GE Healthcare

MAC[™] 600 Service Manual Product Code SPY

2047426-002 Revision G



The information in this manual only applies to MACTM 600 SPY. Due to continuing product innovation, specifications in this manual are subject to change without notice.

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1 Introduction

Manual Information

Revision History

Each page of the document has the document part number and revision letter at the bottom of the page. The revision letter identifies the document's update level. The revision history of this document is summarized in the following table.

Table 1-1. Revision history, PN 2047426-002		
Revision	Date	Comment
А	25 September 2009	Initial release of document
В	31 July 2012	Update classification to DCAR products.
С	26 March 2013	Updated photos in Equipment Identification and Back View. The product and serial number labels were updated. Added the Class I Power Supply to the FRU Part List. In Technical Specifications the Input Current rating was updated.
D	17 April 2013	Include attachment in Agile.
E	3 December 2013	Updating product labels and power supply FRUs.
F	20 July 2016	Updated product labels, connectors, and the new product code to SP5. Updated the block diagram and the mainboard photo.
G	23 February 2017	Updated product code to SPY and added KOE Display FRUs.

Manual Purpose

This manual provides technical information for service representatives and technical personnel to maintain the equipment to the assembly level. Use it as a guide for maintenance and electrical repairs considered field repairable. The manual identifies additional sources of relevant information and technical assistance. See the operator's manual for operating instructions.

Intended Audience

This manual is written for clinical professionals and others who use, maintain, and troubleshoot the MAC 600. The person using the MAC 600 is expected to have a working knowledge of appropriate medical procedures, practices, and terminology used in the treatment of patients.

Contraindications

- This system is not intended for use as a vital signs physiological monitor or for use during patient transport.
- This device is not intended for use with high-frequency surgical units. Disconnect the device from the patient before using the highfrequency surgical units.
- This device is not intended for use with direct cardiac applications.

Warnings, Cautions, and Notices

The terms DANGER, WARNING, CAUTION and NOTICE are used throughout this manual to point out hazards and to designate a degree or level or seriousness. Familiarize yourself with their definitions and significance. Hazard is defined as a source of potential injury to a person.

Table 1-2. Hazard terms		
Term	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.	
CAUTION	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in minor personal injury or product/property damage.	
NOTICE	Indicates a potential hazard or unsafe practice, which, if not avoided, could result in the loss or destruction of property or data.	

Conventions

Table 1-3. Conventions	
Bold text	Indicates keys on the keypad, text to be entered, or hardware terms such as buttons or switches on the equipment.
<i>Italicized</i> text	Indicates terms that identify menu items or options in the system display.

Safety Messages

Additional safety messages provide appropriate safe operation information.

DANGER

Do not use in the presence of flammable anesthetics.

WARNING

CONNECTION TO MAINS – This is class I equipment. The mains plug must be connected to an appropriately grounded power supply.

NOTICE

All shipments of MAC 600 devices to China are Class I. However, for all other countries, the MAC 600 installed base is Class II if the serial number is less than SF713500001PA.

WARNING

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

CAUTION

This equipment contains no user serviceable parts. Refer servicing to qualified service personnel.

U.S. Federal law restricts this device for sale by or on the order of a physician.

Responsibility of the Manufacturer

GE Healthcare is responsible for the effects of safety, reliability, and performance only if:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by us.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.

General

Failure on the part of the responsible individual, hospital, or institutional users of this equipment to implement a satisfactory maintenance schedule could cause equipment failure and health hazards.

To ensure patient safety, use only parts and accessories manufactured or recommended by GE Healthcare.

Contact GE Healthcare before connecting any devices to this equipment that are not recommended in this manual.

Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard.

The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system.

Considerations relating to the choice include:

- Use of the accessory in the patient vicinity.
- Evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 harmonized national standard.

Equipment Symbols

See the MAC 600 operator's manual for information about the symbols used on this product and its packaging.

Service Information

Service Requirements

Refer equipment servicing to GE Healthcare authorized service personnel only. 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 an authorized agent.

Equipment Identification

Every GE Healthcare device has a unique serial number. The serial number appears on the device label and is formatted as shown.



Table 1-4. Equipment Identification	
Item Description	
А	Product label
В	Serial number label

Serial Number Label Format

The serial number label is located on the bottom cover beside the product label.



Table 1-5. Serial Number Label Details		
Item Description		
А	Product part number	
В	Manufacture date in YYYY-MM format	
С	Serial number barcode	
D	Serial Number	

Serial Number Format



The serial number appears as follows:

Table 1-6. Serial Number Format		
Item	Description	
А	The product code for MAC 600 system is SPY	
В	Year Manufactured (00-99) 00 = 2000 01 = 2001 02 = 2002	
С	Fiscal Week Manufactured	
D	Production Sequence Number	
E	Manufacturing Site	
F	Miscellaneous Characteristic	

Product Label

The product label is located on the back of the device next to the external power input.

NOTE

Your product label may vary.



Table 1-7. Product Label		
Item	Item Description	
А	Product name (MAC 600)	
В	Manufacturing Site	
С	C Input power rating	
D Symbols		
See the "MAC 600 Operator's Manual" for a description of the symbols used on this label.		

For your notes

2 Equipment Overview

General Description

The MAC 600 Resting ECG Analysis System is a 10-lead, 12-channel device with an integrated 4.3 inch WQVGA color display and three-inch thermal printer. This is a portable device with a lithium ion battery and smart charger. This device supports AC operation with a 12V ACDC medical grade adaptor. The device can support communication and external storage through serial port and SD card options.

Top View



Table 2-1. Top view		
	Name	Description
А	Writer/Printer	Prints ECG Reports
В	Display	View ECGs of different lead/lead group, heart rate, mode of operation, speed, gain, and filter settings.
С	Keypad	Keys to power on the system, change operating parameters or control operations.

Back View



Table 2-2. Back view		
Legend	Name	Description
A	DC In Socket	Input socket for connecting external ACDC adaptor.
В	SD Card slot	Slot for using the SD card.
С	Product Label	Displays product name, site of manufacture, power specification, and relevant symbols.
D	Serial Port	Port for connecting serial cable.
E	Serial Number Label	Displays product number, date of manufacture, barcode and serial number of the product.

WARNING

SYSTEM LEAKAGE CURRENT – Keep leakage current within acceptable limits when connecting auxiliary equipment to this device. Total system leakage must not exceed 300 microamperes (110V system) or 500 microamperes (220V-250V system).

Side View



Table 2-3. Side View		
Legend Name Description		
А	ECG signal input connector	Connector for patient cable

Keypad



Table 2-4. Keypad		
Legend	Name	Description
А	Power	Turns the system on or off.
В	Power LED	Indicates the unit is plugged in and receiving DC power.
С	Battery LED	 Indicates various battery states: Solid amber light indicates that the battery is charging. Flashing amber light indicates that the battery is low. Off indicates that the battery is fully charged or that the battery is not being charged.
D	ON/OFF LED	Indicates the system is ON.
E	Function (F1 through F4)	Selects screen menu functions.
F	Arrow pad	Moves the cursor left, right, up, or down.
G	Enter (Trim Pad Enter Key)	Press this key every time you want to confirm a selection.
Н	Leads	Scrolls through the leads on display and changes leads during rhythm print.
I	ECG (Green)	Acquires an ECG. Press to acquire a 12SL resting ECG, including measurements and interpretation.
J	Rhythm	Prints a continuous, real-time rhythm ECG strip. Press the Stop key to stop the rhythm strip from printing.
К	esc	To return to the previous menu.

Table 2-4. Keypad		
L	Backspace	Deletes characters
М	Stop	Stops the printing.

Bottom View



Table 2-5. Bottom View		
Legend	Name	Description
А	Battery Compartment	Holds the rechargeable Lithium-Ion battery
В	Option Code Label	Displays the option code label (Optional)

Table 2-6. Option Code Label Contents		
Option	Option Description	
1	Measurement	
2	Measurement and Interpretation	
3	External Storage	
4	Color Display	
5	Transmission	

Table 2-6. Option Code Label Contents	
6	XML Format
7	PDF Format

NOTE

The option label only includes information regarding ordered options. If no options were ordered, this label is not present.

General Description



Hardware/Firmware Architecture:

The MAC 600 hardware subsystems include the following:

- CPU board
- Power management
- Printer control
- Display driver and Isolated ECG acquisition

- Display
- Keypad
- Thermal printer
- External ACDC Power supply (of 100V -240V +/- 10% AC and gives single output of 12V @ 1.5 A)
- Housing
- Battery

3 Troubleshooting

For your notes

General Fault Isolation

Power-up Self-Test

See *Equipment Overview* in the *MAC 600 Operator's Manual* for information regarding the operation of the device.

On power-up, the start-up screen opens.

Press 'ECG' key to record an ECG. 11:50:45 <u>20-Jul-2009</u>		•00 *** _{BPM} ==	
	Patient Cable	Disconnected.	
1 H	avn	VI	V4
	aVE	V2	və VA
Patient Data	25 mm/s	10 nn/n¥) More

NOTE

Battery charging indication and time may vary.

If the equipment is not working properly:

- Is the unit turned on?
- Have you made changes in usage, location, or the environment that could cause the failure?
- Has the hardware or software been modified since last use?
- Is operator error the cause of the problem?
- Are you following the steps as described in the operator's manual.
- Is the battery installed?
- If connected to the AC wall outlet, is the green external power LED glowing?

Poor Quality ECGs

Poor quality ECGs can be caused by factors in the environment, inadequate patient preparation, hardware failures related to the acquisition module, lead wires, cables, or problems in the unit.

Visual Inspection

A visual inspection of the equipment can detect disconnected cables, debris on circuit boards, missing hardware, and loose components. These could cause symptoms, and equipment failures.

NOTE

Perform the visual checks before starting any troubleshooting procedures.

Table 3-1. Visual Inspection List				
SI No:	Area	Look for:		
1	I/O connectors and cables and AC power cord	 Fraying or other damage Bent prongs or pins Cracked housing Loose screws in plugs 		
2	Interface cables	 Excessive tension or wear Loose connection Strain reliefs out of place 		
3	Circuit boards	 Moisture, dust, or debris (top and bottom) Loose or missing components Burn damage or smell of over-heated components Socketed components not firmly seated PCB not seated properly in edge connectors Solder problems: cracks, splashes on board, incomplete feed through, prior modifications or repairs 		
4	Ground wires/wiring	 Loose wires or ground strap connections Faulty wiring Wires pinched or in vulnerable position 		
5	Fasteners	Loose or missing screws or other hardware, especially fasteners used as connections to ground planes on PCBs		
6	Power source	 Faulty wiring, especially AC outlet Circuit not dedicated to system (Power source problems can cause static discharge, resetting problems, and noise.) 		
7	Keypad	 Cuts or cracks in keypad membrane Illegible labels 		
8	LCD display	Scratched or opaque display filter		
9	Battery pack	 Cracked, swollen, or leaky battery pack enclosure Debris on battery pack electrical contacts 		

	Table 3-1. Visual Inspection List				
F	SI No:	o: Area Look for:			
	10	SD card	Cracked SD cardBroken gold contacts		

Performing Diagnostic Tests

Verify that the MAC 600 Resting ECG Analysis System operates properly by running the diagnostic tests. These tests check the operation of the display screen, buzzer, keypad, thermal writer, battery, and communications. Diagnostic tests are useful for troubleshooting problems and the system checkout procedures.

Accessing the System Diagnostics Function

NOTE

Before performing the diagnostic tests, make sure the language is set to English. Refer to the *MAC 600 Operator's Manual* for more details on language settings.

To access the *System Diagnostics* menu:

- 1. Press the **Power** button.
- 2. From the Main Menu, select System Setup.

The following window opens.





NOTE

This window will not open if the *System Setup* password has not been set.

3. Enter the password **1111**.

NOTE

1111 is the factory default password. You can change this password. Use the current password to enter into the *System Setup*. Refer to *"Substitute Master Password"* on page 4-33 if you fail to get the current passoword.

4. Press Enter.

The following window opens.

System Setup	System Setup	
	ECG Basic System Country Setup Transmission Print Setup Save Setup Restore Setup MONU	

System Setup 2

5. Press the F1 and Lead keys together.

The following window opens prompting you to enter the *Service* password.

System Setup	System Setup	
	Service Password	
	Save Setup Restore Setup	

System Setup 3

- 6. Enter service password 7763.
- 7. Press Enter.

The following window opens.

System Diagnostics	Ċ,
System Information Display Tests Buzzer test Keyboard Test Writer Tests Battery Tests Communication Tests Acq. Module Tests SD Card Tests Extempeden Utagnomeree	

System Setup 4

The following sections describe how to perform the specific diagnostic tests.

Testing the System Information

The System Information Test can determine if the MAC 600 system is running the correct software version.

1. From the System Diagnostics menu, select System Information Test.

The following window opens.



Testing System Information

2. Check if the serial number and ARM software version (Application software) are correct.

NOTE

Check with manufacturing for the current ARM software (Application software) version.

3. Press esc to return to the System Diagnostics menu.

Testing the Display

1. From the *Diagnostics* menu, select *Display Tests*.

The following window opens.



Display Tests

2. From the Display tests menu, select Pixel Verification Test.

The following window opens.



Pixel Verification Test

NOTE

If the color option is disabled in the device, display will show a white bar in place of the four color bars.

- 3. Press the right **arrow** key on the keypad to move the color bars horizontally across the screen.
- 4. Verify that the color band pattern (white, green, red, blue) scrolls across the screen.
- 5. Pass the test if the pattern is replicated without discoloration.
- 6. Press **F1** to cycle through the solid color pane (white, green, red, and blue). For each pane, check for black pixels.

NOTE

- 1. Press **F1** while the display is showing blue color pane, the screen will flicker briefly. This is not a problem.
- 2. Ignore the battery icon area on top right corner of the display while doing this test.
- 3. If the color option is not enabled, you will see only a white color pane.
- 7. Pass the test if no more than four black pixels are observed on any single color pane. Note that a black pixel observed on one pane will be observed on every pane.
- 8. Press esc or *return* to return to the *Diagnostics* menu.

NOTE

The Gray Scale Test Patterns is for manufacturing use only.

Testing the Buzzer

1. From the Diagnostics menu, select Buzzer Test.

The following window opens.



- 2. From the Buzzer test menu, select Test Buzzer.
- 3. Listen for a brief tone.
- 4. Press **esc** to return to the *Diagnostics* menu.

Testing the Keypad

1. From the Diagnostics menu, select Keyboard Test.

The following window opens.



 Press each key on the keypad and verify that the response appears in the corresponding representation of that key on the screen.
 When the corresponding key is pressed, a decimal value appears on the screen. That will indicate whether or not the test has passed.

NOTE

Press Esc key in the end, as this will also exit from keyboard test.

See the following table for the decimal value matches that should be present to pass the test.

Table 3-2. : Testing the Keypad				
Кеу	Returned Decimal Value	Returned Character	Symbol on Display	
Number key 1	49	1	1	
Number key 2	50	2	2	
Number key 3	51	3	3	
Number key 4	52	4	4	
Number key 5	53	5	5	
Number key 6	54	6	6	
Number key 7	55	7	7	
Number key 8	56	8	8	
Number key 9	57	9	9	
Number key 0	48	0	0	
Key Backspace	8		del	
Function key F1	1		F1	

Table 3-2. : Testing the Keypad				
Function key F2	129		F2	
Function key F3	130		F3	
Function key F4	131		F4	
Lead key	134		Lead	
Resting ECG key	137		ECG	
Rhythm key	5		Rhy	
Stop key	139		Stop	
Trim Left key	150		٨	
Trim Up key	150		٨	
Trim Right key	150		V	
Trim Down key	150		V	
Trim Center key	149	•	In	
Escape key	27		esc	

3. Press **esc** to return to the *Diagnostics* menu.

Writer Test

1. From the Diagnostics menu, select Writer Tests.

The following window opens.

Fiter Tests		
50 mm/s Test	Pattern	I
25 mm/s Test	Pattern	
5 mm/s Test Roller Test	Pattern	
Continuously Vaim Venu	Run Out	Paper

- 2. Perform the 50mm/s Speed Test.
 - a. Select the 50mm/s Speed Test button. The writer prints the 50 mm/s speed test report.
 - b. Examine the printed report. Use the following criteria to determine if the writer passed or failed the 50mm/s speed test.
 - Count the number of subdivisions printed in a 20mm grid.
 - If the count is between 19-21, the test has passed.

NOTE

We recommend that you use a wider grid such as 50mm for more accurate readings. For a 50mm span, the expected result is a count of 45-55.

- 3. Repeat step 2 for the 25mm/s and 5mm/s speed tests. The pass-fail criteria for each of the remaining tests are the same as indicated above.
- 4. Perform the Roller Test.
 - a. Check that the test pattern printing is consistent. A white or black line across the pattern indicates a defective or missing print head dot. Replace the thermal printer assembly. See "Replacing the Thermal Printer" on page 4-6.
- 5. Perform the Continuously Run Out Paper Test.

This test continuously rolls out the paper. It also shows the number of pages ejected if the unit is set in Z-fold paper mode.

If the number of pages does not increase while in Z-fold paper mode, and if you run out of paper, there is a problem with the Thermal Printer Cue sensor or the paper is not placed correctly. Check the paper placement, if the problem persists replace thermal printer assembly. See "Replacing the Thermal Printer" on page 4-6.

6. Select Main menu and press Enter to return to System Diagnostics.

Battery Tests

 From the *Diagnostics* menu, select *Battery Tests*. The following window opens.



2. Select Battery Status.

The following window opens.

Battery status	É
Battery Voltage - 7.8 VDC	
Charging Battery	
Press the <trim enter="" pad=""> key to exit</trim>	

3. Check the battery voltage from this menu along with charging status.

Battery voltage can range from 6.0 - 8.5V.

If connected to mains, the system displays Charging battery.

If operating from battery, the system displays *Operating on battery power*.

If the battery is fully charged, the system displays AC power ON but not charging.

4. Press **esc** to return to the *Diagnostics* menu.

Communication Tests

1. From the *Diagnostics* menu, select *Communication Tests*. The following window opens.


2. To run the test, connect pin 3 to pin 5 using a jumper and then press any key to start. (For the connector pin outs, refer to the following figure). The test will return a pass/fail for several baud rates.



Table 3-3. Connector Pin Outs		
PIN	NAME	
1	RTS	
2	CTS	
3	TxD	
4	Ground	
5	RxD	
6	DTR	
7	+12V	
8	DSR	

3. If the test passes for all baud rates, the following screen appears with the pass status for all baud rates.

					Ç	P	ort	Loc	opback	(Te	est			
	Con	ine	ct	TX	(Pi	n 3)	to	RX	(Pin	5)	of	SERIA	LINE	
Testing	COM	1	at	120	IO B	aud			Passe	20	375	/375		
Testing	COM	1	at	240	IC B	aud			Passe	ed .	375	5/375		
Testing	COM	1	at	480	0 8	aud			Passe	ed .	375	5/375		
Testing	COM	1	at	960	IO B	aud			Passe	ed	375	3/375		
Testing	COM	1	at	192	00	Bauc	1		Passe	ed	375	/375		
Testing	COM	1	at	384	00	Bauc	1		Passe	ed	375	/375		
Testing	COM	1	at	576	00	Bauc	1		Passe	d	375	/375		
Testing	COM	1	at	115	200	Bau	bL		Passe	ed	375	/375		
		-	est	Co	npl	eted		Pre	ss an	y k	ey	to exil		

4. Press **esc** to return to the *Diagnostics* menu.

Acq. Module Tests

This test is not recommended for service.

SD Card Tests

1. From the *Diagnostics* menu, select *SD Card Tests*.

The following window opens.



2. The SD Card Tests performs a read/write test on the SD card currently installed. The test will respond with a PASS or FAIL.

NOTE

If the card is not formatted correctly, an error message will appear at the bottom of the screen. To format an SD card, follow the error message and Press the F1 key to continue formatting.

- 3. To fix a defect, replace the CPU board. See "Replacing the Main PCB Assembly" on page 4-17.
- 4. Press **esc** to return to the *Diagnostics* menu.

PWA Connector Details

The legends for the PWA Connectors (J1, J2 etc) for the new PWA FRU 2066447-002 are different as compared with the old PWA FRU 2047330-001. Refer the following table for the old and new connector legends:

Connector Description	OLD PWA FRU PN: 2047330-001	NEW PWA FRU PN:2066447-002
Key sheet	J4	J7
Display	J5	J6
Printer	J10	J5
SD Card	J1	J3
Power In	W1	W1
RS232	J2	J2
JATAG	J3	J8
USB	J9	J1
Modem	J12	J9

Connector Description	OLD PWA FRU PN: 2047330-001	NEW PWA FRU PN:2066447-002	
Patient Cable	J7	J11	
Battery	J11	J10	

Equipment Problems

Paper Error Message







Printer Door Open Message



Printing Only Baselines



Battery Error Message





Unit Not Turning ON in Battery Mode





External Power LED Lights Up But Unit Not Switching ON











4 Maintenance

For your notes

Preparing System for FRU Replacement

Prior to performing any disassembly procedure, perform these steps.

CAUTION

Take strict precautions against electrostatic discharge damage while replacing field replaceable units.

Only approved personnel may conduct repairs.

- 1. Power off the system.
- 2. Disconnect the unit from the AC wall outlet.
- 3. Disconnect the power cord from the ACDC adaptor.
- 4. Disconnect the patient cable from the unit.
- 5. Remove the battery as described in "PWA Connector Details" on page 4-4.
- 6. When replacing FRUs, implement ESD protection if applicable.
- 7. Defective or empty LI-Ion batteries should be disposed of in accordance with the applicable legal stipulations or returned to the factory.

WARNING

OPERATOR SAFETY — Repairing the device when powered on may cause injury. Necessary Personal Protective Equipment are recommended while performing maintenance.

WARNING

To ensure patient safety, use only parts and accessories manufactured or recommended by GE Healthcare.

Required Tools and Manuals

Table 4-1. Required tools and manuals				
SI no:	Description			
1	Phillips screwdriver			
2	Anti-static wrist strap			
3	Service manual as needed for reference			
4	Safety tester for measurements according to 60601-1			
5	Connecting wires and clips required for electrical safety tests (optionl)			
6	Multi-meter			
7	Multi Lead ECG simulator			
8	MAC 600 Operator's Manual for reference			
9	Nose Plier			
10	Recommended SD card			

PWA Connector Details

The legends for the PWA Connectors (J1, J2 etc) for the new PWA FRU 2066447-002 are different as compared with the old PWA FRU 2047330-001. Refer the following table for the old and new connector legends:

Table 4-2. PWA Connectors					
Connector Description	OLD PWA FRU PN: 2047330-001	NEW PWA FRU PN:2066447-002			
Key sheet	J4	J7			
Display	J5	J6			
Printer	J10	J5			
SD Card	J1	J3			
Power In	W1	W1			
RS232	J2	J2			
JATAG	J3	J8			
USB	J9	J1			
Modem	J12	Jð			

Table 4-2. PWA Connectors					
Connector Description	OLD PWA FRU PN: 2047330-001	NEW PWA FRU PN:2066447-002			
Patient Cable	J7	J11			
Battery	J11	J10			

Replacing the Battery



- 1. Lift the snap region in the battery cover and slide it out of the bottom cover.
- 2. Remove the battery from its compartment.
- 3. Place the new battery into the battery compartment with the battery label facing downwards, and the battery terminals facing the battery contacts on the PCB. Reverse voltage protection is implemented mechanically.

Replacing the Thermal Printer



Class II version- Earth cable routing:



Class I - Earth cable routing:



Table 4-3. Replacing the Thermal Printer			
Legend Description			
1	Earthing Cable		
2	Fasteners		

- 1. Open the device and printer door as described in "Opening the Device" on page 4-8.
- 2. Open connector J10 for the old PWA and J5 for the new PWA (refer "PWA Connector Details" on page 4-10) to disconnect the flat ribbon printer cable.
- 3. Remove the roller from the printer door.
- 4. Remove the Earthing Cable connecting the printer base with the PCB.
- 5. Remove the two fasteners fastening the base of the printer to the printer bracket.
- 6. Align the mounting holes of the new printer with those on the printer bracket.
- 7. Use the screws to fasten the printer onto the printer enclosure.
- 8. Connect the flat ribbon cable to the printer connector on the PCB.
- 9. Align the roller on the printer door and press it into position.

NOTE

Ensure that the roller gear aligns with the gears of the thermal printer.

Opening the Device





Table 4-4. Opening the Device				
Legend	Description			
1	Detach key sheet FPC from main board			
2	Detach display FPC from main board			

- 1. Remove all cables from the unit, if connected.
- 2. Remove the battery as described in "PWA Connector Details" on page 4-4.
- 3. Turn the device upside down and remove the four fastening screws on the bottom.
- 4. With the keypad facing up, open the printer door along with the roller.
- 5. Raise the top cover of the housing and disconnect the keypad cable from the J4 connector and Display cable from the J5 connector for the old PWA and J6 for the new PWA connector. Refer the following figure for PWA connector details.

PWA Connectors for FRU PN 2047330-001 (old PWA).





PWA Connectors for FRU PN 2066447-002 (new PWA).

PWA Connector Details

Table 4-5. PWA Connectors					
Connector Description	OLD PWA FRU PN: 2047330-001	NEW PWA FRU PN:2066447-002			
Key sheet	J4	J7			
Display	J5	J6			
Printer	J10	J5			
SD Card	J1	J3			
Power In	W1	W1			
RS232	J2	J2			
JATAG	J3	J8			
USB	J9	J1			
Modem	J12	J9			
Patient Cable	J7	J11			
Battery	J11	J10			

Reworking the Power Supply (Class II to Class I)

The MAC600 Class II Power Supply (PS) FRU P/N 2047328-001 is obsolete. The new power supply is qualified as Class I and the P/N is 2047328-002. In order to use the Class I power supply in the MAC600, the safety classification of MAC600 device needs to change from Class II to Class I .



Table 4-6. Power Supply Labels				
Legend	Description			
1	Class II Power Supply label			
2	Class I Power Supply label			

Depending on the Serial number of the device different levels of rework are required. See the following table for further details.

NOTE

All MAC 600 shipments to China are Class I. Therefore, further rework is not required. For China, see "2066456-001 FRU - Power Supply Medical Class I (For China Only)" on page 5-9.

If Serial Number is:	Then Perform:
less than or equal to SF713346059PA	 "Earth Cable Routing" on page 4-12 "Changing the Product Label" on page 4-13 Change the Power Supply FRU (P/N 2047328-002).
between SF713346060PA and SF713496708PA	 "Changing the Product Label" on page 4-13 Change the Power Supply FRU (P/N 2047328-002).
equal to or greater than SF713500001PA	1. Change the Power Supply FRU (P/N 2047328-002).

Earth Cable Routing

Verify the earth cable routing is as shown in the following figure. It should connect screw A and screw B. This is the Class II Earth (ground) cable routing. To change the cable routing to comply with Class I requirements, perform the following procedure.



Table 4-7. Routing the Earth Cable			
Legend	Description		
1	Assembly of the earthing cable with main PCB assembly		
2	Earthing cable assembly location		
A and B	Class II Earth cable routing		
C and D	Class I Earth cable routing		

- 1. Open the device and printer door as described in "Opening the Device" on page 4-8.
- 2. Remove the screws from location A and B.
- 3. Remove the earth cable (2033817-001).
- 4. Using the cable and screws from steps 2 and 3, place the cable on location C and D. The other end D can be connected to either of the screw points on the printer base. Ensure the cable does not touch any components on the PCB board and secure it in place with the screws.

5. Verify the new Earth Cable routing is as shown in the following photo.



- 6. Close the device and do the functional and safety testing for the power supply and Main PCB after the replacement of the FRU. See "Functional Checkout" on page 4-22.
- 7. Open the printer door and Connect the power cord to the ACDC adaptor and adaptor output to the unit. Check for the resistance between power cord ground and printer metal portion. If the value of resistance is greater than 1 Ohm, then it results in failure. Verify the connections if failure happens.
- 8. Proceed to "Changing the Product Label".

Changing the Product Label

The product label is located on the back panel, as shown in the following photo.



Table 4-8. Product Labels			
Legend	Description		
A	Product label		
В	Serial number label		

1. The existing product label shows the product is class II (the double square box on the following label indicates that the device is Class II). Remove this label from the device.



2. The new Class I product label is as follows. Place the new label on the back panel (the label is part of the 2047328-002 FRU).



Replacing the Display

NEC Display (FRU Part# 2047331-001)

KOE Display (FRU Part# 2100910-001)





NOTE Sequence of snap detachment (1,2,3,4,5) is same for both displays.

Table 4-9. Replacing the Display				
Legend	Description			
1, 2, 3, 4, 5	Sequence of snap detachment.			
	Dotted line direction of snap pull.			
\rightarrow	Continuous line direction of display holder pull.			

- 1. Open the device as described in "Opening the Device" on page 4-8.
- 2. Raise the top cover of the housing and disconnect the keypad cable from the J4 connector for the old PWA, or J7 connector for the new PWA and display cable from the J5 connector for the old PWA or J6 connector for the new PWA. Disconnect the display cable connector from the J2 connector on the Daughter PCB (refer "PWA Connector Details" on page 4-10).
- 3. Remove the daughter board from the display holder as described in "Replacing the Daughter PCB assembly" on page 4-19.
- 4. Start with snap number 1, pull the snap out and push the display holder in the direction of the arrow. Follow the same procedure for snaps number 2, 3 and 4.
- 5. Once snaps number 1, 2, 3 and 4 are detached, lift the left side of the display holder and remove the LCD Module from the cover top pocket.
- 6. Pull out the display holder to the left to detach it from snaps number 5 and 6.
- 7. Make sure the O-ring is in place or replace it with the new one.
- 8. Replace the new LCD module in the pocket of cover top, with the cable on the bottom side.
- 9. Place the display holder on the cover top with all the snaps aligned.
- 10. Press the display holder at each snap region, to assemble the display holder to the cover top.
- 11. Snap the daughter board to the display holder.
- 12. Re-connect the display cable to J5 for the old PWA or J6 for the new PWA and the keypad cable to J4 for the old PWA or J7 for the new PWA.
- 13. Re-attach the upper section of the device to the lower section with the four screws.

Replacing the Main PCB Assembly



NOTE

If possible, save the current settings before replacing the PCB assembly. For information about saving system setup, see "Saving Setup" on page 4-30.

Adding Ferrite to the Power Supply

If you are replacing an old PWA with a new PWA, follow these steps to add ferrite to the power supply.

- 1. Switch off the mains supply to the unit.
- 2. Disconnect the ACDC adapter from the mains power cord.
- 3. Disconnect the ACDC adapter cable from the MAC600.
- 4. Unlock the ferrite (74271131) present in the FRU kit using the key (2055233-001) shown in the following figure.



5. Put a turn inside the f errite core near the tip of the ACDC adapter cable that connects the unit, as shown.



- 6. Press the ferrite to close the lock.
- 7. Reconnect the cables.
- 8. Perform functional tests associated with the adapter change.

Replacing the main PCB

NOTE

Before replacing the main PWA we recommend that you update the SW (refer to "Programming MAC 600 Device Without User Interface" on page 4-33) and check if the problem can be resolved.

- 1. Open the device as described in "Opening the Device" on page 4-8.
- 2. Disconnect the display cable from J5, for the old PWA or J6 for the new PWA, the keypad cable from J4 for the old PWA or J7 for the new PWA, and the printer cable from J10 for the old PWA or J5 for the new PWA. (refer "PWA Connector Details" on page 4-10).
- 3. Remove the four screws fastening the PCB assembly to the bottom cover.
- 4. Return the PCB assembly to the factory in the ESD packaging.
- 5. Attach the new main PCB assembly by aligning the mounting holes with those in the bottom cover, and fastening the new PCB assembly to the bottom cover with the screws.
- 6. Connect the display cable to J5 for the old PWA or J6 for thenew PWA, the keypad cable to J4 for the old PWA or J7 for the new PWA, and the printer cable to J10 for the old PWA or J5 for the new PWA (refer "PWA Connector Details" on page 4-10).
- 7. Attach the upper section of the device to the lower section with the four screws.
- 8. Replace the battery in the battery compartment, slide on the cover.

- 9. Enter the serial number and option code (optional) as described in "Restoring Setup" on page 4-30.
- 10. Adjust the time and date. See *MAC 600 operator's Manual* for setting date and time.
- 11. If possible, set the configuration to the previous user settings. If not, select the default settings.

Replacing the Daughter PCB assembly





Old Daughter PCB (Part#2047334-001) New Daughter PCB (Part# 2100913-001)

Table 4-10. Replacing the Daughter PCB Assembly		
Legend	Description	
→←	Press the snap using a nose plier. Lift the PCB board up.	

- 1. Open the device as described in "Opening the Device" on page 4-8.
- 2. Remove the top cover assembly from the bottom cover.
- 3. Disconnect the display cable connector from the J2 connector on the daughter PCB.
- 4. Press the snap for daughter board using the nose pliers and lift the daughter board to detach from the snap.
- 5. Repeat step 4 for all the 3 snap features to completely remove the daughter board from the display holder snap fit mechanism.
- 6. Align and fix the new daughter board to the daughter boardmounting bracket snap fit mechanism.
- 7. Fix the ferrite with double-sided tape in line with J1.
- 8. Connect the display cable connector to the J2 connector on the daughter PCB.

- 9. Connect the display cable to J5 for the old PWA and J6 for thenew PWA and the keypad cable to J4 for the old PWA and J7 for the new PWA (refer "PWA Connector Details" on page 4-10).
- 10. Attach the upper section of the device to the lower section with the four screws.

Preventive Maintenance

The MAC 600 system does not require any periodic calibration.

GE Healthcare does not recommend any preventive maintenance for this system. However, the user may perform the following preventive maintenance steps.

- Recommended Maintenance
- Diagnostic Tests
- Electrical Safety Tests

If further technical assistance is required, contact the nearest GE Healthcare Service Center.

Recommended Maintenance

This section contains the following recommended maintenance:

- Visual inspection
 - Check the device and accessories for mechanical defects, which can impair their functioning.
 - Ensure that the labels and inscriptions on the device relating to safety are clearly legible.
 - See "Visual Inspection List" on page 3-4 for other parts inspection.
- Exterior cleaning
 - Clean the exterior surfaces once per month, and more frequently if needed.
 - Use a clean, soft cloth and water with a mild detergent. Wring excess water from the cloth and wipe down the exterior surfaces of the device.
 - Dry the surfaces with a clean cloth or paper towel.
- Interior cleaning
 - Check for dust on the interior components and clean as needed.
 - Clean the thermal print head periodically to ensure good print quality and longer printer life. To clean the thermal print head:

- 1. Use a disposable wrist strap to avoid static electricity.
- 2. Open the printer door.
- 3. Wipe the glazed surface of the thermal print head gently with wringed swabs dipped in ethyl alcohol.
- 4. When the surfaces are dry, close the printer door.

NOTE

Do not hit the thermal print head with anything hard.

Do not use sand paper on the thermal print head.

Do not add any unnecessary force on the thermal print head.

Battery maintenance

Refer to the *Battery Maintenance* section of the "MAC 600 operator's manual".

Calibration check

Refer to the *Calibration Check* section of the "MAC 600 operator's manual".

WARNING

PROPER MAINTENANCE REQUIRED — Failure to implement the recommended maintenance schedule may cause equipment failure and possible health hazards. All responsible individuals employing the use of this device assume the responsibility for performing the recommended maintenance unless an Equipment Maintenance Agreement exists.

Functional Checkout

The functional checkout procedures apply to all MAC 600 systems.

NOTE

The FRU checkout procedure for any listed FRU also applies to its internal PCBs and components.

FRU replacement procedures are contained within this chapter of the manual.

Table 4-11. FRU Replacement							
FRU Description	Tools. Refer Table 4-1, "Required tools and manuals," on page 4-4	Visual Inspection. Refer Table 3-1, "Visual Inspection List," on page 3-4	Checkout Procedure				
Battery assembly	3, 8	9	1, 4, 5, 11				
Main PCB assembly	1-5, 8, 10	1-5	1-3, 5-15				
Top cover assembly (top cover, key sheet, back panel, key sheet ferrite)	1-3, 8-10	1-8	1, 6, 9, 10				
LCD assembly ((LCD, O-ring, LCD holder, Daughter board, Display cable, display cable ferrite)	1-3, 8-10	3-8	1, 6, 9, 10				
Printer module assembly or Printer base	1-4, 8-10	4, 5	1, 10, 14, 15				
Printer door assembly	3, 8, 9	5	1, 10				
Bottom cover assembly	1-5, 8-101-3,	3-6 and 9	5-15				
Axle for paper roll assembly	3	N/A	N/A				
Power supply	3, 4, 8	1, 6	1, 11, 14, 15				
Battery cover	3	9	1				
Serial cable (2047566-001)	3	1					

Table 4-12. Other Service Events						
Service Event	Tools	Visual Inspection	Checkout Procedure			
No parts replaced	3, 8	1-10	N/A			
Software update - Enable option	3, 8	N/A	1-13			
Post Installation Checkout	3, 8	N/A	1-5, 10, 11			
Annual Electrical Safety tests	3, 4, 8	1-10	1-15			
Check out Procedure

Operational Checks

Perform the functional checkout procedures that are applicable to the replacement procedure that was performed.

- 1. Verify the power-up self-test passed. See "Power-up Self-Test" on page 3-3.
- 2. Verify the serial number restored successfully. See "Serial Number Entry" on page 4-30.
- 3. For units with the option enabled, verify the option enabled again successfully (Enabled options will have in front of the options in option activation window). See *MAC 600 Operators Manual* for "option entry" details.
- 4. Verify that the new battery was charged successfully by checking the battery full indicator after it has been charged for 2-3 hours charging. See *MAC 600 Operator's Manual*.
- 5. Verify the time and date were set successfully. See "Setting the date and time" in the MAC 600 Operator's Manual.

Diagnostic Tests

- 1. Verify the System /Firmware Version was successful. See "Testing the System Information" on page 3-6 for more information.
- 2. Verify the Display Test was successful. See "Testing the Display" on page 3-7 for more information.
- 3. Verify the Buzzer Test was successful. See "Testing the Buzzer" on page 3-8 for more information.
- 4. Verify the Keypad Test was successful. See "Testing the Keypad" on page 3-9 for more information.
- 5. Verify the Writer Tests was successful. See "Writer Test" on page 3-11 for more information.
- 6. Verify the Battery Tests was successful. See "Battery Tests" on page 3-12 for more information.
- 7. Verify the Communication Tests was successful. See "Communication Tests" on page 3-12 for more information.
- 8. Verify the SD card test was successful. See "SD Card Tests" on page 3-14 for more information.

Electrical Safety Checks

- 1. Leakage current tests.
- 2. Ground continuity test.

Electrical Safety Tests

The suggested safety analysis tests comply to the international standard IEC 60601-1. The tests should be performed with safety testing instruments with measuring circuits calibrated according to IEC 60601-1. To ensure personal safety, refer to the "testing instrument's user documentation".

Perform the tests under normal ambient conditions of temperature, humidity and pressure, with line voltage.

The leakage currents correspond to 110% of rated voltage for the tested unit. If this is not taken into account when performing leakage tests, the measured values must be calculated.

Recommended Test Equipment

■ Safety tester for measurements according to 60601-1.

Recommended Test Schedule

- After initial setup.
- Once every 12 months, thereafter, as part of a regular maintenance plan.
- Whenever power sources are affected by servicing.

Ground Resistance Test

Connect the power cord to the ACDC adaptor and adaptor out put to the unit. Check for the resistance between power cord ground and printer metal base. If the value of resistance is greater than 1 Ohm, then it results in failure.

NOTE

The MAC600 is categorized as a Class I device.

NOTE

All shipments of MAC 600 devices to China are Class I. However, for all other countries, the MAC 600 installed base is Class II if the serial number is less than SF713500001PA.

Leakage Current Tests

The following electrical diagram shows the Measuring Circuit [M] required for leakage current. The reading in mV corresponds to mA (leakage current). The safety tester instruments generally work with this

Measuring Circuit $\left[M\right]$ and the displayed values are converted to leakage current.



Earth Leakage (AC line) Current Test



This test measures leakage current of the device. The device has to be turned on and off, and connected to your safety-testing equipment.

Measurements should be taken under the following conditions (refer to "Electrical Safety Tests" on page 4-24):

- Device in ON state
- Polarity switch NORM and RVS
- S1 (neutral) closed and open
- GND switch open

The test has failed if the measured values are greater than:

N.C.	S.F.C
Polarity: NORM & RVS S1 (neutral): closed GND: open	Polarity: NORM & RVS S1 (neutral): open GND: open
Total tests/combinations: 2	Total tests/combinations: 2

N.C.	S.F.C
500 uA (IEC)	
150 uA (UL)	1,000 uA (IEC & UL)

Patient Leakage Current Tests

These tests measure leakage current of the device's floating inputs (patient connections ground).

Patient Leakage Current to Ground



This test measures leakage current from the floating input (patient connection) to ground during normal condition (N.C.) and single fault condition (S.F.C). In all cases, the leakage current is measured from the floating input to ground: The device has to be turned on and off, and connected to your safety testing instrument.

During N.C., measurements should be taken under the following conditions (refer to "Electrical Safety Tests" on page 4-24):

- Device in ON state
- Polarity switch NORM and RVS
- GND switch GND closed
- S1 (neutral) closed

During S.F.C., measurements should be taken under the following conditions (refer to "Electrical Safety Tests" on page 4-24):

- Device in ON state
- Polarity switch NORM and RVS
- GND switch closed, S1 (neutral) open
- GND switch open, S1 (neutral) closed

The test has failed if the measured values are greater than:

N.C.	S.F.C
Polarity: NORM & RVS S1 S1 (neutral): closed GND: closed	Polarity: NORM & RVS S1 (neutral): closed I open GND: open I
Total tests/combinations: 2	Total tests/combinations: 4
10 uA (IEC & UL)	50 uA (EC & UL)

Patient Leakage Current, Mains on Applied Part



WARNING

PERSONAL SAFETY — MAINS VOLTAGE is applied to floating input (patient connection) and patient cables/test plug conductors and safety tester PATIN JACK. For the protection of the person performing these tests, the following values of resistor R may be used:

◆ Type CF — 100 kOhm (220 to 240 V)

Disconnect safety tester from line voltage before connecting patient cable/test plug to device.

• After line voltage has been disconnected, connect the patient cable/test plug to device.

This test performs leakage current tests during single fault conditions (S.F.C.) with line voltage applied to the floating (patient connection) inputs.

In all cases, the leakage current is measured from the floating (patient) inputs jack of the device to ground. To setup the leakage current test:

- 1. Disconnect the safety tester from the line voltage.
- 2. Ground all signal input/output connections (all SIPs/SOPs connected to ground).
- 3. Connect the patient cable/test plug to device.
- 4. Connect the patient cable/test plug to the safety tester.
- 5. Ensure that the person/tester in not touching the patient cable/test plug or floating (patient) input or device conductive surfaces.
- 6. Connect the safety tester to the line voltage.

WARNING

PERSONAL SAFETY — MAINS VOLTAGE is applied to floating input (patient connection) and patient cables/test plug conductors and safety tester PATIN JACK. For the protection of the person performing these tests, the following values of resistor R may be used:

◆ Type CF — 100 kOhm (220 to 240 V)

Disconnect safety tester from line voltage before connecting patient cable/test plug to device.

• After line voltage has been disconnected, connect the patient cable/test plug to device.

During S.F.C., measurements should be taken under the following conditions (refer to "Electrical Safety Tests" on page 4-24):

- Device in ON state
- Polarity switch NORM and RVS
- S1 (neutral) open
- GND switch closed

The test has failed if the measured values are greater than:

N.C.	S.F.C
N/A	Polarity: NORM & RVS S1 (neutral): open open GND: closed
Total tests/combinations: 0	Total tests/combinations: 2
N/A	50 uA (EC & UL)

After completing this test, disconnect the safety tester from line voltage before disconnecting the patient cable/test plug and/or the device.

Verify the current leakage test results meet the requirements. Perform electrical safety checks when indicated. All indicated electrical safety checks require a pass/ fail indication for the steps performed. Record the measurement values in your debrief.

- 1. Verify the equipment does not propose any health hazard. See "Earth Leakage (AC line) Current Test" on page 4-25 and "Patient Leakage Current Tests" on page 4-26, for more information.
- 2. Verify all exposed metal is properly grounded. See "Ground Resistance Test" on page 4-24 for more information.

Table 5. Electrical Safety Checks						
Step		Condition	UUT - ON	Result	Leakage Current Limits	
Earth Le	Earth Leakage Current					
1	Forward Polarity	NC	uA	Pass/Fail	150 uA	
2	Neutral Open, Forward Polarity	SFC	uA	Pass/Fail	1000 uA	
3	Neutral Open, Reverse Polarity	SFC	uA	Pass/Fail	1000 uA	
4	Reverse Polarity	NC	uA	Pass/Fail	150 uA	

Patient Leakage Current To Ground					
1	Forward Polarity	NC	uA	Pass/Fail	10 uA
2	Neutral Open, Forward Polarity	SFC	uA	Pass/Fail	50 uA
3	Ground Open, Forward Polarity	SFC	uA	Pass/Fail	50 uA
4	Ground Open, Reverse Polarity	SFC	uA	Pass/Fail	50 uA
5	Neutral Open, Reverse Polarity	SFC	uA	Pass/Fail	50 uA
6	Reverse Polarity	NC	uA	Pass/Fail	10 uA
Ground Resistance					
1	AC mains power cord ground prong to exposed metal surface (ground lug)	N/A	Q	Pass/Fail	Less than 1 Ohm

NC = Normal Condition; SFC = Single Fault Condition; N/A = Not Applicable

UUT = Unit Under Test

Saving Setup

For saving System set up to an SD card, the SD card option need not be enabled.

- 1. Select Setup.
- 2. Enter the setup password 1111.
- 3. Press Enter.
- 4. Select Save Setup using the arrow and press the Enter key.
- 5. Insert the blank SD card without write protection enabled.
- 6. Select *To SD Card* using the arrow and press the **Enter** key.
- 7. Remove the SD card and press the **esc** key to return to the *System Setup Menu*.

Print Setup

- 1. Select Setup.
- 2. Enter set up password 1111.
- 3. Press Enter.
- 4. Select *Print Setup* using the arrow and press the **Enter** key.

Restoring Setup

From the SD Card:

- 1. Insert the SD card where Setup is stored.
- 2. Select Setup.
- 3. Enter set up password 1111.
- 4. Press Enter.
- 5. Select *Restore Setup* using the arrow and press the **Enter** key.
- 6. Select From SD Card using the arrow and press the Enter key.
- 7. The system will restore set up and return to the System Setup Menu.

Manually restoring the settings :

Refer to the "MAC 600 Operator's Manual" for instructions on manually restoring the settings.

Serial Number Entry

- 1. Select Setup.
- 2. Enter set up password 1111.
- 3. Press Enter.
- 4. Press the Lead and F2 keys together.

- 5. Enter the service password 7763
- 6. Press Enter.
- 7. If the serial number already exists, the system displays the stored serial number on the screen. Press the **Enter** key again if you wish to change the serial number or press the **esc** key to exit the serial number entry screen.
- 8. Enter the serial number using keys 1-10 and by selecting the required character from the corresponding drop-down menu using the **arrow** keys and the **Enter** key. (Use the **back space** key to erase a wrong entry)
- 9. Go to *Return* and press Enter to exit the service menu.

ΝΟΤΕ

To verify if the serial number entry is correct or not, go to system information ("Testing the System Information" on page 3-6) and verify that the serial number displayed matches the one on the serial number label.

Application Software Update

- 1. Connect the external power supply and then switch ON the unit.
- 2. Insert the SD card formatted in FAT 16 file system with the released MAC 600 software.
- 3. Select *Setup* using the function key.
- 4. Enter the set up password 1111.
- 5. Press the **Enter** key.
- 6. Press the Lead and F3 keys together.

A screen will open with the current SW and new SW version.

- 7. Press the Enter key to begin programming.
- 8. The system displays the following messages and then switches OFF.

Copying code to Main memory

Programming Flash

Programming over

System Shutting Down

9. If any error messages are displayed, please correct them accordingly as per the message displayed and press the Enter key to restart programming. To exit programming during error conditions, press the **esc** key.

NOTE

If Boot SW is also updated from the one in the device, the system will display *Update Boot SW* on the screen. Press the Enter key to program Boot.

Do not remove the SD card until programming is complete. After programming is complete, remove the SD card and restart the device for normal operation.

10. To verify the correctness of programming, go to "Testing the System Information" on page 3-6 and check if the displayed ARM Software Version is the latest or not.

BOOT Software Update

- 1. Select Setup.
- 2. Enter set up password 1111.
- 3. Press Enter.
- 4. Press the Lead and F2 keys together.
- 5. Enter the service password 7763.
- 6. Press Enter.
- 7. Select Update Primary Boot using the down arrow key.
- 8. Select *Yes* using the **Enter** and **arrow** keys.

A new window opens, askeing you to confirm whether to continue or not.

- 9. Select Yes using the arrow and Enter keys.
- 10. Select *Return* using the **arrow** key and press **Enter**.
- 11. The system displays the following messages:

Programming Primary boot

Primary boot programming Over

12. Press the esc key to exit service only Setup.

NOTE

Boot SW update is applicable only if the Boot version has changed from the previous version in the device and is not already programmed during ARM software update.

System Log

- 1. Select Setup.
- 2. Enter the set up password 1111.
- 3. Press Enter.
- 4. Press the Lead and F4 keys together.
- 5. Enter service password 7763.
- 6. Insert the blank SD card without write protection enabled.
- 7. Press the **Enter** key to store the Sys log or the **esc** key to exit the screen.

NOTE

The SD card needs to be formatted in FAT 16 file system before use (manufacturer validated SD card is 2GB Transcend and SanDisk). If

the SD card is not formatted, the system will display *Format SD* Card. You may format it by pressing the Enter key and storing the system log or press the esc key to exit without formatting the SD card.

Programming MAC 600 Device Without User Interface

- 1. Copy the released manufacturing software to an empty SD card that has been formatted in a FAT 16 file system.
- 2. In the root folder on the SD card, create a file named Update.com.
- 3. Insert the SD card into the device.
- 4. Connect and switch on the external power supply.
- 5. Switch on the device. The battery LED located on the keypad will start blinking in 15 seconds.
- 6. Wait for 160 seconds. The unit will switch OFF automatically.
- 7. Remove the SD card.

The device is programmed and ready to use.

NOTE

If the battery LED does not blink within 15 seconds, then Program Failure is indicated.

Substitute Master Password

If you do not have access to the system's password, you can create a master password as follows.

- 1. At the prompt for the system password, enter **622600**. A random 6-digit number displays on the screen. For example, **876743**.
- 2. Write the number down and create a new 6-digit number by adding alternating digits from the random number as follows.
 - first and third digits,
 - second and fourth digits,
 - third and fifth digits,
 - fourth and sixth digits,
 - fifth and first digits, and
 - sixth and second digits.

Disregard the 10s column when adding the digits. The new number from the example above would be 440020.

3. Enter the new number, then press the **Enter** key.

The *System Setup* menu displays. This process only works once, so you should reprogram the password permanently.

- 4. Go to the Basic System menu.
- 5. Select Miscellaneous Setup.

- 6. Select the *System password* line and type the new password in the space.
- 7. Press the **Enter** key.
- 8. Select *Save Setup* from the *System Setup* menu.
- 9. Select To system.

5 Parts and Replacements

For your notes

Ordering Parts

General Information

This chapter identifies the FRU parts and FRU kits with part numbers and images. You can order parts for the assemblies, stand-alone FRUs, and FRU kits that are considered field-serviceable. Only items, assemblies, and kits, which have part numbers, provided in this chapter are available as FRUs. To order parts, contact GE Healthcare Service or a GE Healthcare approved vendor.

Accessory Kits

Table 5-1. Accessory kits		
Part Number	Description	
2035819-001	IEC starter kit (includes one Value ECG cable with lead wires, four clamp electrodes, six bulb electrodes, one pack of z-fold paper & gel).	
2035819-002	AHA starter kit (includes one Value ECG cable with lead wires, four clamp electrodes, six bulb electrodes, one pack of z-fold paper & gel).	
2040511-001	DISP Value Starter Kit – IEC (includes one Value ECG cable with lead wires, 2 packs of Disposable Electrodes, One set of Clamps, one pack of z-fold paper & gel).	
2040514-001	DISP Value Starter Kit – AHA (includes one Value ECG cable with lead wires, 2 packs of Disposable Electrodes, one set of Clamps, one pack of z-fold paper & gel).	
2040511-002	DISP Starter Kit - IEC (includes one Multilink ECG cable with lead wires, 2 packs of Disposable Electrodes, one set of Clamps, one pack of z-fold paper & gel).	
2040514-002	DISP Starter Kit - AHA (includes one Multilink ECG cable with lead wires, 2 packs of Disposable Electrodes, one set of Clamps, one pack of z-fold paper & gel).	

Patient Cables

Table 5-2. Patient Cables		
Part Number	Description	
2029890-001	Patient cable, 10 leads, IEC	
2029893-001	Patient cable, 10 leads, AHA	
22341808	CABLE TRUNK 10-LEAD MAC500/1200 ML IEC	
38401816	SET LEADW ML 4MM 10-LEAD 0.7M/1.3M IEC	
22341809	CABLE TRUNK 10-LEAD MAC500/1200 ML AHA	
38401817	SET LEADW ML 4MM 10-LEAD 0.7M/1.3M AHA	

Electrodes

Table 5-3. Electrodes		
Part Number	Description	
2029891-001	Clamp electrode for limb leads, IEC, set of 4, with labels	
2029894-001	Clamp electrode for limb leads, AHA, set of 4, with labels	
2029892-001	Bulb electrode for chest leads, set of 6, with labels	
9490-210	CLIP UNIVERSAL GE 10/PKG	
9623-003P	SILVER MACTRODE PLUS 1000 / CASE	
402207-210	BABYMAC ELECTRODE 10L 50CD/CS	

Consumable

Table 5-4. Consumable		
Part Number	Description	
217 083 18	Electrode cream, 250-ml refill bottle	

Writer Paper

Table 5-5. Writer Paper		
Part Number	Description	
2030887-001	Standard thermal recording paper, 80 mm x 90 mm (width), 10 Z fold pads/ case	
2030888-001	Standard thermal recording paper, 80 mm x 15.7 m, 10 rolls/case	

Service Manual

Table 5-6. Service Manual		
Part Number	Description	Language
2047426-002	MNL SVCE MAC 600 ENGLISH (Printed version)	English
2047426-060	Electronic PDF version of the MAC 600 service manual and the 12SL Physician's Guide	English

Operator's Guides

Table 5-7. Operator's Guide		
Part Number	Description	Language
2047426-001	MNL OPR MAC 600 English	English (ENG)
2047426-004	MNL OPR MAC 600 BUL	Bulgarian (BUL)
2047426-005	MNL OPR MAC 600 CHS	Chinese (CHS)
2047426-006	MNL OPR MAC 600 CRO	Croatian (CRO)
2047426-007	MNL OPR MAC 600 CZE	Czech (CZE)
2047426-008	MNL OPR MAC 600 DAN	Danish (DAN)

Table 5-7. Operator's Guide		
2047426-009	MNL OPR MAC 600 DUT	Dutch (DUT)
2047426-010	MNL OPR MAC 600 EST	Estonian (EST)
2047426-011	MNL OPR MAC 600 FIN	Finnish (FIN)
2047426-012	MNL OPR MAC 600 FRE	French (FRE)
2047426-013	MNL OPR MAC 600 GER	German (GER)
2047426-014	MNL OPR MAC 600 GRE	Greek (GRE)
2047426-015	MNL OPR MAC 600 HUN	Hungarian (HUN)
2047426-016	MNL OPR MAC 600 ITA	Italian (ITA)
2047426-017	MNL OPR MAC 600 JPN	Japanese (JPN)
2047426-018	MNL OPR MAC 600 KOR	Korean (KOR)
2047426-019	MNL OPR MAC 600 LAT	Latvian (LAT)
2047426-020	MNL OPR MAC 600 NOR	Norwegian (NOR)
2047426-021	MNL OPR MAC 600 POL	Polish (POL)
2047426-022	MNL OPR MAC 600 POR BR	Brazilian Portuguese (POR BR)
2047426-023	MNL OPR MAC 600 POR EU	European Portuguese (POR EU)
2047426-024	MNL OPR MAC 600 ROM	Romanian (ROM)
2047426-025	MNL OPR MAC 600 RUSRussian (RUS)	Russian (RUS)
2047426-026	MNL OPR MAC 600 SER	Serbian (SER)
2047426-027	MNL OPR MAC 600 SLO	Slovakian (SLO)
2047426-028	MNL OPR MAC 600 SLN	Slovene (SLN)
2047426-029	MNL OPR MAC 600 SPA	Spanish (SPA)
2047426-030	MNL OPR MAC 600 SWE	Swedish (SWE)
2047426-031	MNL OPR MAC 600 TUR	Turkish (TUR)

QRG P/Ns

Table 5-8. Operator's Guide		
Part Number	Description	Language
2047426-003	MNL QRG MAC 600 English	English (ENG)
2047426-032	MNL QRG MAC 600 BUL	Bulgarian (BUL)
2047426-033	MNL QRG MAC 600 CHS	Chinese (CHS)
2047426-034	MNL OPR MAC 600 CROA	Croatian (CRO)
2047426-035	MNL QRG MAC 600 CZE	Czech (CZE)
2047426-036	MNL QRG MAC 600 DAN	Danish (DAN)
2047426-037	MNL QRG MAC 600 DUT	Dutch (DUT)
2047426-038	MNL QRG MAC 600 EST	Estonian (EST)
2047426-039	MNL QRG MAC 600 FIN	Finnish (FIN)
2047426-040	MNL QRG MAC 600 FRE	French (FRE)
2047426-041	MNL QRG MAC 600 GER	German (GER)
2047426-042	MNL QRG MAC 600 GRE	Greek (GRE)
2047426-043	MNL QRG MAC 600 HUN	Hungarian (HUN)
2047426-046	MNL QRG MAC 600 ITA	Italian (ITA)
2047426-045	MNL QRG MAC 600 JPN	Japanese (JPN)
2047426-046	MNL QRG MAC 600 KOR	Korean (KOR)
2047426-047	MNL QRG MAC 600 LAT	Latvian (LAT)
2047426-048	MNL QRG MAC 600 NOR	Norwegian (NOR)
2047426-049	MNL QRG MAC 600 POL	Polish (POL)
2047426-050	MNL QRG MAC 600 POR (BRZ)	Brazilian Portuguese (POR BR)
2047426-051	MNL QRG MAC 600 POR	European Portuguese (POR EU)
2047426-052	MNL QRG MAC 600 ROM	Romanian (ROM)
2047426-053	MNL QRG MAC 600 RUS	Russian (RUS)
2047426-054	MNL QRG MAC 600 SER	Serbian (SER)
2047426-055	MNL QRG MAC 600 SLO	Slovakian (SLO)
2047426-056	MNL QRG MAC 600 SLOVENE	Slovene (SLN)
2047426-057	MNL QRG MAC 600 SPA	Spanish (SPA)
2047426-058	MNL QRG MAC 600 SWED	Swedish (SWE)
2047426-059	MNL QRG MAC 600 TUR	Turkish (TUR)

Power Cords

Table 5-9. Power Cords		
Part Number	Description	Country
405535-006	Power supply cord RA Hospital Grade 13A 125 V 10 FT	North America/ Central America
401855-018	Power Cord ST CHINA RA PLUG 10A 250V 2.5M	China
401855-101	Power Supply Cord ST CONT EURO 10A 250V 2.5M	Europe
401855-102	Power Supply Cord ST BRITISH 10A 250V 2.5M FSD	Britain
401855-103	Power Supply Cord ST ITALIAN 10A 250V 2.5M	Italy
401855-104	Power Supply Cord ST ISRAELI 10A 250V 2.5M	Israel
401855-107	Power Supply Cord ST SWISS 10A 250V 2.5M	Switzerland
2035953-001	Power Supply Cord ST INDIAN 6A 250V 2.5M	India
401855-109	Power Supply Cord ST DANISH 10A 250V 2.5M	Denmark
40185-110	Power Supply Cord ST AUSTRALIAN 10A 250V 2.5M	Australia
405535-011	PWR SPLY CRD ST-RA PSE 10A 250V 10FTROHS	Japan
401855-005	PWR SPLY CRD ST HARNESS 10A 125V 2M	America Others

MAC 600 Options

Table 5-10. MAC 600 Options	
Part Number	Description
2047228-001	MAC 600 STARTER PKG NO 12SL
2047228-002	MAC 600 ADVISOR PKG 12 SL EXT MEMORY
2047228-003	MAC 600 COMM PKG 12SL EXT MEM COMM

Table 5-11. MAC 600 Upgrade Options	
Part Number	Description
2047927-008	KIT UPGRADE COLOR OPTION
2047927-009	KIT UPGRADE MSRMT
2047927-010	KIT UPGRADE MSRMT+INTRPT
2047927-011	KIT UPGRADE EXT STORAGE

Table 5-11. MAC 600 Upgrade Options	
2047927-012	KIT UPGRADE EXT STOR + SERIAL CBL
2047927-015	KIT UPGRADE PDF FORMAT

Field Replaceable Units (FRUs)

2066456-001 FRU - Power Supply Medical Class I (For China Only)



2047328-002 FRU EXTERNAL POWER SUPPLY - CLASS I



Table 5-12. Power Supply FRU Kit		
ITEM	ITEM ITEM DESCRIPTION	
1	PWR Sply SW 18W SL Power	
2	Product Label - Expedition	
3	Replacement Instructions for Power Supply FRU for MAC 600	

See the instructions for "Reworking the Power Supply (Class II to Class I)" on page 4-11.



	Table 5-13. Mechanical FRU Kit 1
ITEM	

ITEM	ITEM DESCRIPTION
1	SCR DIN7985-M3X10-4.8-Z-A2F (ISO7045)
2	SCR DIN7985-M2X6-4.8-Z-A2F (ISO7045)
3	SCR FH #4-40X1/4" ZINC AHNL.DIN965
4	BUMPON SJ-6125, 15.9MM DIA, 6.35MM THK

FRU - CKT BD MAC 600 CPU Board



2047330-001	FRU - CKT BD MAC 600 CPU BOARD
2066447-002	FRU - PWA MAC 600 (new) (FRU PWA used in MAC 600 Devices having Product Code SP5)

NOTE

FRU PN: 2047330-001 is used in MAC 600 devices having Product Code SF7. This FRU is available as long as stocks last. Order FRU PN: 2066447-002 as a replacement; this is fully backward compatible.

LCD FRU Kit (NEC)



1

2

2047331-001	LCD FRU KIT
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Table 5-14. LCD FRU Kit (NEC)		
ITEM ITEM DESCRIPTION		
1	LCD Module - 4.3"	
2	DISPLAY O-RING - EXPEDITION	

NOTE

FRU PN: 2047331-001 is used in MAC 600 devices having Product Codes SF7 and SP5.

LCD FRU Kit (KOE)



2100910-001	LCD AND DISPLAY O-RING (NEW) FRU KIT
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Table 5-15. LCD FRU Kit (KOE)		
ITEM ITEM DESCRIPTION		
1	LCD MODULE - 4.3 INCH	
2	DISPLAY O-RING - EXPEDITION	

NOTE

Order FRU PN: 2100910-001 as a replacement, only for product code SPY.

FRU - LCD Module Holder - Expedition (NEC)



2047332-001	FRU - LCD MODULE HOLDER - EXPEDITION
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NOTE

FRU PN: 2047332-001 is used in MAC 600 devices having Product Codes SF7 and SP5.

FRU - LCD Module Holder - Expedition (KOE)



2100912-001	LCD MODULE HOLDER (NEW) - FRU

NOTE

FRU PN: 2100912-001 is used in MAC 600 devices having Product Codes SPY.

FRU - Cover Battery - Expedition



Table 5-16. FRU - Cover Battery - Expedition		
ITEM ITEM DESCRIPTION		
1	COVER BATTERY - EXPEDITION	
2	BUMPON SJ-6125, 15.9MM DIA, 6.35MM THK	

FRU - Daughter Board for LCD Module - EXPD'N (NEC)



1

2047334-001 FRU - DAUGHTER BOARD FOR LCD MODULE - EXPD'N (NEC)	
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Table 5-17. FRU - Daughter Board for LCD Module - EXPD'N (NEC)		
ITEM ITEM DESCRIPTION		
1	PCB MAC600 LCD DISPLAY DAUGHTER BOARD	
2	FERRITE - (7427212)	
3	PAD, FLOPPY MAC SERIES (Adhesive)	

NOTE

FRU PN: 2100913-001 is used in MAC 600 devices having Product Codes SF7 and SP5.

FRU - Daughter Board for LCD Module - EXPD'N (KOE)



2100913-001 FRU - DAUGHTER BOARD FOR LCD MODULE - EXPD'N (KOE)	
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Table 5-18. FRU - Daughter Board for LCD Module - EXPD'N (KOE)		
ITEM	ITEM ITEM DESCRIPTION	
1	PCB MAC600 LCD DISPLAY DAUGHTER BOARD	
2	FERRITE - (7427212)	
3	PAD, FLOPPY MAC SERIES (Adhesive)	

NOTE

FRU PN: 2100913-001 is used in MAC 600 devices having Product Codes SPY.

Printer Door FRU Kit



2047335-001	PRINTER DOOR FRU KIT

Table 5-19. Printer Door FRU Kit		
ITEM	ITEM DESCRIPTION	
1	PRINTER DOOR - EXPEDITION	
2	PRINTER DOOR - HINGE COMPONENT	



2047336-001	COVER TOP FRU KIT

Table 5-20. Cover Top FRU Kit		
ITEM	ITEM DESCRIPTION	
1	COVER TOP - EXPEDITION (with Printing)	
2	BACK PANEL - EXPEDITION (with Printing)	
3	CORE FERRITE 7427210	
4	PAD, FLOPPY MAC SERIES (Adhesive)	
5	NAMEPLATE 15MM GE LOGO	
6	MEMBRANE KEY SHEET - EXPEDITION	

Cover Bottom FRU Kit



3

2047337-001 COVER BOTTOM FRU KIT

Table 5-21. Cover Bottom FRU Kit		
ITEM	ITEM DESCRIPTION	
1	COVER BOTTOM - EXPEDITION	
2	BUMPON SJ-6125, 15.9MM DIA, 6.35MM THK	
3	PAPER LIFTING TAPE	
4	PRODUCT LABEL EXPEDITION	

Mechanical FRU Kit 2

1



	2047338-001	MECHANICAL FRU KIT 2
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Table 5-22. Mechanical FRU Kit	
ITEM	ITEM DESCRIPTION
1	PRINTER MOUNTING BASE
2	PATIENT CABLE CONNECTOR HOLDER

FRU Printer Module



2047339-001

FRU PRINTER MODULE

FRU Battery



2047357-001	FRU BATTERY
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FRU Software Update - SD Card



Table 5-23. FRU Software Update - SD Card	
ITEM	ITEM DESCRIPTION
1	CARD SECURE DIGITAL - 2GB
2	LABEL SD CARD FOR MAC600 SW KIT

FRU Cable Kit

2047359-001 FRU CABLE KIT	2047359-001	FRU CABLE KIT
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Table 5-24. FRU Cable Kit		
ITEM	ITEM DESCRIPTION	
1	CABLE FOR EARTHING	
2	FERRITE - (7427212)	
3	PAD, FLOPPY MAC SERIES (Adhesive)	
4	CABLE MAC 600LCD CA	
FRU Serial Cable



2047566-001	ASSY SERIAL CABLE - FERRITE

A Technical Specification

Instrument Type			
Microprocessor augmented automa configuration.	atic electrocardiograph; 10-leadwire, 12 lead simultaneous acquisition with programmable lead		
Processing			
ECG Interpretation:	Marquette 12SL ECG Analysis Program for Adults and Pediatrics		
Computerized measurements:	12-lead analysis		
ECG analysis frequency:	500 samples/second (sps)		
ECG storage:	Optional. 200 ECGs in external memory (SD card)		
Digital sampling rate:	2,000 samples/second/channel		
ECG on-screen preview:	On-screen preview of acquired 10 second ECG waveform and optional 12SL measurement and interpretation.		
Pre-acquisition:	Provides 10 seconds of instantaneous ECG acquisition (after 10 seconds from boot up)		
Dynamic range:	AC Differential ± 5mV, DC offset ±300 mV		
Resolution:	4.88 μV/LSB @ 500 sps		
Frequency response:	-3 dB @ 0.01 to 150 Hz		
Low cut off frequency:	0.01 Hz, 0.02 Hz, 0.16 Hz or 0.32 Hz (-3 dB limits)		
High cut off frequency:	Configurable at 20 Hz, 40 Hz, 100 Hz or 150 Hz		
Common mode rejection:	>100 dB (with AC filter switched on)		
Input impedance:	>100M Ω @ 10Hz, defibrillator protected		
Patient leakage:	<10 µA		
Special acquisition functions:	Disconnected lead detection except RL, excessive AC noise, baseline wander and muscle tremor messages		
Heart rate meter:	30 to 300 BPM $\pm 10\%$ or ± 5 BPM, whichever is greater. Heart rates outside this range will not be displayed		
Start-up time	Less than 7 seconds		
Patient Information			
Supported patient information	Patient ID, Secondary ID, Age, Date of Birth, Gender. Alphanumeric entry in T9 type for patient ID and secondary ID.		
Communication (optional)			
MUSE Cardiology Information System compatible			
Serial cable	ECG Transmission to MUSE Cardiology Information System		
Serial cable	ECG transmission in XML format		
Cardiosoft interface			

SD card interface	Compatible with Cardiosoft V6.51			
Storage (optional)				
ECG Storage Format	GE Healthcare storage format for MUSE and Cardiosoft. XML storage format. PDF storage format			
PDF File name format	User configurable file name, which includes patient ID, secondary ID, Date of Birth, ECG recording date and time.			
Display				
Display type:	4.3 inch (110 mm) diagonal, TFT LCD with LED graphics backlit (color optional)			
Display resolution:	480 X 272 pixels with scrolling waveform			
Display data:	Heart rate, patient ID, clock, battery power indicator, waveforms, lead labels, speed, gain and filter settings, warning messages, information messages, prompts. 12 leads standard display.			
Writer				
Writer technology:	Thermal dot array			
Writer speed:	5, 12.5, 25, & 50 mm/s			
Number of traces:	3 leads + 1 Rhythm or 3 leads; user selectable			
Writer sensitivity/gain:	2.5, 5, 10, 20, 10/5 (split calibration) mm/mV			
Writer speed accuracy:	±5%			
Writer amplitude accuracy:	±5%			
Writer resolution:	Horizontal 40 dots/mm @ 25 mm/s, 8 dots/mm vertical			
Paper type:	Thermal. Z-fold perforated, 280 sheets/pack. Roll paper 15.7 m.			
Languages				
Supported languages:	Netherlands, English, Français, Deutsch, Italiano, Español, Svenska, Japanese, Dansk, Norsk, Magyar, Polski, Cesky, Chinese, Russian, Portuguese			
Report formats				
Thermal printer report formats:	4 by 2.5s 4 by 2.5s + 1 rhythm lead 4 by 3s 4 by 10s Autorhytm (10 second ECG data for 3 leads) Printing of 4 by 10s or Autorhythm for abnormal ECG Continuous 3 channel rhythm			
PDF report format:	(A4)			
Keyboard				
Туре:	Membrane keyboard with tactile feedback			
Electrical				
Power Supply:	External ACDC adaptor or battery operation			

External adaptor specifications			
Input voltage:	100 to 240 VAC ±10%		
Input current:	Maximum 0.5A @ 90 VAC - 240 VAC		
Operating frequency:	50 to 60 Hz ±3Hz		
Output voltage:	12 ± 5%		
Battery specifications			
Battery type:	Replaceable and rechargeable, Lithium Ion		
Battery capacity:	 7.2V typical, 2.25 AH ±10% 360 minutes of continuous operation without recording or 250 ECGs in 2.5 X 4 format at 25 mm/S and 10 mm/mV or 100 minutes continuous rhythm print at 25 mm/S and 10 mm/mV. 		
Battery charge time:	Approximately 3 hours from total discharge (with display off)		
Physical specification			
Height:	Approximately 81 mm		
Width:	Approximately 263 mm		
Depth:	Approximately 208 mm		
Weight: Approximately 1.2 Kg including battery			
Environmental specification			
Temperature			
Operating:	5° to 40°C		
Transport/storage:	-15°C to 50 °C		
Humidity			
Operating:	25% to 95% RH non-condensing		
Transport/storage:	25% to 95% RH non-condensing		
Pressure			
Operating:	700 to 1060 hPA		
Transport/storage:	500 to 1060 hPA		

Certification

Class I, type CF defibrillator proof (for China shipments and for device serial number equal to or greater than SF713500001PA) Class II, type CF defibrillator proof (for device serial number less than SF713500001PA excluding China Shipments)

UL 60601-1 Medical Electrical Equipment, part 1:General Requirements for Safety

CAN/CSA C22.2 No. 601.1 General Requirements for Safety

CE marking for Council Directive 93/42/EEC concerning medical devices

IEC 60601-1 General Requirements for Safety

IEC 60601-1-1 General Requirements for Safety Medical Electrical systems

IEC 60601-2-25 Particular Requirements for the Safety of Electrocardiographs

IEC 60601-2-51 Particular requirements for safety, including essential performance, of recording and analyzing single channel and multi channel electrocardiographs.

IEC 60601-1-2 General Requirements for Safety Electromagnetic Compatibility.

IEC 60601-1-4 General Requirements for Safety – Programmable electrical medical systems

IEC 60601-1-6 General requirements for basic safety and essential performance – Collateral Standard: Usability-Edition 2.0

Meets applicable AAMI EC-11 requirements and AAMI EC 13 (Clause 4.2.7 only)

B Electromagnetic Compatibility

Changes or modification to the MAC 600 system not expressly approved by GE Healthcare could cause EMC issues. This system is designed and tested to comply with applicable regulations regarding EMC and needs to be installed and used according to the EMC information stated as follows.

CAUTION

RADIO FREQUENCY INTERFERENCE — Use of portable phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation.

Do not use RF emitting equipment near the device.

CAUTION

EQUIPMENT INTERFERENCE — If adjacent or stacked use is necessary, the equipment or system should be tested to verify normal operation in that configuration.

The equipment or system should not be used adjacent to, or stacked with, other equipment.

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions EN 55011	Group 1	The MAC 600 uses RF energy for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions EN 55011	Class B	The MAC 600 is suitable for use in all establishments including domestic establishments
Harmonic Emissions EN 61000-3-2	Class A	voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuations/Flicker emissions EN 61000-3-3	Complies	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Immunity test	EN60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/ burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Mains power should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	<5% Ut (>95% dip in Ut) for 0.5 cycles 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95% dip in Ut) for 5 sec	Mains power should be that of a typical commercial or hospital environment. If the user of the MAC i requires continued operation during power mains interruptions, it is recommended that the MAC 600 be powered from an uninterruptable power supply or a battery.
Power frequency(50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

Immunity test	EN60601 test level	Compliance level	Electromagnetic environment-guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the MAC 600, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF EN 61000-4-6	3 Vrms 150 KHz to 80 MHz	3 Vrms 150 KHz to 80 MHz	Recommended separation distance $d = 12 \sqrt{P}$
Radiated RF EN 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m 80 MHz to 2.5 GHz	$d=7.2\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey ^a , should be less than the compliance level in each frequency range ^b . Interference may occur in the vicinity of equipment marked with the following symbol: ((()))
Note 1: At 80 MH: Note 2: These guide	z and 800 MHz, the higher frequ elines may not apply in all situations	ency range applies. . Electromagnetic propagation is affe	ected by reflection from structures, objects and people.
Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MAC 600 is used exceeds the applicable RF compliance level above, the MAC 600 should be observed to verify normal operation. If abnormal performance			

Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

is observed, additional measures may be necessary, such as re-orienting or relocating the MAC 600.

Recommended Separation Distance

The following table provides the recommended separation distances (in meters) between portable and mobile RF communication equipment and the MAC 600 system. The MAC 600 system is intended for use in the electromagnetic environment on which radiated RF disturbances are controlled. The customer or the user of the MAC 600 system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MAC 600 system as recommended below, according to the maximum output power of the communications equipment.

	Separation distance in meters (m) according to frequency of transmitter			
Rated maximum output power of transmitter in watts (W)	150KHz to 80MHz outside ISM bands d = $1 \cdot 2\sqrt{P}$	150KHz to 80MHz outside ISM bands $d = 1 \cdot 2 \sqrt{P}$	80MHz to 800MHz d = 1.2 $\sqrt{\mathbf{P}}$	800MHz to 2.5GHz d = $2.3\sqrt{\mathbf{P}}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23
Note 1: At 80MHz and 800MHz the separation distance of high frequency range applies.				

For transmitters rated at a maximum output power not listed above, the recommended separation distance [d] in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

ΝΟΤΕ

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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