and manufacture of patient monitoring devices, blood pressure cuffs, electrodes, and cardiology ECG recording and analysis devices.

réalisées sur le(s) site(s) de
performed on the location(s) of

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC
8200 WEST TOWER AVENUE - MILWAUKEE, WISCONSIN 53223 - USA

est conforme aux exigences des normes internationales
complies with the requirements of the international standards

ISO 13485 : 2016

Début de validité */ Effective date* **June 8th, 2021 (included)**
Valable jusqu'au */ Expiry date :* **June 7th, 2024 (included)**
Etabli le */ Issued on :* **May 17th, 2021**

DocuSigned by:
Lionel DREUX
A1D80E08C60D47A...

Lionel DREUX
Certification Director

GMED N° 34389–2
Ce certificat est délivré selon les règles de certification GMED / This certificate is issued according to the rules of GMED certification

Renouvelle le certificat 34389-1

Accréditation n°4-0608
Liste des sites accrédités et portée disponible sur www.cofrac.fr

GMED_SQRS-V5-05-2013

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 60146867 0001
Organization:	GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA
Scope:	Design, Development, and Manufacture of Patient Monitoring Systems, Cardiology ECG Recording and Analysis Systems, Invasive Cardiology Equipment Systems and Medical Software

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	32090997.003
Effective date:	2020-08-12
Expiry date:	2023-03-11
Issue date:	2020-08-12

TÜV Rheinland LGA Products GmbH

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Balazs Bozsik
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60131555 0001

Report No.: 21198147 012

Manufacturer:
getemed Medizin- und
Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Products:
Vital signs monitors, cardiac function diagnostic
and telemonitoring systems
(see attachment for products and sites included)

Replaces Approval, Registration No.: HD 60088821 0001

Expiry Date: 2023-10-03

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-10-04

Date: 2018-08-02

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

Doc. 1/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60131555 0001
Report No.: 21198147 012

Manufacturer:
getemed Medizin- und Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Products included:

Recorder, Long-term ECG portable
- CardioMem® and SEER

Long-term ECG evaluation system
- CardioDay®

Electrocardiograph, multi channel
- CardioLink®

Pulse oximeter, physiological monitoring system, neonatal
- VitaGuard® with VitaWin®

ECG-monitor, telemetric
- PhysioMem®

Date: 2018-08-02

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Dipl.-Ing. I. Munkler

TÜVRheinland®

Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60131555 0001
Report No.: 21198147 012

Manufacturer: getemed Medizin- und Informationstechnik AG
Oderstr. 77
14513 Teltow
Deutschland

Sites included:

getemed Medizin- und Informationstechnik AG
Oderstr. 77, 14513 Teltow, Germany

getemed Medizin- und Informationstechnik AG
Otto-Schmerbach-Straße 19, 09117 Chemnitz, Germany

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Dipl.-Ing. I. Munkler

Date: 2018-08-02

GE Healthcare

MAC™ 2000 ECG Analysis System
Operator's Manual

Software Version 1.1
2053535-002 Revision C

English

Publication Information

The information in this manual applies only to MAC™ 2000 Version 1.1. It does not apply to earlier product versions. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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

CE 0459

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	Comments
A	17 October 2012	Internal Release
B	24 April 2013	Customer Release
C	15July 2013	Revisions per SPR HCSDM00204349 relating to IEC 3rd Edition labeling, and SPR HCSDM00222909.

To access other GE Healthcare Diagnostic Cardiology manuals, go to the Common Documentation Library (CDL), located at www.gehealthcare.com/documents, and click ***Cardiology***.

To access Original Equipment Manufacturer (OEM) manuals, go to the device manufacturer's Web site.

Contents

11 Managing Internal Storage

12 System Configuration

1

Introduction

This document describes the ***MAC™ 2000 ECG Analysis System***, also referred to as the "product", "system", or "device". The document is intended to be used by clinical professionals who use, maintain, and/or troubleshoot the system. Clinical professionals are expected to have a working knowledge of appropriate medical procedures, practices, and terminology used in the treatment of patients.

This chapter provides general information required for the proper use of the system and this manual. Familiarize yourself with this information before using the system.

Intended User of this Product

The *MAC™ 2000 ECG Analysis System* is a portable ECG acquisition, analysis, and recording system that is intended for use 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.

Indications for Use

The *MAC™2000 ECG Analysis System* is a portable device intended to be used by or under the direct supervision of a licensed healthcare practitioner using surface electrodes to acquire, analyze, display, and record information for adult and pediatric populations in a hospital, medical professional's facility, clinics, physician's office or outreach centers.

NOTE:
Pediatric populations are defined as patients between the ages of 0 and 15 years.

The *MAC™2000 ECG Analysis System* provides the following modes of operation:

- Resting ECG mode
- Arrhythmia mode
- Exercise mode for exercise stress testing (optional)
- RR analysis mode for RR interval analysis (optional)

The basic system prints 6 or 12 leads of ECG and is upgradeable to provide software options such as 12-lead ECG measurement and interpretive analysis.

Arrhythmia detection is provided for the convenience of automatic documentation. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

Contraindications

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

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

Prescription Device Statement

CAUTION:
United States federal law restricts this device to sale by or on the order of a physician.

Regulatory and Safety Information

This section provides information about the safe use and regulatory compliance of this system. Familiarize yourself with this information, and read and understand all instructions before attempting to use this system. The system software is considered medical software. As such, it was designed and manufactured to the appropriate medical regulations and controls.

NOTE:
Disregarding the safety information provided in this manual is considered abnormal use of this system and could result in injury, data loss, or a voided warranty.

Safety Conventions

A **Hazard** is a source of potential injury to a person, property, or the system.

This manual uses the terms DANGER, WARNING, CAUTION, and NOTICE to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with the following definitions and their significance.

Definitions of Safety Conventions

Safety Convention	Definition
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.

Definitions of Safety Conventions (cont'd.)

Safety Convention	Definition
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.

Safety Hazards

The following messages apply to the system as a whole. Specific messages may also be provided elsewhere in the manual.

WARNING:

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. Refer servicing to authorized service personnel.

WARNING:

PATIENT INJURY–STRANGULATION — Cables present a possible strangulation hazard.

To avoid possible strangulation, route all cables away from the patient's throat. Use a short version of cable for pediatric patients.

WARNING:

PERSONAL INJURY–STUMBLING HAZARD— Patients can become entangled in the cables and leadwires connected to the device, which could cause the patient to stumble or trip.

Route cables and leadwires in a way to avoid creating a stumbling hazard: keep them off the floor, and route leadwires away from the patient's legs and the healthcare provider's work area.

WARNING:

MAGNETIC AND ELECTRICAL INTERFERENCE — Magnetic and electric fields can interfere with the acquisition of ECG readings.

Make sure that all peripheral components operated in the vicinity of the device comply with the relevant EMC requirements. X-ray equipment, MRI devices, radio systems (cellular phones) and so forth, are possible sources of interference because they may emit higher levels of electromagnetic radiation. Verify the performance of the system before use.

WARNING:

EXPLOSION HAZARD — Using this device in the presence of anesthetic vapors or liquids can cause explosions.

Do not use this device in the presence of anesthetic vapors or liquids. Only persons with adequate training in the correct use of this device may use this device.

WARNING:
EQUIPMENT FAILURE — Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge blocks acquisition of the ECG signal.

Whenever patient defibrillation is a possibility, use non-polarizing electrodes (silver-silver chloride construction) for ECG monitoring.

WARNING:
PERSONAL INJURY— Contact with patients during defibrillation can cause serious injury or death.

Do not contact patients during defibrillation. Patient signal inputs labeled with the CF and BF 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:
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:
POOR SIGNAL QUALITY — Improper skin preparation can cause poor signal quality during the ECG recording.

Careful skin preparation is the key to an interference-free ECG.

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:
EXPLOSION HAZARD — Batteries may explode in fires

Do not dispose of the battery by fire. Follow local environmental guidelines concerning disposal and recycling.

WARNING:
ELECTRIC SHOCK HAZARD/SYSTEM MALFUNCTION Liquids inside a device can cause electric shock or system malfunction.

Do not allow liquids to enter the device. If liquids enter the device, turn it off and inform your service technician. Do not use the device until it is checked by a service technician.

WARNING:

ELECTRIC SHOCK — Improper connection of this equipment may cause electric shock.

To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

NOTE:

Follow the instructions provided. Do not position equipment in a way that makes it difficult to disconnect the device when using an appliance coupler, mains plug, or other separable plug as a means of isolation.

Classification of Medical Device

The device is classified as follows, according to IEC 60601-1:

Medical Device Classifications

Category	Classification
Type of protection against electrical shock	Class I internally powered equipment
Degree of protection against electrical shock	Type CF defibrillation-proof applied part
Degree of protection against solids	The IP code for this device is IP20. Protected against solid foreign objects with a diameter of 12.5 mm and greater The object probe, a sphere 12.5 mm diameter, shall not fully penetrate. The jointed test finger 12 mm diameter, 80 mm length, shall have adequate clearance from hazardous parts.
Degree of protection against harmful ingress of liquids (IP20)	The IP code for this device is IP20. Non-protected This device is ordinary equipment (enclosed equipment without protection against ingress of liquids)
Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or with nitrous oxide
Method(s) of sterilization or disinfection recommended by the manufacturer	Not applicable
Mode of operation	Continuous operation

Certification Information

Medical Equipment

With respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601–1, and CAN/CSA C22.2 NO. 601.1.

Recording ECGs During Defibrillation

This equipment is protected against the effects of cardiac defibrillator discharge to ensure recovery, as required by test standards. The patient signal input of the acquisition module is defibrillation-proof. Therefore, 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 might be necessary, use non-polarizing electrodes (which do not form a DC offset voltage when subjected to a DC current) such as silver/silver-chloride types.

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 ratings 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 reference guide for this system for a list of approved electrodes.

Accuracy of Input Signal Reproduction

- Overall System Error meets AAMI EC11 3.2.7.1 requirements. Overall System Error is between or within ±5% or ±40 µV, whichever is greater.
- Frequency Response meets AAMI EC11 3.2.7.2 requirements, using testing methods A and D. Frequency response is between or within ±10% between 0.67 and 40 Hz and between +0 and -10% for 20 ms, 1.5 mV triangular input.

Modulating Effects in Digital Systems

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.

EMI/EMC/RF Safety Information

This system is designed and tested to comply with applicable regulations regarding EMC and must be installed and put into service according to the EMC information stated in the Electromagnetic Compatibility appendix of the Service and/or Operator's manual. Changes or modifications to this system not expressly approved by GE Healthcare could cause EMC issues with this or other equipment.

Before installing or using the device or system, be aware of the proximity of known RF sources, such as the following:

- Radio and TV stations
- Portable and mobile RF communication devices (cell phones, two-way radios)
- X-ray, CT, or MRI devices
  These devices are also possible sources of interference as they may emit higher levels of electromagnetic radiation.

WARNING:
EQUIPMENT MALFUNCTION/INTERFERENCE — Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Do not use portable phones or other electronic equipment that may emit radio frequency (RF) near this system.

WARNING:
EQUIPMENT MALFUNCTION/INTERFERENCE — Do not use the equipment or system adjacent to, or stacked with, other equipment.

If adjacent or stacked use is necessary, test the equipment or system to verify normal operation in the configuration in which you are using it.

WARNING:
ACCESSORIES/COMPONENTS — Adding accessories or components, or modifying the medical device or system, may result in increased EMISSIONS or decreased IMMUNITY of the device or system.

Use the following resources for more information on EMI/EMC and RF concerns:

- The Supplies and Accessories Reference Guide for your system
- Qualified GE Healthcare or approved third-party personnel
- The Electromagnetic Compatibility appendix in your system service or operator's manual

Biocompatibility

The parts of the system described in this manual that come into contact with the patient during the intended use, including all accessories, fulfill the biocompatibility requirements of the applicable standards. If you have questions in this matter, contact your GE Healthcare representative.

Legal Notice

GE Healthcare software contains several fields that can be filled in before performing an ECG. Some of these fields are required, while others are optional and left to the user to assess whether they are needed to perform the exam. The field ***Race*** is one of these optional fields. ***Race*** has been acknowledged by the medical profession as useful to analyze some pathologies. You should be aware that, in some jurisdictions, the processing of data revealing an individual's racial origin is subject to legal requirements, such as obtaining the patient's prior consent. If you elect to collect this type of data, it is your responsibility to ensure that you comply with all applicable legal requirements.

Supplies and Accessories

You should use only supplies and accessories that GE Healthcare recommends. For a list of recommendations, refer to the supplies and accessories reference guide for this system

Contact GE Healthcare before using anything that is not recommended for this system.

Responsibility of the Manufacturer

GE Healthcare is responsible for the safety, reliability, and performance of hardware supplied by GE Healthcare only if the following conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are performed by persons authorized by GE Healthcare.
- The electrical installation of the room where the device is used complies with the requirements of the appropriate local, state, and other government regulations.
- The equipment is used in accordance with the instructions for use.

Responsibility of the Purchaser/Customer

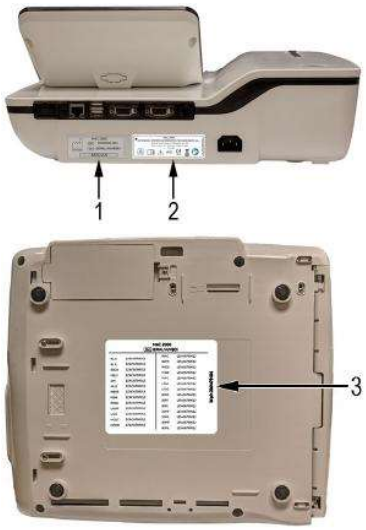
The customer is responsible for providing appropriate desks, chairs, electrical wall outlets, network connections, and analog phone lines, and for locating any of the system components described in this manual in compliance with all local, state, and national codes.

Product and Packaging Information

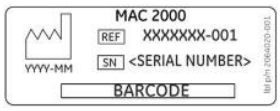
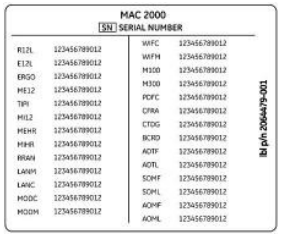
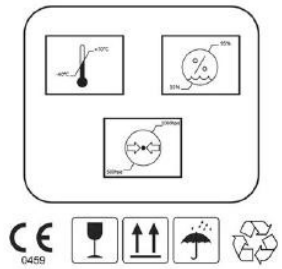
This section identifies the following:

- Hardware labels and their locations on page 16
- Symbol Descriptions on page 17

Hardware Label Locations



Label Descriptions on Hardware and Packaging

Item	Label	Location	Description
1		Back of the device	Product Label Identifies this device. See "Product Label" on page 25 for a description of the label contents.
2		Back of the device	Device Address Label and Rating Plate It provides regulatory and cautionary information. See "Device Address Label and Rating Plate" on page 26 for an explanation of the label.
3		Bottom cover of the device	The Option Code label. Use the option codes to setup the purchased options in your system. See "Options Setup" on page 153 for an explanation of the Option Codes.
4		On the shipping package	Environmental symbols required for shipping.
5		On the shipping package	Battery Shipping Label. FRAGILE—Lithium Ion batteries can cause fire if damaged.
6		On the shipping package	The shipping label.

Symbol Descriptions

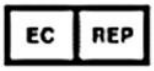
The following table describes symbols or icons that may be on the device or its packaging. Not all of the symbols defined in the table apply to your device or its packaging.

Symbols are used to convey warnings, cautions, prohibitions, mandatory actions, or information. Any symbol on your device or packaging with markings in color indicates there may be a danger, warning, or mandatory action. Any symbol on your device or packaging that is in black and white provides additional information or may

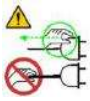
indicate a caution. Familiarity with these symbols assists in the use and disposal of the equipment.

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

Symbol Descriptions

Symbol	Description
	**Catalog or Orderable Part Number** Indicates the manufacturer's catalog or part number.
	**Serial Number** Indicates the manufacturer's serial number.
	**Batch Code or Lot Number** Indicates the manufacturer's batch code or lot number.
	**Date of Manufacture** (Year-Month) Indicates the original manufacture date for this device.
	**Manufacturer** Indicates 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** Indicates the name and address of the authorized representative in the European Community for this device.
Rx Only	**Rx Only** US Federal law restricts this device to sale by or on the order of a physician.
	**12SL** Indicates the device uses the Marquette™ 12SL ECG Analysis Program to analyze and interpret ECG readings.
IPxy	**IP Code (Ingress Protection Rating)** Classifies and rates the degree of protection provided against the intrusion of solid objects (such as body parts like hands and fingers, dust, accidental contact), and liquids. The first numeral (x) represents the degree of protection against the ingress of solid objects. The second numeral (y) represents the degree of protection against the ingress of liquids. For products with an IPxy rating, see the *Classification of Medical Device* in this chapter for a description of that rating. Not all products have an IPxy rating.
	**Class II Equipment** Identifies equipment that meets the safety requirements specified for class II equipment by IEC 60601–1. This device was designed so that it does not require a safety connection to electrical earth (US ground). No single failure results in dangerous voltage becoming exposed and causing an electric shock. This is achieved without relying on an earthed metal casing.

Symbol Descriptions (cont'd.)

Symbol	Description
	**Consult Instructions for Use** Consult the operating instructions.
	**Defibrillation-proof Type BF Applied Part** Identifies a defibrillation-proof type BF 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).
	**Defibrillation-proof Type CF Applied Part** Identifies a defibrillation-proof type CF applied part on medical equipment that complies with IEC 60601–1. This device meets the requirements for protection against electric shock for an earth-free (floating) applied part (one intended for contact with patients) for cardiac application.
	**No User– or Field-serviceable Parts** Do not open or disassemble the device for any reason.
	**Protective Earth** (ground) Identifies the terminal of a protective earth (ground) electrode or any terminal that is intended for connection to an external conductor for protection against electric shock in case of a fault.
	**Non-ionizing Electromagnetic Radiation** Indicates that the equipment emits elevated, potentially hazardous, levels of non-ionizing radiation (electromagnetic energy) for diagnosis or treatment.
	**Follow Instructions For Use** Read and understand the operator's manual before using the device or product. *As a mandatory action sign, this symbol is identified by a blue background and white symbol.*
	**CAUTION:** 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.
	**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.

Symbol Descriptions (cont'd.)

Symbol	Description
	**CAUTION:** 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.
	**CAUTION:** HOT SURFACE Indicates that the marked item may be hot. Take appropriate precautions before touching the item.
	**WARNING:** BODILY INJURY Indicates the presence of mechanical parts that can result in pinching, crushing, or other bodily injury. To avoid risk of bodily injury, keep away from moving parts. Disconnect power before reaching into area or servicing. *As a warning sign, this symbol is identified by a yellow background, black triangular band, and a black symbol.*
	**WARNING:** HAND CRUSHING HAZARD This device contains moving parts that could crush the user's hand. Keep hands clear of the device while it is in operation. Disconnect power before reaching into or servicing the device. *As a warning sign, this symbol is identified by a yellow background, black triangular band, and a black symbol.*
	**WARNING:** BODILY INJURY Indicates the presence of a sharp edge or object that can cause cuts or other bodily injury. To prevent cuts or other bodily injury, do not contact sharp edge of object. *As a warning sign, this symbol is identified by a yellow background, black triangular band, and a black symbol.*

Symbol Descriptions (cont'd.)

Symbol	Description
	**WARNING:** BODILY INJURY Indicates the presence of a potential tip-over hazard that can result in bodily injury. To avoid risk of bodily injury, follow all instructions for maintaining the stability of the equipment during transport, installation, and maintenance. *As a warning sign, this symbol is identified by a yellow background, black triangular band, and a black symbol.*
	**WARNING:** PINCH POINT This device contains moving parts that could pinch body parts. Keep hands clear of the device while it is in operation. Disconnect the power before reaching into or servicing the device. *As a general prohibition sign, this symbol is identified by a white background, red circular band and slash, and a black symbol.*
	**WARNING:** PERSONAL INJURY DO NOT REACH IN Reaching into the equipment can cause personal injury. Do not place hands into any openings. *As a general prohibition sign, this symbol is identified by a white background, red circular band and slash, and a black symbol.*
	**WARNING:** ENVIRONMENTAL OR HEALTH HAZARD Incinerating the device or product could present a risk to the environment or human health. Do not incinerate this device or product. *As a general prohibition sign, this symbol is identified by a white background, red circular band and slash, and a black symbol.*
	**WARNING:** BREAKAGE DUE TO HEAVY LOAD Heavy objects on the surface may cause it to break. Do not load objects heavier than the maximum permissible load indicated for a safe working load. *As a general prohibition sign, this symbol is identified by a white background, red circular band and slash, and a black symbol.*
	**Can Be Recycled** Indicates you may recycle this material or device. Recycle or dispose of in accordance with local, state, or country laws.

Symbol Descriptions (cont'd.)

Symbol	Description
	**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 concerning the decommissioning of your equipment.
	**Contains <heavy metal chemical symbol>** Indicates this equipment contains heavy metal and must not be disposed of as unsorted municipal waste but collected separately. The example shows Lithium Ion.
	**Environmental Friendly Use Period (EFUP)** Per Chinese standard SJ/T11363–2006, indicates the number of years from the date of manufacture during which you can use the product before any restricted substances are likely to leak, causing a possible environmental or health hazard. **NOTE:** • If the device contains less than the maximum concentration of restricted substances, the symbol contains a lowercase ***e*** • This is also referred to as China RoHS.
	**Japan RoHS** Indicates the device or product meets the regulations limit or ban for specific substances in new electronic and electric equipment in Japan. The Green Mark (with the G) indicates the product is within the tolerances of hazardous chemicals. The Content Mark (with the R and letters below) indicates which hazardous substance(s) was used during the manufacturing of the electrical or electronic equipment that exceeds maximum tolerances.
	**Fragile** Indicates the contents are fragile. Handle with care.
	**This Way Up** Indicates the correct upright position of the package.
	**Do Not Stack** Indicates that you should not stack the container or place a load on the container.
	**Keep Dry** Indicates that you need to keep the container away from rain and other sources of moisture.

Symbol Descriptions (cont'd.)

Symbol	Description
	**Humidity Limits** Indicates 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** Indicates 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.
	**Upper Temperature Limit** Indicates the maximum temperature for transportation and handling of this package. The limit is indicated next to the upper horizontal line.
	**Temperature Limits** Indicates the upper and lower temperature limits for the transportation and handling of this package. They are indicated next to the upper and lower horizontal lines.

The following table describes certification symbols that may be used on your device or its packaging. The inclusion of a symbol in this table **does not** indicate that your product was certified by that symbol's governing body and is listed for reference only. To identify which organizations have certified your device, refer to the labeling on your device or its packaging.

Certification Symbol	Description
	**UL Mark** Indicates compliance with applicable Underwriters Laboratories requirements.
	**UL Listed Mark** Indicates compliance with international or regional standards for Underwriters Laboratories safety requirements.
	**UL Listed, Canada/US** Indicates compliance with international or regional standards for Underwriters Laboratories safety requirements in Canada and the United States.
	**UL Classification Mark** Indicates this medical equipment is UL Classified with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 NO. 601.1, and IEC 60601-2-25.
	**UL Classification Mark, Canada/US** Indicates this medical equipment is UL Classified with respect to electric shock, fire, and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 NO. 601.1, and IEC 60601-2-25 for the US and Canada.

Certification Symbol	Description
	**CE Mark** Indicates the device or product conforms with applicable EU (European Union) directives.
	**PCT (GOST-R) Mark** Indicates the device or product conforms with applicable Russian Gosstandart technical and safety standards.
	**NRTL Certification** Indicates the device or product has met the National Recognized Testing Laboratories certification. The NRTL certification attainted is added to the mark of the applicable testing laboratory. The example displays the NRTL certification with the MET Laboratories mark.
	**China Metrology Certification** Indicates the device or product complies with applicable China Metrology Certification requirements.
	**TÜV Rheinland** Indicates the device or product complies with applicable technical and safety requirements following testing by Technischer Überwachungs-Verein, (Technical Inspections Organization).

Installation and Connection

If the installation of this equipment in the USA will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

Contact GE Healthcare for information before connecting any devices to this equipment that are not recommended in this manual or the supplies and accessories reference guide for this system.

Training

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

To see available training, go to the GE Healthcare training Web site (www.gehealthcare.com/training). Select *Education>Product Education-Technical>Diagnostic Cardiology*.

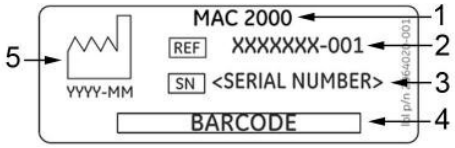
For more self-paced course offerings, tools, and reference guides you may find useful, please visit the GE Healthcare Education Store at www.gehealthcare.com/educationstore.

Equipment Identification

Every GE Healthcare product has a product label that identifies the product name, part number, manufacturing information, and unique serial number. This information is required when contacting GE Healthcare for support.

Product Label

The product label is laid out in the following format. Depending on the product, the label may vary slightly in format, but it contains the same information.

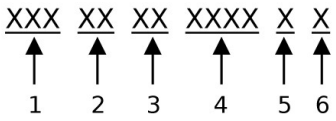


Product Label Format

Item	Description
1	Product description
2	Product part number
3	Device serial number (See "Serial Number Format" on page 25 for more information.)
4	Product bar code
5	Date of manufacture in YYYY-MM format

Serial Number Format

Each device has a serial number that uniquely identifies it and provides important information. You need the product code and the entire serial number before servicing or requesting support for your product. The serial number format is shown in the following illustration:



Serial Number Format

Item	Name	Description
1	Product Code	Three-letter code that uniquely identifies the product line. See "Product Codes" on page 26 for more information.
2	Year Manufactured	Two-digit code identifying the year the device was manufactured. Values range from 00 to 99 For example: 00 = 2000, 04 = 2004, 05 = 2005 (and so on).

Serial Number Format (cont'd.)

Item	Name	Description
3	Fiscal Week Manufactured	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 = first week in January.
4	Product Sequence	Four-digit number identifying the order in which this device was manufactured. Values range from 0001 to 9999.
5	Manufacturing Site	One-letter code identifying the site where the device was manufactured. For example, F = Milwaukee, N = Freiburg, P = Bangalore
6	Miscellaneous Characteristic	For example, P = device is a prototype, R = device was refurbished, U = device was upgraded to meet the specifications of another product code, A= device is in production.

Device Address Label and Rating Plate

The Device Address label and Rating Plate is laid out in the following format. Depending on the product, the label may vary slightly in format.

Item	Description
1	Product description
2	Country of origin
3	Symbols See "Symbol Descriptions" on page 17 for a description of the symbols used on this label.
4	Electrical rating of the device
5	Manufacturer name and address

Product Codes

The product code identifies specific system platforms.

You can identify the product code using the serial number listed on the product label located in one of the following places:

- On the product label attached to the device.
- On the product label provided with the application CD.

For software application systems, you can view the serial number by launching the system application and clicking ***Help*** > ***About***.

For information on launching the application, refer to the service or operator's manual for this system.

Service Information

This section provides information pertaining to the maintenance and servicing of the system. Familiarize yourself with this information before requesting service from GE Healthcare or its authorized representatives.

Service Requirements

For systems with hardware provided by GE Healthcare, failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may result in equipment failure and possible safety hazards.

For software only products, maintenance of the hardware and operating system on which the software resides is the responsibility of the customer.

Regular maintenance, irrespective of usage, is essential to ensure that the components of this system are always functional when required.

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.

Additional Assistance

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

Contact your local GE Healthcare representative to request additional assistance.

Manual Information

This section provides information for the correct use of this manual.

Keep this manual with the equipment at all times and periodically review it. You should request training assistance from GE Healthcare, if needed.

Manual Purpose

The purpose of this manual is to provide the operator with information concerning the safety and use of their ECG system.

Document Conventions

This manual uses the following conventions.

Typographical Conventions

Convention	Description
Bold Text	Indicates keys on the keyboard, text to enter, or hardware items such as buttons or switches on the equipment.
Italicized-Bold Text	Indicates software terms that identify menu items, buttons or options in various windows.
CTRL+ESC	Indicates a keyboard operation. A plus (+) sign between the names of two keys indicates that while holding the first key, you should press and release the second key. For example, Press **CTRL+ESC** means to press and hold the **CTRL** key and then press and release the **ESC** key.
<space>	Indicates that you must press the spacebar. When instructions are given for typing a precise text string with one or more spaces, the point where you must press the spacebar is indicated as **<space>**. This ensures that the correct number of spaces is inserted in the correct positions within the literal text string. The purpose of the < > brackets is to distinguish the command from the literal text within the string.
Enter	Indicates that you must press the **Enter** or **Return** key on the keyboard. Do not type ***Enter***.
>	The greater than symbol, or right angle bracket, is a concise method to indicate a sequence of menu selections. For example, the statement "From the main menu, select ***System*** > ***Setup*** > ***Options*** to open the ***Option Activation*** window" replaces the following: 1. From the main menu, select ***System*** to open the ***System*** menu. 2. From the ***System*** menu, select ***Setup*** to open the ***Setup*** menu. 3. From the ***Setup*** menu, select ***Options*** to open the ***Option Activation*** window.

Illustrations

All illustrations in the manual are provided as examples only. Depending on system configuration, screens in the manual may differ from the screens on your system.

All patient names and data are fictitious. Any similarity to actual persons is coincidental.

Notes

Notes provide application tips or additional information that, while useful, are not essential to the correct operation of the system. They are called out from the body text through a flag word and indentation, as follows:

NOTE:
The tip or additional information is indented below the **NOTE** flag word.

Related Documents

For a complete list of related manuals, refer to the "Related Manuals" appendix in the service manual.

2

Product Overview

This chapter provides a description of the product, its features, and the requirements necessary to operate this system.

Product Description

This system provides two basic modes of operation:

- Resting ECG
  This mode is the standard mode for your system.
- Arrhythmia
  This mode is provided for the convenience of automatically generating documentation.

You can upgrade the basic system with two other modes of operation:

- Exercise
  This mode is for exercise stress testing.
- RR Analysis
  This mode is for RR intervals analysis.

The basic system prints 6 or 12 leads of ECG and provides optional transmission and reception of ECG data to and from a central ECG cardiovascular information system. You can also upgrade it with software options such as 12-lead ECG measurement and interpretive analysis.

Product Specifications

This section describes the device's hardware components and system specifications. Familiarize yourself with this information before using the device.

Hardware Descriptions

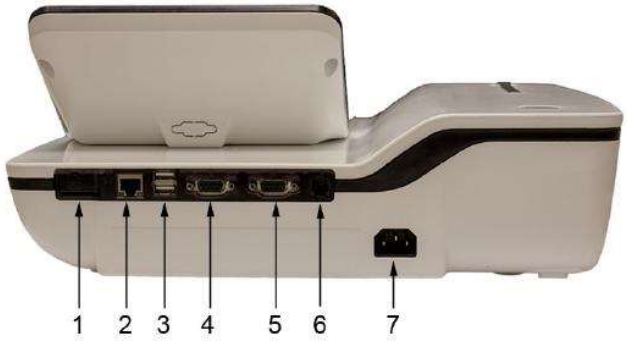
This section identifies the key components of the system hardware. Familiarize yourself with these components, their location, and their use before attempting to use the equipment.

Front View

Front View of Device

Item	Name	Description
1	Display	Presents waveform and text data.
2	Function Keys	Selects menu options on the screen.
3	Keypad	Use to select menu options on the screen.
4	Printer door push button	Opens the printer door.
5	Printer/Printer door	Prints reports.

Rear View



Rear View of Device

Item	Name	Description
1	SD card slot	Connection for Secure Digital (SD) card. This system supports SD cards formatted for the FAT or FAT16 file systems.
2	LAN connection	RJ45 network connector.

Rear View of Device (cont'd.)

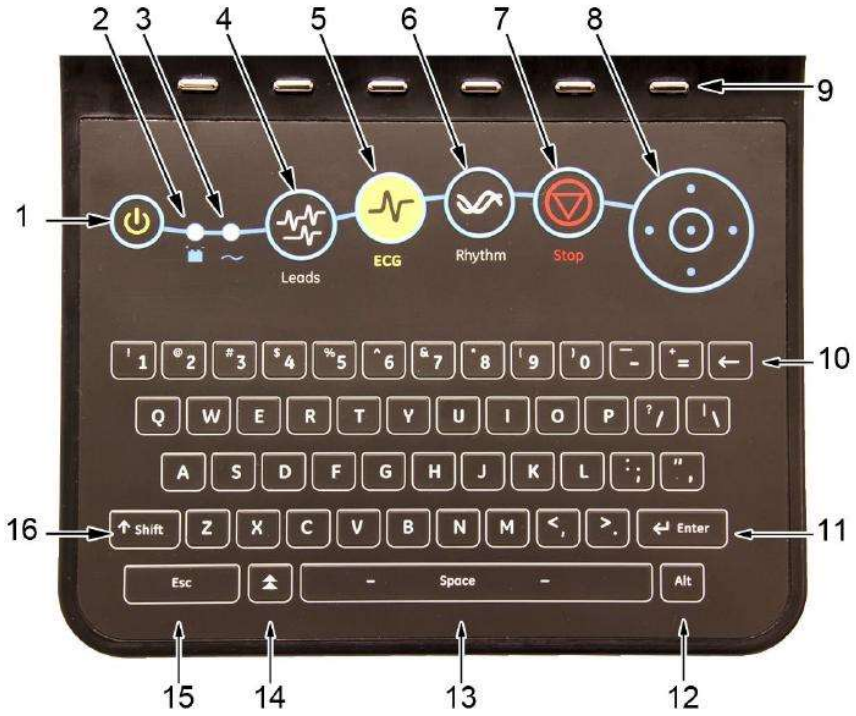
Item	Name	Description
3	USB ports (2)	Standard Universal Serial Bus (USB) connector for USB devices, such as the optional barcode reader, optional USB WiFi Dongle, or an external non-multimedia USB keyboard.
4	COMM A port	Serial connector for data communication with CASE/CardioSoft or MUSE systems.
5	COMM B port	Serial connector for stress devices (bicycle, ergometer, or treadmill).
6	Phone jack	RJ11 connector from the internal modem to an analog phone line.
7	AC Power Cord connection	Standard connector for the AC power cable.

Side View

Side View of Device

Item	Name	Description
1	KISS connection	Connection port for the optional KISS Pump system.
2	ECG Patient Cable connection	D-sub 15–pin female connector for the acquisition cable.

Standard Keypad



Standard Keypad

Item	Name	Description
1	Power on/off	Turns the system on or off.
2	Battery LED	Indicates various battery states: • Steady amber indicates the battery is charging • Flashing amber indicates the battery is low • No light indicates the battery is neither charging nor low
3	Power LED	Indicates the unit is plugged in and receiving power.
4	**Leads** key	Scrolls through the leads and allows you to select the display formats for the lead sequence.
5	**ECG** key	Acquires and prints a 12-lead ECG.
6	**Rhythm** key	Prints real-time continuous rhythm.
7	Writer **Stop**	Stops the printing function.
8	Trimpad/Cursor Control keys	Provides movement through menus and windows. For descriptions on using the trimpad and cursor control keys, see "Using the Trimpad" on page 36.

Standard Keypad (cont'd.)

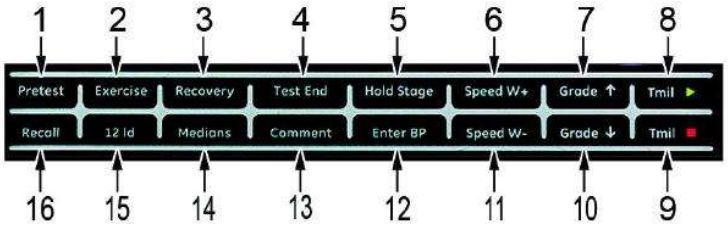
Item	Name	Description
9	Function keys	Use to select menu options on the screen. **NOTE:** There is no marking on the keypad for the function keys. Up to six menu options may be available at any given time, and each option corresponds to a function key directly below the display.
10	Backspace key	Deletes characters.
11	**Enter** key	Use to advance the focus in a window or to select items from the screen.
12	**Alt** key	Switches between different input methods for Japanese and Korean keyboard languages.
13	**Space** bar	Enters a space in the text. As a secondary function, it moves through the menu lists.
14	Option key	Use to enter special characters on non-English keyboards.
15	**ESC** (escape)	Closes a window on a screen.
16	**Shift** key	Use to enter a capital letter. For example, press **Shift** + **p** to type a capital **P**.

Stress Keypad

The stress keypad has the same keys as a standard keypad with the addition of specific stress keys. If you do not have the stress option, you do not have a stress keypad.

Item	Name	Description
1	Stress keys	Controls stress equipment connected to the system.

Stress Keys



Stress Keys

Item	Name	Description
1	**Pretest** stress key	Selects the pretest phase or advances to the next stage within the phase.
2	**Exercise** stress key	Selects the exercise phase or advances to the next stage within the phase
3	**Recovery** stress key	Selects the recovery phase or advances to the next stage within the phase
4	**Test End** stress key	Selects the test end phase.
5	**Hold Stage** stress key	Remains at the current stage.
6	**Speed W+** stress key (Speed/Load up)	Manually increases the treadmill speed or ergometer load.
7	**Grade ↑** stress key (Grade up)	Increases the elevation of the treadmill.
8	**Tmil** stress key	Starts the treadmill during the test
9	**Tmil** stress key	Stops the treadmill during the test.
10	**Grade↓** stress key (Grade down)	Decreases the elevation of the treadmill.
11	**Speed W-** stress key (Speed/Load down)	Manually decreases the treadmill speed or ergometer load.
12	**Enter BP** stress key	Allows you to enter blood pressure values or start a blood pressure measurement.
13	**Comment** stress key	Allows you to enter a comment during the stress test.
14	**Medians** stress key	Prints a median report during the test.
15	**12ld** stress key	Prints a 12-lead report
16	**Recall** stress key	Prints the previous 10 seconds of ECG

Hardware Specifications

See "Technical Specifications" on page 193 for a complete description of all hardware and system specifications for this device.

Optional Software Features

Optional Software Features

Item	Description
QT Correction Formula	The system provides the following QT correction formulas: Bazett (default) Framingham Fridericia
Hookup Advisor	Hookup Advisor alerts users of poor lead quality based on noise measurement and lead-off detection results.
ACI-TIPI	Acute Cardiac Ischemia Time-Insensitive Predictive Instrument (ACI-TIPI) Option (K974199).
Clinical Trials (CT) Data Guard and Audit Trail	CT Data Guard and Audit Trail supports 21 CFR part 11 compliance for the data generated using the device. Option incudes password protection and time stamped audit trails.
ECG Analysis/Interpretation	12SL ECG Analysis Program (V22) K042177.
HEART exercise	HEART exercise v5.2.2.1.

Using the System

This section describes the startup screen, keypad use, and ECG data acquisition.

Startup Screen

Depending on the options you selected for ***Power up*** mode in ***Basic Setup***, one of the following screens is your startup screen:

- Resting ECG
- Stress ECG
- Arrhythmia
- Main Screen
- Order Manager
- A window prompting you to enter your User ID and Password.

NOTE:
The password window is displayed only if you selected the ***High Security Mode*** option in ***Basic Setup***. You can use the system to take a ***STAT ECG*** without logging into the system. Press the function key directly below the ***STAT ECG*** tab to select it.

Using the Keypad

You interact with the system by using the keypad. In addition to entering data as you would on any keypad, you can also use it to do the following tasks:

- Select menu options
- Navigate through data entry fields
- Control optional stress equipment

Using the Function Keys

You can configure the device and initiate an ECG reading by selecting menu options that are across the bottom of the display. Up to six menu options are available at any given time, and each option corresponds to a function key directly below the display.

Press the function key below the corresponding menu option to select it. The following table describes some of the possible options.

Using the Function Keys

Desired Action	Example Results
Take an ECG	Selecting the ***Resting ECG*** menu option opens the Resting ECG function and displays additional menu items related to taking a resting ECG.
Change a setting during an ECG recording	During a resting ECG, selecting the ***25 mm/s*** option changes the speed of the waveform. Other options are available to change different settings.
Open a window	Selecting the ***Patient Data*** option opens the ***Enter Patient Data*** window.
Change menu options	Selecting the ***More*** option displays additional menu options.
Save your selections	Selecting the ***Save*** option allows you to save changes after entering data or changing a configuration.

Using the Trimpad

Use the trimpad to navigate through data entry windows.

Press the arrows to move the cursor left, right, up and down through the data fields.

Press the center button to select the field in which the cursor is currently resting. If the field is associated with a list of valid value, that list is displayed.

Using the Stress Keys

If you purchased the optional stress module, use the stress keys on the keypad to control stress equipment connected to the system. For a description of the stress keys and their function, see "Stress Keys" on page 34.

ECG Data Acquisition

ECG Data Acquisition provides the following:

- Samples with a minimum 500 Hz or 1000 Hz to the ECG processing algorithms and the application software
- Pace enhancement enable/disable through the user interface
- QRS detection and heart rate calculation
- Lead sequences with 6 or 12 leads, where each lead is an element of the set (I, II, III, aVR, aVL, aVF, D, A, J, V1...V6) with an optional –aVR

ECG Data Acquisition supports the following:

- Default high pass filter (0.04 Hz), if ADS is on high pass filter (0.56 Hz)
- Selectable low pass filter (20, 40, 100, 150 Hz)
- Selectable mains filter (50 Hz, 60 Hz)
- Anti Drift System (ADS): Baseline shift correction with finite impulse response high pass filter enable/disable through the user interface in Resting ECG, Stress, and RR analysis modes

The following are selectable data formats for external ECG storage:

- DCAR XML, 500 Hz uncompressed
- DCAR XML, 1000 Hz uncompressed
- Hilltop, 500 Hz DVS
- PDF

External Storage

This system supports a Secure Digital High Capacity (SDHC) card with 4 GB capacity as external storage.

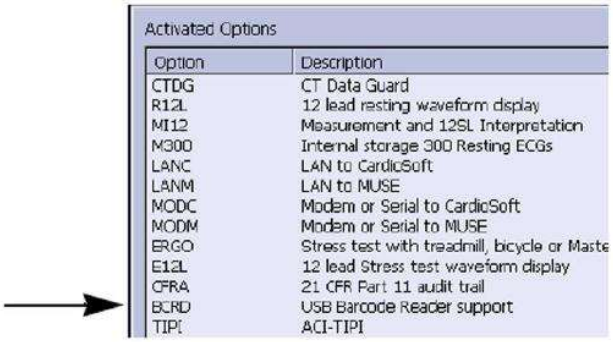
Navigating the User Interface

You can configure the system in a number of ways. The configuration choices you make determine the actions you need to perform in order to proceed from the ***Power up*** display to the ***Main Menu***.

- The ***Power up mode*** selected in ***Basic Setup*** determines which window opens on startup.

- If ***High Security Mode*** is enabled in ***Basic Setup***, you are required to enter a user ID and password.

- The ***BCRD*** option in the ***Option Code*** window indicates that the ***USB Barcode Reader support*** is activated.



The following sections describe how to navigate from the ***Power up*** screen to the ***Main Menu*** for the each possible logon configuration. Use the procedure that applies to your logon configuration settings.

- If your system is configured to power up in the ***Resting ECG*** mode, go to "Resting ECG Power Up Mode" on page 39.
- If your system is configured to power up in the ***Arrhythmia*** mode, go to "Arrhythmia Power Up Mode" on page 39.
- If your system is configured to power up in the ***Main Screen*** mode, go to "Main Screen Power Up Mode" on page 40.
- If your system is configured to power up in the ***Stress ECG*** mode, go to "Stress ECG Power Up Mode" on page 40.
- If your system is configured to power up in the ***Order Manager*** mode, go to "Order Manager Power Up Mode" on page 41.

Resting ECG Power Up Mode

This procedure describes how to navigate to the ***Main Menu*** after powering on the system when ***Resting ECG*** is selected for ***Power up mode*** in ***Basic Setup***.

NOTE:
If you need to perform system setup functions, be sure you log in as a user who is assigned setup editing privileges.

If the system is configured for ***Resting ECG Power Up Mode*** and ***High Security Mode*** is not enabled, the ***Resting ECG*** screen opens on power up. To go to the ***Main Menu***, press **More** > **Main Menu**.

If ***High Security Mode*** is enabled, when the window opens prompting for a user ID and password, use the following procedure:

1. In the ***User ID*** field, enter your user ID.
2. To move the cursor to the ***Password*** field, press **Enter** or the **down arrow** on the **Trimpad**.
3. In the ***Password*** field, enter your password.
4. Press ***Login***.

   The ***Resting ECG*** screen is displayed.

   If the ***Barcode Reader*** option is enabled, a window opens prompting you to ***Scan the Patient barcode***.
5. If the barcode reader prompt is not displayed, press ***Cancel*** > ***More*** > ***Main Menu***.

Arrhythmia Power Up Mode

This procedure describes how to navigate to the ***Main Menu*** after powering on the system when ***Arrhythmia*** is selected for ***Power up mode*** in ***Basic Setup***.

NOTE:
If you need to perform system setup functions, be sure you log in as a user who is assigned setup editing privileges.

If the system is configured for ***Arrhythmia Power Up Mode***, and ***High Security Mode*** is not enabled, the ***Arrhythmia*** screen opens on ***Power up***. To go to the ***Main Menu***, press **Cancel** > **More** > **Main Menu**.

If ***High Security Mode*** is enabled, when the window opens prompting for a user ID and password, use the following procedure:

1. In the ***User ID*** field, enter your user ID.
2. To move the cursor to the ***Password*** field, press **Enter** or the **down arrow** on the **Trimpad**.
3. In the ***Password*** field, enter your password.
4. Press ***Login***.

   The ***Arrhythmia*** screen is displayed.

   If the ***Barcode Reader*** option is enabled, a window opens prompting you to ***Scan the Patient barcode***.
5. If the barcode reader prompt is not displayed, press ***Cancel*** > ***More*** > ***Main Menu***.

Main Screen Power Up Mode

This procedure describes how to navigate to the ***Main Menu*** after powering on the system when ***Main Screen*** is selected for ***Power up mode*** in ***Basic Setup***.

NOTE:
If you need to perform system setup functions, be sure you log in as a user who is assigned setup editing privileges.

If the system is configured for ***Main Screen Power up mode*** and does not have ***High Security Mode*** enabled, the ***Main Menu*** is displayed after powering up the system. You do not need to press any other keys in order to display the ***Main Menu***.

If ***High Security Mode*** is enabled, when the window opens prompting for a user ID and password, use the following procedure:

1. In the ***User ID*** field, enter your user ID.
2. To move the cursor to the ***Password*** field, press **Enter** or the **down arrow** on the **Trimpad**.
3. In the ***Password*** field, enter your password.
4. Press ***Login***.

   The ***Main Menu*** is displayed.

Stress ECG Power Up Mode

This procedure describes how to navigate to the ***Main Menu*** after powering on the system when ***Stress ECG*** is selected for ***Power up mode*** in ***Basic Setup***.

NOTE:
If you need to perform system setup functions, be sure you log in as a user who is assigned setup editing privileges.

If the system is configured for ***Stress ECG Power up mode*** and ***High Security Mode*** is not enabled, the ***Stress ECG*** screen opens on power up. To go to the ***Main Menu***, press ***Cancel*** > ***More*** > ***Main Menu***.

If ***High Security Mode*** is enabled, when the window opens prompting for a user ID and password, use the following procedure:

1. In the ***User ID*** field, enter your user ID.
2. To move the cursor to the ***Password*** field, press **Enter** or the **down arrow** on the **Trimpad**.
3. In the ***Password*** field, enter your password.
4. Press ***Login***.

   The ***Stress ECG*** screen is displayed.

   If the ***Barcode Reader*** option is enabled, a window opens prompting you to ***Scan the Patient barcode***.
5. If the barcode reader prompt is not displayed, press ***Cancel*** > ***More*** > ***Main Menu***.

Order Manager Power Up Mode

This procedure describes how to navigate to ***Main Menu*** after powering on the system when ***Order Manager*** is selected for ***Power up mode*** in ***Basic Setup***.

NOTE:
If you need to perform system setup functions, be sure you log in as a user who is assigned setup editing privileges.

If the system is configured for ***Order Manager Power Up Mode*** and it does not have ***High Security Mode*** enabled, press **Main Menu**. The ***Order Manager*** screen is displayed after turning on the system.

If ***High Security Mode*** is enabled, when the window opens prompting for a user ID and password, use the following procedure:

1. In the ***User ID*** field, enter your user ID.
2. To move the cursor to the ***Password*** field, press **Enter** or the **down arrow** on the **Trimpad**.
3. In the ***Password*** field, enter your password.
4. Press ***Login***.

   The ***Order Manager*** screen is displayed.
5. Press ***Main Menu***.

3

Setting Up the Equipment

Setting up this system consists of the following steps:

1. "Inserting the Battery"
2. "Connecting the AC Power"
3. "Connecting the Patient Cable"
4. "Connecting the Barcode Reader"
5. "Connecting the LAN Option"
6. "Connecting the WiFi Option"
7. "Connecting External Devices (Stress Option)"
8. "Connecting an Internal Modem"
9. "Inserting the Paper"
10. "Turning on the System"
11. "Configuring the Device"
12. "Testing the Device"

Each step is described in more detail in the following sections.

Inserting the Battery

The system is shipped with a lithium ion battery that is charged when inserted into the system connected to AC power.

NOTE:

Do not use the system on battery power until the battery is fully charged, as indicated by the battery charging LED on the keysheet. You may use the system on AC power while the battery is charging.

Connecting the AC Power

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

Use the following instructions to connect the system to an AC power outlet.

Item	Description
1	Female end of the device's power cord connected to the back of the device.
2	Male end of the device's power cord connected to an AC outlet.

1. Connect the female end of the device's power cord (1) to the AC power connector on the back of the device.
2. Plug the male end of the device's power cord (2) into an AC outlet.

   NOTE:
   It is recommended that you plug the device into an uninterruptible power supply (UPS) or a surge suppressor.
3. Check the Power LED to make sure the device is receiving power form the AC outlet.

Connecting the Patient Cable

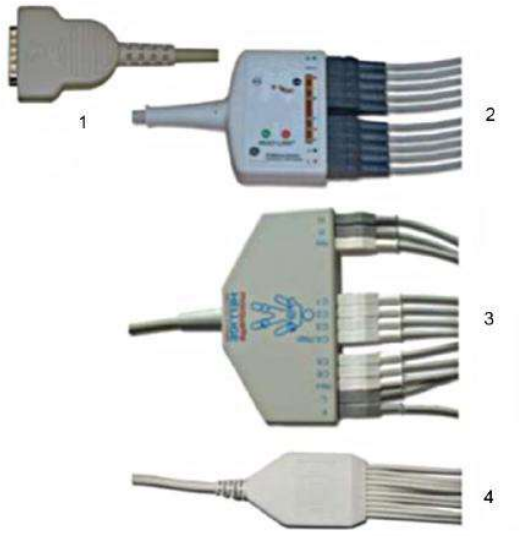
This system supports a variety of patient cables.

WARNING:
HIGH-FREQUENCY BURNS — Use of cables not supplied with this equipment can lead to serious injury.

Use only the acquisition cable that ships with this equipment.

CAUTION:
INACCURACIES IN ECG Improper connection can cause inaccuracies in the ECG.

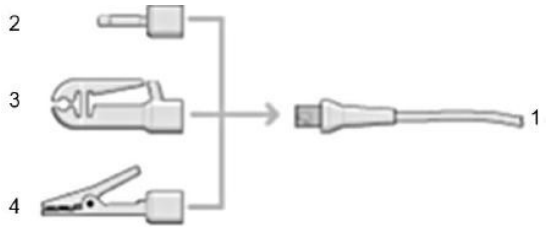
Trace each individual leadwire from its acquisition cable label to the colored connector and then to the proper electrode to ensure that it is matched to the correct label location.



Patient Cables

Item	Name	Description
1	D-Sub 15–pin male connector	Connects to the system's ECG signal input connector. One end of each acquisition cable consists of a D-sub 15–pin male connector.
2	Multi-link Acquisition Cable Leads	The lead end of the multi-link acquisition cable attaches to the leadwire adapters and uses 10 or 12 leadwires.
3	NEHB Acquisition Cable Leads	The lead end of the NEHB acquisition cable attaches to the leadwire adapters and uses 12 leadwires.
4	Value Acquisition Cable leads	The lead end of the value acquisition cable consists of 10 leadwires.

The leadwires require an adapter to connect to an electrode, as shown in the following diagram.



Leadwire Adapters

Item	Description
1	Leadwire end
2	4 mm pin
3	Grabber
4	Mactrode clip

Use the following procedure to connect the patient cable:

1. Assemble the leadwires and adapters.

   See "Replacing Leadwire Adapters" on page 166.

2. Connect the leadwires to the front of the patient cable.
3. Connect the patient cable to the system.

   Ensure the cable is seated securely.

Connecting the Barcode Reader

If the optional barcode reader was purchased with the device, connect it to the USB port on the device.

NOTE:
The BCRD option to use the reader is activated at the factory when the barcode reader is purchased with the device. However, you need to configure the barcode settings for your site before you can use the reader, See Appendix A.

Connecting the LAN Option

If you purchased the LANC (LAN Communication to CardioSoft) or LANM (LAN Communication to MUSE) options, connect an Ethernet cable to the RJ45 network connector on the back of the device.

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

This system is compatible with MUSE v7.1.1 and v8.0.1, and with CardioSoft v6.51, v6.61, and v6.71.

Connecting the WiFi Option

If you purchased a WiFi option, connect the WiFi dongle to the USB port available on the back of the device.

WIFC is WiFi Communication to the CardioSoft system.

WIFM is WiFi Communication to the MUSE system.

This system is compatible with MUSE v7.1.1 and v8.0.1, and with CardioSoft v6.51, v6.61, and v6.71.

Connecting External Devices (Stress Option)

If you purchased the stress option ***ERGO***, connect the external stress device to the system using a serial cable to the COMM B port on the back panel of the device.

This system works with any of the following devices:

- GE model T2100 treadmill
- GE model T2000 treadmill
- eBike ergometer
- Master's Step (acoustic signal only)

Connecting an Internal Modem

If you purchased this system with the internal modem option, connect the modem to an analog phone line using the RJ11 connector on the back of the device.

MODC is Modem Communication to the CardioSoft system.

MODM is Modem Communication to the MUSE system.

This system is compatible with MUSE v7.1.1 and v8.0.1 and with CardioSoft v6.51, v6.61, and v6.71.

Inserting the Paper

Before you can print ECG reports, complete the following steps:

1. Make sure the system is set up for the correct paper size.

   This device can print on the following papers: A4, standard letter (8.5 x 11 inches), or modified letter (8.433 x 11 inches).

   For information on adjusting the printer for the paper size, see "Adjusting the Tray for Paper Size" on page 168.
2. Insert the appropriately sized paper.

Turning on the System

1. Press the power button to turn on the system.
2. Verify the system welcome screen is displayed with no errors.

   NOTE:
   If you encounter any problems powering on the system, see "System Does Not Power Up" on page 176 for further troubleshooting instructions.

Configuring the Device

When the device is ready for operation, configure the system settings using the information in "System Configuration" on page 107.

If you are applying the same settings to multiple devices at the site, export the settings to an SD card and use that card to import the settings to other systems.

Testing the Device

After you have set up and configured the device, test the device completely before using it with patients. Use the following test scenarios:

- Conducting and printing a resting ECG
  See "Recording a Resting ECG" on page 65 for instructions.
- Conducting and printing an arrhythmia ECG
  See "Arrhythmia Mode Recording" on page 77 for instructions.
- Conducting and printing a stress ECG.
  See "Stress Testing" on page 89 for instructions.
- Saving, importing, printing, deleting, transmitting, and exporting records.
  See "Managing Internal Storage" on page 99 for instructions.

4

Preparing the Patient

This chapter provides the procedures for preparing the patient's skin and properly placing electrodes.

NOTE:

These instructions do not cover the application of electrodes for the KISS Electrode Application System (not available in the United States). To use the KISS system, see the KISS operator's manual for instructions.

Preparing the Patient's Skin

Careful skin preparation is the key to an interference-free ECG. Signal quality is indicated on the device via the Hookup Advisor indicator.

1. Select the electrode placement sites for ECG monitoring or diagnosis per the protocol specified by the hospital or physician.

   Refer to "Electrode Placement" on page 50 for diagrams and descriptions of electrode placement for various protocols.

2. Ensure 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. To prepare for a stress test, do the following:

   a. Mark each electrode site with a felt tip pen.

   b. Degrease each site with a skin preparation cream.

   c. Use a mild abrasion to remove the mark left by the felt tip pen.

4. Apply electrodes to the prepared sites.

   Electrodes should be placed only by a physician or ECG technician.

   WARNING:
   SHOCK HAZARD — Touching the conductive elements cancels the protection provided by the isolated signal input.

   Ensure that conductive parts of the electrodes or lead wires do not come in contact with other conductive parts.

5. Look at the lead-check screen for indication of lead problems.

   NOTE:
   Use only electrodes and contact agents recommended by GE Healthcare. The signal quality on the lead-check screen is not indicated until the RA/R and RL/N electrodes are applied. If RA/R becomes disconnected, the system reports that all electrodes are off the patient.

Electrode Placement

This section describes various methods for placing electrodes for both resting and exercise ECGs.

CAUTION:
DELAYED DIAGNOSIS — Improper connection of the leadwires will cause inaccuracies in the ECG.

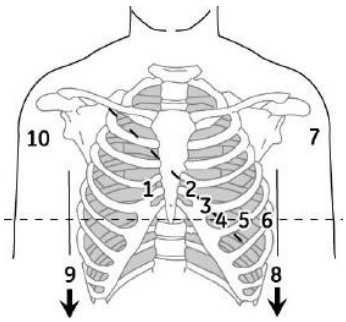
Ensure the leadwires are connected properly. Trace each leadwire from its acquisition module label to its colored connector and then to its electrode to ensure that it is matched to the correct label leadwire connection location.

Resting ECG Placement

The following methods are applicable for resting ECGs.

Standard 12–Lead Placement

To acquire a standard 12–lead ECG, use the placement shown in the following diagram.



12–Lead Electrode Placement

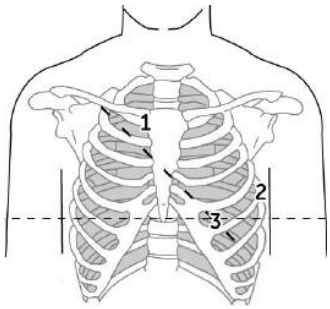
	AHA Label	IEC Label	Description
1	V1 red	C1 red	Fourth intercostal space at the right sternal border
2	V2 yellow	C2 yellow	Fourth intercostal space at the left sternal border

12–Lead Electrode Placement (cont'd.)

	AHA Label	IEC Label	Description
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 purple	C6 purple	Mid-axillary line on the same horizontal level as 4 and 5
7	LA black	L yellow	Left deltoid
8	LL	F green	Above left ankle (Alternate placement, upper leg as close to torso as possible)
9	RL green	N black	Above right ankle (Alternate placement , upper leg as close to torso as possible)
10	RA white	R red	Right deltoid

NEHB Placement

To acquire a NEHB ECG, use the standard 12–lead electrode placement and items 1 and 2 as shown in the following diagram.

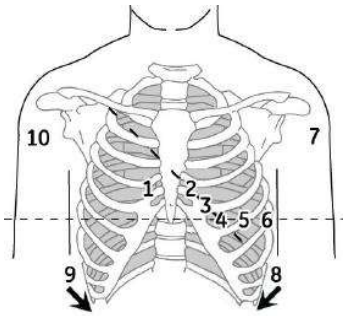


NEHB Electrode Placement

	AHA Label	IEC Label	Description
1	A1 orange	Nst white	Attachment point of the second rib to the right sternal edge
2	A2 orange	Nax white	Fifth intercostal space on the left posterior axillary line (Same position as V7 or C7)
3	V4 blue	Nap white	Mid-clavicular line in the fifth intercostal space (Same position as C4)

Stress 12–Lead Placement

To acquire a stress 12–lead ECG use the placement shown in the following diagram.



12–Lead Stress Electrode Placement

	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 purple	C6 purple	Mid-axillary line on the same horizontal level as 4 and 5
7	LA black	L yellow	Left deltoid
8	LL red	F green	Above left ankle (Alternate placement, upper leg as close to torso as possible)
9	RL green	N black	Above right ankle (Alternate placement, upper leg as close to torso as possible)
10	RA white	R red	Right deltoid

5

Entering Patient Information

The following sections describe how to enter patient information using the following methods:

- With an internal keypad or external keyboard
- With a barcode reader

Entering Patient Information With an Internal Keypad or External Keyboard

Patient information should be entered for each new patient from whom readings are taken. Use the following procedure to enter the information if you do not use a barcode reader or if you want to modify or add to the patient data entered with a barcode reader.

NOTE:
Patient information may be retained from a previous patient. Be sure to check the patient information screen for each new patient. Data assigned to the wrong patient causes erroneous patient information that can affect diagnosis and treatment of the patient(s).

1. Open the ***Enter Patient Data*** window.

   For Resting ECG, press ***Main Menu*** > ***Resting ECG*** > ***Patient Data*** to open the window.

   For Arrhythmia or Stress, the window opens automatically when you initially select the application.

   For subsequent patients, you need to do one of the following to reopen the ***Enter Patient Data*** window.

   - In Arrhythmia mode, press ***Start Recording*** > ***New Patient***.
   - In Stress mode, press ***Patient Data***.

2. Enter the patient information, or press ***Patient List*** to select a patient from the established list.

   NOTE:
   If you select a patient from the ***Patient List***, only the first page of patient information is reused; you need to manually enter all subsequent pages.

3. Use the **Page up** and **Page down** keys to move through the patient data windows.

   NOTE:
   If the ***CTDG*** (***Clinical Trial Data Guard***) option is activated, you enter clinical trial data on the last window.

4. When all the patient data has been entered, press ***Save*** to save the data.

Entering Patient Information with a Barcode Reader

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

Before you can use the barcode scanner, you need to verify that it is connected to the system and that the system is correctly configured to use the peripheral.

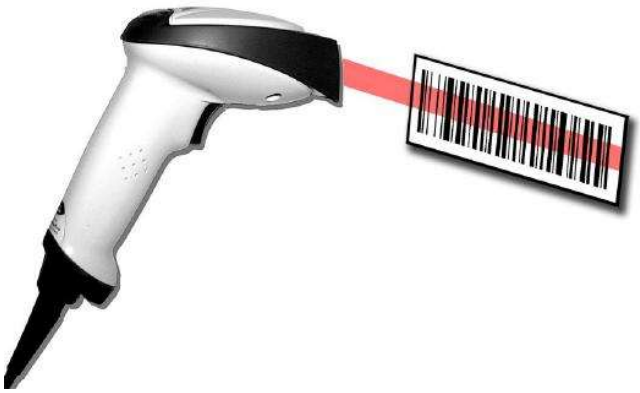
If it is not connected, follow the instructions for connecting and configuring the barcode reader in the section "Connecting the Barcode Reader" on page 46 and Appendix A "Creating Barcodes " on page 185.

Scanning the Barcode

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

1. When the following prompt is displayed on the screen, scan the patient's barcode:

   Scan the Patient Barcode

   The following message is displayed on the screen: ***Please wait***.

   The barcode reader beeps. The first ***Patient Data*** window opens with the data from the patient's barcode entered in the appropriate fields.

2. Confirm that the data entered from the patient's barcode is accurate.

3. Enter or modify patient information as necessary.

   Refer to "Entering Patient Information With an Internal Keypad or External Keyboard" on page 55 for details.

4. After verifying that the patient information is correct, press ***Save*** to save the patient data.

Downloading Patient Demographics

The method for downloading patient demographics depends on the option you purchased and the input method you selected.

You will use one of the following option codes:

- ADTF-ADT — Patient demographics download using the MUSE system or a non-MUSE system
- ADTL-ADT — Patient demographics download using a non-MUSE system

You can download patient demographics using the following input methods. The one you use depends on your system settings.

For information on setting this option, see "Basic Setup" on page 107.

- Internal keypad
- External keyboard
- Barcode Reader

Using the Barcode Reader

Use the following procedure to query the database and select the patient demographics using a barcode reader.

1. Navigate to ***Resting ECG***.
2. Select the ***Patient Data*** menu.

   A dialog box opens instructing you to scan the patient barcode.

3. Scan the patient barcode using the barcode reader.

   A dialog box opens with the scanned ***Patient ID***.

4. Click ***OK*** to accept the selection.

   The patient demographic data is downloaded and displayed.

Using the Internal Keypad or External Keyboard

Use the following procedure to query the database and select the patient demographics using the internal keypad or external keyboard.

1. Navigate to ***Resting ECG***.
2. Select the ***Patient Data*** menu.

   A dialog box opens instructing you to enter the ***Patient ID***.

3. Enter the ***Patient ID*** using the internal keypad or external keyboard.
   A dialog box opens with the ***Patient ID*** you entered.
4. Click ***OK*** to accept the selection.
   The patient demographic data is downloaded and displayed.

6

Order Manager

The MAC 2000 system may retrieve orders from a Hospital Information System (HIS) through MUSE or non-MUSE systems. There are two types of order managers: Simple Orders and Advanced Order Manager.

You can complete orders using any of the communication media outlined in the following section.

Communication Media

MUSE or non-MUSE systems can communicate with the MAC 2000 system in the following ways:

- **SD Card**
  If you are communicating to MUSE systems, this is only available with MUSE v7.1.1 or later.
- **Modem**
  You can only connect to an internal modem.
- **Local Area Network (LAN)**
  Connect the MAC system to the LAN through the communications port of the MAC system.
- **Direct Serial Connection**
  Connect the MAC system to the remote system using a standard serial cable.
- **Wireless**
  Connect the MAC system to the remote system using a USB wireless module connected to the MAC system.

This system is compatible with MUSE v7.1.1 and v8.0.1, and CardioSoft v6.51, v6.61, and v6.71.

Simple Orders

Simple Orders provides an interface to quickly download and execute one order at a time. To use Simple Orders, you need to enable either the ***SOML*** or ***SOMF*** option. When the options are enabled, the **Orders** function key is available on the ***Resting ECG*** screen.

When you select the **Orders** function key, this system queries for orders in the default location you set in ***Communication Setup***. As a response to this query, the system

displays a list of available orders at the location specified. You can select a single order from the list. The ***Patient Information*** screen of the Resting ECG application opens with the information populated from the order.

Use the following procedure to execute orders in Simple Orders.

1. Navigate to ***Resting ECG*** in the application.
2. Select ***More*** > ***Orders***.
   The system displays a list of orders available at the default location.
3. Select an order and press **Load**.
   The selected single order is automatically downloaded from the remote system and populated in the ***Patient Information*** screen.

You can also automatically execute a single order if the ***Auto Execute Single Order*** setting is enabled in ***Resting ECG Setup*** and only one open order for the given location is present in the remote system.

Use the following procedure to automatically execute a single order:

1. Navigate to ***Resting ECG*** in the application.
2. Select ***More*** > ***Orders***.
   The single order available at the default location is automatically downloaded from the remote system and populated in the ***Patient Information*** screen.

Advanced Order Manager

Advanced Order Manager provides an interface to download and store multiple orders on the system and execute them later. To use Advanced Order Manager, you need to enable either the ***AOML*** or ***AOMF*** option.

Advanced Order Manager is available as a separate application named ***Order Manager*** on the main menu of the system.

The Advanced Order Manager application has an interface that displays a list of orders that are already downloaded to the system. The application allows you to query for orders from the remote systems based on multiple locations. All matching orders are displayed as the response to this query and you can download a single order or multiple orders to the system. The downloaded orders are displayed as open resting ECG orders in the application main screen.

Downloading Orders

Regardless of the method you use to communicate with the remote system, use the following procedure to receive orders:

1. From the ***Main Menu***, select ***Order Manager***.

   The ***Order Manager*** window opens.

2. Select ***Load Orders***.

   A pop-up window opens.

3. Enter the location(s) from which you want to retrieve orders.

   Locations must match the locations used on the remote system. Separate multiple locations with commas (for example 1, 13, 55).

4. Press **Enter**.

   The system connects to the remote system and retrieves a list of matching orders.

5. To select one order from the list, use the **Select** function key to select the order you want and press **Enter**.

   If you need to select multiple orders, use the **trimpad** and the **Enter** key to highlight multiple orders.

6. After you have selected all the orders you want to download, press the **Load Orders** function key.

   The system loads and stores the selected orders.

7. Proceed to "Selecting and Completing Orders" on page 61.

The downloaded order list displays the ***Patient Name***, ***Patient ID***, ***Room***, ***Time***, ***Type***, ***Location***, and ***Order Number***. The list changes as you navigate the list. You can select and execute only one order at a time from the list. When you select an order, the resting ECG application opens and the ***Patient Information*** window is populated with the patient demographics from the selected order.

An order is completed when the ECG record is saved or transmitted to the MUSE or non-MUSE system. Completed orders are marked as completed.

Selecting and Completing Orders

After you have orders on the system, use the following procedure to select and complete them.

1. On the ***Order Manager*** window, choose ***Select***.

   The cursor moves to the list of available orders.

2. Select the order you want to use and press **Enter**.

   A window opens with the order details.

3. Do one of the following:

   - To select a different order, select ***Cancel***.
     The detail window closes and you return to the ***Order Manager*** window.
   - To use the selected order, select ***Okay***.
     - If the ***TIPI*** option is activated, the ***Patent Information*** window opens with the information from the order.
     - If the ***TIPI*** option is not activated, select ***Patient Data*** to open the ***Patient Information*** window.

4. Enter or correct the patient data.

5. Acquire an ECG for the order and save or transmit the acquired ECG.

6. Select ***Main Menu*** to return to the ***Main Menu*** window.

7. Select ***More*** > ***Order Manager*** to return to the ***Order Manager*** application.

   An asterisk (*) on the left side of the ***Patient Name*** indicates that the order is completed.

Using the Order Manager Interface

You can do the following things with orders:

- Sort the list.
- Print the list.
- Delete single, multiple, completed, or all stored orders.

Order Manager Interface Options

Option	Description
Select	Selects the patient from the ***List of orders*** and displays the patient information in an editable format.
Load Orders	Obtains the orders from the MUSE system and displays them on the ***Order List Display*** screen.
Delete Orders	Provides the user a set of options to delete orders stored locally on the device. See "Deleting Orders" on page 62.
Sort Orders	Allows the user to sort the orders based on a user-selected field.
Print	Prints the selected order.
Main Menu	Returns the user to the ***Main Menu***.

Deleting Orders

You can automatically delete a stored order when the associated ECG record is automatically deleted, by enabling ***Auto Order Deletion*** in the ***Order Manager Setup*** screen. See "Order Manager Setup" on page 156.

You can also configure automatic order deletion separately from automatic record deletion. In this case, the system does not automatically delete a stored order when the associated ECG record is manually deleted.

Use the following procedures to access the ***Delete Orders*** menu and delete orders stored locally on the device.

Accessing the Delete Orders Menu

Use the following procedure to access the ***Delete Orders*** menu.

1. On the ***Main Menu***, select ***Order Manager***.

   The ***Order Manager Interface*** window opens with a list of local orders displayed.

2. Select ***Delete Orders***.

   The available options on the menu change.

3. Do one of the following:

   - To select orders to delete, proceed to "Deleting Specific Orders" on page 63.
   - To delete all of the orders on the device, proceed to "Deleting All Orders" on page 64.
   - To delete all completed orders on the device, proceed to "Deleting Completed Orders" on page 64.

4. To cancel without deleting any order, select ***Cancel***.

   You return to the ***Delete Orders*** menu options.

Deleting Specific Orders

On the ***Delete Orders*** menu, use the following procedure to delete one or more specific orders.

The cursor is placed at the first order in the list of orders.

1. Select the order(s) you want to delete.

   - Use **Page Up**, **Page Down**, and the **trimpad** to navigate through the list of orders.
   - To select an order, highlight it and press **Enter**.

2. Select as many orders as necessary.

   NOTE:
   If you select an order that has not been processed, a window opens to ask whether you want to delete the unprocessed order.

   - Select ***Yes*** to continue deleting the unprocessed order.
   - Select ***No*** to cancel the selection.

3. After you have selected all of the orders to delete, select ***Delete Selected***.

   The following message is displayed: ***Are you sure you want to delete the orders?***

4. Do one of the following:

   - To delete the selected orders, select ***Yes***.
     The orders are deleted and you return to the ***Delete Orders*** menu options.
   - To cancel the deletion, select ***No***.
     The orders are not deleted and you return to the ***Delete Orders*** menu options.

Deleting All Orders

On the ***Delete Orders*** menu, use the following procedure to delete all of the orders.

1. Select ***Delete All***.

   The following message is displayed: ***Are you sure you want to delete the orders?***

2. Do one of the following:

   - To delete all of the orders, select ***Yes***.
     The orders are deleted and you return to the ***Delete Orders*** menu options.
   - To cancel the deletion, select ***No***.
     The orders are not deleted and you return to the ***Delete Orders*** menu options.

Deleting Completed Orders

On the ***Delete Orders*** menu. use the following procedure to delete all completed orders:

1. Select ***Del Completed***.

   The following message is displayed: ***Are you sure you want to delete all completed orders?***

2. Do one of the following:

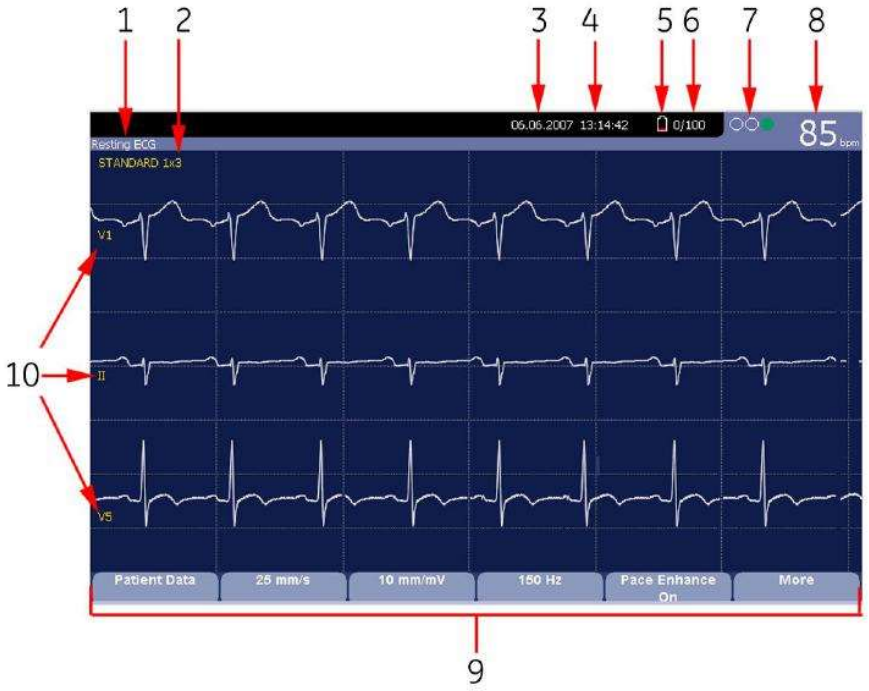
   - To delete all of the completed orders, select ***Yes***.
     The orders are deleted and you return to the ***Delete Orders*** menu options.
   - To cancel the deletion, select ***No***.
     The orders are not deleted and you return to the ***Delete Orders*** menu options.

NOTE:
Non-MUSE systems, such as EMR Gateway and Optima EMS, are GE Healthcare proprietary systems.

7

Recording a Resting ECG

The Resting ECG function is part of the basic ECG cart system. ***Resting ECG*** mode is the default ***Power up*** mode. When the system is turned on, the Resting ECG display is similar to the following screen. You can modify the default in the ***Basic Setup***.



Resting ECG Display

Item	Name	Description
1	ECG Type	The following are valid types of ECGs: • Resting ECG • Arrhythmia • Stress Test
2	Display Format	Format of current waveforms. Press **Leads** to cycle through all 12 leads.

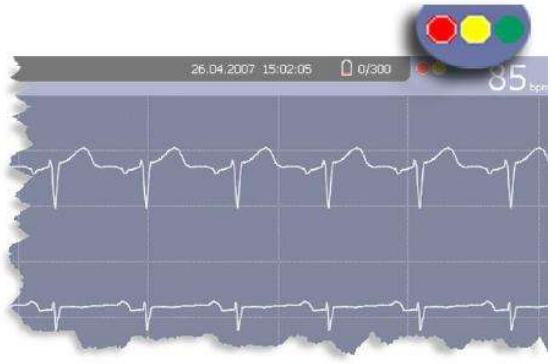
Resting ECG Display (cont'd.)

Item	Name	Description
3	Date	Current system date.
4	Time	Current system time.
5	Battery status indicator	Displays the current battery level. For a description of the battery status indicator see "Battery Status Indicator" on page 172.
6	Internal storage indicator	This indicator is displayed only if the internal storage option is enabled. It displays the approximate number of ECG records that you can store in the remaining memory. X represents the number of ECGs that you can store in the remaining memory. YY represents the total number of ECGs that the system can store. YY can be either 100 (if the M100 option is activated) or 200 (if the M200 option is activated). The difference equals the number of ECGs currently stored in the system.
7	Hookup Advisor Indicator	A tool for monitoring the quality of ECG signals. For more information, see "Hookup Advisor" on page 66.
8	Patient's Heart Rate	Current patient heart rate measured in beats per minute.
9	Menu Options	The list of available menu options changes depending on the function and the current location within that function. For more information, see "Using the Function Keys" on page 36.
10	Lead Labels	Identifies each waveform and indicates the waveform quality. Yellow = a noisy lead Red = disconnected lead

Hookup Advisor

This system offers the Hookup Advisor feature, which is a tool for monitoring the quality of ECG signals, and is available in the Resting, Arrhythmia, and RR Analysis applications. It can reduce or eliminate the occurrence of poor technical quality ECGs, save time, and prevent the need for retakes.

The Hookup Advisor is displayed as a three-circle indicator in the upper right corner of the screen.



The following table describes each of the indicator's conditions.

Hookup Advisor Indicators

Indicator	Description
Red	Indicates a leadfail condition or extreme baseline shifts. The red indicator is always the left-most circle of the of the indicator and flashes when lit.
Yellow	Indicates muscle artifact, power line interference, baseline wander, or electrode noise. The yellow indicator is always the middle circle of the of the indicator. **NOTE:** In RR Analysis mode, the yellow indicator is not active. RR Analysis supports only the red and green indicators of Hookup Advisor.
Green	Indicates acceptable signal quality. The green indicator is always the right-most circle of the of the indicator.

When the lead quality is red or yellow, a message describing the lead problem or status is displayed on the screen.

Hookup Advisor continuously reviews the ECG data for acceptable lead quality.

When an ECG is acquired, Hookup Advisor runs a complete and more comprehensive assessment of the full 10 seconds of ECG data and possibly prompts the user regarding any poor lead quality conditions.

- If ***Preview before analysis*** is turned off in the system setup, a lead quality message and prompt may be displayed, depending on the current lead quality level and the Prompt level in the system setup. If a message and prompt is displayed, the lead quality indicator will reflect the overall 10-second lead quality.
- If ***Preview before analysis*** is enabled, the system setup Prompt level is disregarded and the system immediately displays the Preview screen. Any lead quality messages will be displayed in this screen along with the overall 10-second lead quality indicator.

In either case, users may then do either of the following:

- Select ***Continue*** to continue (print the ECG).
- Select ***Cancel*** to cancel.

Resting ECGs

A resting ECG is the default mode of the ECG cart system, although you may change this in the system configuration. This section describes how to record a resting ECG and the available options.

Recording a Resting ECG

The following steps describe how to conduct a resting ECG.

NOTE:
To take a stat ECG, go directly to step 6.

1. Prepare the patient as described in "Preparing the Patient" on page 49.
2. Select ***Patient Data*** and enter the patient data as described in "Entering Patient Information" on page 55.
3. Adjust the ***Speed***, ***Gain*** and ***Low pass filter*** until the waveforms are configured as desired.
4. If the patient has a pacemaker, turn on ***Pace Enhance***.

   For more information, see "ECG Options" on page 69.
5. Select ***More*** > ***Printer Leads*** to scroll through the leads or change the lead format.
6. When the waveforms are configured, press **ECG** to begin the acquisition.

   A progress bar indicates the percentage of the data acquired. When the acquisition is complete, one of the following occurs, depending on the setting of the ***Preview Before Analysis*** option on the ***Resting ECG Setup*** window.

   - If the ***Preview Before Analysis*** option is enabled, a preview of the 10–second ECG is displayed. Continue with step 7.
   - If the ***Preview Before Analysis*** option is not enabled, the ECG data is analyzed and printed after it is acquired. Proceed to step 8.
7. While reviewing the preview, do one of the following:

   - Discard the reading and press ***Cancel***. Begin again from step 3.
   - Wait for the menu options to change and then continue with step 8.
8. Use the options to change patients, to print a copy of the ECG, or to save, transmit, or reanalyze the data.

   For more information on each option, see "Post-Acquisition Options" on page 71.

ECG Options

This system provides several options for configuring an ECG. The options, presented as option keys across the bottom of the display, are listed in the following tables.

ECG Options–First Row

Option	Description
Patient Data	Opens the patient data entry window.
25 mm/s **NOTE:** The initial measurement displayed is set in ***System Configuration*** > ***Resting ECG Setup***.	Changes the speed of the waveform on the display and printout. Changing the speed also changes the speed at which the wiper bar moves across the display. Measurement is in millimeters per second (mm/s) and includes the following options: • 25 mm/s • 50 mm/s • 12.5 mm/s - 5 mm/s • 12.5 mm/s When the option includes two speeds (12.5 mm/s - 5 mm/s), the first speed is for the display and the second speed is for the printout. Changing the measurement here does not change the measurement set in ***System Configuration***.
10 mm/mV. **NOTE:** The initial measurement displayed is set in ***System Configuration*** > ***Resting ECG Setup***.	Changes the magnitude of the ECG signal on the display or in the report. Measurement is in millimeters per millivolt (mm/mV) and includes the following options: • 5 mm/mV • 10 mm/mV • 20 mm/mV • 40 mm/mV • 2.5 mm/mV • Automatic The larger the selected measurement, the larger the waveform. Only the representation of the waveform changes; signal strength is not affected. **NOTE:** If ***Automatic*** is selected, the system calculates the best gain based on the peak-to-peak amplitudes of all displayed leads and the selected display format. Changing the measurement here does not change the measurement set in ***System Configuration***.

ECG Options–First Row (cont'd.)

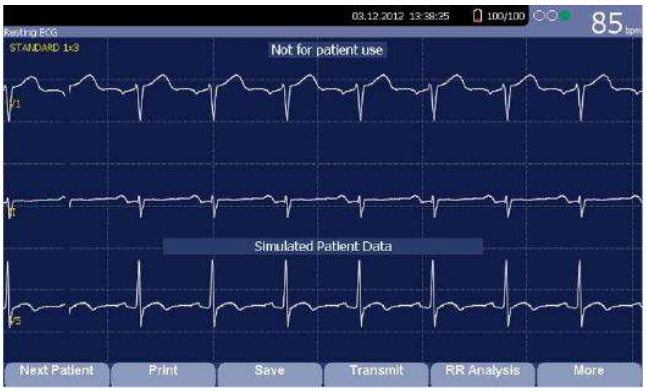
Option	Description
150 Hz **NOTE:** The initial measurement displayed is set in ***System Configuration*** > ***Resting ECG Setup***.	Eliminates noise in the waveform by restricting which frequencies are included. Frequencies are measured in Hertz (Hz) and include the following options: • 20 Hz • 40 Hz • 100 Hz • 150 Hz Selecting a frequency eliminates signals that exceed that frequency. The smaller the frequency selected, the more signal is filtered out. For example, a filter of 40 Hz displays only signals at 40 Hz or less; signals greater than 40 Hz are ignored. Changing the measurement here does not change the measurement set in ***System Configuration***.
Pace Enhance	Improves the readability of pacemaker ECGs. Options are ***On*** and ***Off***.
More	Toggles between the first row of options (previous) and the second row of options (following).

ECG Options–Second Row

Option	Description
Printer Leads **NOTE:** The initial measurement displayed is set in ***System Configuration*** > ***Resting ECG Setup***.	Selects which leads to include in the printout. Options are: • First 6 • Second 6 • Rhythm 6 • 12 Use this option only when conducting rhythm ECGs. For more information, see "Generating a Rhythm Report (Manual Recording)" on page 74. Changing the measurement here does not change the measurement set in ***System Configuration***.
ADS	Toggles the anti-drift system (***ADS***) ***on*** and ***off***. ADS helps reduce baseline drift.
Main Menu	Exits ***Resting ECG*** and returns you to the ***Main Menu***.
More	Toggles between the first row of options (previous) and the second row of options (following).

Post-Acquisition Options

In addition to setup options, the Resting ECG functionality offers additional options after an ECG is acquired. The following screens and tables describe the option keys across the bottom of the display.

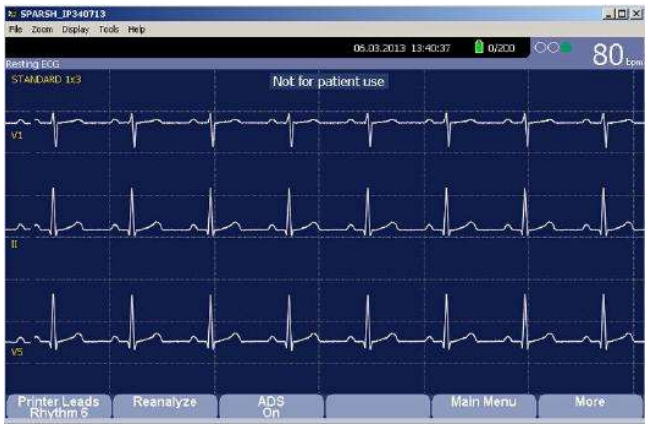


Post-Acquisition Options—Screen One

Option	Description
Next Patient	Displays two new options: • ***New Patient*** opens a blank ***Patient Information*** window. • ***Same Patient*** opens the ***Patient Information*** window populated with data from the previous patient.
Print	Prints the ECG report.
Save	Stores the current ECG report. This option is available only if the internal storage option is enabled.
Transmit	Sends the current ECG report to the location defined on the ***Communication Setup*** window. This option applies only if a valid LAN or Modem communication option is enabled. Refer to "System Configuration" on page 107 for more information.
RR Analysis	Allows you to enter into RR Analysis mode.
More	Returns to the setup options. For more details, refer to "ECG Options" on page 69.

Post Acquisition Options—Screen Two

Option	Description
Next Patient	Opens the patient entry window allowing you to enter or select a new patient.
Speed	Changes the speed of the waveform on the display and printout. Changing the speed also changes the speed the wiper bar moves across the display.
Gain	Changes the magnitude of the ECG signal on the display or in the report. Measurement is in millimeter per millivolt (mm/mV).
Filter	Eliminates noise in the waveform by restricting which frequencies are included. Frequencies are measured in Hertz (Hz).
Pace Enhance	Standardizes the pace spike. Options are On and Off.
More	Toggles between the second and third row of acquisition options.



Post Acquisition Options—Screen Three

Options	Description
Printer Leads Rhythm	Selects which leads to include in the printout.
Reanalyze	Allows you to edit the global measurements and T-wave dispersion. This option is available only if the ***Measurement*** option is enabled and the ***Reanalysis*** option is selected in the ***Resting ECG Setup*** window. For more information, refer to "Resting ECG Setup" on page 112.
ADS	Toggles the anti-drift system (***ADS***) on and off. ***ADS*** helps reduce baseline drift.
Main Menu	Exits the Resting ECG function and returns to the Main Menu.
More	Toggles between the second and third row of acquisition options.

Special Considerations

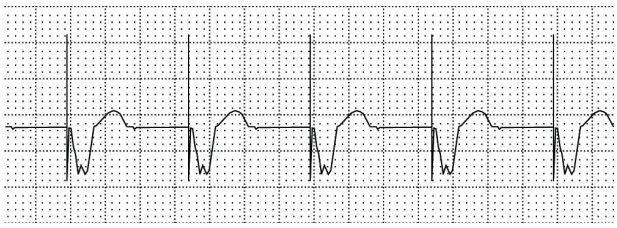
When recording ECGs, you need to make special considerations for the following situations:

- Recording ECGs of pacemaker patients
- Recording ECGs during defibrillation

Recording ECGs of Pacemaker Patients

Because of slow paper speed, pacer pulses cannot be displayed directly on the ECG recording. For example, with a paper speed of 50 mm/s and a pulse duration of only 0.5 ms, the width of the recorded pacer pulse would be only 0.025 mm.

If ***Pace Enhance*** is enabled, the recorder reduces the pulse amplitude and expands its width to make pacer pulses easier to identify. The system records the pulse with the correct polarity, a width of 5 ms, and equal amplitude in all leads. Depending on the polarity of the pacer pulse in leads I and II, the pacer pulse in lead III may be suppressed. The following figure of an ECG recording with pacer pulses shows the amplitude of the reverse current.



Recording ECGs During Defibrillation

NOTICE:

EQUIPMENT DAMAGE — Damaged cables can cause mechanical problems.

Before connecting the cable to the device, check it for signs of physical damage. Do not use a damaged cable.

For patient safety, use only the original GE Healthcare patient cable.

WARNING:

SHOCK HAZARD — Touching the patient, electrodes, or leadwires during defibrillation can cause a shock.

During defibrillation, do not touch the patient, the electrodes, or the leadwires.

Observe all defibrillator safety information.

This equipment is protected against the effects of cardiac defibrillator discharge to allow the ECG trace to return after defibrillation, as required by test standards.

The patient signal input is defibrillation-proof; it is not necessary to remove the ECG electrodes before defibrillating the patient if non-polarizing electrodes are being used.

When using stainless steel or silver electrodes, the defibrillator discharge current may cause the electrodes to retain a residual charge, causing an electrode polarization or DC offset voltage. This blocks ECG signal acquisition for several minutes. If polarizing electrodes are used, GE Healthcare recommends that you disconnect the leadwires from the patient before delivering the shock.

To prevent polarization, GE Healthcare recommends the use of non-polarizing disposable electrodes with defibrillation recover ratings as specified in AAMI EC12 3.2.2.4 (MMS PN 9623-105 Silver MacTrodes, MMS spec TP9623-003), which requires the polarization potential of an electrode pair not exceed 100 mV five seconds after a defibrillation discharge.

Generating a Rhythm Report (Manual Recording)

The ***Resting ECG*** mode allows you to generate Rhythm Reports, which are printed reports only. They do not have computer-generated interpretation or measurements, and you cannot store them to internal memory or transmit them. Use the following steps to generate a Rhythm Report.

1. Prepare the patient as described in "Preparing the Patient" on page 49.
2. Verify that the system is in ***Resting ECG*** mode.

   If the system is not in ***Resting ECG*** mode, on the ***Main Menu*** press ***Resting ECG***.
3. Enter the patient data as described in "Entering Patient Information" on page 55.
4. Adjust the ***Speed***, ***Gain***, and ***Low Pass Filter*** until the waveforms are configured as desired.

   For more information, see "ECG Options" on page 69.
5. If the patient has a pacemaker, press ***Pace Enhance***.

   For more information, see "ECG Options" on page 69.

6. Press **Leads** to scroll through all 12 leads.

   For more information on display formats, see "Resting ECG Setup" on page 112.

7. Press ***More*** > ***Printer Leads*** to select the appropriate option.

   For more information on the ***Printer Leads*** option, see "ECG Options" on page 69.

8. Press **Rhythm** to begin recording the ECG.

9. Press **Stop** to stop the ECG recording.

If you press **Rhythm** after pressing **Stop**, the new report either begins printing immediately on the current sheet of paper or advances to a new page, depending on the setting of the field: ***Start rhythm report on a new page***. This field is located on the ***Resting ECG Setup*** window. See "Resting ECG Setup" on page 112 for details.

8

Arrhythmia Mode Recording

The Arrhythmia mode is part of the basic ECG cart system. The interface of the Arrhythmia mode is similar to the interface for the Resting ECG mode. For more information on the Resting ECG interface, see "Recording a Resting ECG" on page 65.

Recording in Arrhythmia Mode

This section describes the process for recording an arrhythmia report, the waveform options, and the printing options.

Recording Arrhythmia ECGs

1. Prepare the patient as described in "Preparing the Patient" on page 49.
2. Select ***Main Menu*** > ***Arrhythmia***.

   The ***Enter Patient Data*** window opens.
3. Enter the patient data as described in "Entering Patient Information" on page 55.
4. Adjust the gain, speed, filter, and pacemaker enhancement as necessary.

   Refer to "Arrhythmia Recording Options" on page 78.
5. After the settings are adjusted as required, select ***Start Recording*** to begin the arrhythmia ECG.
6. After you have recorded an adequate amount of information, press ***Stop Recording***.

   Two new options become available: ***Confirm Stop*** and ***Continue Recording***.
7. Do one of the following:
   - If you need to record additional information, press ***Continue Recording***. This returns to the recording mode. Repeat from step 6.
   - If you have determined enough information was recorded, press ***Confirm Stop***.
     Report options become available.

If you want to print the Arrhythmia recording, continue with "Printing an Arrhythmia Report" on page 79.

Arrhythmia Recording Options

Arrhythmia Options- first row

Option	Description
Start Recording	Starts the arrhythmia reading. If you did not fill out the Patient Data to select a patient, you receive the following message: ***No Patient Selected. Do you want to continue without patient data?*** 1. Select the ***No*** tab to continue. The ***Enter Patient Data*** window opens. 2. Enter the information on each page and select ***Save***. 3. Select ***Start Recording***.
25 mm/s **NOTE:** The initial measurement displayed is set in ***System Configuration*** > ***Arrhythmia Setup***.	Changes the speed of the waveform on the display and printout. Changing the speed also changes the speed at which the wiper bar moves across the display. Measurement is in millimeters per second (mm/s) and includes the following options: • 25 mm/s • 50 mm/s • 12.5 mm/s - 5 mm/s • 12.5 mm/s When the option includes two speeds (12.5 mm/s - 5 mm/s), the first speed is for the display and the second speed is for the printout. Changing the measurement here does not change the measurement set in ***System Configuration***.
5 mm/mV **NOTE:** The initial measurement displayed is set in ***System Configuration*** > ***Arrhythmia Setup***.	Changes the magnitude of the ECG signal on the display or in the report. Measurement is in millimeters per millivolt (mm/mV) and includes the following options: • 5 mm/mV • 10 mm/mV • 20 mm/mV • 40 mm/mV • 2.5 mm/mV • Automatic The larger the selected measurement, the larger the waveform. Only the representation of the waveform changes; signal strength is not affected. **NOTE:** If ***Automatic*** is selected, the system calculates the best gain based on the peak-to-peak amplitudes of all displayed leads and the selected display format. Changing the measurement here does not change the measurement set in ***System Configuration***.

Arrhythmia Options- first row (cont'd.)

Option	Description
20 Hz **NOTE:** The initial measurement displayed is set in ***System Configuration*** > ***Arrhythmia Setup***.	Eliminates noise in the waveform by restricting which frequencies are included. Frequencies are measured in Hertz (Hz) and include the following options: • 20 Hz • 40 Hz • 100 Hz • 150 Hz Selecting a frequency eliminates signals that exceed that frequency. The smaller the frequency selected, the more signal is filtered out. For example, a filter of 40 Hz displays only signals at 40 Hz or less; signals greater than 40 Hz are ignored. Changing the measurement here does not change the measurement set in ***System Configuration***.
More	Toggles between the first row of options (previous) and the second row of options (following).

Arrhythmia Options second row

Option	Description
Pace Enhance	Improves the readability of pacemaker ECGs. Options are ***On*** and ***Off***.
Patient Data	Opens the ***Patient Data Entry*** window. This tab is available only if you did not complete the ***Portent Data Entry*** window earlier.
Main Menu	Exits the ***Arrhythmia*** function and returns to the ***Main Menu***.
More	Toggles between the first row of options and the second row of options

Printing

You can manually generate an arrhythmia printout in a table format, an episode format, or a summary format.

Printing an Arrhythmia Report

Use the following procedure to print an Arrhythmia report.

1. Select the type of Arrhythmia report you want to print and press the appropriate function key.
   - To print the summary report, press ***Print Summary***.
   - To print the table report, press ***Print Table***.
   - To print the arrhythmia episodes, press ***Print Episodes***.

Refer to "Arrhythmia Printing Options" on page 80 for details.

2. Review the report as necessary.

   For more information, refer to "Arrhythmia Codes" on page 80.

Arrhythmia Printing Options

When printing an arrhythmia report, you have the following options:

Arrhythmia Printing Options

Option	Description
Print Summary	Prints a combined report that includes both the ***Table*** and ***Episode*** formats.
Print Table	Prints a breakdown of the recording in tabular format. The report includes: • the analysis duration in minutes and seconds • the artifact duration in minutes and seconds • a code for each event type recorded • the number of each event type recorded For a description of the possible event codes, refer to "Arrhythmia Codes" on page 80.
Print Episodes	'Prints a standard waveform report of the recorded events. The signal from all recorded leads is printed and each event is marked with the corresponding arrhythmia code. For a description of the possible event codes, see "Arrhythmia Codes" on page 80 .
Main Menu	Exits the ***Arrhythmia*** function and returns to the ***Main Menu***.
More	Toggles between the arrhythmia recording options and the arrhythmia printing options.

Arrhythmia Codes

The following table identifies the codes used on the Arrhythmia reports and the events they represent.

Code	Arrhythmia Event
A	Artifact
ASYSTO	Asystole, limit value 3s
CPLT	Ventricular couplet (2 PVCs)
ESC	Ventricular escape beat
L	Learn phase
PAU1	Pause of 1 missed beat
PAU2	Pause of 2 missed beats
PCAP	Pacemaker capture

Code	Arrhythmia Event
PERR	Pacemaker error
PSVC	Premature supraventricular contraction
PVC	Premature ventricular contraction
QRSL	Learned QRS complex
RUN	Ventricular run (3 PVCs)
VBIG	Ventricular bigeminy
VFIB	Ventricular fibrillation/flutter
VTACH	Ventricular tachycardia (>3 PVCs)

9

RR Analysis

RR Analysis is an optional mode of the system. It detects hidden patterns underlying the complex dynamic phenomena of heart rate variability (HRV) and measures the cardiac RR intervals. This option is not available in the U.S.

RR Analysis Mode

This section outlines the procedure for generating an RR Analysis report and describes the available setup, waveform, and output options.

RR Analysis Settings Window

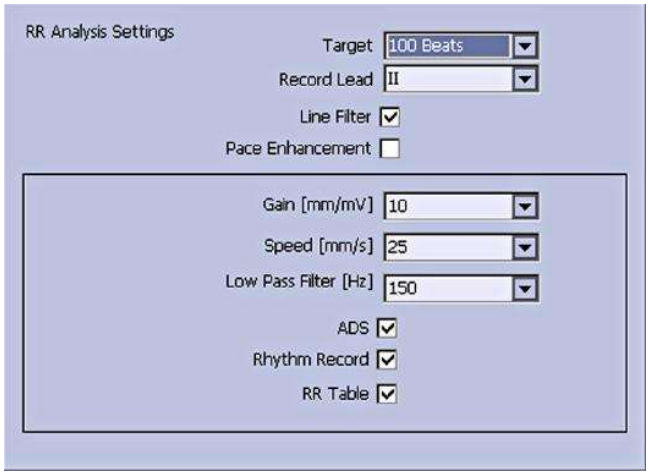
Option	Description
Start Test	Starts the RR Analysis test.
Patient Data	Opens the ***Patient Data Entry*** window.
RR Analysis Setup	Configures the RR Analysis test. See "RR Analysis Setup" on page 83 for details.
Main Menu	Exits the RR Analysis mode and returns to the ***Main Menu***.

RR Analysis Setup

The ***RR Analysis Setup*** function allows you to configure the RR Analysis report, including:

- Target
- Record lead
- Waveform parameters
- Report options

1. Prepare the patient as described in "Preparing the Patient" on page 49.
2. From the device ***Main Menu***, press ***RR Analysis***.
3. Press ***Patient Data*** and enter the patient data as described in "Entering Patient Information" on page 55.
4. Press ***RR Analysis Setup*** and adjust the setup options as necessary.


RR Analysis Settings
Target
100 Beats
Record Lead
II
Line Filter
Pace Enhancement
Gain [mm/mV]
10
Speed [mm/s]
25
Low Pass Filter [Hz]
150
ADS
Rhythm Record
RR Table

RR Analysis Settings Window

Field	Description
Target	Selects the target of the test. Available options are: • 100 Beats • 200 Beats • 300 Beats • 400 Beats • 500 Beats • 1 min • 2 min • 3 min • 4 min • 5 min
Record Lead	Selects which rhythm lead is displayed and stored. Available options are: • I • II • III • aVR • aVL • aVF • V1 • V2 • V3 • V4 • V5 • V6
Line Filter	Enables/disables the line filter defined in ***Country Setup***. See "Country Setup" on page 141 for more information.
Pace Enhancement	Improves the readability of pacemaker ECGs. Options are ***On*** and ***Off***.

RR Analysis Settings Window (cont'd.)

Field	Description
Gain [mm/mV]	Sets the magnitude of the ECG signal. Measurement is in millimeters per millivolt (mm/mV) and includes the following options: • 2.5 mm/mV • 5 mm/mV • 10 mm/mV • 20 mm/mV • 40 mm/mV • Automatic The larger the selected measurement, the larger the waveform. Only the representation of the waveform changes; signal strength is not affected. **NOTE:** If ***Automatic*** is selected, the system calculates the best gain based on the peak-to-peak amplitudes of all displayed leads and the selected display format.
Speed [mm/s]	Changes the speed of the waveform on the display and printout. Changing the speed also changes the speed at which the wiper bar moves across the display. Measurement is in millimeters per second (mm/s) and includes the following options: • 12.5 mm/s • 25 mm/s • 50 mm/s
Low Pass Filter [Hz]	Eliminates noise in the waveform by restricting which frequencies are included. Frequencies are measured in Hertz (Hz) and include the following options: • 20 Hz • 40 Hz • 100 Hz • 150 Hz Selecting a frequency eliminates signals that exceed that frequency. The smaller the frequency selected, the more signal is filtered out. For example, a filter of 40 Hz displays only signals at 40 Hz or less; signals greater than 40 Hz will be ignored.
ADS	Enables or disables ADS (Anti Drift System).
Rhythm Record	Enables/disables the printing of the rhythm lead waveform on the report.
RR Table	Enables/disables the printing of the RR table on the report.

5. Press ***Save*** to record your settings.
6. Continue with "Acquiring a Recording for an RR Analysis Report" on page 87.

Acquiring a Recording for an RR Analysis Report

1. Press ***Start Test***.

   The device begins to acquire the ECG. The target beats, acquired beats, and acquired time are updated in real time on the screen.
2. While the ECG is being acquired, you can do any of the following:
   - Change the ***Speed***.
   - Change the ***Gain***.
   - Change ***Low Pass Filter***.
   - Toggle ***Pace Enhancement***.

   For more information on any of these options, see "RR Analysis Setup" on page 83.

   When the target is achieved, the system automatically stops, and displays a preview of the summary results, histogram, trendgram, and output options.
3. While reviewing the preview, execute one of the output options described in "Output Options" on page 87.

Output Options

The following options are available after the RR Analysis test completes:

Output Options

Option	Description
Press ***Return***.	Discards the reading and returns to pre-test status. Repeat the steps in "Acquiring a Recording for an RR Analysis Report" on page 87.
Press ***Main Menu***.	Discards the reading, exits the RR Analysis mode, and returns to the ***Main Menu***.
Press ***Print***.	Accept the reading and prints the RR Analysis Report on the thermal printer.
PDF Export	Accepts the reading and exports the RR Analysis Report to a PDF file.

10

Stress Testing

The Stress mode is an optional feature that allows you to conduct stress tests with any of the following devices.

Stress Equipment	Description
Supported treadmills and ergometers	Supported equipment connects to the ECG cart system through the serial port labelled COMM A on the back of the device. You can control the equipment through this connection. When a test phase changes, a signal is sent from the system to the equipment to change the speed, grade, or load, as appropriate. You can also manually override the equipment from the ECG cart keyboard. See "Stress Test Keys" on page 92, for more information. Supported equipment includes the following: • T2000 and T2100 • eBike
Ergometers with remote start	This equipment also connects to the ECG cart system through the serial port labelled COMM A on the back of the device. However, the system does not control the equipment. Instead, when the equipment changes load, it signals the system, which changes test stages accordingly.
Unsupported treadmills and ergometers	Unsupported equipment does not connect to the ECG cart system. Instead of signaling the equipment when a test phase changes, the system notifies the operator, who manually adjusts the equipment's parameters.
Master Step	This equipment does not connect to the system. The system emits a tone to instruct the patient when to take a step.

Stress tests include the following parameters:

- Patient data
- Waveform speed and gain
- Pacemaker enhancement
- Finite residual filter
- Printer leads
- Report format

- Target heart rate
- Test protocol

You cannot store the results of the test to internal storage or the external SD card. Instead, you must print the results. You can select any of the following report formats:

- ***Summary Report***
- ***Tabular Summary***
- ***Trend Report***
- ***ST Trend Report***
- ***ST Summary Report***
- ***Episode Report***

To use the Stress ECG mode, you must meet the following conditions:

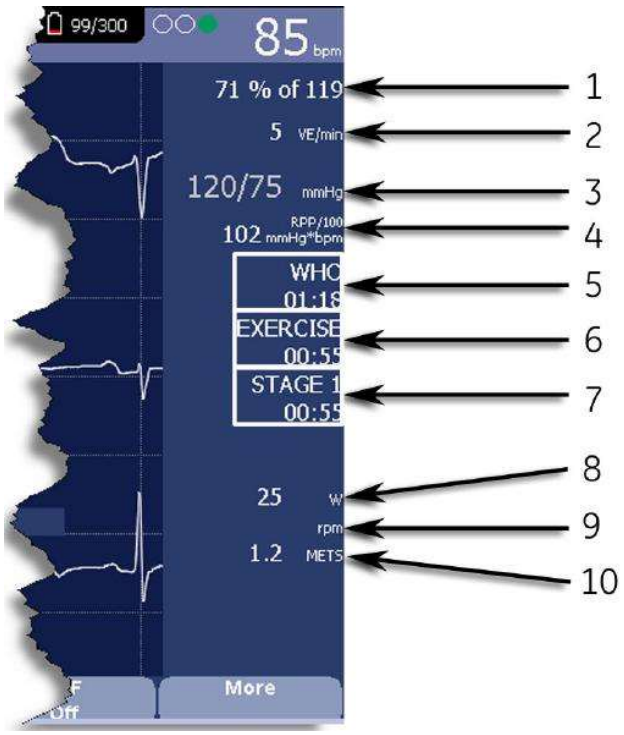
- You must purchase the ***ERGO*** option and add it to the system.
  For more information, see "Options Setup" on page 153.
- You must select the correct equipment on the ***Basic System Setup***.
  For more information, see "Basic Setup" on page 107.
- You must configure the ***Stress ECG Setup*** correctly.
  For more information, see "Stress ECG Settings" on page 124.

Stress Mode Interface

The Stress ECG mode uses two special features: a *Stress Test Information Bar* and *Stress Test Keys*. It also offers several configuration options.

Stress Test Information Bar

The ***Stress ECG*** mode adds an information bar on the right side of the ECG cart system display, as seen in the following illustration. Descriptions of the bar's key elements follow the illustration.



Stress Test Information Bar

Item Number	Feature	Description
1	Target Rate	The target heart rate and the current heart rate's percentage of that target.
2	VE/min	Ventricular ectopics per minute (also known as premature ventricular contraction). This is calculated as the sum of all Premature Ventricular Contractions (PVCs) and Ventricular Escape beats (ESCs) detected in the past 60-second interval.
3	Blood Pressure	Blood pressure in mmHg (millimeters of mercury) or kPa (kilopascals), depending on the *Blood Pressure Unit* setting on the *Country Settings* window. For more information, see "Country Setup" on page 141.
4	RPP/100	The Rate-Pressure Product divided by 100. The rate-pressure product is calculated by multiplying the systolic blood pressure with the current heart rate. The product is then divided by one hundred. For example, an RPP of 10200 displays as 102.
5	Protocol	Name of the current test protocol and its total duration in minutes and seconds.

Stress Test Information Bar (cont'd.)

Item Number	Feature	Description
6	Phase	Name of the current test phase and its total duration in minutes and seconds.
7	Stage	Name of the current test stage and its total duration in minutes and seconds. Displays in red when the system is in manual mode.
8	Speed/Load	Speed of the treadmill or load of the ergometer. Speed may be displayed as km/h (kilometers per hour) or mph (miles per hour) depending on the *Speed Unit* selected on the *Country Settings* window. Load is displayed in watts. For more information, see "Country Setup" on page 141.
9	Grade/RPM	The grade for a treadmill, in percent, or the revolutions per minute for an ergometer.
10	METS	Metabolic equivalent of the current exercise level.

Stress Test Keys

The Stress keys are described in "Stress Keys" on page 34.

Stress Options

This ECG cart system provides several options for configuring a Stress ECG. The options, presented as option keys across the bottom of the display, are listed in the following tables.

Stress Option Keys–First Row

Option	Description
Patient Data	Opens the patient data entry window.
Sweep Speed	Changes the speed of the waveform on the display and printout. Changing the measurement also changes the speed of the wiper bar on the display. The measurement is in millimeters per second (mm/s) and includes the following options: • 25 mm/s • 50 mm/s • 12.5 mm/s - 5 mm/s • 12.5 mm/s When the option includes two measurements (12.5 mm/s - 5 mm/s), the first speed is for the display and the second speed is for the printout.

Stress Option Keys–First Row (cont'd.)

Option	Description
Gain	Changes the magnitude of the ECG signal on the display or in the report. The measurement is in millimeters per millivolt (mm/mV) and includes the following options: • 5 mm/mV • 10 mm/mV • 20 mm/mV • 40 mm/mV • 2.5 mm/mV • Automatic The larger the selected measurement, the larger the waveform. Only the representation of the waveform changes; signal strength is not affected. **NOTE:** If ***Automatic*** is selected, the system calculates the best gain based on the peak-to-peak amplitudes of all the displayed leads and the selected display format.
Low Pass Filter	Toggles through the ***Low Pass Filter*** options: 20 Hz, 40 Hz, 100 Hz, and 150 Hz. It defaults to the setting selected on the ***Stress Setup*** window. (See "Stress ECG Settings" on page 124 for more information.) If the ***ADS*** filter type was selected in ***Stress Setup***, this softkey is displayed regardless of whether the filter is on or off. If the ***FRF*** filter type was selected in ***Stress Setup***, this softkey is displayed only if the filter is off.
ECG Filter Type	Toggles on and off the ECG filter type (***ADS*** or ***FRF***) selected on the ***Stress Setup*** window. In addition, if the ***FRF*** filter type was selected, toggling the filter off also displays the ***Low Pass Filter*** softkey.
More	Toggles between the first and second row of options.

Stress Text Option Keys—Second Row

Option	Description
Pace Enhance	Increases the readability of pacemaker ECGs. Options are ***On*** and ***Off***.
Printer Leads	Selects which leads to include in the printout. Options are: • First Six • Second Six • Rhythm Six • 12 Use this setting only when conducting rhythm ECGs. For more information, see "Generating a Rhythm Report (Manual Recording)" on page 74.

Stress Text Option Keys—Second Row (cont'd.)

Option	Description
Select Protocol	Selects a predefined set of test criteria. For more information, see "Editing Stress Protocols" on page 128.
Report Format	Selects the components and episodes to include in the report. Allows you to override the defaults set on the ***Stress ECG Setup*** window. For more information, see "Stress ECG Settings" on page 124.
Target HR	Enter the maximum heart rate calculated for the patient based on weight, gender, age, and condition. The ECG cart system monitors the heart rate against this target.
More	Toggles between the first, second, and third row of options.

Stress Text Option Keys—Third Row

Option	Description
Main Menu	Exits the ***Stress ECG*** function and returns to the ***Main Menu***.
More	Toggles between the first, second, and third row of options.

Conducting Stress Tests

There are two basic processes for conducting a stress test:

- Conducting a stress test with a treadmill or ergometer
- Conducting a stress test with a Master's Step device

Each process is described in this section. For information on the ***Stress Mode*** interface, see "Stress Mode Interface" on page 90.

Conducting a Stress Test with a Treadmill or Ergometer

Use the following instructions to conduct a stress test with a treadmill or ergometer. The process is essentially identical for all devices with only minor differences between supported equipment, unsupported equipment, and ergometers with remote start. Deviations for specific accessories are noted where appropriate.

WARNING:

PATIENT INJURY — When on a moving treadmill, a patient could fall and sustain an injury.

To minimize the possibility of a falling caused by the belt's sudden movement, have the patient step onto the belt only after it begins moving.

When conducting stress tests on a supported treadmill, press the **Stop TM** button twice to immediately stop the belt in the case of an emergency (for example, if the patient stumbles or falls while the belt is moving).

1. Prepare the patient as described in "Preparing the Patient" on page 49.
2. On the ***Main Menu*** press the ***Stress ECG*** option.

   The ***Enter Patient Data*** window opens.

3. Enter patient data as described in "Entering Patient Information" on page 55.
4. Adjust the stress options as necessary:

   This includes the speed and gain, finite residual filter, pacemaker enhancement, printer leads, test protocol, report format, and target heart rate. For more information on setting these options, see "Stress Options" on page 92.
5. Record a preliminary ECG.

   This may be a seated, standing, supine, or hyperventilating ECG, depending on the requirements of the selected protocol.
6. Begin the pretest phase.
   a. Have the patient get on the device.
   b. Press the **Pretest** key.
   c. Allow the patient to warm up before beginning the exercise phase of the test.

      NOTE:
      On supported treadmills, press **Start TM** to start the belt.
7. When the patient is ready to begin the stress test, press the **Exercise** key.

   During the test, you can use the stress keys to hold the current stage, enter blood pressure, add a comment, change the displayed leads, and toggle the finite residual filter. With supported equipment, you can also use the stress keys to adjust the equipment's speed, grade, or load. With unsupported equipment, the equipment must be adjusted manually at the equipment itself.

   For more information on making these adjustments, see "Stress Test Keys" on page 92.
8. When the exercise phase is complete, press the **Recovery** key to begin the recovery phase of the test.

   NOTE:
   When using an ergometer with remote start, you do not need to press the **Recovery** key because the recovery phase begins automatically at the end of the last stage. However, you can press the **Recovery** key to begin the recovery phase before the last stage ends.

   On supported treadmills, the belt begins to slow and the grade drops to 0%. On supported ergometers, the load begins to lighten. On unsupported treadmills and ergometers, these adjustments must be made manually.

   Continue to monitor the patient and record the ECG until the device stops.
9. When the recovery phase is over, press the **Test End** key.

   The menu options at the bottom of the screen change to ***Confirm Test End*** and ***Continue Test***. Do one of the following:

   - To return to the test, press ***Continue Test***.
     The previous menu options return. Continue to record the ECG as needed. When you are done, repeat this step.
   - To stop the test, press ***Confirm Test End***.

The menu options change. Continue to step 10.

10. Do any of the following, as necessary.

    - Press ***Next Patient*** to test another patient.
      You are warned that testing another patient discards the results of the current test. Do one of the following:
      - Press ***No*** to cancel the change in patients and return to the current test. You can either print the current test report or change the report formats.
      - Press ***Yes*** to erase the current test results and test a new patient. Repeat from step 3 for the next patient.
    - Press ***Print*** to print the test's report.
      The report prints with the selected format options.
    - Press ***Report Format*** to modify the report format.
      The ***Report Format*** window opens. Select the options you want to include in the report and press ***Save***. You can now print the test's report.

Conducting a Stress Test with a Master's Step Device

Use the following instructions to conduct a stress test with a Master's Step device, if it is selected in ***Basic Setup***.

1. Prepare the patient as described in "Preparing the Patient" on page 49.
2. On the ***Main Menu*** press ***Stress ECG***.

   The ***Enter Patient Data*** window opens.
3. Enter patient data as described in "Entering Patient Information" on page 55.

   Be sure you enter accurate information for ***Date of Birth***, ***Gender***, and ***Weight***. The number of steps is determined by these three parameters.

   For more information on using Master's Step, see "Master's Step Data" on page 189.
4. Adjust the stress options as necessary:

   This includes the speed and gain, finite residual filter, pacemaker enhancement, printer leads, test protocol, report format, and target heart rate. For more information on setting these options, see "Stress Options" on page 92.
5. Record a preliminary ECG.

   This may be seated, standing, supine, or hyperventilating, depending on the requirements of the selected protocol.
6. Begin the pretest phase to allow the patient to warm up.
   a. Remove the leadwires from the patient, but leave on the electrodes.

      This prevents the patient from tripping on the leadwires during the test.
   b. Instruct the patient to take a step whenever the system beeps.
   c. Press the **Pretest** key.

7. Press the **Exercise** key to begin the test.

   The duration of the exercise phase is dependent on the selected protocol:

   - ***SINGLE*** is 90 seconds
   - ***DOUBLE*** is 180 seconds
   - ***TRIPLE*** is 270 seconds

   When the test is complete, the first ***POSTEXER.*** stage begins and the ***ELECTR.ON*** message is displayed.

8. Reattach the leadwires to the electrodes.

   The median report prints at pre-configured intervals during the post exercise stages. When the last post exercise stage is complete, a summary report with trends and tables prints.

11

Managing Internal Storage

The ***File Manager*** provides an interface to the system's optional internal storage. It provides the tools to:

- Import records from an external source
- Print the internal storage directory
- Search stored records
- Edit a record's patient data
- Delete records
- Print records
- Transmit records to an external device
- Export records to a secure digital card or shared directory

You can print resting ECGs or save them to internal storage. You can only print arrhythmia and stress ECGs.

You can store resting ECGs automatically or manually:

- To save resting ECG records automatically, on the ***Resting ECG Settings*** window, select the ***Auto Store ECG*** check box. For more information, see "Resting ECG Setup" on page 112.
- To save resting ECG records manually, after the resting ECG is acquired, press ***Save***. For more information, see "Post-Acquisition Options" on page 71.

To enable internal storage, you must enable the M100 option, ***Internal Storage for 100 ECGs***, or the M200 option, ***Internal Storage for 200 ECGs*** (at a 500 Hz sampling rate).

Importing Records

In addition to saving ECGs recorded with the system, you can also import ECG records to internal storage from the following sources:

- Secure Digital (SD) cards
- CardioSoft systems connected via serial port or modem
- MUSE systems connected via modem

No additional set up is required to import from an SD card.

To import data via serial port or modem you need to do the following:

- Purchase and activate the appropriate communications option.
  For more information see "Options Setup" on page 153.
- Configure the system's data communication settings.
  For more information, see "Communication Setup" on page 131.

NOTE:
Imported records have a ***Sent*** status of ***Recv*** and you cannot edit, transmit or export them.

Use the following instructions to import a record into internal storage:

1. On the ***Main Menu*** press ***File Manager***.

   The ***File Manager*** window opens.

2. Press ***Import***.

   The function keys change.

3. Select the appropriate import source from the following options:
   - To import ECGs via serial port, press ***Serial***
     The serial port opens. The system waits while the external device transmits the records.
   - To import ECGs via modem, press ***Modem***.
     The modem initializes. The system waits while the external device transmits records.
   - To import ECGs from an SD card, insert the SD card and press ***SD Card***.
     A list of the available ECGs on the card opens. Continue with step 4.
4. Select the records you want to import from the SD card.
5. When the correct records are selected, press ***Import***.

Printing the File Manager Directory

Use the following instructions to print the directory of ECGs stored in internal memory:

1. On the ***Main Menu*** press ***File Manager***.

   The ***File Manager*** window opens.

2. Press ***Print Directory***.

   The directory prints on the writer.

Finding Records

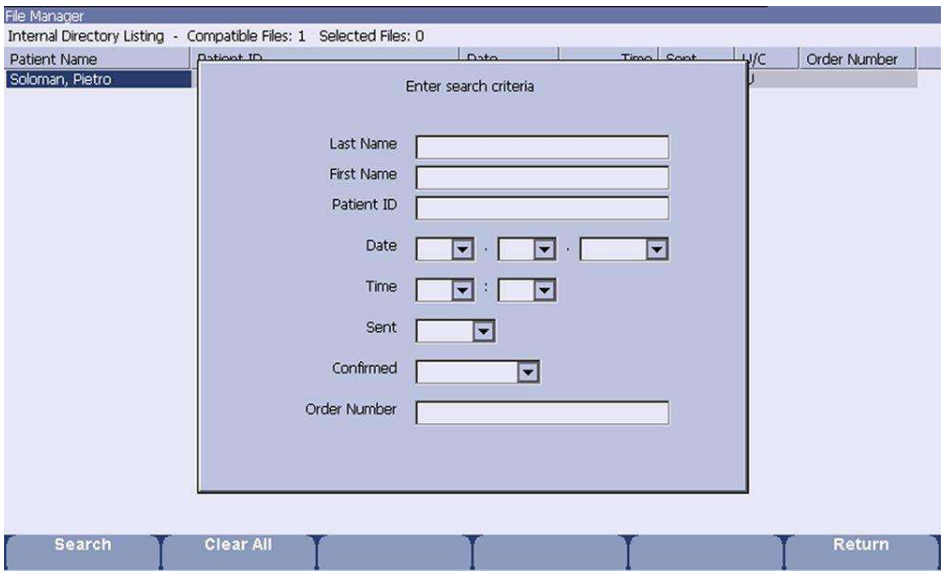
The ***File Manager*** may have up to 200 records to manage (if the M200 option is enabled), making it difficult to find a specific record. To help you locate a record or a group of records, use the following instructions.

1. On the ***Main Menu***, press ***File Manager***.

   The ***File Manager*** window opens.

2. Press ***Search***.

   The ***Enter Search Criteria*** window opens.



3. Enter your search criteria.
4. Press ***Search***.

   The ***File Manager*** retrieves all the records that match your search criteria.

5. To clear the search results, do one of the following:
   - Press ***Main Menu*** > ***File Manager***.
   - Press ***Search*** > ***Return***.
   - Press ***Search*** > ***Clear All*** > ***Search***.

Editing Patient Data

Use the following instructions to edit a record's patient data:

1. On the ***Main Menu*** press ***File Manager***.

   The ***File Manager*** window opens.

2. Press ***Select***.

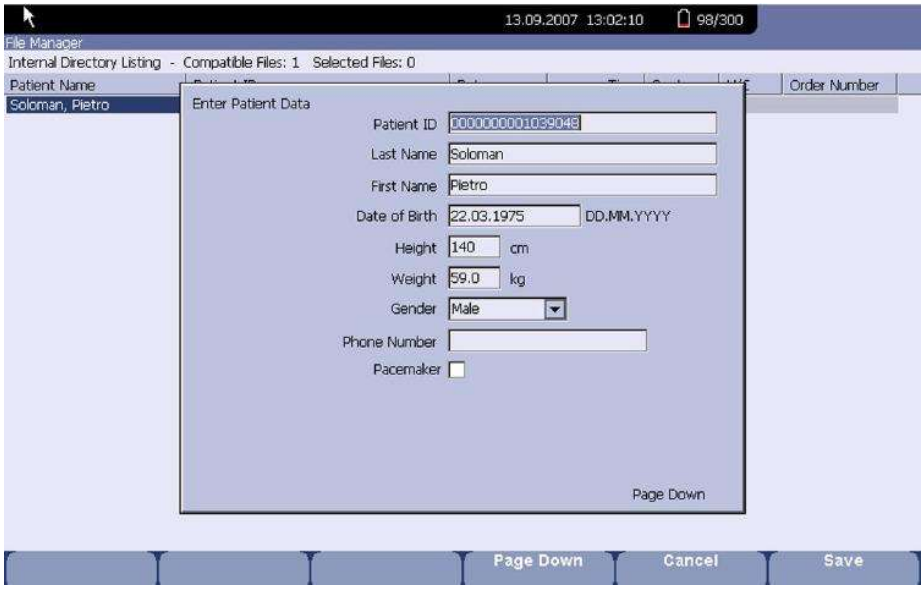
   This enters the ***File Manager*** into ***Select*** mode.

3. Use the **trimpad** to select the record you want to edit.

   NOTE:
   You cannot edit the patient data for records that were imported to internal storage. Imported records have a ***Sent*** status of ***Recv***.

4. Press ***Edit***.

   The ***Enter Patient Data*** window opens.



5. Edit the information as appropriate.

   For instructions on editing patient information, see "Entering Patient Information" on page 55.

6. After the information is updated, press ***Save***.

   The updated information is saved, and you return to the ***File Manager*** window.

NOTE:
If you only edit demographic information, the record is still transmitted to the MUSE system as an unconfirmed record.

Previewing Records

Use the following instructions to preview recorded patient data:

1. From the ***Main Menu***, press ***File Manager***.

   The ***File Manager*** window opens.

2. Press ***Select*** and use the **trimpad** to select the record you want to preview.

3. Press ***Preview***.

   A window opens with the record for you to review.

4. After reviewing the record, press ***Return*** and return to the ***File Manager***.

Deleting Records

Use the following instructions to delete all records from internal storage:

1. On the ***Main Menu***, press ***File Manager***.

   The ***File Manager*** window opens.

2. Do one of the following.

   - To delete select records, press ***Select*** and use the **trimpad** to select the record(s) you want to delete.
   - To delete all the records in storage, press ***Select All***.

3. Press ***Delete***.

   A window opens and prompts you confirm that you want to delete the selected record(s).

4. Do one of the following:

   - To cancel the deletion, press ***No***.
   - To delete the record(s), press ***Yes***.

Printing Records

Use the following instructions to print records:

1. On the ***Main Menu***, press ***File Manager***.

   The ***File Manager*** window opens.

2. Do one of the following:

   - To print select records, press ***Select*** and use the **trimpad** to select the record(s) you want to print.
   - To print all the records in storage, press ***Select All***.

3. Press ***Print***.

   The selected records are printed on the writer.

Transmitting Records

Use the following instructions to transmit records from internal storage to an external device.

Before transmitting a record, you must do the following:

- Purchase and activate a communication option.
  See "Options Setup" on page 153 for more information.
- Configure data communications.

See "Communication Setup" on page 131 for more information.

- Connect the device to the communication option.
  - To set up a LAN connection to a CardioSoft system, see "Connecting the LAN Option" on page 46.
  - To set up a WiFi connection to a CardioSoft system, refer to "Connecting the WiFi Option" on page 46.
  - To set up a WiFi connection to a MUSE system, refer to "Connecting the WiFi Option" on page 46 .

NOTE:
For more information on setting up a LAN or WiFi connection to a MUSE system, refer to the *LAN Option Installation and Troubleshooting Guide*. To locate the part number for this manual, refer to "Related Documents" in the service manual.

Use the following procedure to transmit records

1. On the ***Main Menu***, press ***File Manager***.

   The ***File Manager*** window opens.

2. Do one of the following:

   - To transmit select records, press ***Select*** and select the record(s) you want to transmit.

     NOTE:
     You cannot transmit records that were imported to internal storage. Imported records have a ***Sent*** status of ***Recv***.

   - To transmit all the records in storage, press ***Select All***.

3. Press ***Transmit***.

   One of two things happens, depending on the number of locations defined in ***Communications Setup***:

   - If only one location is defined, the files are transmitted to the default location.
   - If multiple locations are defined, a window listing the locations opens. Select the correct location and press ***OK***.

Exporting Records

You can export records from internal storage to a Secure Digital card or a shared directory, in either a Hilltop/XML or PDF format. The maximum number of records you can export in XML format is determined by which storage option is enabled:

- If ***M100*** is enabled, the maximum is 100.
- If ***M200*** is enabled, the maximum is 200 (with a sampling rate of 500 Hz).
- Records exported in PDF format have no maximum limit.

NOTE:
The SD card capacity and manufacturer determine data transfer rates and storage space. This may affect the time required to read or write to the SD card. It may also limit the number of records that you can store on the card. GE Healthcare recommends you use Secure Digital High Capacity (SDHC) cards with a capacity of 4 GB, either supplied by GE Healthcare or manufactured by SanDisk.

Setting Up Export Options

The requirements for setting up export differ depending on the export method:

- To export XML data to an SD card, you must first enable Export XML in ***Communication Setup***.
- To export PDF files to an SD card, you must first enable the ***PDFC*** (PDF Export) system option. Refer to "Options Setup" on page 153 for details.
- To export either Hilltop/XML or PDF to a shared directory, you must do the following:
  - Purchase and activate the ***LAN Communications to CardioSoft*** (***LANC***) option *or* ***WiFi Communications to CardioSoft (WIFC)*** option.
    Refer to "Options Setup" on page 153 for details.
  - Define the shared directory setting on ***Communications Setup***.
    Refer to "Options Setup" on page 153 for details

Exporting Records

Once the necessary configurations are complete, use the following instructions to export records from internal storage:

1. On the ***Main Menu***, press ***File Manager***.

   The ***File Manager*** window opens.

2. Select the record(s) you want to export.

   - To export select records, press ***Select*** and use the **trimpad** to select the records you want to export.

     NOTE:
     Records that are imported to internal storage cannot be exported from internal storage in Hilltop or XML formats; those records can be exported in PDF format. Imported records have a ***Sent*** status of ***Recv***.

   - To export all records in storage, press ***Select All***.

3. Press ***More*** > ***Export***.

   The function keys change. Depending on which options were activated, the function keys may include ***Hilltop XML***, ***PDF***, and ***Return***.

4. If you are exporting to an SD card, insert the card into the SD card slot.

   Make sure the card has sufficient free space for the selected records and that it is not write-protected.

   NOTE:
   If you do not enter the SD card into the SD card slot, you receive the following warning when attempting to export data to the card:

   SD Card is not present.

   Refer to "SD Card Not Present" on page 178 for further instructions.

5. Press the appropriate function key:
   - To export in both XML and Hilltop formats, press ***Hilltop XML***.
   - To export in PDF format, press ***PDF***.
   - To return to the previous set of function keys, press ***Return***.

   If you press ***Hilltop XML*** or ***PDF***, one of two things happens, depending on your system configuration:
   - If a shared directory was configured, the ***Select Export Destination*** window opens.
     Go to step 6
   - If a shared directory was not configured, the records are automatically exported in the selected format to the SD card.
     When the export is complete, one of two things happens, depending on the selected format:
     - For the ***Hilltop XML*** format, the screen clears and the function keys change.
     - For the ***PDF*** format, a summary window opens with the number of records that exported successfully and the number that failed to export. Press ***OK*** to close the summary window.
       If you want to select additional records to export, return to step 2 or continue to step 6.
6. In the ***Select Export Destination*** window, select the appropriate export destination:
   - To export to an SD card, select ***SD Card***.
   - To export to the shared directory, select ***Shared Directory***.

   NOTE:
   When exporting to a shared directory, the device logs on to the directory with the user name and password defined on the ***Communications Setup*** window. If either of those values are incorrect, you receive an error message. Correct the user name and password on the ***Communications Setup*** window and repeat the export process.
7. Press ***OK***.

12

System Configuration

System Configuration provides access to functions that allow you to customize the system settings and to utilities to help manage those settings. This chapter describes the settings managed by each function and the process followed by each utility.

NOTE:

Configuration changes can cause data loss. After making configuration changes, you MUST return to the ***Main Menu*** to ensure the changes are saved.

Depending on which options were activated, some of these functions may not be available on your system.

Basic Setup

The ***Basic Setup*** function allows you to define the following information:

- Institutional identification
- Default physicians
- System settings
- Stress test accessory (if the ***ERGO*** stress test option is activated)
- System security
- Time servers

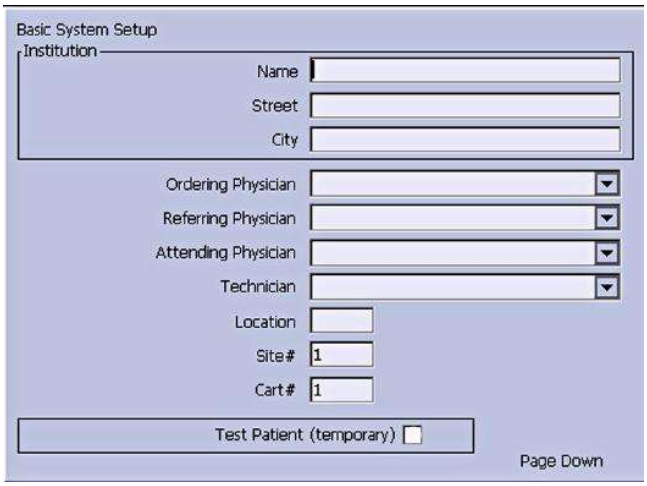
NOTE:

You must add physicians in ***User Setup*** before they can be picked as default physicians. For more information, see "User Setup" on page 149.

For more information on the ***ERGO*** and ***CFRA*** options, see "Options Setup" on page 153.

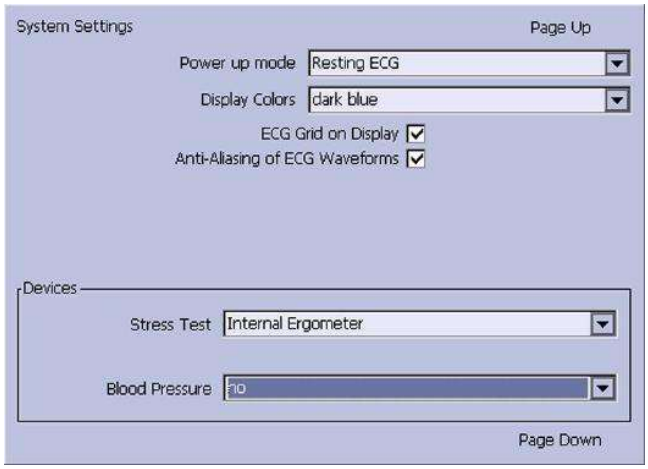
To access ***Basic Setup***, on the ***Main Menu***, press ***System Configuration*** > ***Basic Setup***.

The following tables describe each setting available on ***Basic Setup***.



Basic Setup Fields—Page 1

Field	Description
Name	The name of the institution.
Street	The street address of the institution.
City	The city where the institution is located.
Ordering Physician	The physician who ordered the ECG. Defaults on any patient records created on the system.
Referring Physician	The physician who referred the patient. Defaults on any patient records created on the system.
Attending Physician	The physician who supervised the ECG. Defaults on any patient records created on the system.
Technician	The technician who conducted the ECG. Defaults on any patient records created on the system.
Location	Location ID where the device is located. Defaults on any patient records created on the system.
Site #	This field is required to store ECG reports on a cardiology information system such as the MUSE system.
Cart #	Unique cart number of the device. Defaults on any patient records created on the system.
Test Patient (temporary)	Enables/disables simulated ECGs. When enabled, simulated waveforms are generated in the resting, arrhythmia, RR analysis, or stress ECG functions. This is useful for demonstration, training, or testing purposes. **NOTE:** This setting clears when the system is reset.

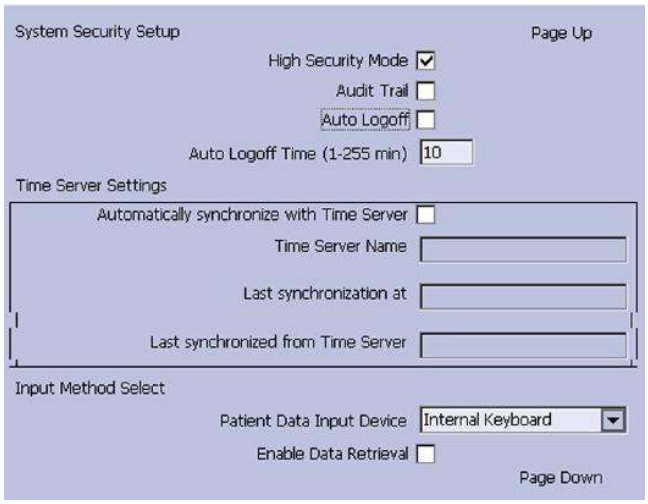


Basic Setup Fields–System Settings

Field	Comment
Power up mode	Determines which screen is displayed when the system is powered on. Available options are: • ***Resting ECG*** (default) • ***Arrhythmia*** • ***Main Screen*** • ***Stress ECG*** • ***Order Manager***
Display Colors	Determines the appearance of the ECG display. Select a color combination that is legible for you.
ECG Grid on Display	Determines whether a grid is displayed behind the waveforms. A grid may make reading the ECG easier. The default is ***on***.
Anti-Aliasing of ECG Waveforms	Determines whether anti-aliasing is applied to waveforms to reduce distortion caused by the video display. The default is ***on***.

Basic Setup Fields–System Settings (cont'd.)

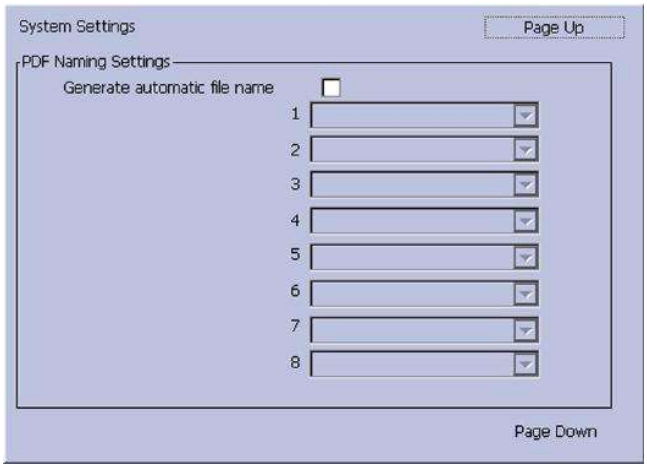
Field	Comment
Stress Test	Identifies the device used to perform the stress test. Available options are: • Internal Ergometer • Ergometer eBike • Internal Treadmill • Treadmill T2000 • Treadmill T2100 • Master's Step device This field is only available if the ***Stress*** option is enabled. For information on enabling stress tests, see "Stress ECG Setup" on page 124. For information on conducting stress tests, see "Stress Testing" on page 89.
Blood Pressure	Indicates whether the patient's blood pressure should be taken by the stress device. Available options are: • No • In ergometer This field is only available if the ***Stress*** option is enabled.



Basic Setup Fields–System Security Setup

Field	Comment
High Security Mode	When ***High Security Mode*** is enabled, users are prompted to enter an ID and password when logging on to the system. You must add each user in ***User Setup***.
Audit Trail	Copies the system audit trail in XML format to an SD card and then clears the audit trial on the system. For more information see "Exporting the Audit Trail" on page 159.
Auto Logoff	Determines whether the system automatically logs the user off after a predefined period of inactivity. See also ***Auto Logoff Time***. This is available only if ***High Security Mode*** is enabled.
Auto Logoff Time (1–255 min)	Determines the length of inactivity, in minutes, before the system logs off the user. This is available only if ***High Security Mode*** is enabled.
Automatically synchronize with Time Server	Enables/disables automatic synchronization with an external time server either on the institution's network or the Internet. You must activate a LAN option to set this option.
Time Server Name	Identifies the server with which the device synchronizes its time. This can be a server on the institution's network or on the Internet. Contact your server administrator for this information.
Last synchronization at	Display-only field that identifies when the last synchronization occurred.
Last synchronized from Time Server	Display-only field that identifies where the last synchronization occurred.
Patient Data Input Device	Allows the user to select the input methods to download patient demographics. The available options are: • Internal Keypad • External keyboard • Barcode Reader
Enable Data Retrieval	If this option is enabled, the user can download patient demographics.

If the ***PDFC*** option is enabled, you receive the ***System Settings–PDF Naming Settings*** window.



Basic Setup Fields–System Settings (PDF Naming Settings)

Field	Description
Generate automatic file name	Select the checkbox; the numbered fields are enabled. Use the drop-down arrow to select each setting.

For more information, see "Customizing the Naming Convention" on page 158.

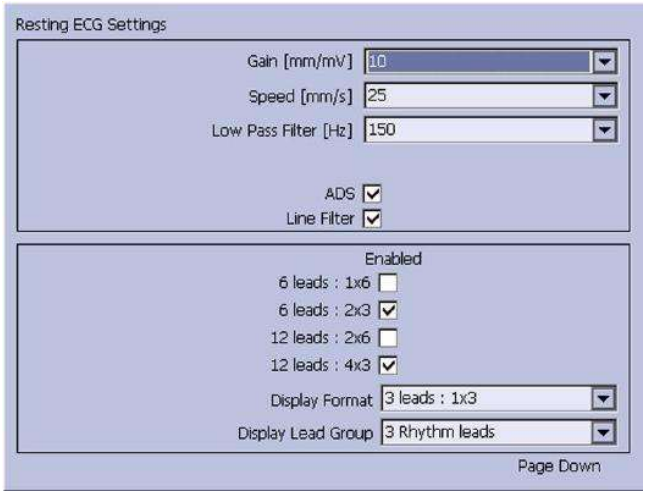
Resting ECG Setup

The ***Resting ECG Setup*** window allows you to define:

- Waveform parameters
- Lead usage
- Analysis options
- Lead sequence
- Report options
- Storage options (if the internal storage option is activated)
- Transmission options (if a communications option is activated)

To access the ***Resting ECG Setup*** window, on the ***Main Menu*** press ***System Configuration*** > ***Resting ECG Setup***.

The following tables describe each setting available on ***Resting ECG Setup***.

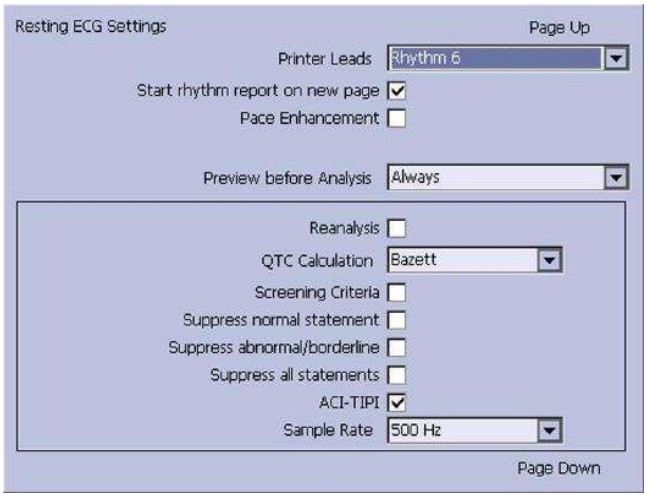


Resting ECG Setup Fields–Page 1

Field	Comment
Gain	Sets the amplitude of the ECG signal. Measurement is in millimeters per millivolt and includes the following options: • 2.5 mm/mV • 5 mm/mV • 10 mm/mV • 20 mm/mV • 40 mm/mV • Automatic The larger the selected measurement, the larger the waveform. Only the representation of the waveform changes; signal strength is not affected. **NOTE:** If ***Automatic*** is selected, the system calculates the best gain based on the peak-to-peak amplitudes of all displayed leads and the selected display format.
Speed	Changes the speed of rhythm printing and the wiper bar movement across the display. Measurement is in millimeters per second (mm/s) and includes the following options: • 5 mm/s (rhythm) / 12.5 mm/s (display) • 12.5 mm/s • 25 mm/s • 50 mm/s

Resting ECG Setup Fields–Page 1 (cont'd.)

Field	Comment
Low Pass Filter	Sets the maximum frequency to include in the waveform. Restricting frequencies can help eliminate noise in the waveform. Frequencies are measured in Hertz (Hz) and include the following options: • 20 Hz • 40 Hz • 100 Hz • 150 Hz Selecting a frequency eliminates signals above that frequency. For example, if you select 40, only signals that have a frequency of 40 Hz or lower are included in the waveform.
ADS	Toggles the anti-drift system (***ADS***) on and off. ***ADS*** helps reduce baseline drift.
Line Filter	Enables/disables the line filter defined in ***Country Setup***.
6 leads: 1x6	Enables/disables a display option that shows one six-waveform column.
6 leads: 2x3	Enables/disables a display option that shows two three-waveform columns.
12 leads: 2x6	Enables/disables a display option that shows two six-waveform columns.
12 leads: 4x3	Enables/disables a display option that shows four three-waveform columns.
Display Format	Selects the display format of the resting ECG. The default value is ***3 leads: 1x3***. Other values depend on which of the previous two fields are set.
Display Lead Group	Determines which group of leads is displayed. The available values depends on which ***Display Format*** is selected. For example, if ***3 Leads: 1x3*** is selected, the available values are: • 3 rhythm leads • 1st group • 2nd group • 3rd group • 4th group



Resting ECG Setup Fields–Page 2

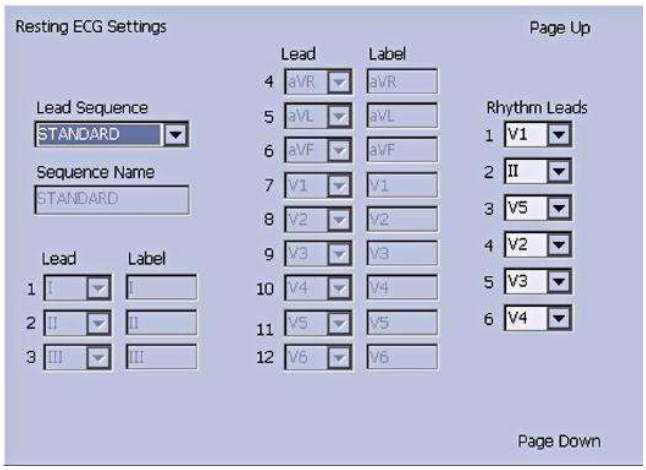
Field	Comment
Printer Leads	Identifies the default set of leads to use for printing. The values are: • First 6 • Second 6 • Rhythm 6 • 12
Start rhythm report on new page	Determines whether the rhythm report prints on a separate page.
Pace Enhancement	Increases the readability of pacemaker ECG either by augmenting small pace pulses or by truncating large pace pulses. If enabled, pace enhancement is done in two steps: 1. Add a marker (1.5 mV amplitude, 6 ms duration) to the electrode signal. 2. Limit the sum to 0.5 mV in the lead signal.
Preview before Analysis	Determines waveform preview options. Values include: • ***No*** Waveforms are never previewed. • ***Always*** Waveforms are always previewed. • ***Yellow electrodes*** Waveforms are previewed when the ***Hookup Advisor*** indicator shows a yellow or red electrode. • ***Red electrodes*** Waveforms are previewed when the ***Hookup Advisor*** indicator shows a red electrode. For additional information, see "Hookup Advisor" on page 66.

Resting ECG Setup Fields–Page 2 (cont'd.)

Field	Comment
Reanalysis	Enables/disables the reanalysis feature, which allows you to adjust the following ECG measurements: • P Duration • PR Interval • QRS Duration • QT Interval This is available only if ***Audit Trail*** is disabled and one of the following options is activated: ***ME12***, ***MEHR***, ***MI12***, or ***MIHR***. For more information on activating options, see "Options Setup" on page 153.
QTC Calculation	Determines which formula is used to correct QT calculations. Available options are: • Bazett QTc = QT √HR\60 Bazett is available only if the MEHR or MIHR option is activated. • Framingham QTc = QT + 154 (1 — 60/HR) Framingham is available only if the ME12 or MI12 option is activated. • Fridericia QTc = QT^3 √HR/60 Fridericia is available only if the ME12 or MI12 option is activated. **NOTE:** In all formulas, HR = Heart Rate.
Screening Criteria	Enables/disables the inclusion of the screen criteria. This setting is available only if the ***MI12*** option is activated.
Suppress normal statement	Enable/disables the inclusion of the normal statement. This setting is available only if the ***MI12*** option is activated.
Suppress abnormal/borderline	Enable/disables the inclusion of the abnormal/borderline statements. This setting is available only if the ***MI12*** option is activated.
Suppress all statements	Enable/disables the inclusion of all statements. This setting is available only if the ***MI12*** or ***MIHR*** option is activated.

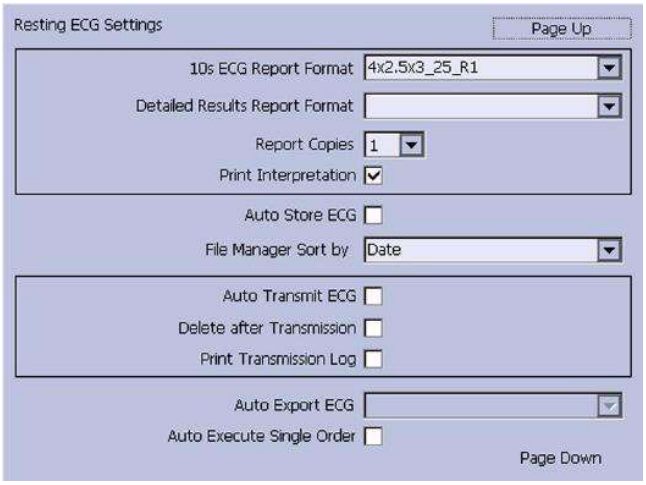
Resting ECG Setup Fields–Page 2 (cont'd.)

Field	Comment
ACI-TIPI	Enables/disables the inclusion of the ACI-TIPI (Acute Cardiac Ischemia Time Insensitive Predictive Instrument) statement and enables the ***Chest Pain*** field on the ***Patient Information*** window. To include ACI-TIPI statements, the following conditions must be met: • ***MI12*** or ***ME12*** system option is activated • TIPI system option is activated • ACI-TIPI is enabled • 10s ECG Report Format is enabled • Print Interpretation is enabled • Patient data includes: gender, date of birth, and chest pain indication • Patient cannot be a pediatric patient (15 years or younger) as calculated form the date of birth
Sample Rate	Determines the report frequency. Options are ***500 Hz*** or ***1000 Hz***. 1000 HZ is supported only for XML output.



Resting ECG Setup Fields–Page 3

Field	Description
Lead Sequence	Determines the lead sequence to use. Values are: • ***Standard*** • ***Cabrera*** • ***NEHB*** • ***SEQ4*** ***SEQ4*** allows you to configure a custom 12-lead sequence using the following fields. If either ***12SL*** option (***ME12*** or ***MI12***) is activated, you must select leads I (-I), II (-II), V1, V2, V3, V4, V5, and V6 for a correct 12SL analysis.
Sequence Name	Set the display name for a custom lead sequence. Available only if ***SEQ4*** is selected for the ***Lead Sequence***.
1–12 Lead	Twelve fields that allow you to define the sequence in which the leads are displayed. Available only if ***SEQ4*** is selected for the ***Lead Sequence***.
1–12 Label	Twelve fields that allow you to define the labels that are displayed/printed for the corresponding leads. Available only if ***SEQ4*** is selected for the ***Lead Sequence***.
1–6 Rhythm Leads	Six fields that allow you to define the rhythm leads and their sequence. You can select the rhythm leads for all four lead sequences.



Resting ECG Setup Fields–Page 4

Field	Description
10s ECG Report Format	Determines how the ***10s ECG*** report prints. If no format is selected, the report does not print. The values are: • 1x10x12_25 • 1xx10x12_50 • 2x10x6_25 • 1x10x3_25 • 2x5x6_25 • 2x5x6_50 • 2x5x6_25_R1 • 4x2.5x3_25 • 4x2.5x3_25_R1 • 4x2.5x3_25_R3 • 4x2.5x3_25_R2_P • H1 • H2 If the CTDG option is enabled, the report format is 4x2.5x3_25_R2_P.
Detailed Results Report Format	Determines how the ***Detailed Results*** report prints. If no format is selected, the report does not print. The values are: • Median_25 • Median_50
Report Copies	Determines how many copies of the selected report print. The values are: • 0 • 1 • 2 • 3 • 4 • 5
Print Interpretation	Determines whether ECG interpretation prints on the report. Available only if either the ***MI12*** or ***MIHR*** option is activated.

Resting ECG Setup Fields–Page 4 (cont'd.)

Field	Description
Auto Store ECG	Determines whether the ECG is automatically stored on the internal storage. This is available only if the M100 or M200 internal storage option is activated. For more information, see "Options Setup" on page 153.
File Manager Sort by	Determines the field by which the File Manager sorts records in internal storage. This is available only if the M100 or M200 internal storage option is activated. Available options are: • Patient Name • Date • Patient ID • Order Number
Auto Transmit ECG	Determines whether the ECG is transmitted automatically to an external device. Available only if one of the communications options is activated. For more information, see "Options Setup" on page 153.
Delete After Transmission	Determines whether the ECG is deleted from internal storage after it is transmitted to an external device. Available only if one of the communications options is activated. For more information, see "Options Setup" on page 153.
Print Transmission Log	Determines whether the transmission log prints after an ECG is transmitted from ***File Manager*** to an external device. Available only if one of the communications options is activated. For more information, see "Options Setup" on page 153.
Auto Export ECG	Determines whether the ECG is automatically exported in Hilltop, Hilltop/XML, or PDF format to the shared directory location. This is available only if the user has configured and enabled shared directory settings in the ***Communication Setup***. Availability of Hilltop/XML format depends on whether ***Export XML*** option was enabled in ***Communication Setup***. Availability of PDF format depends on ***PDFC*** option activation in ***Options Setup***. For more information, see "Communication Setup" on page 131.
Auto Execute Singe Order	Determines whether the single order requested by the user is automatically downloaded and executed. This is available only if the ***SOML/SOMF*** simple order manager options are activated in ***Options Setup***.

If the ***PDFC*** option is enabled, you receive the ***Resting ECG Settings–PDF Export Setup*** window.

Resting ECG Setup Fields–Page 4 (PDF Export Setup)

Field	Description
10s ECG Report Format	Determines how the 10s ECG report prints to a PDF file. The options are: • 4x2.5x3_25 • 4x2.5x3_25_R1 • 4x2.5x3_25_R3 • MUSE1 • MUSE2 • 1x10x12_25 **NOTE:** Options MUSE1 and MUSE2 are not available in the Chinese version.
Baseline Auto Adjust	Enables/disables the PDF export. Available only when the ***1x10x12_25*** of ***10s ECG Report Format*** option is selected.

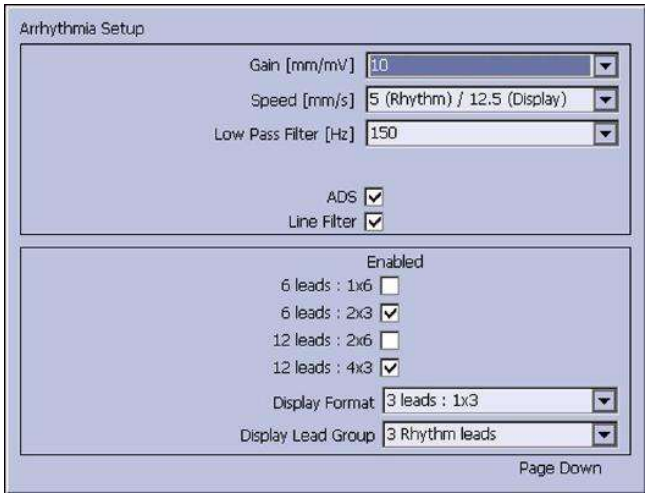
Arrhythmia Setup

The ***Arrhythmia Setup*** function allows you to define:

- Waveform parameters
- Lead usage
- Analysis options
- Lead sequence
- Report options

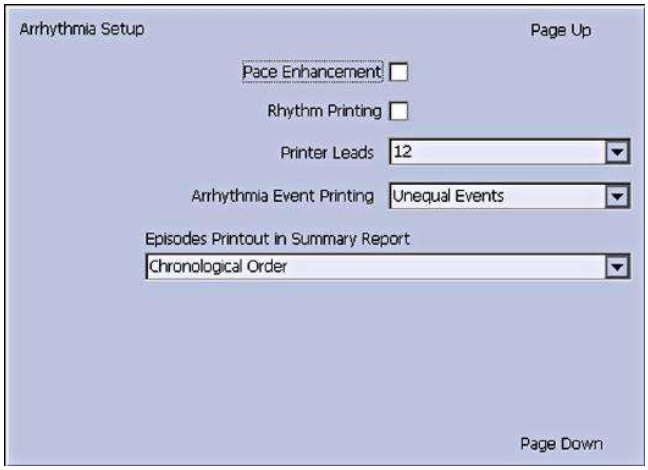
To access ***Arrhythmia Setup***, on the ***Main Menu*** press ***System Configuration*** > ***Arrhythmia Setup***.

Most of the fields on the ***Arrhythmia Setup*** windows are the same as those on ***Resting ECG Setup***. The following tables list the arrhythmia settings that are unique or differ from resting ECG. For all other fields, see "Resting ECG Setup" on page 112.



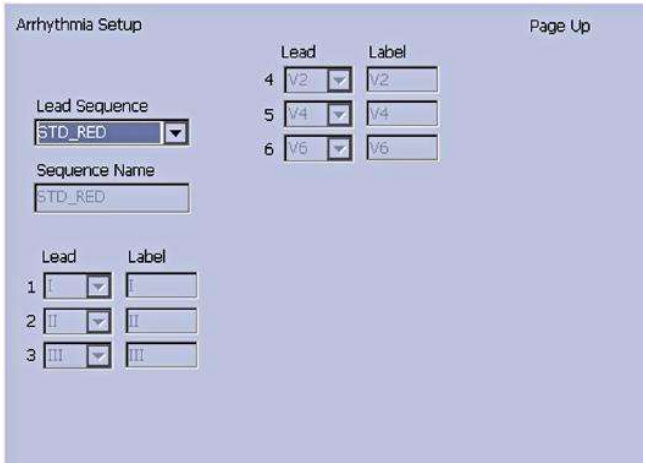
Arrhythmia Setup Fields–Page 1

Field	Description
ADS	Enables/disables the ***Anti-Drift System***, which helps reduce baseline shift. In ***Arrhythmia*** mode, this setting is always available.



Arrhythmia Setup Fields–Page 2

Field	Description
Rhythm Printing	Determines whether the rhythm report starts automatically when recording starts.
Arrhythmia Event Printing	Determines which events print on the Arrhythmia Report: • All events • Unequal events • No event printing
Episodes Printout in Summary Report	Determines how arrhythmia events print. Options are: • Chronological order • Priority order • Only episodes with ventricular events • No episodes



Arrhythmia Setup Fields–Page 3

Field	Description
Lead Sequence	Determines the lead sequence to use. ***Arrhythmia Setup*** includes the following options in addition to the four options available in the ***Resting ECG Setup***: • ***STD_C*** • ***STD_RED*** • ***STD_LI*** • ***CABR_LI*** • ***NEHB_6*** • ***HIGH_C***
1–6 Rhythm Leads	Six fields that allow you to define the rhythm leads and their sequence. You can select the rhythm leads for all four lead sequences. If you chose any of the following in ***Lead Sequence***, the rhythm leads are not displayed: • STD_C • STD_RED • STD_LI • CABR_LI • NEHB_6 • HIGH_C

Stress ECG Setup

Stress ECG Setup is available only if the ***ERGO Stress Test*** option was activated. For more information, see "Options Setup" on page 153.

The ***Stress ECG Setup*** differs from the resting or arrhythmia ECGs. In addition to defining the stress ECG settings, you can create, edit, or delete test protocols.

Stress ECG Settings

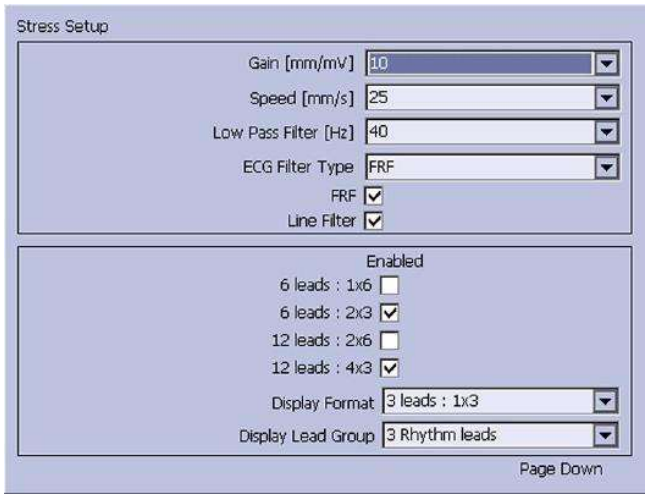
The ***Stress ECG Setup*** function allows you to define:

- Waveform parameters
- Lead usage
- Analysis options
- Report options
- Lead sequence

To access the Stress ECG Setup, on the ***Main Menu*** press ***System Configuration*** > ***Stress ECG Setup***.

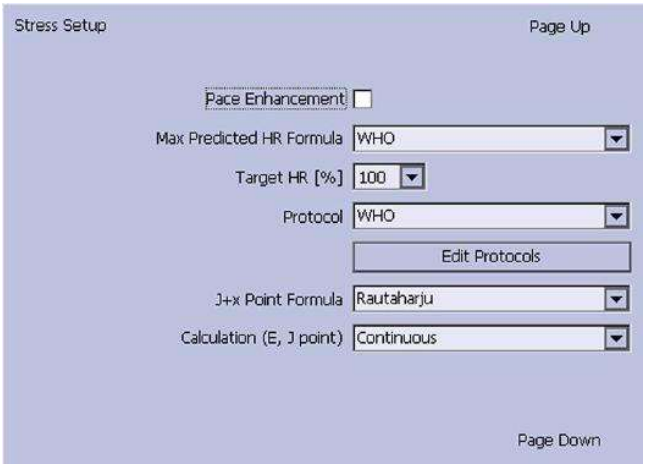
Many of the fields on the ***Stress ECG Setup*** windows are the same as those on the ***Resting ECG Setup*** or the ***Arrhythmia Setup***. The following tables list the settings that

are unique or differ from the resting or arrhythmia setups. For all other fields, see "Resting ECG Setup" on page 112 or "Arrhythmia Setup " on page 121.



Stress ECG Setup Fields–Page 1

Field	Comment
ECG Filter Type	Determines which method to use to filter the ECG signal. Options are: • ADS ***Anti-Drift System*** – reduces baseline shift • FRF ***Finite Residual Filter*** – reduces noise and artifacts The selection also determines the behavior of the ***Lower Pass Filter [Hz]*** and ***ADS/FRF*** fields.
ADS/FRF	Enables/disables the selected ***ECG Filter Type***. The label for this field changes depending on the filter type selected.



Stress ECG Setup Fields–Page 2

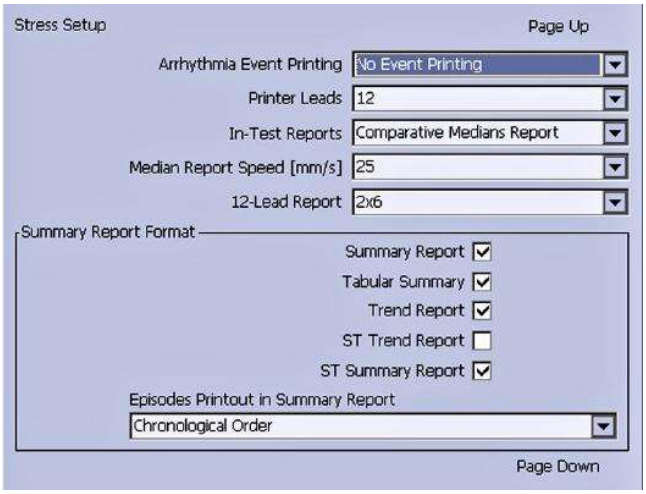
Field	Comments

Max Predicted HR Formula	Determines the formula that predicts the patient's maximum heart rate. Options are:
	• ***WHO***
	This formula, recommended by the World Health Organization, subtracts the patient's age from 220. For example, a patient who is 50 years old has a maximum predicted heart rate of *220 - 50 = 170*.
	• ***AHA***
	This formula, recommended by the American Heart Association, varies depending on the age of the patient.
	  • < 25 years old = 160 bpm
	  • > 75 years old = 115 bpm
	  • 25—75 years old = 160 – (age – 25) * 0.9
	For example, a patient who is 50 years old has a maximum predicted heart rate of 160 - (50-25) * 0.9 = 138.

Target HR [%]	Determines the percentage of the maximum predicted heart rate the stress test is targeting.
Protocol/Master's Step Mode	Determines which protocol conducts the stress test. The protocol determines the test phases, stages, stage durations, stage loads, and the times at which auto reports are printed and blood pressure is recorded. You can create custom protocols by selecting the ***Edit Protocols*** button. For more information, see "Editing Stress Protocols" on page 128. **NOTE:** If ***Master's Step device*** is selected as the ***Stress Test Device*** in ***Basic Setup*** (see "Basic Setup" on page 107), this field is labeled ***Master's Step Mode*** instead of ***Protocol***.

Stress ECG Setup Fields–Page 2 (cont'd.)

Field	Comments
J+x Point Formula	Determines the method that calculates the post J-Point. Options are: • 0 ms • 10 ms • 20 ms • 40 ms • 80 ms • Rautaharju (default value) • RR/16 The numeric values (0 ms—80 ms) add the selected number of milliseconds to the J-point
Calculation (E, J point)	Determines when the select J+x point formula is used. Valid options are: • Single The E and J points are calculated once in the beginning and remain unchanged during the stress test. • Continuous The E and J points are continuously updated during the PRETEST, EXERCISE, and RECOVERY phases of the stress test.



Stress ECG Setup Fields–Page 3

Field	Comments
In-Test Reports	Determines the format of the report. Options are: • Median Report • Comparative Medians Report
Median Report Speed [mm/s]	Determines the speed in millimeters per second at which the waveforms are represented on the report. Options are: • 25 • 50
12-lead Report	Determines the layout of a 12-lead report. Options are: • 1x12 One column showing 10 seconds from all 12 leads. • 2x6 Two columns each showing 5 seconds from 6 leads.
Summary Report	Determines whether the summary report format is included in the stress report.
Tabular Summary	Determines whether the tabular report format is included in the stress report.
Trend Report	Determines whether the trend report format is included in the stress report.
ST Trend Report	Determines whether the ST trend report format is included in the stress report.
ST Summary Report	Determines whether the ST summary report format is included in the stress report.
Episodes Printout in Summary Report	Determines how episodes are presented in the stress report. Options are: • Chronological Order • Priority Order • Only Episodes with Ventricular Events • No Episodes

Editing Stress Protocols

The following pre-defined stress test protocols are available.

Pre-defined Stress Test Protocols

Device	Protocols		
Treadmills	BRUCE	MODBRUCE	NAUGHTON
	ELLESTAD	MODBALKE	USAFSAM
	SLOW USAFSAM	CORNELL	BALKEWARE
	MODBALKEWARE	ADENOSINE	DOBUTAMINE
	PERSANTINE		

Pre-defined Stress Test Protocols (cont'd.)

Device	Protocols		
Ergometers	WHO	WHO50	WHO75
	HOLLMANN	BAL	STD.FRANCE
	MODWHO	CONCONI	
Master's Step	SINGLE	DOUBLE	TRIPLE

Most treadmill and ergometer protocols consist of three pre-defined *phases*: ***Pretest***, ***Exercise***, and ***Recovery***. Each phase can include multiple stages that define the parameters of the test. The parameters differ slightly depending on the device, as seen in the following table.

Stress Test Parameters

Parameter	Treadmill	Ergometer	Master's Step	Comment
Stage	✓	✓	The stage name.	The stage name.
Stage Time	✓	✓	✓	The stage duration, in minutes.
Speed	✓		The treadmill speed in kilometers or miles per hour, depending on the ***Country Setup***.	The treadmill speed in kilometers or miles per hour, depending on the ***Country Setup***.
Grade [%]	✓			The percentage of increase in the treadmill's elevation.
Basic Load (W)		✓	The load at which the ergometer operates, in watts.	The load at which the ergometer operates, in watts.
Store Median First	✓	✓		The interval at which the first median reading is stored.
Store Median Repeat	✓	✓	The interval at which a subsequent median reading is stored.	The interval at which a subsequent median reading is stored.

Stress Test Parameters (cont'd.)

Parameter	Treadmill	Ergometer	Master's Step	Comment
BP First	✓	✓		The interval at which the first blood pressure reading is stored.
BP Repeat	✓	✓	The interval at which subsequent blood pressure readings are stored.	The interval at which subsequent blood pressure readings are stored.

You can modify the pre-defined protocols to create custom protocols. Use the following instructions to create a custom protocol:

1. On the ***Main Menu*** press ***System Configuration*** > ***Stress ECG Setup***.

   The ***Stress ECG Setup*** window opens.

2. Press ***Page Down***.

   The second page opens.

3. Select ***Edit Protocols*** and press either **Enter** or the **trimpad**.

   For treadmills and ergometers, the ***Select Protocol*** window opens to display applicable protocols. Perform step 4 through step 16.

   For ***Master's Step*** devices, the ***Edit Master Step Post-Exercise*** window opens to display the display the post-exercise stages. Perform step 8 through step 12.

4. Press ***Add***.

   A list of templates opens.

5. Select the template on which you want to base the new protocol.

   The templates are based on the existing protocols. An ***Empty Protocol*** is also available.

6. Press ***OK***.

   The ***Add Protocol*** window opens.

7. Type a name for the new protocol and press ***OK***.

   The ***Protocol*** window opens with all the stages from the template. You can now add, edit, or delete stages.

8. To add a stage, do the following:

   a. Select the stage that precedes the new stage.

   b. Press ***Add Stage***.

      The selected stage is duplicated.

   c. Edit the duplicate stage as appropriate.

      See step 9.

9. To edit a stage, do the following:
   a. Select the stage to edit.
   b. Press ***Edit***.

      The ***Edit Stage*** window opens.
   c. Modify the stage parameters as appropriate.

      Refer to the table preceding these instructions for a description of each parameter.
   d. When you are done, press ***OK***.

      The ***Edit Stage*** window closes.
10. To delete a stage, do the following:
   a. Select the stage you want to delete.
   b. Press ***Delete Stage***.

      The selected stage is deleted.
11. To remove custom ***Master's Step*** stages, press ***Factory Defaults***.

    NOTE:
    Reset treadmills and ergometers to factory defaults at the protocol level. See step 15.
12. Repeat steps 8 through 10 as necessary.
13. To rename the protocol, do the following:
   a. Press ***Edit Name***.

      The ***Edit Name*** window opens.

      NOTE:
      This option is not available when editing a ***Master Step*** protocol.
   b. Change the name as appropriate.
   c. Press ***OK***.

      The protocol's name is changed.
14. When you are done with the stages, press ***Save***.

    This saves your changes and returns you to the previous window.
15. To remove custom protocols, press ***Factory Defaults***.
16. When the protocol is done, press ***Return***.

    The protocol is saved and you return to the ***Select Protocol*** window.

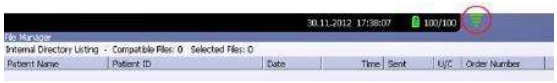
Communication Setup

The ***Communication Setup*** function allows you to define the following settings:

- Basic communication settings
- Shared directory settings
- Destination location settings
- Modem settings (if a modem option is activated)

- LAN settings (if a LAN option is activated)
- Wireless settings (if a WiFi option is activated)

  NOTE:
  This MAC device displays a signal strength indicator for WiFi.

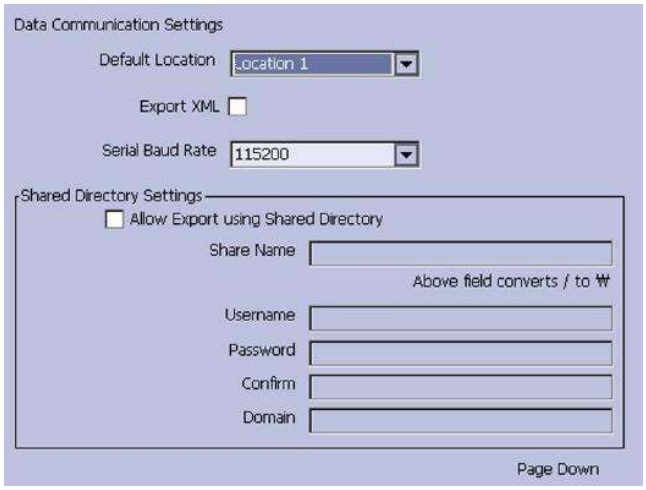


- DCP settings

NOTE:
This system is compatible with MUSE v7.1.1 and v8.0.1, and CardioSoft V6.51, V6.61, and V6.71.

To access the ***Communication Setup***, on the ***Main Menu*** press ***System Configuration*** > ***More*** > ***Communication Setup***.

The following tables describe the settings on ***Communication Setup***.



Communication Setup–Data Communication Settings Fields

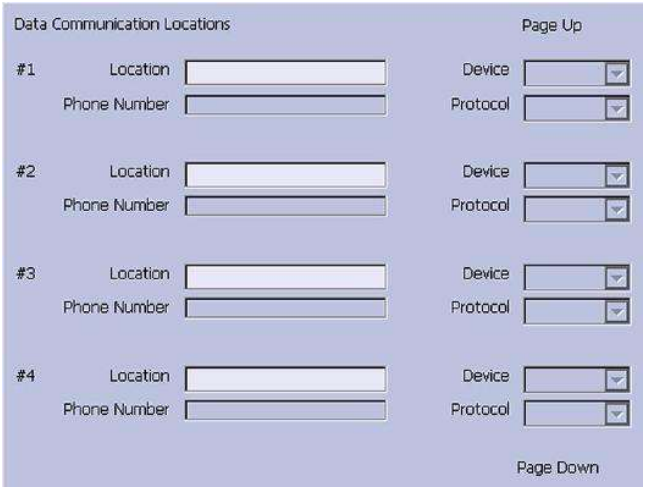
Fields	Description
Default Location	Determines which of the four available communication locations is the default. The locations are defined on Page 2 of this *Communication Setup Fields* table.
Export XML	Determines whether ECG records are transmitted as XML. If this field is set, ECG records exported to an SD card are stored in both XML and Hilltop formats. If this field is not set, ECG records exported to an SD card are stored only in Hilltop format. **NOTE:** This field is displayed only if the M100 or M200 (Internal storage) option is activated.

Communication Setup–Data Communication Settings Fields (cont'd.)

Fields	Description
Serial Baud Rate	Determines the speed at which data is transmitted across the serial communications port when using a modem. **NOTE:** This field is displayed only if the ***Modem Communications to CardioSoft (MODC)*** or ***Modem Communications to MUSE (MODM)*** option is activated.
Allow Export Using Shared Directory	Determines whether ECG records can be exported to a shared network drive. **NOTE:** This field is displayed only if the ***LAN Communications to CardioSoft (LANC)*** or ***WiFi Communications to CardioSoft (WIFC)*** option is activated. If this field is checked, the following five fields become available (***Share Name***, ***Username***, ***Password***, ***Confirm***, and ***Domain***).
Share Name	Identifies the name of the shared network drive. It must be the share drive's name; IP addresses are not supported. This field allows a maximum of 256 characters. This field is available only if the ***Allow Export Using Shared Directory*** field is checked.
Username	Identifies the user name that the system uses to log on to the shared directory. The user must be set up on the domain with the appropriate permissions to access the shared directory. This field allows a maximum of 30 characters. This field is available only if the ***Allow Export Using Shared Directory*** field is checked.
Password	Identifies the password that the system uses to log on to the shared directory. This field allows a maximum of 30 characters. This field is available only if the ***Allow Export Using Shared Directory*** field is checked.

Communication Setup–Data Communication Settings Fields (cont'd.)

Fields	Description
Confirm	Re-enter the password in this field to confirm that the password was entered correctly. This field is available only if the ***Allow Export Using Shared Directory*** field is checked.
Domain	Identifies the user's domain. This field allows a maximum of 30 characters. This field is available only if the ***Allow Export Using Shared Directory*** field is checked.



Communication Setup–Data Communication Locations

Field	Description
Location	Identifies the name of a communication location that receives the transmission from the system. You can define up to four locations.
Device	Identifies the type of device to use to transmit data to the location. Options are: • Serial • Modem • LAN Modem and LAN are available only if the corresponding option was activated. This field becomes active only after a corresponding location is entered.

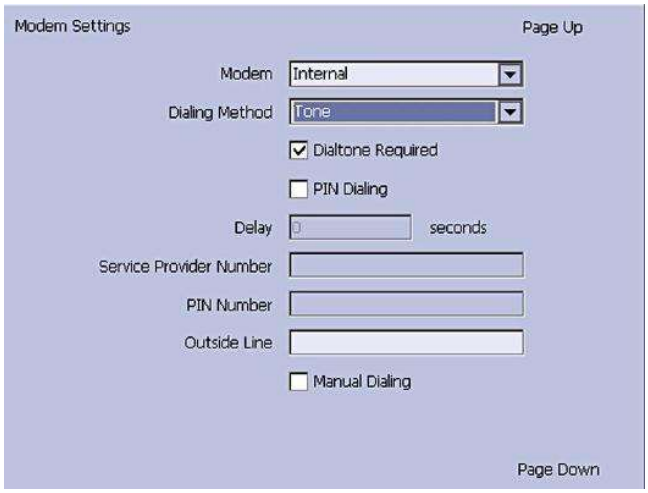
Communication Setup–Data Communication Locations (cont'd.)

Field	Description
Phone Number	Identifies the location's phone number. This field is available only if the selected device is ***Modem***.
Protocol	Determines the protocol to use to communicate with the device. Options are: • A5 • CSI • DCP Select ***CSI*** for MUSE connections and ***A5*** for CardioSoft connections. ***DCP*** is available only if the selected device is ***LAN***. **NOTE:** • When using DCP to connect to the MUSE 8.0.1 system and get orders, the MUSE system only returns orders that have a location value. • When using DCP to connect to the MUSE 8.0.1 system to get orders, the MUSE system does not return the order priority (Normal, Preop, Stat).

This system can use several protocols to communicate test data and retrieve patients or orders. You should choose the protocol based on systems with which you want to connect, the data you want to send and receive, and the connection type (LAN, WiFi, modem, or serial).

- ***DCP***
  This is a newer protocol that is faster than CSI and A5. DCP does not require this system to use a fixed IP address. It is currently compatible with the MUSE 8.0 system or later, and other GE Healthcare systems that support DCP. It supports retrieving patient demographics and orders and sending patient tests. You can use it with LAN or WiFi connections.
- ***CSI***
  This is a protocol that receives a connection from a server and requires a fixed IP address. It is currently compatible with all versions of the MUSE system and CardioSoft system v6.6 and later. It supports retrieving patient demographics and orders and sending patient tests. You can use it with LAN, WiFi, modem, and serial connections.
- ***A5***

This is a serial protocol that you can use for backward compatibility. It is compatible with all versions of the CardioSoft system. It supports sending patient tests. You can use it with modem or serial connections.

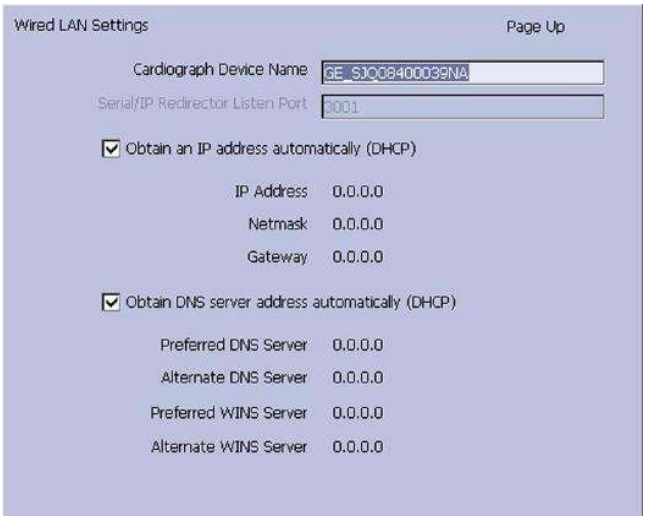


Communication Setup–Modem Settings Fields

Field	Description
Modem	Informs the user that the device is using the internal modem.
Dialing Method	Determines whether the system uses a tone or pulse to dial.
Dialtone Required	Determines whether the system must receive a dial tone before dialing.
PIN Dialing	Identifies whether a personal identification number (PIN) is required to dial out. If this field is checked, you must complete the following three fields (***Delay***, ***Service Provider Number***, and ***PIN Number***).
Delay	Determines how long, in seconds, the system should pause between dialing the ***Service Provider Number*** and the ***PIN Number*** and between dialing the ***PIN Number*** and the ***Outside Line***.
Service Provider Number	Identifies the service provider's access telephone number.
PIN Number	Identifies the personal identification number to enter.

Communication Setup–Modem Settings Fields (cont'd.)

Field	Description
Outside Line	Identifies any access numbers that must be dialed to reach an outside line.
Manual Dialing	Determines whether the system automatically dials. If this field is checked, the connection must be made manually. If this field is cleared, the system automatically dials and you must complete the following fields: • ***Dialing Method*** • ***Dialtone Required*** • ***PIN Dialing***



The following fields are only displayed if one or both of the following options is activated:

- LAN communications to a CardioSoft system (***LANC***)
- LAN communications to a MUSE system (***LANM***)

Communication Setup–Wired/Wireless LAN Settings Fields

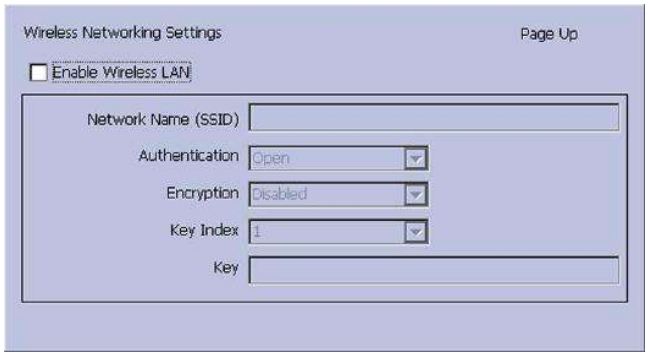
Field	Description
Cardiograph Device Name	Identifies the name of the device on the network. By default, the value is set to ***GE_<serial number>***. A valid network device name contains between 1 and 20 alphanumeric and underscore characters. The first character must be a letter. This field is available only if a ***LAN*** or ***WIF*** option was activated.
Serial/IP Redirector Listen Port	Identifies the port where the device should listen for incoming serial/IP connections. These communications must match the values defined on the transmitting MUSE system. This setting only applies to the CSI protocol.
Obtain an IP address automatically (DHCP)	Determines whether the device automatically receives an IP address from the network. If this box is checked and LAN communication to a MUSE system is enabled, you must configure the DHCP server to reserve a static IP address for the device. Contact your network administrator for assistance. If this field is checked, the ***IP Address***, ***Netmask***, and ***Gateway*** fields are display only. If this field is cleared, you must complete those fields.
IP Address	Identifies the IP address of the device. If the ***Obtain an IP address automatically (DHCP)*** field is cleared, you must define a unique IP address.
Netmask	Identifies the netmask of the device. If the ***Obtain an IP address automatically (DHCP)*** field is deared, you must define a netmask.
Gateway	Identifies the IP address of the gateway for the device to use. If the ***Obtain an IP address automatically (DHCP)*** field is cleared, you must enter the gateway's IP address.
Obtain DNS service address automatically (DHCP)	Determines whether the device automatically obtains a DNS (Domain Name Server) IP address. If this field is checked, the following two fields are display-only. If this field is cleared, you must define the IP address of the DNS servers to use.
Preferred DNS Server	Identifies the IP address of the primary DNS server used to resolve Internet domain names.
Alternate DNS Server	Identifies the IP address of the secondary DNS server used to resolve Internet domain names.

Communication Setup–Wired/Wireless LAN Settings Fields (cont'd.)

Field	Description
Preferred WINS Server	Identifies the IP address of the primary WINS server used to resolve Windows host names. You must have the correct WINS address configured if you are using a shared folder for communication.
Alternate WINS Server	Identifies the IP address of the secondary WINS server used to resolve Windows host names. You must have the correct WINS address configured if you are using a shared folder for communication.

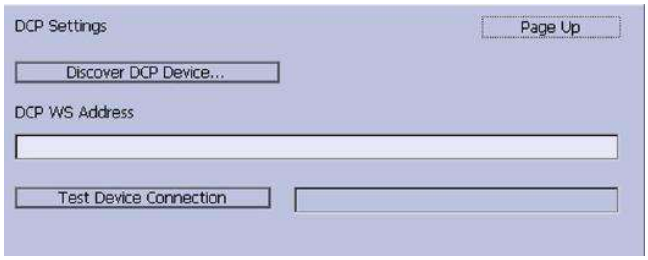
The following fields are only displayed if one or both of the following options is activated:

- WiFi communications to a CardioSoft system (***WIFC***)
- WiFi communications to a MUSE system (***WIFM***)



Communication Setup—Wireless Networking Settings

Field	Description
Enable Wireless LAN	Enables/disables wireless LAN connectivity (WiFi). Check the field to enable WiFi. Clear the field to disable WiFi. The field is cleared by default. **NOTE:** In order to connect to WiFi, please insert the USB WiFi device after the device status indicates it is working. Otherwise, WiFi is not connected correctly.
Network Name (SSID)	Specifies the name of the wireless local area network (WLAN). This filed allows a maximum of 32 characters. **NOTE:** When the Network name is empty, the system connects to any available network. The system uses Infrastructure Mode (Wireless access point) to provide the connection with Enterprise network or internet.
Authentication	Specifies the authentication protocol. Values are: • Open • Shared • WPA-PSK • WPA2–PSK
Encryption	The user net configuration determines the encryption. Values are: • Disabled • WEP
Key Index	This field depends on the user's network configuration. This field is only available when the encryption is WEP. Values are: • 1 • 2 • 3 • 4
Key	ASCII or Hexadecimal characters (0-9, A-F) for encryption. This field depends on the user's network configuration.



Communication Setup–DCP Settings Fields

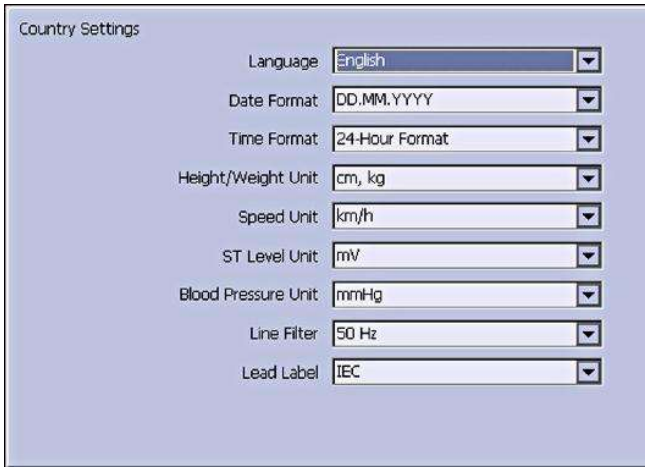
Field	Description
Discover DCP Device	Allows you to discover GE Healthcare systems that support DCP servers on the same network subnet as this system. This command returns a list of DCP servers and you can select one of them for communication. Usually there is only one server from which to choose. If no servers are displayed, you can enter one manually.
DCP WS Address	Displays the address of the DCP server to use for communication. You can locate this address using ***Discover DCP Device*** or enter it manually. A server address has the form ***http://<server-name>:<port>/SendTest***, where <***server-name***> is the server name or IP address and <***port***> is the server port number, usually 9240.
Test Device Connection	Allows you to test the connection to the selected DCP server. The status of the connection is displayed in the text box.

Country Setup

The ***Country Setup*** function allows you to define the following:

- System language
- Date and time formats
- Measurement units
- Line filter
- Lead label

To access the ***Country Setup***, on the ***Main Menu*** press ***System Configuration*** > ***More*** > ***Country Setup***.



The following table identifies the settings on ***Country Setup***.

Country Setup Fields

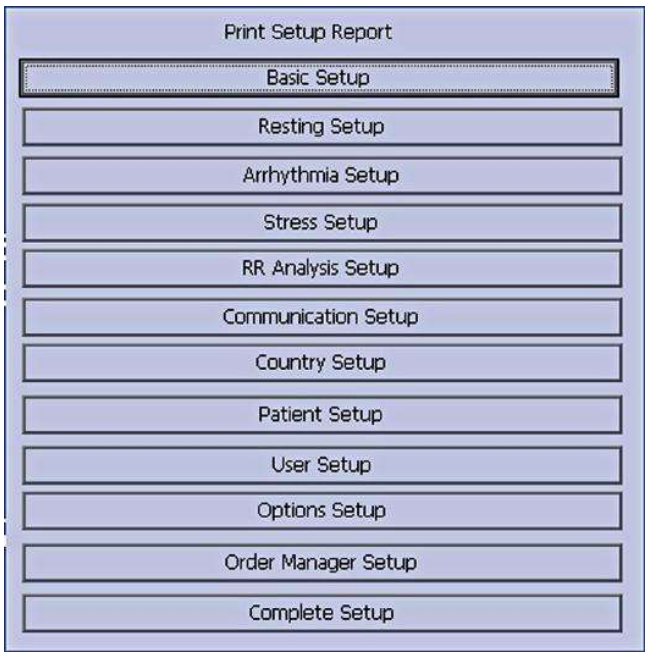
Field	Comments
Language	Determines the language the interface and reports use.
Date Format	Determines the format in which dates are displayed. Options are: • DD.MM.YYYY • MM/DD/YYYY • YYYY-MM-DD
Time Format	Determines whether the system uses a 12–hour or a 24–hour format.
Height/Weight Unit	Determines whether the system uses metric measurements (cm, kg) or American measurements (in, lb) for patient weight and height.
Speed Unit	Determines whether the speed of stress devices is measured in kilometers per hour (km/h) or miles per hour (mph).
ST Level Unit	Determines whether the ST segment is measured in millivolts (mV) or millimeters (mm).
Blood Pressure Unit	Determines whether blood pressure is measured in millimeters of mercury (mmHg) or kilopascals (kPa).

Country Setup Fields (cont'd.)

Field	Comments
Line Filter	Determines the frequency of the line filter. Options are 50 Hz and 60 Hz.
Lead Label	Determines whether the system labels leads using the standards of the International Electrotechnical Commission (IEC) or the American Heart Association (AHA).

Print Setup Report

The ***Print Setup Report*** utility prints a report of individual settings or the complete system settings. You may use the report to verify that all of your devices are configured identically or as a reference if you need to re-configure a device.



Use the following instructions to print a setup report:

1. On the ***Main Menu*** press ***System Configuration*** > ***More*** > ***Print Setup Report***.
2. On the ***Print Setup Report*** window, select the report you want to print.
   - ***Basic Setup***
   - ***Resting Setup***
   - ***Arrhythmia Setup***
   - ***Stress Setup***
   - ***RR Analysis Setup***
   - ***Communication Setup***
   - ***Country Setup***

- *Patient Setup*
- *User Setup*
- *Options Setup*
- *Order Manager Setup*
- *Complete Setup*

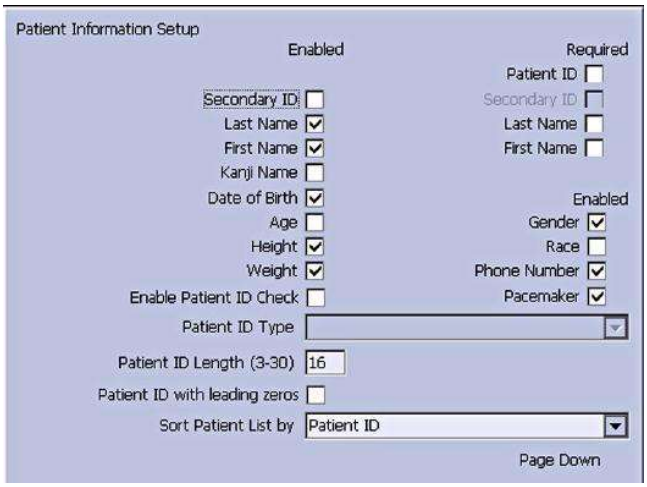
3. When you are done, press ***Return*** to return to the ***Main Menu***.

Patient Setup

The ***Patient Setup*** function allows you to define the following information:

- Available and required patient information
- Available test information
- Available clinical trial information
  This is available only if the ***CTDG CT Data Guard*** option is activated.
- Barcode reader settings
  This is available only if the ***BCRD USB Barcode Reader*** option is activated

To access ***Patient Setup***, on the ***Main Menu*** press ***System Configuration*** > ***More*** > ***Patient Setup***.



The following tables identify the settings on ***Patient Setup***.

Patient Information Setup Fields

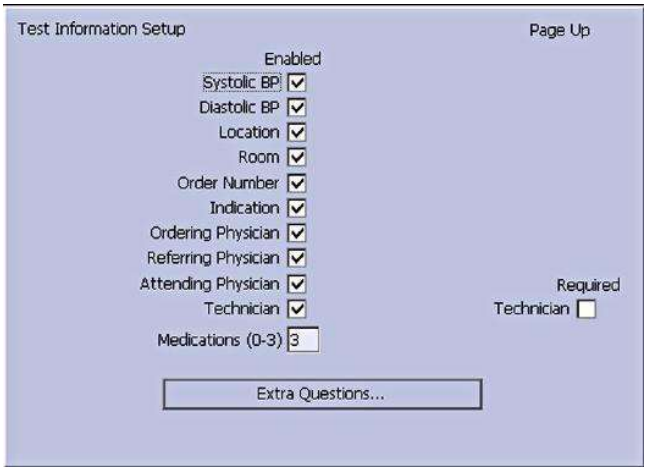
Field	Description
Patient ID	Determines whether the patient ID is required. On reports, it is labelled ***ID***.
Secondary ID	Determines whether a secondary patient ID is available when entering patient data and whether it is required. It can only be required if it is first enabled. On reports, it is labelled ***ID 2***.

Patient Information Setup Fields (cont'd.)

Field	Description
Last Name	Determines whether the patient's last name field is available when entering patient data and whether it is required. It can only be required if it is first enabled.
First Name	Determines whether the patient's first name field is available when entering patient data and whether it is required. It can only be required if it is first enabled.
Kanji Name	Determines whether the Kanji name field is available when entering patient data.
Date of Birth	Determines whether the date of birth field is available when entering patient data.
Age	Determines whether the age field is available when entering patient data.
Height	Determines whether the height field is available when entering patient data.
Weight	Determines whether the weight field is available when entering patient data.
Gender	Determines whether the gender field is available when entering patient data.
Race	Determines whether the race field is available when entering patient data.
Phone Number	Determines whether the phone number field is available when entering patient data.
Pacemaker	Determines whether the pacemaker field is available when entering patient data.
Enable Patient ID Check	Determines whether additional checks are performed to ensure that the patient ID meets the requirements of the national patient ID used in Scandinavian countries. If this field is set, you must select the appropriate ***Patient ID Type***.
Patient ID Type	This field is available only if the ***Enable Patient ID Check*** field is set. This field determines which type of ID is used and, therefore, which checks to perform. Options are: • Swedish Patient ID • Danish Patient ID • Norwegian Patient ID When a patient ID is entered, the system verifies its format, extracts the patient's gender and date of birth, and populates those fields if they are enabled.
Patient ID Length (3-30)	Defines the maximum length of the patient ID within the range of 3 to 30 characters. This field is available only if the ***Enable Patient ID Check*** field is cleared.

Patient Information Setup Fields (cont'd.)

Field	Description
Patient ID with leading zeros	Determines whether the system should prefix the ***Patient ID*** with zeroes to fill in the length of the ***Patient ID*** specified in the field ***Patient ID Length***. For example, If the user selected the length of the ***Patient ID*** field as 10 and entered the PID **PID098**, it is displayed by the system as **0000PID098**.
Sort Patient List by	Determines the field by which the patient list is sorted. Options are: • Patient ID • Secondary ID • Patient Name

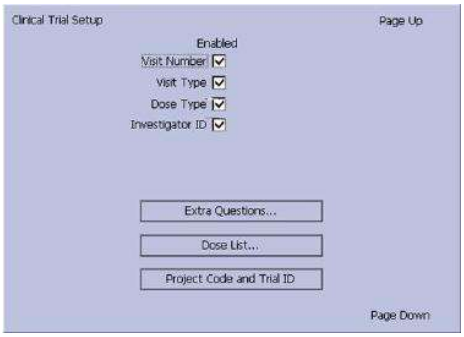


Test Information Window

Fields	Comments
Systolic BP	Determines whether the systolic blood pressure field is available when entering test information.
Diastolic BP	Determines whether the diastolic blood pressure field is available when entering test information.
Location	Determines whether the location field is available when entering test information.
Room	Determines whether the room field is available when entering test information.
Order Number	Determines whether the order number field is available when entering test information.
Indication	Determines whether the indication field is available when entering test information.
Ordering Physician	Determines whether the ordering physician field is available when entering test information.

Test Information Window (cont'd.)

Fields	Comments
Referring Physician	Determines whether the referring physician field is available when entering test information.
Attending Physician	Determines whether the attending physician field is available when entering test information.
Technician	Determines whether the technician field is available when entering test information and whether it is required. It is required only if it is enabled.
Medications (0-3)	Determines the number of medications that you can enter into the test information window.
Extra Questions...	Opens the ***Extra Questions*** window, which allows you to define up to four custom fields. Each field consists of a ***Prompt*** and a ***Type***. The ***Prompt*** can be up to 10 characters. The ***Type*** can be any of the following: • Alphanumeric • Numeric • Yes/No/Unknown

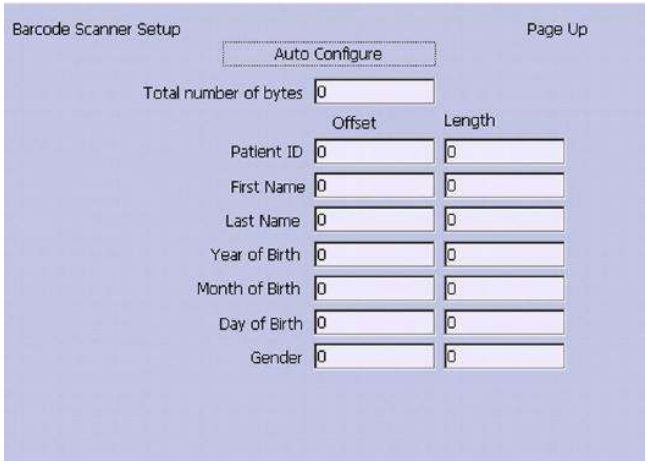


Patient Setup—Clinical Trial Setup Window

Field	Comments
Visit Number	Determines whether the visit number field is available when entering clinical trial information.
Visit Type	Determines whether the visit type field is available when entering clinical trial information.
Dose Type	Determines whether the Dose Type field is available when entering clinical trial information. If this field is set, use ***Dose List...*** to define the types of doses that are available when entering clinical trial information.
Investigator ID	Determines whether the investigator ID field is available when entering clinical trial information.

Patient Setup—Clinical Trial Setup Window (cont'd.)

Field	Comments
Extra Questions	Opens the ***Extra Questions*** window, which allows you to define up to fie custom clinical test fields. Each field consists of a ***Prompt*** and a ***Type***. The ***Prompt*** can be up to 10 character. The ***Type*** can be any of the following: • Alphanumeric • Numeric • Yes/No/Unknown
Dose List	Opens the ***Dose List*** window, which allows you to define the dose types that will be available when entering clinical trial information. Doses are plain text up to 32 alphanumeric characters. The user can add up to 20 does.
Project Code and Trial ID	Identifies the Project Code and Trial ID that are displayed when entering clinical trial information. Allows the user to define up to five sets of ***Project Code and Trial ID***.



Barcode Scanner Setup

Field	Comments
Auto Configure	Automatically configures the barcode reader. When you click this link, you are prompted to scan a configuration barcode created by the site's IT department. For more information on creating the barcodes, see "Creating Barcodes" on page 185.
Total number of bytes	Identifies the total number of bytes on the barcode.

Barcode Scanner Setup (cont'd.)

Field	Comments
Offset	Identifies the position of the initial character of the corresponding field.
Length	Identifies the number of characters for the corresponding field.

User Setup

The ***User Setup*** function allows you to define the following:

- User names
- User identification
- User roles
- User privileges

Users entered in setup can be selected for system defaults and patient information. If ***High Security Mode*** is enabled, anyone who uses the system must be set up as a user with a user ID, a password, and privileges to log on to the system. For more information on setting system defaults and enabling ***High Security Mode***, see "Basic Setup" on page 107.

To access ***User Setup***, on the ***Main Menu*** press ***System Configuration*** > ***More*** > ***User Setup***.

When you run ***User Setup***, the ***Edit User Lists*** window opens to offer four choices:

- Ordering Physicians
- Referring Physicians
- Attending Physicians
- Technicians

When you select one of these roles, a list of existing users with that role opens. You can now add, edit, and delete users.

The following table identifies the settings on ***User Setup***.

Field	Comment
Last Name	Identifies the user's surname. This field is required and allows a maximum of 40 alphanumeric characters.
First Name	Identifies the user's given name. This field is optional, but if used, allows a maximum of 20 alphanumeric characters.
User ID	Defines a unique ID for the user. If ***High Security Mode*** is enabled, the user needs to enter this ID to log on to the system. This field is required and allows a maximum of 30 alphanumeric characters. **NOTE:** The system does not prevent duplicate IDs. If the same ID is used more than once, only the first user created with the ID is able to log on to the system.
MUSE ID	Defines the ID with which the user logs on to the MUSE system. This field is used if reports from this system are transmitted to a MUSE system.
Ordering	Determines whether the user fills the role of ordering physician. If this is the role that was selected on the ***Edit User List*** window, this field is checked by default. You may select multiple roles, but you must select at least one role.
Referring	Determines whether the user fills the role of referring physician. If this is the role that was selected on the ***Edit User List*** window, this field is checked by default. You may select multiple roles, but you must select at least one role.
Attending	Determines whether the user fills the role of attending physician. If this is the role that was selected on the ***Edit User List*** window, this field is checked by default. You may select multiple roles, but you must select at least one role.
Technician	Determines whether the user fills the role of technician. If this is the role that was selected on the ***Edit User List*** window, this field is checked by default. You may select multiple roles, but you must select at least one role.
Password	Defines the password the user must enter along with the ***User ID*** to log on to the system if ***High Security Mode*** is enabled. This field must be between 6 and 30 alphanumeric characters.
Retype Password	Confirms the password was entered correctly.
Edit Setup	Enables/disables the user's ability to edit system setup information.
Edit Date and Time	Enables/disables the user's ability to edit system date and time.
Edit Users	Enables/disables the user's ability to edit user information.
Edit Record	Enables/disables the user's ability to edit ECG records.

Field	Comment
Delete Record	Enables/disables the user's ability to delete ECG records.
Transmit Records	Enables/disables the user's ability to transmit ECG records.

NOTE:
In the fields ***Edit Users*** and ***Edit Setup***, privileges are required by the activated user to activate ***High Security*** mode.

In the fields ***Edit Setup*** and ***Delete Record***, privileges are required by the activated user to export the system audit trail log.

Select Setup

The ***Select Setup*** utility allows you to save up to five system configurations and switch between them. This is useful if the system is shared by departments or used in multiple clinical trials.

Use the following instructions to save and load configuration files:

1. On the ***Main Menu*** press ***System Configuration*** > ***More*** > ***More*** > ***Select Setup***.

   The ***Select Setup*** window opens. The name of the setup the system is using currently is displayed in the ***Loaded Setup*** field.

2. To save a copy of the current setup, do the following:

   a. Press ***Save As***.

      The ***Setup Name*** window opens.

   b. Type a name for the configuration and press ***Save***.

      The configuration is saved, and the ***Setup Name*** window closes.

3. To load a different setup, do the following:

   a. Select the setup you want to load.

   b. Press ***Load Setup***.

   c. Restart the system.

      You must power the device off and then on for all setup changes to take effect, especially if the new setup includes a change to the language setting; the language does not change until the system restarts.

4. To delete a setup file, do the following:

   a. Select the file you want to delete.

   b. Press ***Delete***.

      You are prompted to confirm the deletion.

   c. Press ***OK***.

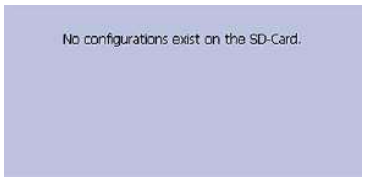
      NOTE:
      You cannot delete a configuration that is currently loaded.

5. To change the name of a system setup file, do the following:
   a. Select the setup file you want to change.
   b. Press ***Edit Name***.
      The ***Setup Name*** window opens.
   c. Type the new name and press ***Save***.
6. To remove all custom settings, do the following:
   a. Select the setup file you want to reset.
   b. Press ***Factory Defaults***.
   c. When prompted to confirm, press ***Save***.
7. When you are done, press ***Return*** to exit.

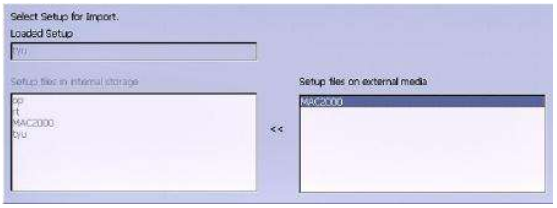
Import Setup

The ***Import Setup*** utility allows you to import up to five system setup files from another device that were exported to an SD card. This feature is useful to sites with multiple systems that need to have the same or similar setups.

1. Insert the SD card with the saved setup file.
   If you do not have a valid SD card, you receive the following message:



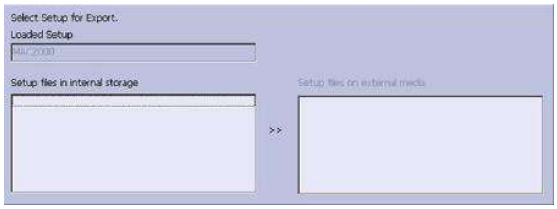
2. On the ***Main Menu*** press ***System Configuration*** > ***More*** > ***More*** > ***Import Setup***.
   The ***Select Setup for Import*** window opens.



   All saved settings on the device are listed in the left column. All saved settings on the SD card are listed in the right column.
3. In the right pane, select the setup file you want to import.
4. Press ***Import***.
   The selected file is copied to the device and is displayed in the left column.
5. Repeat step 3 through step 4 for each saved configuration file you want to import.
6. When you are done, press ***Return***.

Export Setup

The ***Export Setup*** utility allows you to export saved settings from the device to an SD card. You can then use the SD card to import the settings to another device, greatly simplifying the installation and configuration of multiple devices.



1. Insert an SD card into the SD card slot in the back panel, as shown in the following illustration:

2. Push the SD card into the slot to seat it in place.
3. On the ***Main Menu*** press ***System Configuration*** > ***More*** > ***More*** > ***Export Setup***.

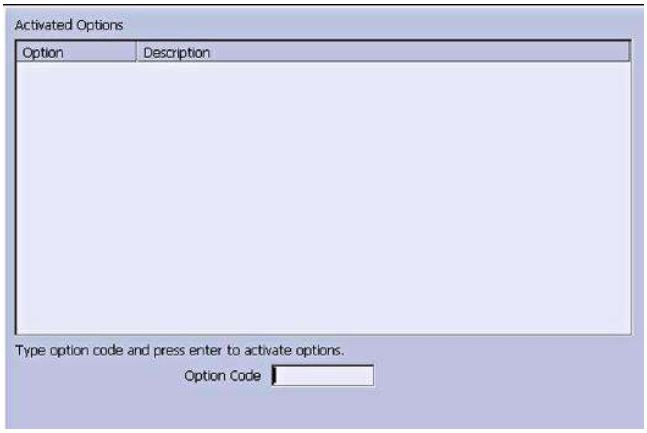
   The ***Select Setup for Export*** window opens. All saved settings on the device are listed in the left column. All saved settings on the SD card are listed in the right column.
4. In the left pane, select the setup file you want to export.
5. Press ***Export***.

   The selected file is copied to the SD card and is displayed in the right column.
6. Repeat step 4 through step 5 for each saved configuration file you want to export.
7. When you are done, press ***Return***.

Options Setup

The ***Options Setup*** function allows you to activate options by entering ***Option Codes***, which are generated for a specific serial number and can only activate options on the device with that serial number.

All purchased options are activated when the system ships. If you purchase a new option or re-activate an option, use the following instructions:



1. On the ***Main Menu*** press ***System Configuration*** > ***More*** > ***More*** > ***Options Setup***.
2. In the ***Option Code*** field, type the 12–digit activation code.

   You can find activation codes for purchased options on the ***Active Code Summary Sheet*** provided with the system or with additional purchased options.
3. Press **Enter**.

   The ***Option Activated*** message is displayed at the bottom of the window.
4. Repeat step 2 through step 3 for any additional options you want to activate.
5. Press ***Save*** to save the configuration options.

Option Codes

Option Code	Name
CTDG	CT Data Guard
R12L	12–Lead display for Resting ECG. This is always active.
ME12	12SL Measurement
MEHR	HEART Resting Measurement
MI12	12SL Measurement and Interpretation
MIHR	HEART Resting Measurement and Interpretation
M100	Storage for 100 ECGs
M200	Storage for 200 ECGs.
LANC	LAN Communication to the CardioSoft system
LANM	LAN Communication to the MUSE system
MODC	Modem or serial communication to the CardioSoft system
MODM	Modem or serial communication to the MUSE system
ERGO	Stress test with treadmill, bicycle, or Master's Step test. This is a 6–lead waveform display.
E12L	12–Lead display for Stress Test

Option Codes (cont'd.)

Option Code	Name
CFRA	21 CFR Part 11 Audit Trail
BCRD	USB Barcode Reader
TIPI	ACI-TIPI (Acute Cardiac Ischemia — Time Insensitive Predictive Instrument) This option is disabled if MEHR or MIHR is enabled.
RRAN	RR analysis
PDFC	PDF file copy
WIFC	WiFi to the CardioSoft system
WIFM	WiFi to the MUSE system
SOML	Simple Orders from non-MUSE systems
SOMF	Simple Orders from MUSE and non-MUSE systems
AOMF	Order Manager for MUSE and non-MUSE systems
AOML	Order Manager for non-MUSE systems
ADTF	ADT (Patient Demographics) downloaded from MUSE and non-MUSE systems
ADTL	ADT (Patient Demographics) downloaded from non-MUSE systems

Service Setup

The ***Service Setup*** option allows service personnel to configure the following:

- ***Device Settings***
- ***Event Log***
- ***System Diagnostics***
- ***Software Update***
- ***Format Flash***
- ***Open Command Prompt***

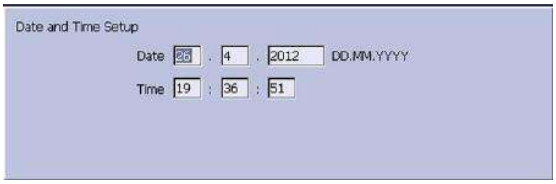
Service personnel need to enter the service password to gain access to the system.

Refer to the service manual for your system for more details.

Date/Time Setup

The ***Date/Time Setup*** function allows you to configure the system's date and time settings.

To access ***Date/Time Setup***, on the ***Main Menu*** press ***System Configuration*** > ***More*** > ***More*** > ***More*** > ***Date/Time Setup***.

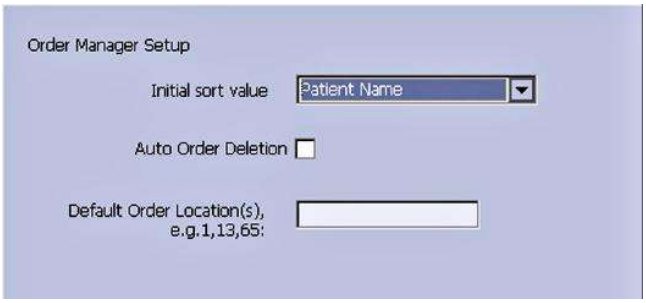


The following table identifies the settings on ***Date/Time Setup***.

Date and Time Setup Fields

Field	Description
Date	Sets the current system date. The format of the fields depends on the date format selected on ***Country Setup***. For more information, see "Country Setup" on page 141.
Time	Sets the current system time. If the ***Automatically Synchronize with Time Server*** field is set on ***Basic Setup***, any changes made to the time are overwritten during the next synchronization. For more information, see "Basic Setup" on page 107. **NOTE:** Daylight Saving Time changes take effect only after a restart.

Order Manager Setup



Order Manager Setup Fields

Field	Comment
Initial sort value	Determines how the ***Order Manager*** initially sorts the ECGs. Select one of the following values: • Patient Name • Patient ID • Location
Auto Order Deletion	If enabled, the system deletes orders associated with ECG files that were deleted automatically. Automatic deletion of ECG files can happen in the following conditions: • ***Delete after Transmission*** field on the ***Resting ECG Setup*** window is enabled and the associated ECG file was successfully transmitted to a receiving system. • After the successful transmission of an ECG file associated with an order, provided the ECG was never saved on the system.
Default Order Location(s), for example 1,13,65:	Identifies the locations displayed on the prompt when downloading orders. This will typically be the device's location (see "Basic Setup" on page 107). If the device is used in multiple locations, enter multiple locations and separate them with commas: 1,3,10, and so on.

RR Analysis Setup

The RR Analysis Setup function allows you to configure the RR Analysis report. For details, see "RR Analysis Setup" on page 83.

PDF File Naming Convention

The device provides two types of naming conventions:

- Default Naming
- Customize Naming

Default Naming Convention

To help identify the exported PDF files, they are automatically named with the following descriptive components:

```
product_version_serial_ECGmode_cartID_creationdata.pdf
```

For example:

```
GEMAC2000_1.0_SDS07410016WP_resting_1_2007-11-22T17-56-32.pdf
```

The following table identifies each component in the example:

Components of the File Naming Convention

Value	Component Description
GEMAC2000	Product name: this is always GEMAC2000.
1.0	Software version: this varies based on the software version installed.
SDS07410016WP	The device serial number: this varies from device to device.
resting	ECG mode: this is either ***resting*** (Resting ECG mode) or ***rrana*** (RR Analysis mode).
1	Cart ID: this varies from device to device. The Cart ID is the same as the ***Cart #*** field in ***Basic Setup***. For more information see "Basic Setup" on page 107.
2007-11-22T17-56-32	Creation data:. this consists of the following subcomponents: • 2007 - Year the PDF was written. • 11 - Month the PDF was written. • 22 - Date the PDF was written. • T - Indicates the following numbers are time. • 17 - Hour, in 24 hour format, the PDF was written. • 56 - Minute the PDF was written. • 32 - Second the PDF was written.

Customizing the Naming Convention

Users can name the PDF files according to their own requirements by using given elements:

1. On the ***Main Menu***, press ***System Configuration***.

   The ***System Configuration*** window opens.

2. Press ***Basic Setup***.

   The ***Basic Setup*** window opens.

3. Press ***Page Down*** to the ***PDF Naming Settings*** option.
4. Select the ***Generate Automatic File Name*** check box.

   The following elements are available:

   - ***Patient ID***
   - ***Last Name***
   - ***First Name***
   - ***Date of Birth***

- ***Procedure***
  Procedure means ***ECG Mode***. This is either ***resting*** (Resting ECG mode) or ***rrana*** (RR Analysis mode).
- ***Date of Test***
- ***Export Date***
- ***Secondary ID***

5. Press ***Save*** and return to the ***System Configuration*** window.

Retrieving Your Password

If the system is set up for ***High Security Mode*** and you forget your password, use the following procedure to access the system:

1. Contact GE Healthcare Technical Support and provide the serial number of the device you want to access.

   GE Healthcare Technical Support generates a temporary, device-specific name and password that you can use for 24 hours.

2. Log in to the system with the user ID ***MACService*** and the password provided by GE Healthcare Technical Support.

   NOTE:
   If the keypad on the device does not include the letters for the ***MACService*** user ID, type **6227378423** for the user ID.

3. Immediately after logging into the system, verify the name and password for your device.
4. Record this information and store it in a secure location for future reference.

Exporting the Audit Trail

The ***Audit Trail Export*** function copies the system audit trail in XML format to an SD card and then clears the audit trail on the system. If a previous audit trail exists on the SD card, it IS overwritten automatically by the new audit trail.

GE Healthcare recommends exporting the audit trail weekly to long term storage to meet archive requirements. If the audit trail is not exported regularly, it consumes storage space and reduces the number of ECGs that you can store on the device

To export an audit trail, the following conditions must be met:

- ***High Security Mode*** must be enabled.
  To enable ***High Security Mode***, see "Basic Setup" on page 107.
- ***Audit Trail*** must be enabled.
  To enable ***Audit Trail***, see "Basic Setup" on page 107.
- You must have ***Edit Setup*** and ***Delete Records*** permissions set.
  To set permissions for Edit Setup and Delete Records, see "User Setup" on page 149.

Use the following procedure to export the audit trail to an SD card:

1. Insert an SD card into the device.
2. On the ***Main Menu***, press ***System Configuration*** > ***More*** > ***More*** > ***More*** > ***Export Audit***.

   After the audit trail is copied to the SD card and cleared from the system a message notifies you that the export was successful.

After the XML file is exported, you can review or print the audit trail as needed. For more information on how to parse the XML file for viewing or printing, refer to the *GE Cardiology Open XML Reference Manual*. To locate the part number for this manual, refer to "Related Documents" in the service manual.

13

Maintenance

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

- Device
- Cables and leadwires
- Paper
- Battery

See the documentation provided with your peripherals for additional maintenance procedures.

This device does not require any calibration.

Equipment Cleaning and Storage

The device is designed to require little more than regular inspection and cleaning to function properly. Qualified GE Healthcare service personnel should perform any additional maintenance.

CAUTION:

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 device, turn it off, unplug it from AC power, and remove the battery.
- Do NOT immerse any part of the equipment in water.

Inspecting the Equipment

Perform a visual inspection daily, preferably before the equipment's first use each day. During the inspection, verify that the device meets the following minimum conditions:

- The case and display screen are free of cracks and other damage.
- All plugs, cords, cables, and connectors are free of kinks, frays, and other damage.
- All cords and connectors are securely seated.
- All keys and controls operate properly.

If you notice any items that need repair, contact an authorized service representative to make the repairs. Discontinue using the device until the appropriate repairs can be made.

Cleaning the Device

Clean the exterior surface of the device monthly, or more frequently if needed.

Cleaning Materials to Use

Use the following materials to clean the device:

- Mild dishwashing detergent
- Clean, soft cloth
- Water

Cleaning Materials to Avoid

DO NOT use any of the following materials to clean the device, because their use may damage equipment surfaces.

- Organic solvents
- Ammonia-based solvents
- Abrasive cleaning agents
- Alcohol
- Virex
- Sani-Master

Cleaning the Device Surfaces

Use the following procedure to clean the surfaces of the device.

1. Dilute mild dishwashing detergent in water to create a cleaning solution.
2. Soak a clean cloth in the solution and wring out any excess.
3. Thoroughly wipe the surface of the device with the damp cloth.

   Do NOT drip the solution or any liquid on the writer assembly.

   Avoid contact with open vents, plugs, or connectors.
4. Repeat step 2 and step 3 as necessary until the surface is adequately cleaned.
5. Wipe the surfaces with a dry, clean cloth or paper towel.

Cleaning, Disinfecting, and Storing ECG Cables and Leadwires

In addition to keeping the system clean and in good repair, it is important to keep the cables and leadwires clean and disinfected. This section provides instructions for cleaning, disinfecting, and storing ECG cables and leadwires to extend their life and

protect patients. Cables and leadwires come into contact with patients and should be cleaned and disinfected after every use.

NOTE:
For devices with the KISS system, refer to the KISS operator's manual for cleaning and disinfecting information.

Cleaning Guidelines

Observe the following guidelines when cleaning and disinfecting the cables, leadwires, and electrodes for your system.

- Follow the cleaning instructions exactly.
- Wring excess disinfectant from the wipe before using it.
- Never immerse the device, cables, or leadwires in any liquid, as this may corrode metal contacts and affect signal quality.
- Do not allow liquids to collect around the connection pins. If this happens, blot them dry with a soft, lint-free cloth.
- Never use conductive solutions or solutions that contain chlorides, wax, or wax compounds to clean the device, cables, or leadwires.
- Never use solutions or products that contain any type of Ammonium Chloride such as, but not limited to:
  - Dimethyl Benzyl Ammonium Chloride
  - Quaternary Ammonium Chloride solutions
  - Abrasive cleaners or solvents of any kind
  - Acetone
  - Ketone
  - Betadine
  - Alcohol-based cleaning agents
  - Sodium salts
- Never autoclave or steam clean the device, cables, or leadwires.
- Do not use any of the accessories until thoroughly dry.
- Do NOT immerse either end of a cable or leadwire connector in any solution. Immersing or soaking the connector ends may corrode metal contact ends and affect signal quality.
- Do NOT let liquids collect around the connection pins.
  If this happens, blot them dry with a soft, lint-free cloth.

Cleaning and Disinfecting Cables and Leadwires

Proper cleaning and disinfecting prolongs the life of the cables and leadwires. Failure to use the proper cleaning solutions or to follow the proper procedures can result in the following:

- Damage or corrosion
- Diminished signal quality
- Product discoloration
- Metal part corrosion

- Brittle wires and connectors
- Reduced cables and leadwires life
- Device malfunction
- Voided warranty

Cleaning the Cables and Leadwires

Use the following procedure to clean the cables and leadwires:

NOTE:

- While performing the following procedure, use care in cleaning the leadwires to prevent pulling the wires from the connector ends, because the metal connections can be pulled away from the connectors.
- Cleaning removes dirt and marks but does not disinfect the cables and leadwires.

1. Remove the cables and leadwires from the device before cleaning.
2. Wipe them with a cloth lightly moistened with a mild solution of soap and water.

   Do not use any of the following cleaning products, or products that contain the same active ingredients and solutions, which are known to cause the problems previously listed:

   - Sani-Cloth® Wipes
   - Ascepti® Wipes
   - HB Quat®
   - Clorox® Wipes (they do not contain bleach)
   - Over-the-counter detergents (such as Fantastic®, Tilex®, and so on)
3. Wipe the cables and leadwires with a dry, clean cloth or paper towel and let them air dry.

Disinfecting the Cables and Leadwires

Use the following procedure to disinfect the cables and leadwires:

1. Clean and dry the cables and leadwires before disinfecting them.

   See "Cleaning the Cables and Leadwires" on page 164 for instructions.

2. Wipe the cables and leadwires with a soft, lint-free cloth that is moistened with an appropriate disinfectant.

   Use the following solutions, as recommended in *APIC Guidelines for Selection and Use of Disinfectants (1996)*:

   - Sodium hypochlorite (5.2% household bleach) minimum 1:500 dilution (minimum 100 ppm free chlorine) and maximum 1:10 dilution.
   - Any sodium hypochlorite wipe product that meets the previous guidelines.

3. Dry the cables and leadwires with a clean cloth or paper towel and let them air dry for at least 30 minutes.

   NOTE:

   - Drying times vary based on the environmental conditions.
   - DO NOT use excessive drying techniques, such as ovens, forced heat, or sun drying.

Storing Cables and Leadwires

To ensure that the cables and leadwires are in proper working order, use the following guidelines to store them when not in use:

- Store cables and leadwires in a dry, well-ventilated area.
- Hang cables and leadwires vertically
- Do NOT coil cables or leadwires around the device.

Cleaning, Disinfecting, and Sterilizing Reusable Electrodes

Clean reusable electrodes immediately after using them on a patient.

Cleaning and Disinfecting Reusable Electrodes

Use the following procedure to clean and disinfect the reusable electrodes:

1. Use warm water and a small brush to remove any cream or gel from the electrode.

   Do not use pointed or sharp objects for cleaning.

2. Disinfect the electrodes with alcohol-free disinfectant.

   Ensure that the connectors and sockets do not get wet.

Sterilizing Reusable Electrodes

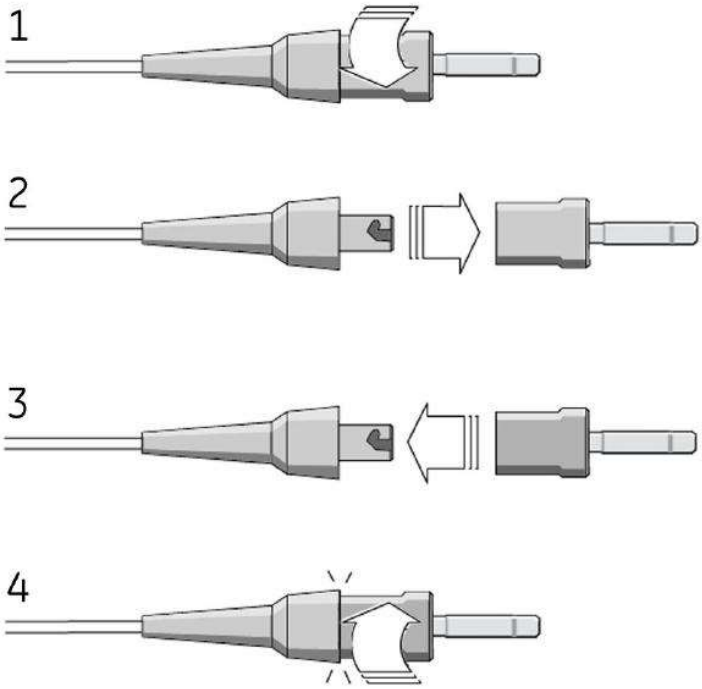
Use the following procedure to sterilize reusable electrodes:

The only approved sterilization method is gas sterilization.

1. Sterilize reusable electrodes with ethylene oxide gas (EtO) at a maximum temperature of 50°C (122°F).
2. After sterilization is complete, follow the manufacturer's recommendations for required aeration.

Replacing Leadwire Adapters

Although proper cleaning and storage prolong the life of leadwires, you eventually need to replace the leadwire adapters. The following illustration shows the proper method for replacing adapters.



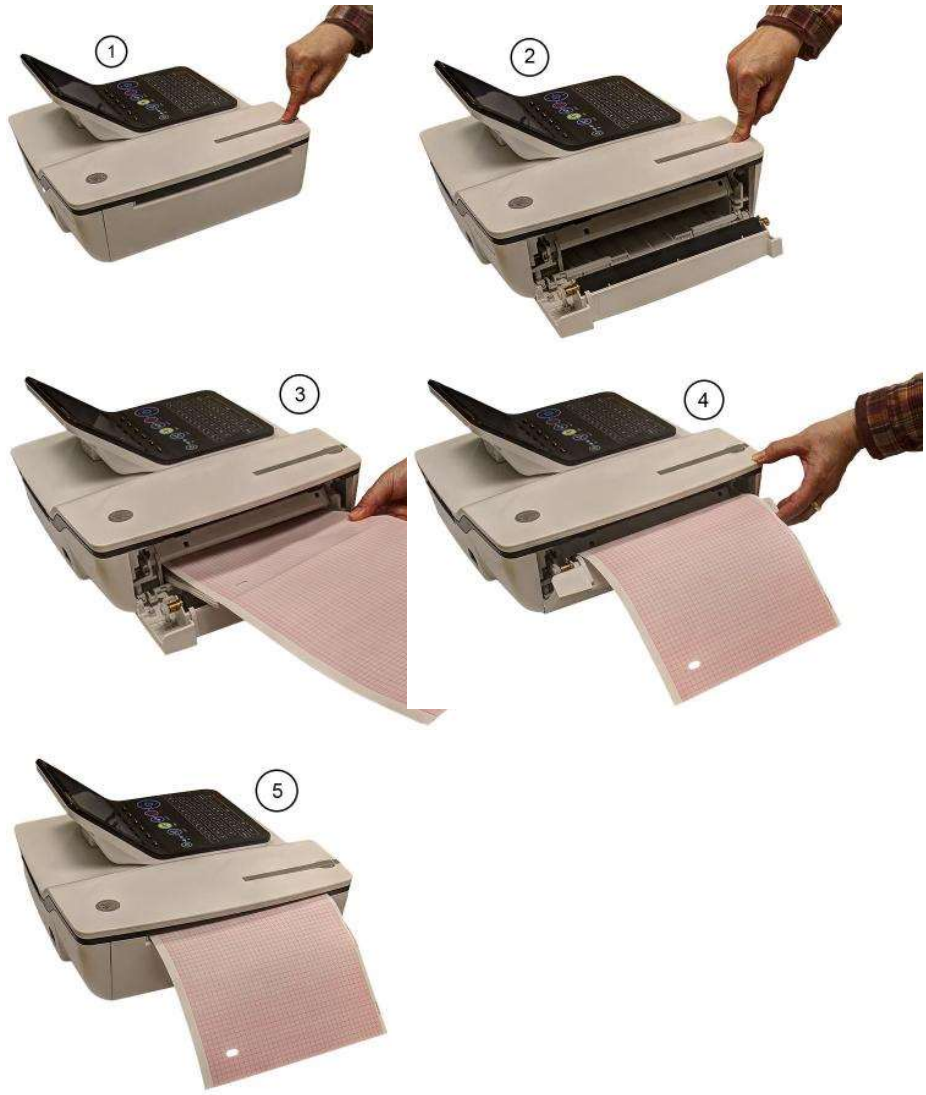
Paper Maintenance

For the proper handling of the device's thermal writer, you need to know how to do the following:

- Replace the paper
- Adjusting the tray for paper size
- Remove the paper pack
- Store the thermal paper

Replacing Paper

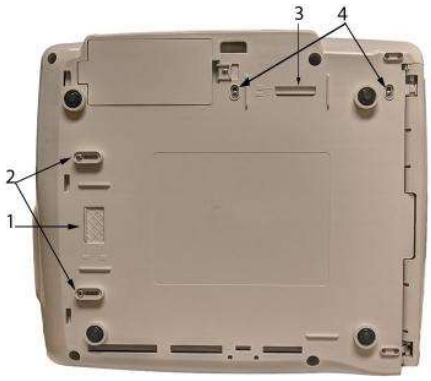
Use the following procedure to add or replace paper:

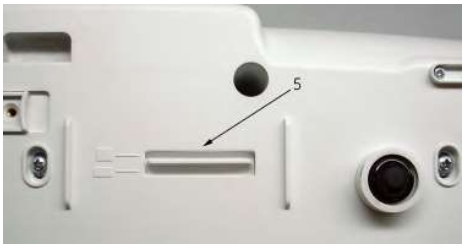


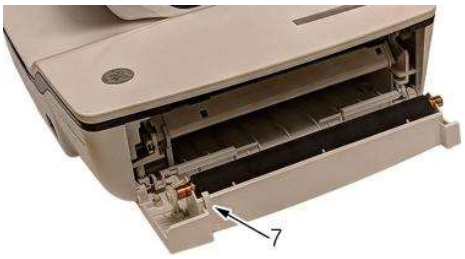
1. Press the push button on the top of the device (1) to open the printer door (2).
2. Extend the top sheet of the pack of paper and insert the pack into the paper compartment (3).

   Align the top sheet of the paper to the line located on the near side of the printer door.
3. Close the printer door (4) until it clicks into place (5).

Adjusting the Tray for Paper Size







Adjusting the Tray for 8.5 x 11 inches or A4

Use the following procedure to adjust the tray for the correct paper size if you are using letter (8.5 x 11 inches) or A4 paper.

1. Turn the device over so the bottom of the device is facing you.
2. Loosen the length and width fasteners (2 and 4) situated close to the paper spacers.
3. Slide the spacers (1 and 3) to the appropriate position for the paper size that you are using.
4. Tighten the screws (2 and 4) in the selected position.
5. Turn the device to the upright position and press the push button to open the printer door (6).
6. If you are using letter size (8.5 x 11 inches), remove the paper spacer post print (7).

NOTE:

If you are using A4 paper, the paper spacer post print should be snapped on. By default, the tray is set to A4 paper and therefore the paper spacer post print is in place.

Adjusting the Tray for Modified Letter Paper (8.433 x 11 inches)

Use the following procedure to adjust the tray for modified letter paper (8.433 x 11 inches).

1. Press the push button to open the printer door (6) and insert the modified letter paper.
2. Turn the device over so the bottom of the device is facing you.
3. Loosen the screws for the paper tray spacer (4).
4. Slide the spacer (3) until it presses the paper that is already loaded.

   Ensure that the paper spacer (5) is positioned in between the letter and A4 symbol.
5. Tighten the screws (4) with the spacer (5) at this position.
6. Loosen the other set of screws for the paper spacer (2).
7. Move the spacer (1) to the letter symbol.
8. Tighten the screws (2) with the spacer (1) at this position.

Removing the Paper Pack

Use the following procedure and pictures to remove the pack of paper from the device.

Use the following procedure to remove the paper pack from the printer:

1. Press the push button on the top of the device to open the printer door (1).
2. Lift up the pack of paper (2).
3. Press the pack of paper against the top plate of the paper compartment (3).
4. Pull the pack of paper out of the device (4).

Storing Thermal Paper

When imaged and stored properly, ECG tracings resist fading for several years. If your retention requirements exceed five years, consider using GE Healthcare Archivist paper.

To ensure the tracing is imaged properly, the device must be maintained in accordance with its service manuals and technical memoranda.

To ensure the tracing lasts for the paper's expected lifespan, observe the following guidelines when storing your printouts:

- Store in a cool, dark, and dry location.
  - Standard paper
    Temperature must be less than 27°C (80°F).
    Relative humidity must be less than 65%.
  - Archivist paper
    Temperature must be less than 40°C (104°F).
    Relative humidity must be between 40% and 60%.
- Avoid exposure to bright light or UV sources.
  Sources of ultraviolet light include sunlight, fluorescent lights, halogen lights, mercury vapor lamps, and germicidal lamps.
- Avoid contact with cleaning liquids and solvents.
  Solvents to avoid include alcohols, ketones, esters, ether, and so forth.
- Store thermal paper separately in manila folders or polyester or polyimide protectors.
  Plastic document protectors, envelopes, or sheet separators made of polystyrene, polypropylene, or polyethylene do not degrade thermal traces. However, these materials afford no protection against fading from external causes.
- Do NOT store thermal papers with any of the following:
  - carbon or carbonless forms
  - document protectors, envelopes, and sheet separators containing polyvinyl chloride or other vinyl chlorides.
  - non-thermal chart papers or any other products containing tributyl phosphate, dibutyl phthalate, or any other organic solvents

    NOTE:
    Many medical and industrial charts contain these chemicals.
- Do NOT use mounting forms, pressure-sensitive tapes, and labels that use solvent-based adhesives.
  Use only mounting forms and pressure-sensitive tapes made with starch or water-based adhesives.

Battery Maintenance

The device uses a rechargeable battery containing lithium-ion cells. The battery contains an integrated electronic fuel gauge and a safety protection circuit.

Because of the bias current needed to operate the integrated electronics, the battery discharges even when it is not installed in the device. The rate at which it discharges is dependent on the ambient temperature at which it is stored. The higher the

temperature, the more quickly it discharges. To prolong the battery's charge when not in use, store the battery in a cool, dry location.

A new, fully-charged battery should last for approximately 3 hours of normal operation. An on-screen LED indicates the condition and capacity of the battery's charge. (For more information on the battery gauge, refer to "Front View" on page 30 and "System Errors" on page 181). When the LED flashes amber, connect the device to AC power to charge the battery to full capacity.

As the battery ages, the full charge capacity of the battery degrades and is permanently lost. As a result, the amount of charge that is stored and available for use is reduced. When the capacity is no longer sufficient for your daily operation, you need to replace the battery.

Replacing the Battery

WARNING:

ENVIRONMENTAL HAZARD — Do NOT dispose of the battery by fire or burning.

Follow local environmental guidelines concerning disposal and recycling.

Use the following procedure to replace the battery:

1. Unplug the device from the AC adapter.
2. Gently turn the device over and remove the screw holding the battery cover.

3. Push the tab to remove the cover of the battery compartment.

4. Gently lift the cover of the battery compartment.

5. Remove the battery from the compartment.

6. Place the new battery in the compartment and push until it clicks into place.

7. Replace the cover on the battery compartment.

   It should click into place.

8. Tighten the screw to hold the cover in place.

Conditioning the Battery Pack

To maintain the storage capacity of the battery installed in the device, GE Healthcare recommends that you condition the battery once every 6 months to recalibrate its electronic fuel gauge. A condition cycle consists of an uninterrupted "charge-discharge-charge" cycle.

Use the following instructions to condition the battery:

1. Insert the battery into a device that is not recording patient tests.

   For details, refer to "Replacing the Battery" on page 171.

2. Disconnect the AC mains power from the device.
3. Enter the ***Battery Status Service Diagnostic*** window.

   For details on accessing the ***Battery Status Service Diagnostic*** window, refer to this device's service manual.

4. Allow the battery to discharge until its ***Charge Level*** is less than 90%.
5. Turn off the device and reconnect the AC mains power.
6. Allow the battery to fully charge.

   The **Battery LED** is steady amber while it is charging and turns off when charging is complete.

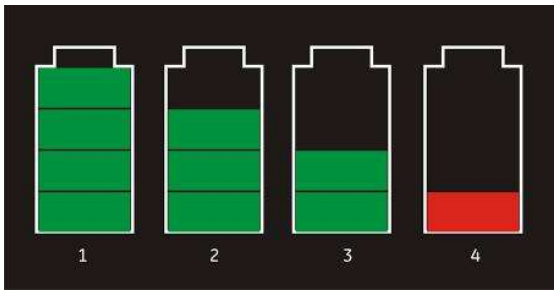
7. Remove the AC mains power and turn on the device.
8. Allow the battery to discharge until the device shuts down.
9. Reconnect the AC mains power to the device and leave the device turned off.
10. Allow the battery to fully charge.

    When the **Battery LED** indicator stops flashing and shines steadily, the battery is fully charged and the conditioning cycle is complete.

Battery Status Indicator

The battery status indicator is located on the top of the screen. For the exact location, see the screen in "Recording a Resting ECG" on page 65.

The following diagram and table describe the battery status.



Battery Status

Item	Description
1	The battery is fully charged and above 75%.
2	The battery charge is above 50%.
3	The battery charge is above 25%.
4	The battery charge is below 25%. This status is also used when the battery charge is unknown.

Supplies and Accessories

For a list of available supplies and accessories, refer to the supplies and accessories reference guide for this device.

14

Troubleshooting

This section identifies some of the more common problems with the system and lists their potential causes and solutions. If the information in this section cannot resolve your issue, contact GE Healthcare Technical Support.

General Troubleshooting Tips

Use the following general troubleshooting tips to help diagnose problems not specifically discussed elsewhere in this chapter.

- Thoroughly inspect the equipment.
  Disconnected or loose cables, missing hardware, and damaged equipment can cause what may seem to be unrelated symptoms or equipment failure.
  For additional information, refer to "Inspecting the Equipment" on page 161.
- Verify the equipment was not modified.
  Unauthorized modifications to the equipment may cause unexpected results, poor performance, or system failure.
  If the equipment has unauthorized modifications, contact GE Healthcare Technical Support.
- Verify the software was not updated.
  Updated software may change system functionality. If the user is unaware of the changes, they may seem to be unexpected results.
  If the software has been updated, refer to the revised Operator's Manual to determine whether the update changed features.
- Verify whether there were changes in the equipment's location or environment that could cause the failure.
  For example, equipment that emits radio waves could cause interference during acquisition.
  If the environment or location has changed, try using the equipment in the original location to determine whether the problem persists.
- Verify the problem was not caused by operator error.
  Repeat the scenario and compare that to the operation as described in the manual. If the operator deviated from the manual, repeat the task using the instructions as written.

If these steps do not resolve the problem, refer to the following sections for specific problems and solutions. If the problem still cannot be resolved, contact GE Healthcare Technical Support.

Frequently Asked Questions (FAQ)

This section addresses frequently asked questions concerning maintenance, system setup, and clinical topics.

Question	Procedure
How do I save changes I have made to the System Configuration?	Refer to "Export Setup" on page 153.
How do I restore system setups from the SD card?	Refer to "Import Setup" on page 152
How do I obtain a printed record of the System configuration file?	Refer to "Print Setup Report" on page 143.
I need to reactivate the options on my system. Where can I find the Option Codes?	The codes are listed on the last page of your printed setup report. Refer to "Print Setup Report" on page 143. They are also found on a label next to the battery compartment.
Why won't any of the ECGs I perform save to the SD card?	Refer to "Exporting Records" on page 104.
Should I clean the device?	Refer to "Maintenance". "Equipment Cleaning and Storage" on page 161.
What is the capacity of the battery?	Refer to the Battery information in "Product Overview". "Hardware Specifications" on page 35.
I need to provide the address of the device to the network administrator to enable the LAN communication option. How do I obtain the address?	After the LANM/LANC option is enabled and the network cable connected, you can obtain the IP address from "Communication Setup" on page 131 .

Equipment Problems

The following issues are discussed in this section:

System Does Not Power Up

If the system does not power up, do the following:

- Verify the device is turned on.
  If it is not, turn the device on. Refer to "Turning on the System" on page 47 for instructions.
- Verify the battery is installed and charged.
  Refer to "System Errors" on page 181 for instructions on verifying whether the battery is installed and charged.

Refer to "Replacing the Battery" on page 171 for instructions on installing the battery.

- Verify the device is connected to an AC power outlet.
  Refer to "Connecting the AC Power" on page 43 for instructions.
- Verify the equipment is receiving power from the outlet.
  If the device is receiving power, the **Power LED** is lit.

ECG Data Contains Noise

If the acquired ECG data displays unacceptable noise levels, do the following:

- Check the patient's position.
  The patient should remain motionless during the acquisition of a resting ECG.
- Use the ***Hookup Advisor*** indicator to help determine the cause of the noise.
  For more information, refer to "Hookup Advisor" on page 66.
- Verify the electrodes are placed properly.
  Refer to "Electrode Placement" on page 50 for information on proper electrode placement.
- Verify the electrodes are applied correctly.
  You must remove perspiration, excessive hair, lotions, and dead skin cells from the electrode site.
  Refer to "Preparing the Patient's Skin" on page 49 for more information.
- Check for defective or expired electrodes.
  Replace the electrodes if there are any questions about their effectiveness.
- Check for defective, broken, or disconnected leadwires.
  Replace the leadwires if there are any questions about their effectiveness. Refer to "Connecting the Patient Cable" on page 44.
- Consider using filters, ***ADS***, and ***FRF*** to help eliminate or reduce ECG noise.
  For more information, refer to "ECG Options" on page 69, "Arrhythmia Printing Options" on page 80, or "Stress Options" on page 92.

External Stress Equipment does not Move

If the external stress equipment does not move automatically when expected, do the following:

- Verify the correct stress equipment is selected in ***Basic Setup***.
  For more information, refer to "Basic Setup" on page 107.
- Verify the selected stress equipment is supported.
  For a list of supported stress equipment, refer to "Connecting External Devices (Stress Option)" on page 47.
- Verify the stress equipment is connected to the cart.
  External stress equipment is connected to the cart through a serial cable. For more information, refer to "Rear View" on page 30.
- Verify the protocol is set up to activate the stress equipment.
  The protocol can set the stress equipment's speed and grade or load. For more information, refer to "Editing Stress Protocols" on page 128.
- Verify the **Stop TM** button is not depressed.
  For more information, refer to "Stress Test Keys" on page 92.

Paper Jams

If the paper jams while printing, do the following:

- Verify the paper was inserted correctly.
  For details, refer to "Replacing Paper" on page 167.
- Verify the paper tray spacers are set appropriately for the paper size.
  For details, refer to "Adjusting the Tray for Paper Size" on page 168.

Import/Export/Save Errors

The following issues are discussed in this section:

SD Card Not Present

If you receive an error message stating that the SD card is not present or cannot be found, do the following:

- Verify an SD card is inserted into the card slot on the device.
  For details, refer to "Rear View" on page 30.
- Verify the SD card is seated firmly.
  The SD card clicks into place when seated firmly.
- Verify the SD card is formatted for a ***FAT*** or ***FAT16*** file system.

To verify an SD card is formatted for the correct file system, do the following:

1. Insert the card into an SD card reader attached to a PC.
2. Copy any files you want to save from the SD card to a folder on the PC.
3. Using the Windows ***Format*** command, specify either ***FAT*** or ***FAT16*** for the file system and format the card.

   NOTE:
   Formatting the SD card erases any existing files on the card.

4. Copy the files from the folder on the PC to the newly formatted SD card.

Cannot Import or Transmit Records via Modem

If you receive an error while attempting to import or transmit ECG records via modem, do the following:

- Verify the correct communication option was activated.
  The system supports two options for communicating via modem: ***MOD C*** (for communicating with a CardioSoft system) and ***MOD M*** (for communicating with a MUSE system). For more information, refer to "Options Setup" on page 153.
- Verify the modem is connected to an analog telephone line using a standard RJ11 phone jack.
  For more information, refer to "Rear View" on page 30.

- Check ***Communications Setup*** to verify the correct dialing method is selected and configured accurately.
  For details, refer to "Communication Setup" on page 131.
- If transmitting records, check the selected location to verify the following:
  - ***Modem*** is the selected device.
  - The ***Phone Number*** is correct.
  - The correct ***Protocol*** is selected.
    For details, refer to "Communication Setup" on page 131.

Cannot Transmit Records via LAN

If you receive an error while attempting to transport records via LAN, sue the following procedure:

1. Verify the correct communication option was activated.

   The system supports two options for communicating via LAN:

   - LANC (for communicating with a CardioSoft system)
   - LANM (for communicating with a MUSE system

   For more information on setting up LAN communication, see "Options Setup" on page 153.
2. Verify the LAN cable is connected properly to the LAN connection slot.

   For information on where the LAN cable connects to the device, see "Rear View" on page 30.
3. Check communication setup to verify whether the IP, Netmask, Gateway, and DNS addresses are all correct.

   For details on checking addresses, see "Communication Setup" on page 131.

Cannot Transmit Records via WiFi

If you receive an error while attempting to transmit records via WiFi, use the following procedure:

1. Verify the correct communication option was activated.

   The system supports two options for communicating via WiFi:

   - WIFC (for communicating with a CardioSoft system
   - WIFM (for communicating with a MUSE system.

   For more information on setting up LAN communication, see "Options Setup" on page 153.
2. Verify the WiFi dongle is connected properly to the USB port on the rear of the device.

   If the WiFi dongle is not working, try changing the port.

   For information on where the WiFi dongle connects to the device, see "Rear View" on page 30.

3. Check communication setup to verify whether the IP, Netmask, Gateway, and DNS addresses are all correct.

   For details on checking addresses, see "Communication Setup" on page 131.

4. Check whether the wireless LAN is enabled and the authentication details are correct.

   For information on the wireless LAN setup, see "Wireless Networking Settings" in "Communication Setup" on page 131.

Cannot Export to Shared Directories

To resolve errors received while attempting to export ECG records to a shared directory, do the following:

- Verify the ***LANC*** communication option was activated.
  Refer to "Options Setup" on page 153 for information on activating options.
- Verify connectivity by checking the following:
  - The network cables are connected.
  - The ***IP***, ***netmask***, ***gateway***, and ***DNS*** server addresses are all correct.
    Refer to "Communication Setup" on page 131 for instructions on setting these values.
  - The two systems can communicate.
    To verify this, ping the device from the file server.
- Verify the logon information is correct.
  Check the user name, password, and domain information. Refer to "Communication Setup" on page 131 for information on the log on information.
- Verify share and directory permissions.
  Ensure that the account used to log on to the shared directory has read/write/create permissions to both the share and the directory.
  Refer to Microsoft Windows online help for instructions on how to set user permissions.

Acquisition/Printer Error Messages

If you receive an acquisition/printer error message, along with an error code, use the following table to determine what you need to do.

Message	Action
Message displays for a short duration and then stops.	No action to take.
Message displays persistently.	Try rebooting the system.
Message displays persistently, even after rebooting the system.	Contact GE Healthcare Service.

Report Errors

This section addresses the following report error: "ACI-TIPI Statement is not Included on Report" on page 181.

ACI-TIPI Statement is not Included on Report

If the ACI-TIPI statement is not displayed when expected, do the following:

- Verify the ***ACI-TIPI*** option is activated.
  For information on activating the ***ACI-TIPI*** option, refer to "Options Setup" on page 153.
- Verify ***ACI-TIPI*** is enabled on the ECG.
  For information, refer to "Resting ECG Setup" on page 112.
- Verify the information ***ACI-TIPI*** requires was entered.
  The ACI-TIPI statement prints only if the patient's gender, date of birth, and chest pain indication are included in the patient information.
- Verify the patient is 16 years old or older.
  The ACI-TIPI statement does not print for pediatric patients.
- Verify the original ECG was acquired in an electrocardiograph with the ***ACI-TIPI*** option.
  If you attempt to print an ECG that was imported from an external device, the cart does not generate an ACI-TIPI statement; it prints only if the statement was saved as part of the ECG.

System Errors

The following table identifies some potential errors that may occur while you are operating the system, the possible causes, and a recommended course of action to resolve the error.

If performing the recommended actions does not resolve the problem, contact authorized GE Healthcare service personnel.

Problem	Cause	Solution
 This icon is displayed and the battery LED is flashing.	System is operating from the battery and the battery charge is low.	Connect the system to an AC outlet to charge the battery.
 This icon is displayed and the battery LED is not lit.	System is operating from AC power and battery is not installed.	Install a battery.
The system does not power up while operating from battery power.	Battery is fully discharged.	Connect the system to an AC outlet to charge the battery

Problem	Cause	Solution
The system powers down while operating from battery power.	Battery is fully discharged	Connect the system to an AC outlet to charge the battery
You are prompted to enter ***User ID*** and/or ***Password*** while attempting to export records to a shared network directory.	The ***User ID*** and/or ***Password*** defined on the ***Communication Setup*** window ("Communication Setup" on page 131) are incorrect.	1. Press **Esc** to close the prompt. 2. Exit the export program. 3. Run ***Communication Setup***. 4. Enter the correct ***User ID*** and ***Password*** for the shared directory and save the new values. 5. Export the records.
User cannot log on to the system.	***High Security Mode*** is enabled and the user's ***User ID*** or ***Password*** were entered incorrectly.	Try the following: • Verify the user is setup in the system. Refer to "User Setup" on page 149. • Verify the user typed the ***User ID*** and ***Password*** correctly. • Contact the administrator to reset the user's ***User ID*** or ***Password***. • Contact GE Healthcare technical support to obtain a temporary supervisor password.

Problem	Cause	Solution
The following error message is displayed while printing: ***Printer internal error – Printing not possible***	The printer encountered a temporary condition that caused it to stop printing the current report.	To restart any of the following reports, push the appropriate button: • Rhythm Report in Resting ECG Mode • Arrhythmia recording in Arrhythmia Mode • In-test Reports in Stress Test Mode All other reports restart automatically.
The following error message is displayed while printing: ***Battery low – Printing not possible***	The battery is low and does not have enough charge to power the printer.	Try the following: • Allow the battery to charge to 50% before printing again. • Connect the device to an AC outlet. • Power down the device then power it back on.

A

Creating Barcodes

The following sections provide the information you need to configure bar codes.

The barcode reader can read any of the following codes:

- 39
- 39EX
- 128
- PDF-417
- Interleaved Code 2 of 5
- Data Matrix

Regardless of which code is used, the site's IT department must do the following:

- Set up the patient data scheme.
- Configure the barcode reader.

NOTE:
All data resides in fixed-width fields. The bar code must be programmed to add "trailing spaces" after fields shorter than the fixed length of the fields your system is using.

Setting Up the Patient Data Scheme

Use the following rules to set up a data scheme, including patient demographic data, for your barcodes.

Patient Data Scheme

Item	Byte Length
Patient ID	The ***Patient ID*** length should not exceed the 30–character maximum and should be equal to the ID length set up on the system in the ***Patient Setup*** window. If the system is communicating with a MUSE system, the length of the ***Patient ID*** should be the same as the Patient ID that the MUSE system uses.
Last Name	40 (maximum)
First Name	20 (maximum)

Patient Data Scheme (cont'd.)

Item	Byte Length
Year of birth	4
Month of birth	2
Day of birth	2
Gender	1

Configuring the Barcode Reader

Configure the barcode reader on the ***Patient Setup*** window. You can choose to configure it manually or automatically. The requirements for each method are described in the following sections.

Configuring the Barcode Reader Manually

The following table identifies the available fields for configuring your bar code reader.

Manual Bar Code Reader Configuration Fields

Field	Description and Byte Length
Total number of bytes	Enter the total number of bytes contained in the patient bar code. This is usually the sum of the bytes listed in the following fields.
Patient ID offset	Enter the Patient ID's ***Offset***.
Patient ID length	Enter the Patient ID's ***Length***. Be aware of the following criteria when setting the length: • Can be from 3 to 30 • Should equal the ID length set up on the ***Patient Question*** window • Should equal the patient ID length for the MUSE CV system with which the MAC system communicates.
First name offset	The patient's first name ***Offset***.
First name length	The patient's first name ***Length***. Be aware of the following criteria when setting the length: • value can be from 0 to 20 • should equal the length from the MUSE CV system with which the MAC system communicates. **NOTE:** The MAC system does not support "long" names; if the MUSE system uses long names, this field should be set to its maximum value.
Last name offset	The patient's last name ***Offset***.

Manual Bar Code Reader Configuration Fields (cont'd.)

Field	Description and Byte Length
Last name length	The patient's last name ***Length***. Be aware of the following criteria when setting the length: • value can be from 0 to 40 • should equal the length from the MUSE CV system with which the MAC system communicates **NOTE:** The MAC system does not support "long" names; if the MUSE system uses long names, this field should be set to its maximum value.
Year of birth offset	The year the patient was born. Enter the field's ***Offset***
Year of birth length	The year the patient was born. Enter the field's ***Length*** The length must be set to 4.
Month of birth offset	The month the patient was born. Enter the field's ***Offset***.
Month of birth length	The month the patient was born. Enter the field's ***Length***. The length must be set to 2.
Day of birth offset	The day the patient was born. Enter the field's ***Offset***.
Gender offset	The patient's gender. Enter the field's ***Offset***.
Gender length	The patient's gender. Enter the field's ***Length***. The length must be set to 1.

Configuring the Barcode Reader Automatically

You can configure the barcode reader automatically by scanning a barcode that has been set up using the following information:

Automatic Bar Code Reader Configuration Fields

Item	Character Used to Reserve Byte Space
Patient ID	9
First name	5
Last name	6
Year of birth	3
Month of birth	1
Day of birth	2
Gender	M or m for male F or f for female

B

Master's Step Data

The following sections provide the information you need to run a ***Master's Step*** stress test.

Master's Step Table

The following table identifies the number of steps to set according to the patient's age, gender, and weight.

Weight (kg)	Gender	Age (Years)														
		5–9	10–14	15–19	20–24	25–29	30–34	35–39	40–44	45–49	50–54	55–59	60–64	65–69	70–74	75–79
18–22	Male	35	36													
	Female	35	35	33												
22–26	Male	33	35	32												
	Female	33	33	32												
27–31	Male	31	33	31												
	Female	31	32	30												
32–35	Male	28	32	30												
	Female	28	30	29												
36–40	Male	26	30	29	29	29	28	27	27	26	25	25	24	23	23	22
	Female	26	28	28	28	28	27	26	24	23	22	21	21	20	19	18
41–44	Male	24	29	28	28	28	27	27	26	25	24	23	22	22	21	22
	Female	24	27	26	27	26	25	24	23	22	21	20	19	18	18	17
45–49	Male	22	27	27	28	28	27	26	25	25	24	23	22	22	21	20
	Female	22	25	25	26	26	25	24	23	22	21	20	19	18	18	17
50–53	Male	20	26	26	27	27	26	25	25	24	23	22	22	22	21	20
	Female	20	23	23	25	25	24	23	22	21	20	19	18	18	17	16
54–58	Male	18	24	25	26	27	26	25	24	23	22	22	21	21	20	19
	Female	18	22	22	24	24	23	22	21	30	19	18	18	17	16	15
59–63	Male	16	23	24	25	26	25	24	23	23	22	21	20	20	19	18
	Female	16	20	20	23	23	22	21	20	19	19	18	17	16	15	15
64–67	Male		21	23	24	25	24	24	23	22	21	20	20	19	18	18
	Female		18	19	22	22	21	20	19	19	18	17	16	15	15	14
68–72	Male		20	22	24	25	24	23	22	21	20	20	19	18	18	17
	Female		17	17	21	20	20	19	19	18	17	16	16	15	14	13

Weight (kg)	Gender	Age (Years)														
		5–9	10–14	15–19	20–24	25–29	30–34	35–39	40–44	45–49	50–54	55–59	60–64	65–69	70–74	75–79
73–76	Male		18	21	23	24	23	22	22	21	20	19	18	18	17	17
	Female		15	16	20	19	19	18	18	17	16	16	15	14	13	12
77–81	Male			20	22	23	23	22	21	20	19	18	18	17	17	16
	Female		13	14	19	18	18	17	17	16	16	15	14	13	13	12
82–85	Male			19	21	23	22	21	20	19	19	18	17	16	16	15
	Female			13	18	17	17	17	16	16	15	14	14	13	12	11
86–90	Male			18	29	22	21	21	29	18	17	17	16	15	15	14
	Female			12	17	16	16	16	15	15	14	13	13	12	12	11
91–93	Male				19	21	21	20	19	18	17	16	16	15	14	14
	Female				16	15	15	15	14	14	13	13	12	11	11	10
94–99	Male				18	21	20	19	18	17	17	16	15	14	14	13
	Female				15	14	14	14	13	13	13	12	11	11	11	10
100–104	Male				17	20	20	19	18	17	16	15	14	13	13	12
	Female				14	13	13	13	13	12	12	11	11	10	10	09

ST-T Changes

The existence of any ST-T change is assessed by classifying ST-T into three assessment levels:

- **Positive**
  One of the following criteria must be met on 2 or more leads:
  - ST Depression ≥ 0.1 mV
  - ST Elevation≥ 0.2 mV
  - T wave change ≥ 1.0 mV
- **Borderline**
  One of the following criteria must be met on any lead:
  - ST Depression ≥ 0.05 mV
  - ST Elevation ≥ 0.1 mV
  - T wave change ≥ 0.5 mV
- **Negative**
  This is assessed if neither the Positive nor Borderline criteria are met.

To following formulas are used to calculate the values in the previous criteria:

- ST depression = (rest ST - post J) - (post exercise ST - post J)
- ST depression = (rest ST - post J) - (post exercise ST - post J)
- T wave change = absolute value of (rest T wave amplitude - post-exercise T wave amplitude)
- (ST - post J: amplitude at the post J point)

When the assessment is positive or borderline, the lead with the largest change prints.

C

Technical Specifications

System Specifications

Hardware Device

Item	Specifications
Device type	Portable, integrated unit
Width	390 mm (15.4 in)
Depth	330 mm 13.0 in)
Height	200 mm (7.9 in)
Weight	approx. 5 kg (11.0 lb) (including battery, without paper)
CRT Interface	No CRT interface connector
USB Port	Two USB 2.0 ports available
Mechanical design	Housing with built-in graphics display SW on mainboard

Environmental Conditions

Item	Operating Specifications	Transport/Storage Specifications
Temperature	+10°C to +40°C (50°F to 104°F)	-40°C to +70°C (-40°F to 158°F)
Relative humidity	20% to 95% (RH non-condensing)	15% to 95% (RH non-condensing)
Pressure	700 hPa to 1060 hPa (Altitude range: 3010.9m to –381.9m [9878.28 ft. to –1252.95 ft.])	500 hPa to 1060 hPa (Altitude range 5570m to -380m [18274.28 ft. to –1246.72 ft]).

Display

Item	Specifications
Type	7–inch (177.8 mm) color TFT graphics display with support of minimum 32K colors
Resolution	WVGA – 800 x 480 pixels

Display (cont'd.)

Item	Specifications
Data	Heart rate, patient ID, clock, battery power indicator, waveforms, lead labels, speed, gain and filter settings, warning messages, prompts, and help messages. Standard display: 6 leads Optional display: 12 leads
Traces	3, 6, 12
Sweep Speed	12.5, 25, and 50 mm/s
Filtered ECG	The raw or filtered ECG curves are displayed on the screen as selected by the user.

Keypad

Item	Specifications
Pad	Membrane board with tactile feedback
Keys	Soft function keys Full alphanumeric keyboard (Qwerty key set) Writer controls Trimpad cursor controls
Keypad	Standard keypad with additional function keys. Keypad and lettering are water resistant and meet MDM4021 Cleaning and Chemical Resistance Performance Guidelines
Functions	Standard Stress

Printer

Item	Specifications
Technology	Integrated thermal dot array
Paper Speed	5, 12.5 mm/s at ±10% accuracy 25, 50 mm/s at ±2% accuracy
Printer motor speed	Report printing within 25 seconds
Number of traces	Up to 12 ECG traces sampled at 500 or 1000 Hz
Sensitivity/gain	2.5, 5, 10, 20, 40 mm/mV with ±5% accuracy
Speed accuracy	5, 12.5 mm/s at ±5% 25, 50 mm/s at ±2%
Amplitude accuracy	±5%
Horizontal resolution	40 dots/mm at 25 mm/s in rhythm mode
Vertical resolution	8 dots/mm
Paper type	Z-fold thermal with pre-printed grid and perforation
Paper size	215 mm x 280 mm (8.5 in x 11 in) (letter) 210 mm x 295 mm (8.25 in x 11.6 in) (A4) 214.2 mm x 279.4 mm (8.43 in x 11 in) (modified letter)
Paper tray capacity	Holds up to 150 sheets

Electrical

Item	Specifications
Power supply	Internal AC/DC or battery operation
Input voltage	100–240 VAC ±10%
Input current (Maximum power consumption)	1.5A at 115V to 230V AC
Input frequency	47–63 Hz
Safety requirement	IEC60601–1 protection class I
Fuse requirement	Phase and neutral meet UL/IEC requirements
Power inlet socket	IEC C14 type

Battery

Item	Specifications
Type	Replaceable and rechargeable, Lithium Ion
Capacity	14.4V, 2.2 AH ±10% 100 single page resting ECG recording or 3 hours (typical) of continuous monitoring without printing (minimum)
Charge time	Approximately 3.5 hours from total discharge (with device off)

Acquisition, Processing, and Performance

LEDs

Item	Specifications
Battery charging	Steady amber: Battery charging Flashing amber: battery low Off: battery fully charged (when connected to AC Mains); neither charging nor low (when running on battery)
External power	Steady green: external power connected Off: no external power

ECG Data Acquisition

Item	Specification
ECG front end	Internal ECG front end with DSP provides 10 simultaneously sampled electrode channels
Signal input	Type CF
Amplitude resolution	4.88 µV ±1% per LSB @ 500 SPS
Dynamic range	AC differential: ±5 mV DC offset: ±300 mV
Frequency range	0.04 to 150 Hz
Common mode rejection	>135 dB with 50/60 Hz filter on

ECG Data Acquisition (cont'd.)

Item	Specification
Input impedance	>10 MΩ @ 10 Hz
Patient leakage current	<10 µA normal condition (NC) <50 µA single fault condition (SFC)
Remote control	Advancing to the next stage can be initiated from the bicycle ergometer.

Processing

Item	Specifications
Processor	Application: 32 bit ARM9 processor Peripheral Management: 32 bit ARM Cortex-M3 processor Signal Chain Processing: 400 MHz DSP
ECG Interpretation	Marquette 12SL™ ECG Analysis Program for adults and pediatrics Heart Algorithm (Stress)
Computerized measurements	12-lead analysis
ECG analysis frequency	500 or 1000 samples/second/channel
Digital sampling rate	16000 samples/second/channel for normal data acquisition
Pace sample rate	75K samples/second/channel
ECG on-screen preview	On-screen preview of acquired 10-second ECG waveform
Acquisition mode	Pre-acquisition or post acquisition, provides 10 seconds of instantaneous ECG acquisition
Resolution	4.88 µV/LSB
Frequency range	0.04 to 150 Hz
Low cutoff frequency	0.04 Hz (-3 dB limits)
High cutoff frequency	Configurable at 20 Hz, 40 Hz, 100 Hz, 150 Hz
Common mode rejection	>135 dB (with 50/60 Hz filter on)
Input impedance	>10 MΩ @ 10 Hz (defibrillator protected)
Patient leakage	<10 µA NC <50 µA SFC
Electrodes monitored for disconnection	Every electrode except RL and RA
Heart rate meter	30 to 300 BPM
Operating system	Microsoft Windows CE 6.0
Startup time	Less than 30 seconds.
ECG transmission	Resting ECGs can be transferred via the serial interface, modem, LAN, as well as SD-card from the MAC2000 system to other ECG systems (CardioSoft/CardioSys, MUSE) for further processing and archiving. In addition, Resting ECG can be received via serial line, modem, and SD Card.

Processing (cont'd.)

Item	Specifications
Patient Data	Patient information entry: Patient ID, Secondary Patient ID, Height, Weight, Gender, Race, Pacemaker Patient, Systolic BP, Diastolic BP, Location#, Room, Order Number, Phone Number, Medication, Ordering Physician, Referring Physician, Attending Physician, Technician, Test indication, four user-definable fields.
Electrode connections	RA, RL, LA, LL, V1–V6, Nax, Nst
Detection of pacemaker pulse	Lower scale: 0.2 ms duration, 0.5 mV amplitude Higher scale: 2.0 ms duration, 250 mV amplitude
Archiving	ECG data is printed out Internal memory is present on this system.
External Storage	SD Card available for storage
Input/Output Interface	RS232 port for connectivity to MUSE systems v7.1.1 and v8.0.1 and CASE/CardioSoft systems V6.51, V6.61, and CardioSoft V6.71, and remote control signal from ergometers
Ethernet interface	RJ45 connector
Channels	6, 12
QRS detection	Available
Muscle filter	20 Hz, 40 Hz, 100 Hz, 150 Hz
Automatic baseline correction	User-selectable

Operating Modes, Features, and Options

Operating Modes and Features

Item	Specifications
Resting ECG Mode	Records and prints 12-lead resting ECGs with 10 seconds duration as a standard feature.
Arrhythmia Mode	Continuously monitors ECG and prints report when arrhythmia events of the user-selected class occur
Exercise/Stress Test Mode	Exercise mode for exercise stress testing
RR Analysis Mode	RR Analysis for RR interval analysis
Hookup Advisor	Provides visual indication of signal quality
Multi-language support	User Interface supports 19 languages User Manual supports 31 languages
Order Manager	Provides an interface for managing orders

Accessories

Item	Specification
Consumables	Electrodes, leadwires, cables, and so forth For a complete list of all available supplies and accessories for this system, refer to the *MAC™ 2000 Supplies and Accessories Reference Guide*.
Barcode Scanner	Use to enter patient information from a patient barcode
Secure Digital High Capacity (SDHC) Card	4 GB

Product Options

For a complete list of product options and codes, refer to "Options Setup" in the operator's manual.

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