MAC™ 400 Resting ECG Analysis System Safety and Warnings Guide

The **MAC™ 400 Resting ECG Analysis System Safety and Warnings Guide** provides guide details, safety information and symbols definitions.

Guides information

The MAC 400 Resting ECG Analysis System Guides contain the instructions necessary for operating the MAC 400 system in accordance with its function and intended use.

The information in these guides only applies to MAC 400 system software version 1. It does not apply to earlier software versions. Due to continuing product innovation, specifications in these guides are subject to change without notice.

Intended audience

The MAC 400 Resting ECG Analysis System Guides are intended for persons who use, maintain, or troubleshoot this equipment.

Revision history

The document part number and revision letter are on the bottom of each page. The revision letter identifies the document's update level.

Revision History 2032589-001		
Revision	**Date**	**Comment**
A	15 May 2007	Initial release of document
B	15 June 2007	Revised per MVP feedback
C	16 July 2007	Revised IPD
D	11 September 2007	Revised heading.
E	17 March 2008	Updated "Equipment Symbols".

Product reference

The product described in these guides is the MAC 400 resting ECG analysis system. It may be referred to as "the system" throughout these documents.

Conventions

These conventions are used in the MAC 400 system guides:

Bold text	Indicates keys on the keyboard, text to be entered, or hardware items such as keys or switches on the equipment.
Italicized text	Indicates terms that identify menu items or options in the system display window.

CE marking information

The MAC 400 system bears the CE mark "CE-0459", notified body GMED, indicating its conformity with the provisions of the Council Directive 93/42/EEC, concerning medical devices and fulfills the essential requirements of Annex I of this directive. The system delivers 3-channel ECG recordings in automatic and arrhythmia modes and 1 or 3-channel ECG recordings in manual mode. The country of manufacture can be found on the equipment labeling.

The safety and effectiveness of this device have been verified against previously distributed devices. All standards applicable to presently marketed devices may not be appropriate for prior devices (for example, electromagnetic compatibility standards). This device will not impair the safe and effective use of previously distributed devices.

NOTE: Electromagnetic compatibility information can be found in the "MAC™ 400 Resting ECG Analysis System Service Manual".

Product use and classification

Recommendations

Operating the system near radio frequency (RF) electromagnetic interference (EMI) above the conditions defined in the electromagnetic compatibility (EMC) Standard EN60601-1-2 for Radiated Immunity (field strengths above 3 volts per meter) may cause waveform distortions.

Portable and mobile RF communications equipment can affect medical electrical equipment. Users should consider RF sources, such as radio or TV stations and hand-held or mobile two-way radios, when installing a medical device or system. Adding accessories or components, or modifying the medical device or system may degrade the EMI performance. Consult with qualified personnel regarding changes to the system configuration.

Medical electrical equipment requires precautions regarding EMC and needs to be installed and used according to the EMC information provided in the product service manual. The use of accessories, transducers and cables other than those specified or sold by the manufacturer may result in increased emissions or decreased immunity of the system. The system should not be used nearby or stacked with other equipment. If stacking or using near other equipment cannot be avoided, observe to verify normal operation. Review the AAMI Committee Technical Information Report (TIR) 18, "Guidance on Electromagnetic Compatibility of Medical Devices for Clinical/Biomedical Engineers" for details on evaluating and managing an EMI environment in the hospital. Take the following actions to reduce the risk of medical device EMI and achieve EMC:

- Assess the EMC environment of the facility and identify radio transmitters and/or areas where critical medical devices are used such as the emergency room and intensive care units.
- Increase the distance between sources of EMI and susceptible devices.
- Remove the devices that are highly susceptible to EMI.
- Lower the power transmitted from electrical and electronic equipment (EMI sources) under hospital control (i.e. paging systems).
- Label devices susceptible to EMI.
- Educate facility staff (nurses and doctors) to identify, and recognize, potential EMI-related problems.

Classification

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

Type of protection against electrical shock	Class I or internally powered equipment.
Degree of protection against electrical shock	Type CF defibrillation-proof applied part.
Degree of protection against harmful ingress of water	Ordinary equipment (enclosed equipment without protection against ingress of water, IPX0).
Degree of safety of application in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Methods of sterilization or disinfection recommended by the manufacturer	Not applicable.
Mode of operation	Continuous operation.

Responsibility of the manufacturer

GE 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 GE.
- 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.

Intended use

The MAC 400 device is for use under the direct supervision of a licensed healthcare practitioner. The system is intended to acquire, measure and record information from adult and pediatric populations. The basic system delivers 3-channel ECG recordings in automatic and arrhythmia modes and 1 or 3-channel ECG recordings in manual mode. The arrhythmia detection provides the convenience of automatic documentation. It is not designed to provide alarms for arrhythmia detection. 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 patient from the device before using the high frequency surgical units. This device is not intended for use with direct cardiac applications.

Biocompatibility

The parts of the product described in these guides, including all accessories, that come in contact with the patient during the intended use, fulfill the biocompatibility requirements of the applicable standards. Please contact GE or its representatives with any questions.

Safety information

Definitions

The terms danger, warning, and caution are used in these guides to point out hazards and to designate a degree or level of seriousness. Familiarize yourself with their definitions and significance. A hazard is defined as a source of potential injury to a person.

DANGER indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION indicates a potential hazard or unsafe practice which, if not avoided, could result in personal injury or product/property damage.

NOTE provides application tips or other useful information to ensure that you get the most from your equipment.

The safety information given in this manual is classified as follows.

Warning	Description
Accidental spills	To avoid electric shock or device malfunction, liquids must not enter the device. If liquids enter the device, stop using it and have it checked by a service technician before further use.
Battery operation	If the integrity of the protective earth conductor is in doubt, operate the unit from its battery.
Cables	To avoid possible strangulation, route all cables away from patient's throat.
Connection to mains	This is Class I equipment. The mains plug must be connected to an appropriate power supply.
Defibrillator precautions	Do not come into contact with patients during defibrillation. Serious injury or death could result. 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 the recommended cables and lead wires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.
Electrodes	Polarizing electrodes (stainless steel or silver constructed) may cause the electrodes to retain a residual charge after defibrillation. A residual charge will block acquisition of the ECG signal. Whenever patient defibrillation is a possibility, use nonpolarizing (silver/silver chloride construction) electrodes for ECG monitoring.
Magnetic and electrical interference	Magnetic and electrical fields can interfere with proper performance of the device. Make sure that all external devices operated near the device comply with the relevant EMC requirements. X-ray equipment or MRI devices may interfere with system performance because they may emit higher levels of electromagnetic radiation.
Explosion hazard	Do NOT use in the presence of flammable anesthetics vapors or liquids.
Interpretation hazard	Computerized interpretation is only significant when used in conjunction with clinical findings. A qualified physician must over read all computer generated tracings.
Operator	Medical technical equipment such as this electrocardiograph system must only be used by persons who have received adequate training in the use of such equipment and are capable of applying it properly.
Shock hazard	Improper use of this device presents a shock hazard. Failure to observe the following warnings may endanger the lives of the patient, the user, and bystanders. Disconnect from the power source before disconnecting the cable from the device to reduce the risk of inadvertently introducing metal parts in the sockets of the power cord and coming in contact with line voltage.
Site requirements	Do not route cables in a way that they may present a stumbling hazard. For safety reasons, connectors for patient cables and lead wires are designed to prevent disconnection if pulled on. For devices installed above the patient, adequate precautions must be taken to prevent them from dropping on the patient.

Caution	Description
Accessories (supplies)	To ensure patient safety, use only parts and accessories manufactured or recommended by GE. Parts and accessories must meet the requirements of the applicable IEC 60601 series safety standards and essential performance standards.
Proper lead wire connection	Improper connection will cause inaccuracies in the ECG. Trace each individual lead wire from its acquisition module label to the colored connector and then to the proper electrode to ensure that it is matched to the correct label location.
Before installation	Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.
Disposables	Disposable devices are intended for single use only. Do NOT reuse, as performance may degrade or contamination could occur.
Equipment damage	Devices intended for emergency application must not be exposed to low temperatures during storage and transport to avoid moisture condensation at the application site. Wait until all moisture has vaporized before using the device.
Electric shock	To reduce the risk of electric shock, do NOT remove cover (or back). Refer servicing to qualified personnel.
Power requirements	Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label. If not, do not connect the system to the power line. This equipment is suitable for connection to public mains as defined in CISPR 11.
Low battery shut down	If the battery is not charged for a long enough period of time or after multiple attempts to power on following a low-battery shut down, the system shifts to a second level of deep discharge protection. If device is turned on, it might call for a 1 to 2 minute continuous self test. Charge the battery for a minimum of half an hour before using device. We recommend that you keep the unit charged to avoid a low-battery shut down.
Serviceable parts	This equipment contains no user serviceable parts. Refer servicing to qualified service personnel.
Supervised use	This equipment is intended for use under the direct supervision of a licensed healthcare practitioner.

General information

Recording ECGs during defibrillation

This equipment is protected against the effects of cardiac defibrillator discharge to ensure recovery, as required by test standards. The patient signal input of the acquisition module is defibrillation-proof. It is not necessary to remove the ECG electrodes prior to defibrillation. When using stainless steel or silver electrodes, a defibrillator discharge current may cause the electrodes to retain a residual charge causing a polarization or DC offset voltage. Electrode polarization blocks acquisition of the ECG signal. If a defibrillation procedure is necessary, use non-polarizing electrodes, such as silver/silver-chloride types, to avoid a DC offset voltage when subjected to a DC current. If using polarizing electrodes, disconnect the lead wires from the patient before delivering the shock. Electrode defibrillation recovery allows the ECG trace to return after defibrillation. We recommend using nonpolarizing disposable electrodes with defibrillation recovery ratings as specified in AAMI EC12 3.2.2.4. (MMS P/N 9623-103P Silver Mactrodes™, MMS spec. TP9623-003). AAMI EC12 requires that the polarization potential of an electrode pair does not exceed 100 mV, five seconds after a defibrillation discharge.

Recording ECGs of pacemaker patients

The system does not support pacer pulse detection.

WARNING: PATIENT HAZARD — If several adverse conditions exist at once, pacer pulses might be interpreted and counted as QRS complexes. Pacemaker patients should always be watched closely.

Accuracy of the input signal reproduction

- Overall system error is tested using the method described in AAMI EC11 3.2.7.1. Overall system error is ±5 %.
- Frequency response is tested using the method described in AAMI EC11 3.2.7.2 methods A and D.

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. These variations may occur more in pediatric recordings. If this variation is observed, be aware that the origin of amplitude variations is not entirely physiologic. For measuring voltages of Q, R, and S waves, use the QRS complexes with the largest deflection of the particular waves.

Parts and accessories

To ensure patient safety, use only parts and accessories manufactured or recommended by GE. Parts and accessories must meet the requirements of the applicable IEC 60601 series safety standards and essential performance standards.

Equipment symbols

Symbol	Description/Function
	Type CF equipment. The acquisition module is protected from defibrillation shocks.
	The flashing yellow LED indicates you must connect to AC power to re-charge the battery.
	Consult instructions for use.
	Consult accompanying documents for cautions.
	Classified with respect to electric shock, fire, mechanical, and other specified hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No. 601.1, EN 60601-2-25, EN 60601-1, IEC 60601-1-2: 2001, IEC 60601-2-51.
IPX0	Indicates that the device is classified as Ordinary Equipment (enclosed equipment without protection against ingress of water).
	Indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
	Fuse.
	Do not throw or dispose of in fire!
 Li-Ion	Contains "Lithium Ion". This symbol indicates "General recovery/recyclable" and must not be disposed of as unsorted municipal waste and must be collected separately.
	Manufacturer name and address.
 YYYY-MM	Date of Manufacture (Year-Month).
 LOT	Batch code of paper or battery.
 REF	Catalogue number (Part number).

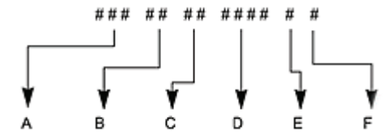
Symbol	Description/Function
 SN	Serial number.
 EC REP	European authorized representative.
	The packaging of this product can be recycled.
	Humidity limitation.
	Atmospheric pressure limitation.
	Environment-friendly Use Period per Chinese standard SJ/T11363-2006 (China specific).
	PCT. GOST marking symbolizing conformity with applicable Russian Gosstandart technical and safety standards.

Service requirements

Refer equipment servicing to GE 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 or an authorized agent.

Equipment identification

Every GE device has a unique serial number for identification on the device label.



A	Product code is SCT
B	Year manufactured (00-99) 00 = 2000, 01 = 2001, and so on
C	Fiscal week manufactured
D	Production sequence number
E	Manufacturing site
F	Miscellaneous characteristic

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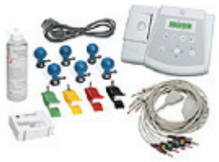
MAC™ 400 Resting ECG Analysis System Installation and Setup Guide

The **MAC™ 400 Resting ECG Analysis System Installation and Setup Guide** provides instructions for initial installation and setup of your system.

Before you begin

Remove the device and accessories from the box, and keep on a flat dry surface, away from direct sunlight, heat sources & dust.



A. Confirming the box contents

- MAC 400 resting ECG analysis device
- Four limb clamp electrodes
- Six bulb electrodes
- Patient ECG cables/lead wires
- Power cable
- Pack of z-fold paper (280 sheets)
- Electrode cream
- CD containing a service manual and 12SL™ Physicians Guide
- User guide

B. Charging the battery

The MAC 400 system needs a charged battery to print an ECG. Charge the battery for three hours for full power. A fully charged battery allows for 100 automatic mode ECGs or 100 minutes of arrhythmia/ manual mode recording.

1. Connect the device to a power source.
2. Turn on the power (a **green light** indicates that AC mains is connected).
3. After charging for three hours, unplug the power cord from both the device and the power source.

Recharge when you see a **yellow light** above the **power** key.

C. Loading paper

The MAC 400 system supports the use of standard thermal recording paper in either z-fold pads or roll paper.

1. Locate the printer assembly.
2. Gently pull back the printer assembly door to open the door latch.



3. Open the z-fold paper pack.
4. Ensure that the black paper guide is on the top and place the paper in the tray.
5. Advance the first sheet and close the door. Make sure that the paper is positioned on the pressure roller and that the door locks into place on both sides.

A red line at the top of the last ten sheets indicates that the paper supply is low. Change paper as needed.

NOTE: For instructions on loading roll paper, see the "MAC™ 400 Resting ECG Analysis System Maintenance Guide".

Initial system setup

THE SETUP MENU

Press **on/off** to turn on the device, and then, press **configuration** to access the setup menu. Use the setup menu to navigate between system settings and select the options you want. For more information, see System Symbols and System Menu Descriptions on page 4.

THE SYSTEM PARAMETERS TOOLS

Use these tools and guidelines to help you define the operating parameters.

1. Use **up/down cursor** to select a menu item.
2. Use **right/left cursor** to select the desired setting.
3. Always press **enter** to confirm your selection.
4. Always press **configuration** to save and exit the setup menu.

SETTING OPTIONS FOR INITIAL USE

A. Selecting a language

Different languages are available for the display text and printed ECG reports.

1. Press **configuration** to display the *language* selection menu.

2. Use the **right/left cursor** to select the language.
3. Press **enter** to confirm your selection.

B. Selecting the lead notations

There are two different lead notation options: *AHA* and *IEC*.

1. Use the **up/down cursor** to select *Notation*.
2. Use the **right/left cursor** to select *AHA* or *IEC*.
3. Press **enter** to confirm your selection.

C. Setting the date and time

Set the date and time for printed ECG reports.

To set the date:

1. Use the **up/down cursor** to select *Date*.
2. Use the **right/left cursor** to set the date.
3. Press **enter** to confirm your selection.

To set the time:

1. Use the **up/down cursor** to select *Time*.
2. Use the **right/left cursor** to set the time.
3. Press **enter** to confirm your selection.

D. Selecting heart rate limit values

1. Use the **up/down cursor** to select *HR control*. The cursor flashes on the low limit value.
2. Use the **right/left cursor** to change the low limit value, in increments of 5 BPM, between 30 and 120 BPM.
3. Press **enter** to confirm your selection.
4. Use **right/left cursor,** change the high-limit value (between 80 and 240 BPM).
5. Press **enter** to confirm.

NOTE: After setting these options, you must press **configuration** to save the options and exit the setup menu.

Heart rate indication

THE BASICS

WARNING PATIENT HAZARD — The MAC 400 system is not intended for use as a vital signs physiological monitor. When needed, use a device intended for vital signs monitoring.

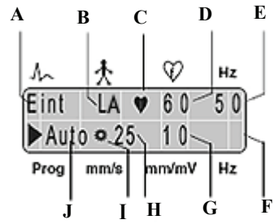
When the heart rate indication function is enabled, the automatic switchoff is disabled. Conditions of high and low heart rate are indicated in all operating modes, even when not recording. This function can be disabled in the setup menu. The default heart rate limits are *45* and *130* BPM, and can be modified in the setup menu. If the heart rate exceeds one of the set values, the system emits an audio signal. This audio signal ceases automatically when the heart rate returns to the permitted range or when you press **QRS beep**. The audio signal will not recur if it was silenced with **QRS beep**. The audio signal recurs only when the heart rate exceeds one of the limit values again.

E. Hooking up the starter kit

Once you have customized your settings, connect the patient cable to the device (A) on the right side panel.

Default settings for auto mode

When you turn on the device, the system default is automatic mode. Factory defaults have the following functions and settings (the most important settings are indicated on the display):



A	*Lead* sequence: *Standard* = Einthoven (I, II, III), Goldberger(aVR, aVL, aVF), Wilson 1 (V1, V2, V3), Wilson 2 (V4, V5, V6).
B	Lead fail indicator: Indicates a disconnected electrode. For example, LA indicates that the left arm electrode is disconnected.
C	QRS indicator: The heart symbol blinks with every detected systole.
D	Heart rate: Detects the patient's heart rate. In this example, it is *60* BPM.
E	*AC filter*: *On* (enabled) (*50* Hz).
F	*Muscle filter*: *Off* (disabled).
G	*Sensitivity* (gain): *10* mm/mV.
H	Paper *speed*: *25* mm/s.
I	Rotating symbol: Displays when the ECG data acquisition or recording is active.
J	Operating mode: *Automatic*.

Additional default settings (not indicated on the display):

- *Notation*: *AHA*.
- *ADS*: Enabled.
- Report format: *Simultaneous*, *short*.
- *Override*: Disabled.

NOTE: For further descriptions of the settings, see System Menu Descriptions on page 4.

MAC™ 400 Resting ECG Analysis System Installation and Setup Guide

System setup

The system setup function allows you to customize many of the MAC 400 system settings. Once you customize and save your settings, they will activate each time you turn on the system.

System symbols

Symbol	Description
	ECG lead indicator.
	Heart rate in beats per minute (BPM).
	Lead fail indicator.
Hz (top)	*AC filter* (line frequency) in Hertz (Hz).
Hz (bottom)	*Muscle filter* in Hertz (Hz).
Prog	Operating mode: *manual*, *automatic* or *arrhythmia*.
mm/s	Paper *speed* in millimeters per second (mm/s).
mm/mV	*Sensitivity* (gain) in millimeters per Millivolt (mm/mV).
	Power key: press to turn on and off.
	**Cursor control** keys: press to move the cursor up, down, right or left to select menu items and change settings.
	Enter key: press to confirm selections during device configuration.
	**Start/Stop** key: press to start or stop a recording.
	**Lead selection** key: press to change the ECG leads. The key is only enabled when a patient cable is connected.
	**Copy** key: press to print additional report copies.
	**QRS beep** key: Press to enable/disable QRS beep and audio signals alerting to specific events, and to clear the error message.
	**Configuration** key: press to access/quit setup menu.

System menu descriptions

NOTE: Angular brackets [ ] identify default setting.

Menu Item	Options	Description
Language	*[English]*/Chinese/ French/Dutch/ Italian/Spanish/ Portuguese/Russian/ Polish/Czech/ Hungarian/German	Select a language for the display and printed reports. **NOTE**: When you choose Chinese or Russian, changes only affect printed reports. The display remains in English.

Menu Item	Options	Description
Notation	*[AHA] IEC*	Electrode designations: AHA: RA, LA, RL, LL, V1 to V6. IEC: R, L, F, N, C1 to C6.
Lead	*[Stand.]* (Standard) *Cabr.* (CABRERA)	Standard lead sequence: I, II, III, aVR, aVL, aVF, V1 to V6. Cabrera lead sequence: aVL, I, -aVR, II, aVF, III, V1 to V6.
Report format	*[Sim]* (Simultaneous) *Seq* (Sequential)	In automatic mode, the system collects and saves 12 standard leads for 10 seconds. The leads are recorded in 4 groups of 3 leads each.
Report format (simultaneous reports only)	*[Short] Long*	All recorded leads reflect the same period of time: long format = 10 seconds, short format = 3 seconds.
Rhythm recording (sequential reports only)	*Yes [No]*	A recorded 10-second period is divided into 4 segments (quarters) of 2.5 seconds: The first 3 leads reflect the first 2.5-second quarter, the second group reflects the second quarter and so on. A 10-second rhythm recording can be added.
Override	*On [Off]*	When enabled, the device starts recording in automatic mode, even if an electrode is disconnected.

Menu Item	Options	Description
No. of leads (manual mode)	*[3] 1*	Number of leads recorded in manual mode: 1 or 3.
Speed (in mm/s)	*[25] 50*	Paper speed: 25 or 50 mm/s.
Sensitivity (Gain)	*5 [10] 20*	5, 10 or 20 mm/mV.
AC filter (line frequency)	*[50] 60 Off*	Suppression of interference: "50" for countries with 50-Hz power line. "60" for countries with 60-Hz power line.
Muscle filter	*On [Off]*	Suppression of muscle artifact.
Filter frequency (only if muscle filter is ON)	*20 [35]*	Selection of muscle filter frequency. **NOTE**: filters may suppress diagnostically relevant portions of the signal. Only enable filters when necessary.
ADS (Anti Drift System)	*[On] Off*	In case of wandering baselines, restores the baseline to its original position. ADS causes a signal delay of 4 seconds.
Paper	*[F] R*	F - fan-fold (z-fold) paper. R - roll paper.
HR control	*[On] Off*	Enables/disables the HR indication function in Automatic and Manual Mode. If disabled, the MAC 400 turns off when the system is idle for 5 minutes.
HR control low limit and high limit (in increments of 5 BPM) high limit must be at least 5 BPM above low limit)	*[45] [130]* 30 to 120 and 80 to 240	Selection of heart rate limit values. Cursor left reduces the value, cursor right increases it. Low limit range: 30 to 120 BPM. High limit range: 80 to 240 BPM.

Menu Item	Options	Description
Cut-off frequency	*0.01 0.04 [0.08] 0.16*	Selection of the lower cut-off frequency of the signal transmission range: 0.01, 0.04, 0.08 or 0.16 Hz.
Contrast	(increase) (decrease)	Cursor right increases contrast. Cursor left decreases contrast.
QRS beep	*Off [On]*	If turned on, the system beeps with every detected systole.
Date	Chinese language: *YYYY.MM.DD* All other languages: *DD.MMM.YYYY*	Change the date. Adjust with cursor right/left, press the **enter** key to confirm and save.
Time	24-hour format e.g. 17:50 (*HH:MM*)	Adjust with cursor right/left, press the **enter** key to confirm and save.
Factory defaults	*Yes* *No* (default always remains as no)	Select "Yes" to restore the factory default settings.
Print configuration list	*Yes* *No* (default always remains as no)	Select "Yes" to print a list of all device settings.

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MAC™ 400 Resting ECG Analysis System Operator Guide

The MAC™ 400 Resting ECG Analysis System Operator Guide provides instructions for using the device to record ECGs.
Before recording an ECG, you must prepare the patient and set up the electrode and lead wire connections.

A. Prepping the patient's skin

Prep the skin to help ensure an interference-free ECG. To prep the skin:

1. Shave hair from the area and degrease each electrode site with alcohol.
2. Use an abrasive pad or skin prep cream to remove the epidermal skin layer at each site.

B. Applying electrodes

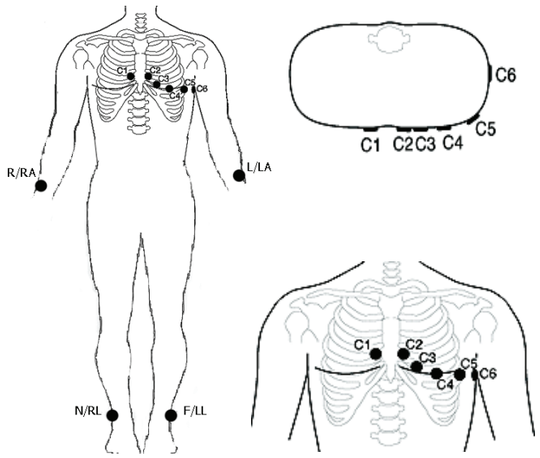
Apply electrode cream or gel to the electrode sites and attach the suction bulbs (or optional disposable electrodes) at each site. In situations where hair is present, electrode cream or gel helps to seal the electrodes. If using electrode paper, moisten it with water and apply it to the patient's skin at the application points.

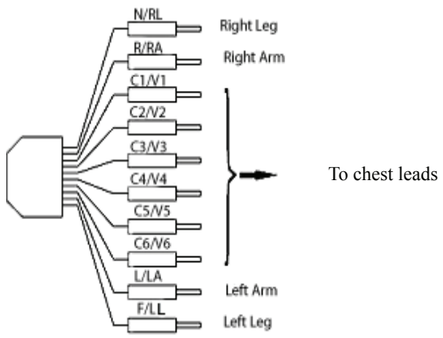
Apply a small amount of electrode cream or gel to the metal electrode of each clamp. Apply the clamp electrodes to the limbs as indicated in the Electrode Placement table.

C. Recording standard leads

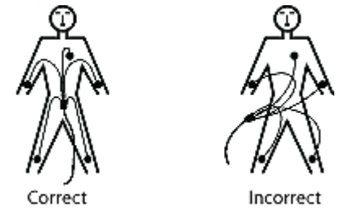
Four limb and six chest electrodes must be applied to the patient for acquisition of the standard leads I, II, III, aVR, aVL, aVF, and V1/C1 to V6/C6. Connect the six bulb electrodes to the chest lead wires and the four clamp electrodes to the limb lead wires.

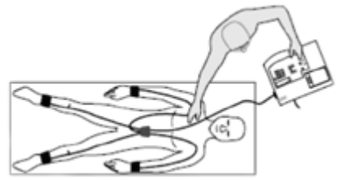
D. Connecting the lead wires (as indicated)





E. Arranging the patient cable (as shown)





ELECTRODE PLACEMENT

This table explains the location of each placement and identifies the labels for *AHA* or *IEC* notations.

AHA Label	IEC Label	Electrode Placement
V1 red	C1 red	Fourth intercostal space at the right sternal border.
V2 yellow	C2 yellow	Fourth intercostal space at the left sternal border.
V3 green	C3 green	Midway between C2/V2 and C4/V4.
V4 blue	C4 brown	Mid-clavicular line in the fifth intercostal space.
V5 orange	C5 black	Anterior auxiliary line on the same horizontal level as C4/V4.
V6 purple	C6 purple	Mid-auxiliary line on the same horizontal level as C4/V4 and C5/V5.
LA black	L yellow	Above left wrist (alternate placement: left deltoid).
LL red	F green	Above left ankle (alternate placement: upper leg close to torso).
RL green	N black	Above right ankle (alternate placement: upper leg close to torso).
RA white	R red	Above right wrist (alternate placement: right deltoid).

NOTE: Alternate placements apply when using disposable electrodes.

F. Recording an ECG in all operating modes

1. Turn on the device and wait for the self-test to end.
2. Apply all **electrodes** to the patient and connect the patient **cable** to the device.
3. Using the **cursor** keys, select the operating mode: *Automatic*, *Manual* or *Arrhythmia*.
4. Check the device settings:
   - Lead (*standard, CABRERA*)
   - *Speed* (*50*, *25* mm/s (*5* mm/s for *manual* and *arrhythmia* modes))
   - *Sensitivity* (gain) (*20*, *10*, *5* mm/mV)
   - *Muscle filter* (*off*, *20/35* Hz)
   - *AC filter (on, off)*
5. If required, use the **lead selection** to change the lead/lead group or the **cursor** keys to modify other settings.

NOTE: For details on changing settings, see the MAC™ 400 Installation and Setup Guide.

6. Wait for the patient to lie motionless and press **start/stop** to initiate signal acquisition and recording.

Operating modes

The MAC 400 system has three operating modes for recording ECGs. Once you determine the mode you want to use and adjust the settings, follow the operating instructions.

NOTE: The factory default sets the heart rate (HR) indication function active in all operating modes. The default HR limits are *45* BPM and *130* BPM. These limits can be changed from the setup menu. At least four QRS complexes are required for correct determination of the heart rate.

AUTOMATIC MODE

The default operating mode for the system is automatic mode. When initiated in automatic mode, the system simultaneously acquires 12 leads of ECG for a period of 10 seconds and then recording proceeds automatically. The system measures the ECG and records the results on a report. You can choose between *simultaneous* and *sequential* report formats:

- Simultaneous format records all leads representing the same period of time (either 10 seconds = *long* format, or 3 seconds = *short* format).
- For sequential recordings, the 10-second signal acquisition period is divided into four segments of 2.5 seconds each. The first three recorded leads represent the first segment (0-2.5 seconds), the second group of leads represents the second segment, and so on. You may also choose to record a 10-second rhythm strip.

You may choose *standard* or *CABRERA* lead sequence recordings. The factory default records all 12 leads simultaneously on four sheets, each representing a period of 3 seconds.

To print a duplicate report, press the **copy** key. Before printing the copy, you may change the speed, gain, leads and report format.

NOTE: If lead failure occurs, the system will operate in automatic mode only if the override function is enabled in the setup menu.

MANUAL MODE

In manual mode, the system simultaneously records *1* or *3* (default) leads of ECG in real-time.

ARRHYTHMIA MODE

In arrhythmia mode, the system continuously scans the ECG and initiates a recording. Specific conditions trigger the recording, which continues as long as the condition(s) exist. These recordings include a 5-second period before the event. The first 30 seconds are recorded at the selected paper *speed*, then at 5 mm/s. When the **start/stop** key is pressed, the system prints two pages and then checks for conditions.
Conditions that initiate a recording are:

- A heart rate exceeding one of the set limit values.
- QRS complexes with an RR interval shorter than 0.8 times or greater than 1.5 times the RR interval averaged over the 4 preceding RR intervals.

Between events, you may initiate a 10-second recording with the **copy** key.

NOTE: In arrhythmia mode, the heart rate indication function is always active and cannot be disabled. Silence the audio signal emitted when the heart rate exceeds either limit by pressing **QRS beep**.

NOTES FOR MANUAL AND ARRHYTHMIA MODE ECGS

The following conditions apply to the system when operating in either manual or arrhythmia mode.

- If you change the paper speed, gain, lead group or filter settings during a recording, the system briefly stops, advances the paper to the next fold or a few millimeters and then resumes recording.

These settings can not be changed for the first two pages of recording in arrhythmia mode.

- Information can be lost following a change of device settings.
- If the *ADS* (Anti-Drift System) is enabled, there is a short delay to activate this function before recording starts.

Report documents

The length and scope of the reports can vary depending on the operating mode and selected lead and report format.

MEASUREMENT RESULTS

Following the ECG recording, the system prints one page of measurement results including patient information and recording details.

INTERPRETIVE STATEMENTS (OPTIONAL)

With the interpretive statements option active, the system prints an interpretive statement after the measurement results. Since it is not possible to enter a patient's age, the data is interpreted as an adult ECG.
For a detailed description of the ECG measurement and interpretation program, refer to the *12SL™ Physician's Guide*.

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MAC™ 400 Resting ECG Analysis System Maintenance Guide

The **MAC™ 400 Resting ECG Analysis System Maintenance Guide** provides maintenance and troubleshooting details for the device.

Cleaning and disinfecting exterior surfaces

Clean and disinfect exterior surfaces monthly, or more often as needed. To clean exterior surfaces:

1. Use a clean, soft cloth and an agent or disinfectant that contains alcohol and is commonly used in hospitals.

NOTE: Do not use disinfectants with a phenol base or peroxide compounds.

2. Wring excess water/solution from the cloth. Do NOT drip water or any liquid on the device and avoid open vents, plugs, or connectors.
3. Dry surfaces with a clean cloth or paper towel.

Patient cables and lead wires maintenance

Clean and disinfect cables and lead wires as specified and depending on activity.

CLEANING AND DISINFECTING PATIENT CABLES AND LEAD WIRES

1. Remove cables and lead wires from the system before cleaning.
2. Avoid pulling long wires from connector ends. Metal connections can be pulled away from the connectors.
3. To clean cables and lead wires, wipe using a lightly moistened cloth with mild soap and water. Then, wipe off excess moisture and allow to air dry.

CAUTION: EQUIPMENT DAMAGE, SIGNAL DETERIORATION — Any contact of disinfectant solutions with metal parts may cause corrosion. Avoid using disinfectant solution around the metal parts.

4. To disinfect cables and lead wires, wipe exterior with a soft, lint-free cloth. Use the following solution as recommended in the 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 above guidelines can be used.

NOTE: Wring excess disinfectant from the cloth before using.

5. Wipe off cleaning solutions with a clean, lightly-moistened cloth.
6. Dry thoroughly with a dry, lint-free cloth and let air dry for at least 30 minutes. Do not to let liquid "pool" around the connection pins.

NOTE: Drying times may vary based on environmental conditions. Do NOT use excessive drying techniques, such as oven, forced heat or sun drying.

STORING CABLES AND LEAD WIRES

- Store in a dry well-ventilated area.
- Vertically hang cables and lead wires.
- Do not coil lead wires or cables tightly around the device.

CLEANING AND DISINFECTING ELECTRODES

Clean reusable electrodes immediately after use on a patient.

1. Peel off the adhesive foil before cleaning the electrodes (any extra adhesive can be removed with benzene).
2. Use warm water and a small brush to remove cream or gel. Do not use pointed or sharp objects for cleaning.
3. Disinfect the electrodes with alcohol-free disinfectant. Ensure that connectors and sockets do not get wet.

NOTE: Discard disposable adhesive electrodes immediately after use. Do NOT reuse.

STERILIZING ELECTRODES

The only approved sterilization method is gas sterilization.
Sterilize with ethylene oxide gas (EtO) at a maximum temperature of 50° C/122° F. After EtO sterilization, follow the manufacturer's recommendations for required aeration.

NOTE: Frequent sterilization reduces the useful life of cables and lead wires.

Printer maintenance

CLEANING THE PRINTHEAD

If the printer is not functioning properly, you may need to clean dust and foreign particles from the printhead. To clean the printhead:

1. Separate the platen from the printer.
2. Gently wipe off the heating element part of the surface with cotton swabs and ethyl alcohol.
3. Replace the platen when it is completely dry.

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

REPLACING PAPER

The MAC 400 system uses z-fold writer paper pads. Optional roll paper can be ordered.

NOTE: Use only original GE writer paper.

This paper has a special coating that prevents contamination and debris collection on the printhead, and electrostatic buildup.
The thermosensitive layer and the printhead characteristics are exactly matched.
Using other paper may result in recordings of poor quality. The printhead may wear out prematurely, and use of other paper may void the warranty.

CAUTION: RISK OF SKIN BURNS — The printhead gets hot when recording. Do not to touch the thermal printhead when inserting the paper.

INSTALLING ROLL PAPER

The MAC 400 system comes with z-fold paper, but you can use the approved roll paper.

NOTE: You must change the system settings from *z-fold* to *roll* paper.

1. Open the printer door, locate the spindle and remove any leftover paper.
2. Slide the paper roll onto the spindle.
3. Place the roll, with the print side (red grid) facing the thermal printhead, into the compartment by fitting the spindle into the grooves on either side.
4. Unroll the beginning of the paper and close the door. Make sure that the paper is exactly positioned on the pressure roller and that the door locks into place on both sides.

STORING THERMAL PAPER

NOTE: To ensure maximum image life, store thermal paper separately in manila folders or polyester/polymide protectors.

To avoid deterioration or fading, follow these precautions:

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

Technical inspection

For safety, the equipment requires regular maintenance. To ensure functional and operational safety of the device, technical inspections should be performed annually by persons with adequate training and experience.
These checks can be carried out by GE within the framework of a service contract.
Inspections include the following checks:

- Visual inspection of equipment and accessories for signs of mechanical damage that may impair the device functions.
- Visual inspection of the device labeling for legibility.
- Functional test as described in the service manual.
- Measurement of the resistance of the non-fused, earthed conductor and the equivalent leakage current as per local regulations.

NOTE: The device does not require any other maintenance.

Order information

Always refer to the most recent list of accessories. For a complete list of MAC 400 system supplies and accessories, go to www.gehealthcare.com.

Disposal of the product

The product described in this guide must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.

WARNING: EXPLOSION HAZARD —

Batteries may explode in fires. Do not dispose of the battery by fire or burning.

Follow local environmental guidelines concerning disposal and recycling.

Error messages

Message	Cause	Solution
Paper Error	The system is out of paper. Paper jam. Wrong paper type inserted (z-fold/roll).	Check paper supply. Remove jammed paper. Set up the system for correct paper type. Clear message with
Door Open	Printer door not closed properly.	Close printer door correctly. Clear message with .
Battery Error	Battery not present. Battery not functioning properly.	Check for battery. Check that contacts are clean. Notify service to check and replace the battery. Clear message with
ATTENTION!!! Over-temperature	The printer mechanism has heated up due to heavy use.	Turn off device and power on after 3 to 4 minutes. If problem recurs with normal use, notify service.
Test failed! CODE: 1 VECTOR	Power on self-test failed.	Contact service and have device repaired before using it again.
Test failed! CODE: 2 RAM	Power on self-test failed.	Contact service and have device repaired before using it again.
Test failed! CODE: 4 ROM	Power on self-test failed.	Contact service and have device repaired before using it again.
Test failed! CODE: 5 DSP	Power on self-test failed.	Contact service and have device repaired before using it again.

Troubleshooting tips

These errors may occur while operating this system. If you perform the recommended actions and the condition remains, contact GE Service for assistance.

Problem	Cause	Solution
Periodic superimposition of AC line interface (*50*/*60* Hz) (See Figure 2)	Interference from the power line	Ground bed, verify position of the lead wires, switch on the *AC filter*.
Superimposition of irregular interference signals (See Figure 1)	Muscle artifact caused by patient movements, hiccup, coughing	The patient should be warm and resting comfortably (place cushions under arms and knees). Enable *muscle filter* (*20* Hz/*35* Hz), if necessary.
The printed date and time are incorrect.	Built-in lithium ion battery is depleted. The battery has a life of approximately 5 years.	Notify service to check the battery.
The **green LED** does not light up, although the recorder is connected to the power line.	Defective AC power adapter or fuse.	Notify service to check the fuses.
Recorder does not write over the entire paper.	Paper compartment not properly closed.	Printer door must lock into place on both sides.
No paper transport after activation of an operating mode or the recorder does not stop and continues to feed paper.	The paper pad was inserted in the wrong direction, so that the cue marker cannot be identified.	Insert the paper pad as instructed in the MAC 400 Resting ECG Analysis System Installation and Setup Guide.
Improper printing	Adhesion of dust and foreign materials to paper can deteriorate the life of the printer head and plate.	Clean the printhead as indicated in this guide.
Battery error	Internal system temperature may be higher than the recommended battery charging range. Faulty battery	Switch off the mains and restart recording in battery mode. (We recommend recording ECGs in battery mode and charging the battery when the system is not in use.) Notify service to check the battery.

BASELINE ROLL

PROBLEM

The MAC 400 system is equipped with automatic baseline adjustment and anti-drift system (*ADS*) to ensure artifact-free recording. At the beginning of the recording the automatic baseline adjustment verifies the incoming signal and adjusts the baseline position accordingly. During recording, the anti-drift system continuously checks the baseline position and returns the baseline to its normal level (See Figure 1).
If electrodes are not properly applied, these measures may not fully compensate for artifact. Electrodes applied without conductive gel may induce high polarization voltages that can cause the amplifier to overrange. A straight line is recorded instead of the ECG (see Figure 1). *ADS* returns this line to its normal position, and a baseline ensues for approximately one second.

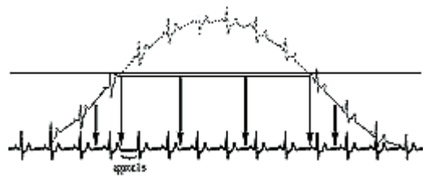

figure 1

SOLUTION

- Apply the electrodes according to instructions.
- Do not apply the electrodes on top of clothing.
- Use a contact agent (moist electrode paper, electrode cream, spray, etc.).
- Wait approximately 10 seconds before initiating a recording.The polarization voltages stabilize if the electrodes are properly applied. If not, the electrode concerned is indicated on the display (*R/RA, L/LA, F/LL, C1/V1 to C6/V6*).

NOTE: The system does not support lead fail indication for the *N/RL* electrode. If the ECG is extremely noisy, the *N/RL* electrode may not be properly connected. Check and reconnect.

If it becomes necessary to verify the raw ECG signal, switch off the *ADS* function and all filters (*35* Hz/*20* Hz *muscle filter*, *AC filter*). Activate the AC line filter (*50* Hz/*60* Hz) in the presence of strong AC line interference.

figure 2

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