MAC® 500
Version 2.2

Operator's Manual
2003361-004 USA Revision B

GE Medical Systems
Information Technologies

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GE Medical Systems
Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA
Tel: +1.414.355.5000
800.558.5120 (US only)
Fax: +1.414.355.3790

GE Medical Systems *Information Technologies* GmbH
Postfach 60 02 65
D-79032 Freiburg, Germany
Tel: +49.761.45.43.0
Fax: +49.761.45.43.233

Revision History

This manual is subject to the GE Medical Systems *Information Technologies (GEMS IT)* change order service. The revision code, a letter that follows the document part number, changes with every update of the manual.

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Headquarters

GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA
Telephone: 414.355.5000 or
800.558.5120 (US only)
Fax: 414.355.3790

Europe

GE Medical Systems *Information Technologies*
Postfach 60 02 65
D-79032 Freiburg Germany
Telephone: +49.761.4543.0
Fax: +49.761.4543.233

Australia

GE Medical Systems (Australia) Pty Ltd.
13 South Street
Rydalmere NSW 2116
Australia
Telephone: +61.2.9975.5501
Fax: +61.2.9975.5503

Japan

GE Medical Systems, Japan
67-4 Takakura-cho
Hachiojii-shi, Tokyo 192-003, Japan
Telephone: +81.42.648.2944
+0120-055-919 (toll free inside Japan only)
Fax: +81.42.648.2902

Hong Kong

GE Medical Systems Hong Kong Limited
11th Floor, The Lee Gardens
33 Hysan Avenue
Causeway Bay, Hong Kong
Telephone: +852.2100.6300
Fax: +852.2100.6292

Southeast Asia

GE Pacific
298 Tion Bahru Road #15-01/06
Central Plaza, Singapore 168730
Telephone: +65.277.7620
Fax: +65.277.7600

General Information

- Standards compliance:

  European Council Directive 93/42/EEC

  IEC60601-1-2/EN 60601-1-2 "Electromagnetic Compatibility - Medical Electrical Equipment"

  CISPR11 / EN 55011 "Radio interference emission"

  IEC 60601, protection class I

  MDD class IIb

- The symbol  means: Consult accompanying documents. It indicates points which are of particular importance in the operation of the device.
- The warranty does not cover damage resulting from the use of unsuitable accessories and consumables from other manufacturers.
- On request *GEMS IT* will provide a service manual.
- The *GEMS IT* quality management system complies with the standards EN ISO 9001 and EN 46001.

For your notes

For your notes

1 Introduction to the MAC® 500 System

The MAC® 500 is a compact 3-channel electrocardiograph for battery and line-power operation.

The MAC® 500 has three operating modes: 12 Lead, 3 Lead and Auto Rhythm, and meets all demands on modern electrocardiographs.

In the 12 Lead Mode the MAC® 500 simultaneously acquires 12 leads of ECG for a period of 10 seconds and then prints them out. You can choose between simultaneous and sequential recordings.

In simultaneous recordings all leads represent 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 4 segments of 2.5 seconds each. The first 3 recorded leads represent the first segment (0-2.5 seconds), the second group of 3 leads represents the second segment (2.5 to 5 seconds), etc.

You can choose between the standard lead sequence and the CABRERA sequence for the recording.

One version of the MAC® 500 comes with an ECG measurement program which, in the 12 Lead Mode, provides a patient data sheet with ECG measurement results (Figure 5-3).

With the Interpretation option activated, this version of the MAC® 500 will also print the interpretative statements after the measurement results (Figure 5-8).

In the 3 Lead Mode the MAC® 500 records 3 leads of continuous ECG data (or 1 lead, if the default setting is changed in the setup menu).

In the Auto Rhythm Mode the MAC® 500 will analyze the ECG and automatically starts recording

– when the heart rate exceeds the set upper or lower limit

– when QRS complexes are detected whose RR interval is shorter than 0.8 times or greater than 1.5 times the RR interval averaged over the 4 preceding QRS complexes.

The MAC® 500 continues recording until the triggering event ceases. The first 30 seconds are recorded at the selected speed, then the recorder switches to a paper speed of 5 mm/s.

Numerous device settings can be customized to meet each user's special requirements.

The device is not intended for intracardial use.

The device is not intended for use as a vital-signs physiological monitor.

Caution

Patient Hazard — Medical technical equipment such as the MAC® 500 must only be used by qualified and trained personnel.

Figure 1-1. The MAC® 500 system

2 Controls and Indicators

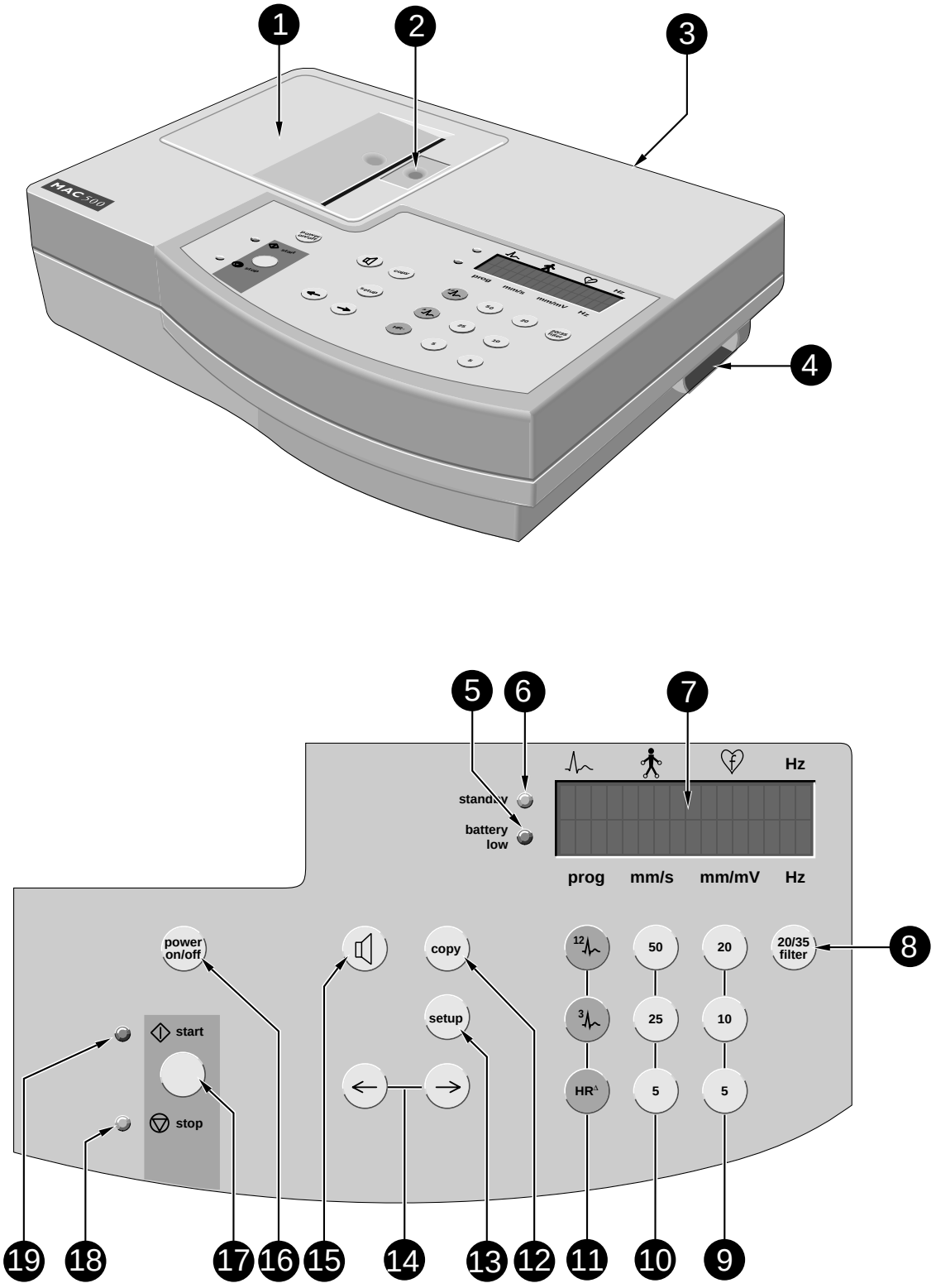


Figure 2-1. Controls and Indicators

1 *Cover of paper compartment*

2 *Spring lock to open the paper compartment*

3 *Power connector*

4 *Patient cable connector (type CF, highly insulated, defibrillation-proof)*

5 *"battery low" indicator (yellow): when it lights up, the battery needs to be charged*

6 *"standby" indicator (green): when it lights up, the MAC® 500 is connected to the mains and operates on line power*

7 *2-line character display*

8 *Enables/disables muscle filter (20/35 Hz)*

9 *Gain selection keys - 5, 10, 20 mm/mV*

10 *Paper speed selection keys - 5, 25, 50 mm/s (5 mm/s only in 3 Lead and Auto Rhythm Modes)*

11 *Mode selection keys*

12 *Prints additional report copies (e.g. after change of lead sequence) and the 10-second ECG in Auto Rhythm Mode*

13 *Displays the setup menu*

14 *ECG lead selection in 3 Lead and Auto Rhythm Modes, cursor control keys for navigating in the setup menu*

15 *Enables/disables QRS beep, silences audio signals*

16 *Power switch (ON/OFF)*

17 *Starts and stops the recorder in the selected mode*

18 *Yellow indicator is lit when selected mode is disabled*

19 *Green indicator is lit when selected mode is enabled*

Explanation of the signs and symbols used on the device


Observe the operator's manual


Type CF signal input, highly insulated, defibrillation-proof


Start


Stop


ECG lead


Lead-fail indicator


heart rate (BPM)


QRS beep/audio signals


Cursor control, lead selection


12 Lead Mode


3 Lead Mode


Auto Rhythm Mode

3 Safety Information, Startup and Performance Test

3.1 Safety Information

- This manual is an integral part of the device. It should always be kept near the device. Close observance of the information given in the manual is a prerequisite for proper device performance and correct operation and ensures patient and operator safety. **Please note that information pertinent to several chapters is given only once. Therefore, carefully read the manual once in its entirety.**
- To ensure patient safety, the specified measuring accuracy, and interference-free operation, we recommend to use only original *GEMS IT* components. The user is responsible for application of unsuitable accessories from other manufacturers.
- This manual is in conformity with the device specifications and standards on safety of electromedical equipment valid at the time of printing. All rights are reserved for devices, circuits, techniques, software programs, and names appearing in this manual.
- The terms danger, warning, and caution are used throughout this manual to point out hazards and to designate a degree or level of seriousness. Hazard is defined as a source of potential injury to a person.

Danger

indicates an imminently hazardous situation which, if not avoided WILL result in death or serious injury.

Warning

indicates a potentially hazardous situation which, if not avoided, COULD result in death or serious injury.

Caution

indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or product/property damage.

- *GEMS IT* is responsible for the effects on safety, reliability, and performance of the device, only if
  - assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by *GEMS IT*,
  - the electrical installation of the relevant room complies with the requirements of the appropriate regulations, and
  - the device is used in accordance with the instructions for use.

The safety statements presented in this chapter refer to the equipment in general and, in most cases, apply to all aspects of the device. There are additional safety statements in the other chapters which are specific to the topic described. The order in which safety statements are presented in no way implies order of importance.

DANGERS

EXPLOSION HAZARD — Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.

WARNINGS

ACCESSORIES (SUPPLIES) — Use only the original *GEMS IT* cables. Do not connect other signal sources to the cables. The user is responsible for the use of accessories from other manufacturers.

ACCIDENTAL SPILLS — To avoid electric shock or device malfunction liquids must not be allowed to enter the device. If liquids have entered a device, take it out of service and have it checked by a service technician before it is used again.

BEFORE USE — Before putting the system into operation visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately.

BEFORE USE — Before using the device, the operator must verify that it is in correct working order and operating condition. For instructions, refer to section 3.3 “Testing the Performance” in this chapter.

CONDUCTIVE CONNECTIONS — Do not allow electrodes to come into contact with conductive parts. The neutral electrode, in particular, must not be connected to earth.

DISCONNECTION FROM MAINS — When disconnecting the system from the power line, remove the plug from the wall outlet first. Then you may disconnect the power cord from the device.

MOISTURE CONDENSATION — Devices intended for emergency application must not be stored or transported at temperatures which cause moisture condensation at the application site. Wait until all moisture condensation has evaporated before using the device.

MPSO—The use of a multiple portable socket outlet (MPSO) for a system will result in an enclosure leakage current equal to the sum of all individual earth leakage currents of the system if there is an interruption of the MPSO protective earth conductor. Do not use an additional extension cable with the MPSO as it will increase the chance of the single protective earth conductor interruption.

OPERATOR — The user must have received adequate training in the use of the MAC® 500 and must be capable of applying it properly.

POWER SUPPLY — The device must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect the monitor from the power line and operate it on battery power, if possible.

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

CAUTIONS

MAINTENANCE — Regular preventive maintenance should be carried out annually, inspections of equipment with measuring functions should be done every two years (refer to chapter 12 “Cleaning, Disinfection and Maintenance”).

PERFORMANCE CHECKS — Check the device performance once a month, strictly following the instructions outlined in section 3.3 “Testing the Performance”.

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 this is not the case, do not connect the system to the power line until you adjust the unit to match the power source.

VENTILATION REQUIREMENTS — Set up the device in a location which affords sufficient ventilation. The ventilation openings of the device must not be obstructed. The ambient conditions specified in the technical specifications must be ensured at all times.

DEFIBRILLATOR PRECAUTIONS — 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 leadwires. Proper placement of defibrillator paddles in relation to the electrodes is required to ensure successful defibrillation.

DISPOSAL — Dispose of the packaging material, observing the applicable waste control regulations and keeping it out of children’s reach.

ELECTROCAUTERY PRECAUTIONS — To prevent unwanted skin burns, apply electrocautery electrodes as far as possible from all other electrodes, a distance of at least 15 cm/ 6 in. is recommended.

EMC — Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

INTERFACING OTHER EQUIPMENT — Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical engineering personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer’s instructions for use, and system standards IEC 60601-1-1/EN 60601-1-1 must be complied with.

NOTES

- The MAC® 500 is designed to comply with IEC 60601/ EN 60601 requirements. It is Class I equipment/equipment with a built-in rechargeable electrical power source. The device is not suitable for intracardiac use. The device is suitable for continuous operation.
- Choose a location which affords an unobstructed view of the monitor's screen and easy access to the operating controls.
- The MAC® 500 has no additional protection against ingress of water.
- Medical technical equipment such as the MAC® 500 must only be used by persons who have received adequate training in the use of such equipment and who are capable of applying it properly.
- At the end of its service life; the MAC® 500 and its accessories must be disposed of in compliance with the special waste control regulations for electronic parts. If you have any questions in this matter, please contact *GEMS IT* Medical Systems.

Literature

Medical Device Directive 93/42/EEC

EN 60601-1/1990 + A1: 1993 + A2: 1995: Medical electrical equipment. General requirements for safety

EN 60601-1-1/9.1994 + A1 12.95: General requirements for safety. Requirements for the safety of medical electrical systems. Requirements for the safety of medical electrical systems.

EN 60601-2-25/1993: Medical electrical equipment. Part 2: Special requirements for the safety of electrocardiographs.

IEC Publication 513/1994: Fundamental aspects of safety standards for medical equipment.

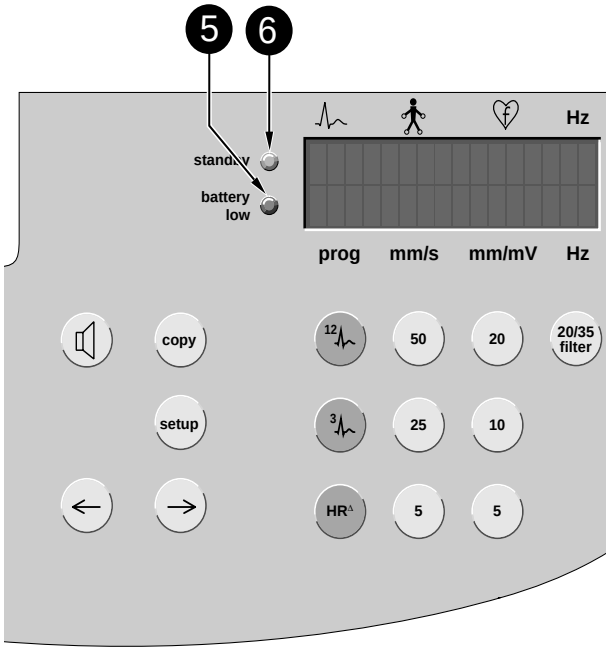


Figure 3-1. Indicators

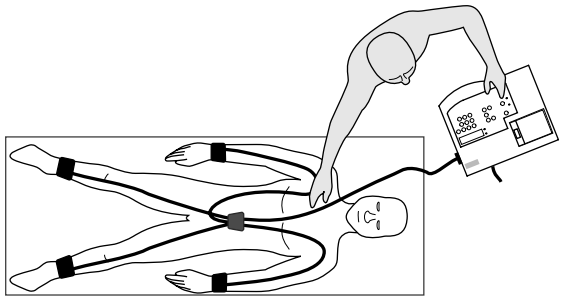


Figure 3-2. Arranging the MAC® 500 and examination couch

Figure 3-3. Power input

3.2 Starting Up the MAC® 500

Power Supply

– The MAC® 500 operates on line power or on power from the rechargeable battery.

– The battery is automatically charged when the device is connected to the power line (indicator **6** (Figure 3-1) is lit when the battery is charging). It is not necessary to turn the device on for charging. In order to have the battery fully charged at all times, leave the MAC® 500 connected to the power line. A depleted battery needs 6 hours to recharge.

– Indicator (**5**) lights up when the battery needs charging.

– A new, fully charged battery provides power to record at least 50 12 Lead ECGs. Have the battery replaced by a service technician when the capacity drops to about 25 recordings.

Starting Up and Connecting the MAC® 500

– The MAC® 500 must not be used or stored in moist and/or dusty rooms. Further, it must not be exposed to direct sunlight or other sources of heat.

– Figure 3-2 shows a practical arrangement between patient and recorder. For interference-free operation, it is important that the patient cable and the power cord do not run parallel.

- Use the power cord to connect the recorder to the power line (Figure 3-3). Use only the original power cord or an equivalent cable.

The MAC® 500 is shipped with a fully charged battery. Please note that the battery needs to be charged when the battery indicator (**5**) lights up.

- Insert writer paper as described in chapter 10.

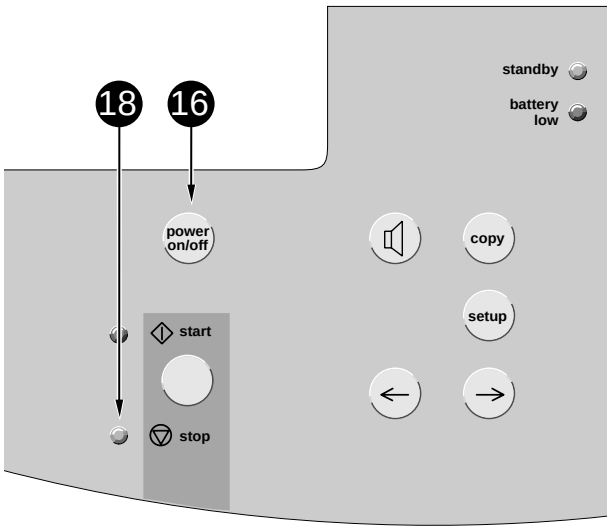


Figure 3-4. Operating controls and indicators

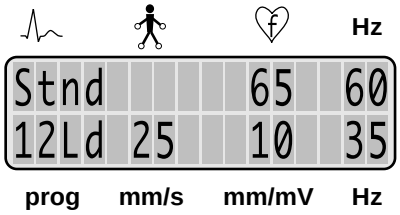


Figure 3-5. Display after successful MAC® 500 self-test

3.3 Testing the Performance

- Using the power switch (**16**), turn on the MAC® 500. The yellow indicator (**18**) lights up.

On power up the device runs an automatic self-test. It defaults to the 12 Lead Mode (Figure 3-5), unless a malfunction is identified. If a malfunction is detected, the system will display an error message. Contact *GEMS IT* Service for further information.

When a patient cable is not connected, two ^^ symbols appear on the display in place of the lead-fail indicator. Also, the MAC® 500 will emit an audio signal to inform you that the cable is missing.

The ^^ symbols on the display disappear as soon as you connect the cable. At the same time the lead-fail detection function is enabled. The MAC® 500 will again emit an audio signal and alert you to one of the missing electrodes, until a patient is connected. The audio signal can be silenced with .

After application of all required electrodes, the MAC® 500 automatically enables the HR indication function (chapter 8 "Heart-Rate Control").

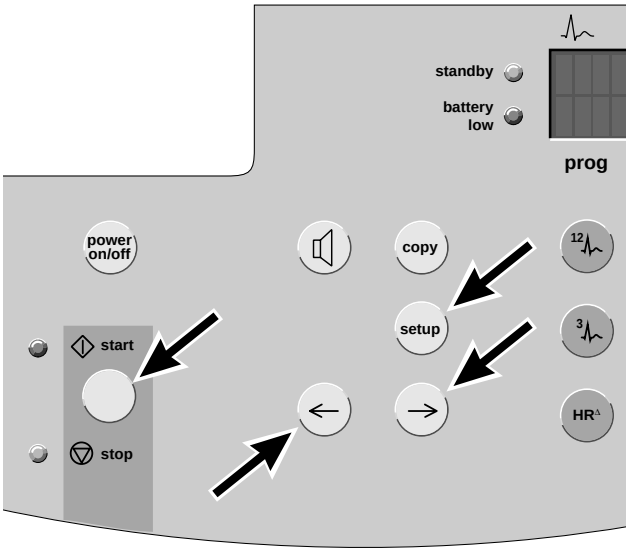


Figure 3-6. Controls required for language selection

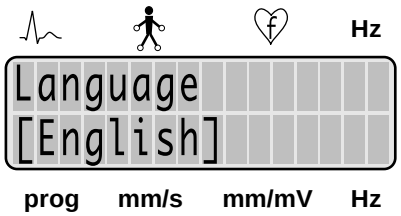


Figure 3-7. Selected language

3.4 Selecting the Language, Customizing the Recorder

Selecting the Language

For the displayed texts and reports you can choose among various languages.

- Press setup to display the language selection menu: Figure 3-7 will appear.
- Use the cursor keys ← → to select the language and confirm your selection with ◇▽.
- Exit the menu with setup.

Parameter	Default	Options
Language	[English]	further languages
Notation	[AAMI]	IEC
Leads	[Standard]	Cabrera
Report format	[Sequential]	Simultaneous
- when choosing "sequential" Rhythm lead	[Yes]	No
- when choosing "simultaneous"	[Short]	Long
Override Mode	[On]	Off
Patient Data sheet*	[No]	Yes
Leads	[3]	1
Speed	[25]	50
Sensitivity	[10]	5, 20
AC Filter	[60]	50, off
Muscle Filter	[On]	Off
Muscle Filter	[35]	20
ADS (cubic spline)	[On]	Off
HR Control	[On]	Off
HR-Control	[45], [130]	30 to 120, 80 to 240
Cut-off Frequency	[0.08]	0.04; 0.16
Contrast		< reduce, > increase
QRS Beep	[2] (medium)	0 (off), 1 (low), 3 (loud)
Date		
Time		
Option no.**	for "Interpretation" option	
Factory Defaults	[No]	Yes
Print	[No]	Yes (printout of all settings)

Figure 3-8. The MAC® 500 setup menu (on the display the active selections are shown in angular brackets [ ])

Customizing the Device Settings

The MAC® 500 allows you to customize numerous settings to suit your personal needs and preferences. The MAC® 500 will save these settings as the user defaults and will activate them each time it is turned on. Figure 3-8 lists all settings that can be customized, the middle column shows the factory defaults. Please refer to chapter 11 "The Setup Menu" for a detailed explanation of how to customize the device settings.

* not part of MAC® 500 with measurement program

** only for MAC® 500 with measurement program

4 Preparations for ECG Recording

4.1 Connecting the Patient Cable

The 10-lead cable is used for acquisition of the standard ECG leads (Standard, Augmented, Chest).

- Connect the patient cable to the ECG signal input (**4**, Figure 4-1).

When a patient cable is not connected, two ^^ symbols appear on the display in place of the lead-fail indicator. Also, the MAC® 500 will emit an audio signal to inform you of the missing cable.

The ^^ symbols disappear as soon as you connect the cable. At the same time the lead-fail detection function is enabled. The MAC® 500 will again emit an audio signal and alert you to one of the missing electrode, until a patient is connected. The audio signal can be silenced with . After application of all required electrodes, the MAC® 500 automatically enables the HR indication function (chapter 8 "Heart-Rate Control").

Warning

Shock Hazard — For reasons of safety, use only the original GEMS IT patient cables. Do not connect other signal sources to the cable.

Note

The signal input is highly insulated and defibrillation-proof (only if the original GEMS IT patient cables are used). These patient cables ensure patient safety and protect the device during defibrillation and electrosurgery.

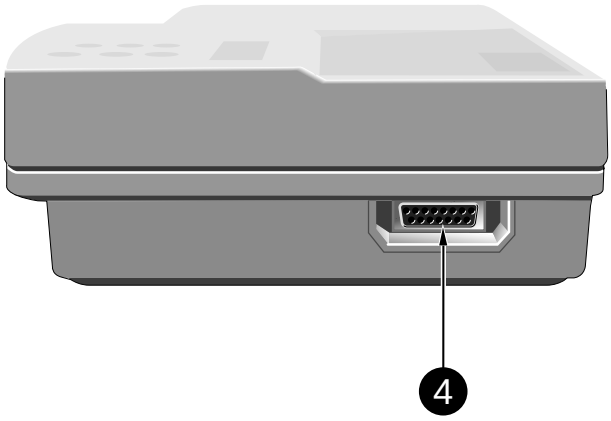


Figure 4-1. ECG signal input (type CF, highly insulated, defibrillation proof)

Note

Use silver-silver chloride electrodes when recording the ECG of a patient who may have to be defibrillated. (Refer to chapter 9 "ECG Recording During Defibrillation" for details.)

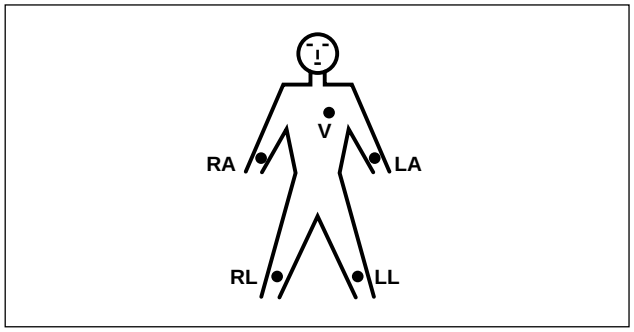


Figure 4-2. Applying limb-lead electrodes

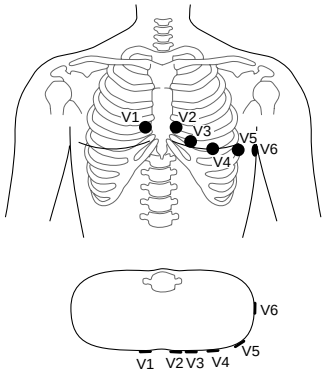


Figure 4-3. Chest electrode application points

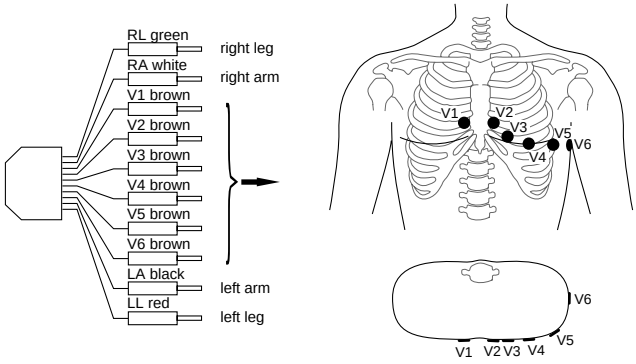


Figure 4-4. Connecting the patient cable (10-lead cable, standard leads)

4.2 Applying the Electrodes

Applying Electrodes (Limb Leads)

Careful application of the electrodes is the key to an interference-free ECG.

Refer to the illustration shown in Figure 4-2.

RA (white)	electrode on right arm
LA (black)	electrode on left arm
LL (red)	electrode on left leg
RL (green)	electrode on right leg

Applying Suction Electrodes (Thorax)

- Shave and clean application points, if necessary.

Application Points for Standard Leads (I, II, III, aVR, aVL, aVF, V1 to V6)

Four limb and six chest electrodes must be applied for the acquisition of the standard leads. Attach the limb electrodes above the wrists and ankles. Figure 4-3 shows the chest lead application points.

V1 in the 4th intercostal space at the right sternal edge

V2 in the 4th intercostal space at the left sternal edge

V3 on the level of the 5th rib midway between between V2 and V4

V4 in the 5th intercostal space on the left midclavicular line

V5 on the left anterior axillary line between V4 and V6

V6 on the mid-axillary line at the level of V4

Connect the 10-wire patient cable as shown in Figure 4-4.

Warning

Shock Hazard — Avoid contact between electrodes and conductive parts The neutral electrode, in particular, must not come into contact with ground.

Artifact Due to Poor Electrode Application

This device is equipped with state-of-the-art electronic utilities to insure artifact-free recording. Among these are the **automatic baseline adjustment** and the **anti-drift system** (ADS). 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 if it wanders (Figure 4-5).

When electrodes are not properly applied, these measures may not fully compensate for artifact. High polarization voltages induced by electrodes applied without conductive gel may cause the amplifier to overrange, so that a straight line will be recorded instead of the ECG (see Figure 4-5). ADS will return this line to its normal position, and a baseline ensues for approx. 1 second. Blocking can be initiated manually by disconnecting the RA electrode.

Remedy

- 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 approx. 10 seconds before initiating a recording. After the 10-second period the polarization voltages have stabilized, provided the electrodes are properly applied. If this is not the case, the electrode concerned is indicated on the display (RL, RA, LA, LL, V1 to V6).
- 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).

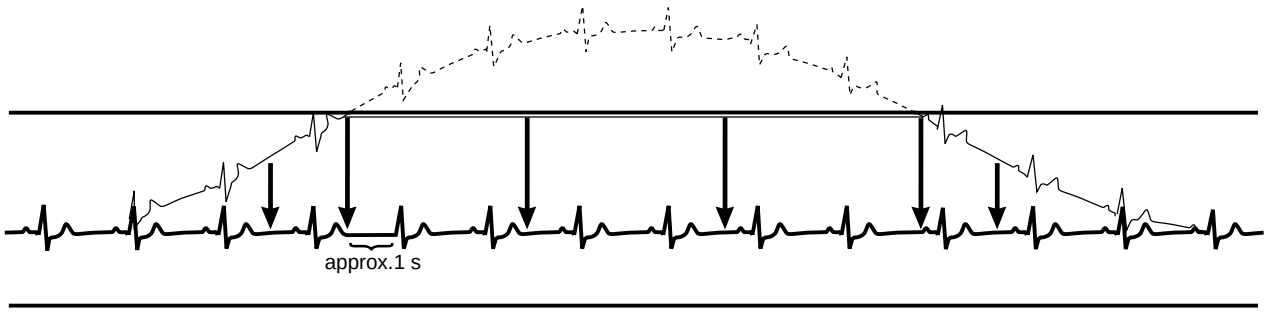


Figure 4-5. Sample recording

5 12 Lead Mode

5.1 The Basics

Note

- ***With the factory defaults unchanged, the HR indication function is active in all operating modes. The HR limit values are 45 BPM and 130 BPM. These limits can be changed from the setup menu. Further details on this subject can be found in chapter 8 "Heart-Rate Control" and chapter 11 "The Setup Menu".***
- ***At least 4 QRS complexes are required for correct determination of the heart rate.***
- ***In the presence of lead failure the MAC® 500 will operate in the 12 Lead Mode only if "Override" is enabled in the setup menu (chapter 11 "The Setup Menu").***

Warning

Patient Hazard — The MAC® 500 is not intended for use as a vital signs physiological monitor.

In the 12 Lead Mode the MAC® 500 simultaneously acquires 12 leads of ECG for a period of 10 seconds. When initiated with the ◇▽ key, the recording proceeds automatically. Furthermore it measures the ECG and documents the results on the ECG report.

You can choose between sequential and simultaneous recordings.

For sequential recordings the 10-second signal acquisition period is divided into 4 segments of 2.5 seconds each. The first 3 recorded leads represent the first segment (0-2.5 seconds), the second group of 3 leads represents the second segment (2.5 to 5 seconds), etc.

In simultaneous recordings all leads represent the same period of time (either 10 seconds = long format, or 3 seconds = short format).

You can choose between the standard and the CABRERA lead sequences for recording (chapter 11 "The Setup Menu").

With the factory defaults unchanged, the MAC® 500 will write a sequential 12 lead ECG followed by a rhythm strip (leads II, aVF, V5). The MAC® 500 with the optional measurement program will also print a patient data sheet including measurement results.

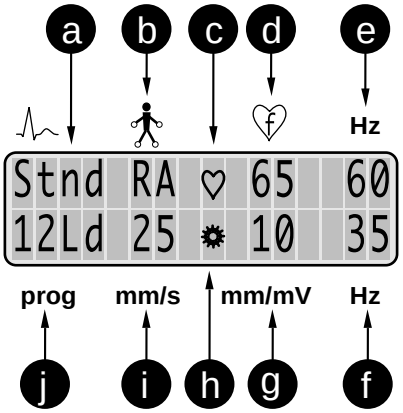


Figure 5-1. 12 Lead mode display

- ***a*** *Lead sequence (Stnd = standard, Cab1 = CABRERA)*
- ***b*** *Lead-fail indication*
- ***c*** *QRS indicator*
- ***d*** *Heart rate*
- ***e*** *AC line filter (60 Hz) enabled*
- ***f*** *Muscle filter (35 Hz) enabled*
- ***g*** *Gain*
- ***h*** *"Collecting Data" indicator*
- ***i*** *Paper speed*
- ***j*** *Operating mode*

****RA* right arm electrode disconnected***

****LA* left arm electrode disconnected***

****LL* left leg electrode disconnected***

****RL* right leg electrode disconnected***

****V1* chest electrode V1 disconnected***

****V2* chest electrode V2 disconnected***

****V3* chest electrode V3 disconnected***

****V4* chest electrode V4 disconnected***

****V5* chest electrode V5 disconnected***

****V6* chest electrode V6 disconnected***

Messages indicating disconnected electrodes

5.2 Recording

Upon power up, the MAC® 500 defaults to the 12 Lead Mode.

– Having first applied the electrodes, please wait about 10 seconds for the signal to stabilize (see "Artifact Due to Poor Electrode Application" in section 4.2).

With the factory defaults unchanged, the MAC® 500 selects the following functions and settings after power up (the most important settings are indicated on the display, Figure 5-1):

– the "Standard" lead sequence (I, II, III, aVR, aVL, aVF, V1 to V6; Stnd = Standard, Cab1 = CABRERA) - **a**

– a gain of 10 mm/mV - **g**

– a paper speed of 25 mm/s - **i**

– the AC line filter (60 Hz) is active - **e**

– the muscle filter (35 Hz) is active - **f**

– the anti-drift system (cubic spline) is enabled

– the report format is sequential and includes the rhythm leads (and patient data sheet – MAC® 500 with optional measurement program)

– pressing copy initiates repeated printouts of the ECG

– Before starting the recording with ◇▽, check that there is no lead-fail indication on the display - **b**, Figure 5-1. If the lead-fail message persists after you have checked the electrode connections, there could be a break in the patient cable and the cable should be replaced. Also check the paper supply.

– Press ◇▽ to initiate the recording.

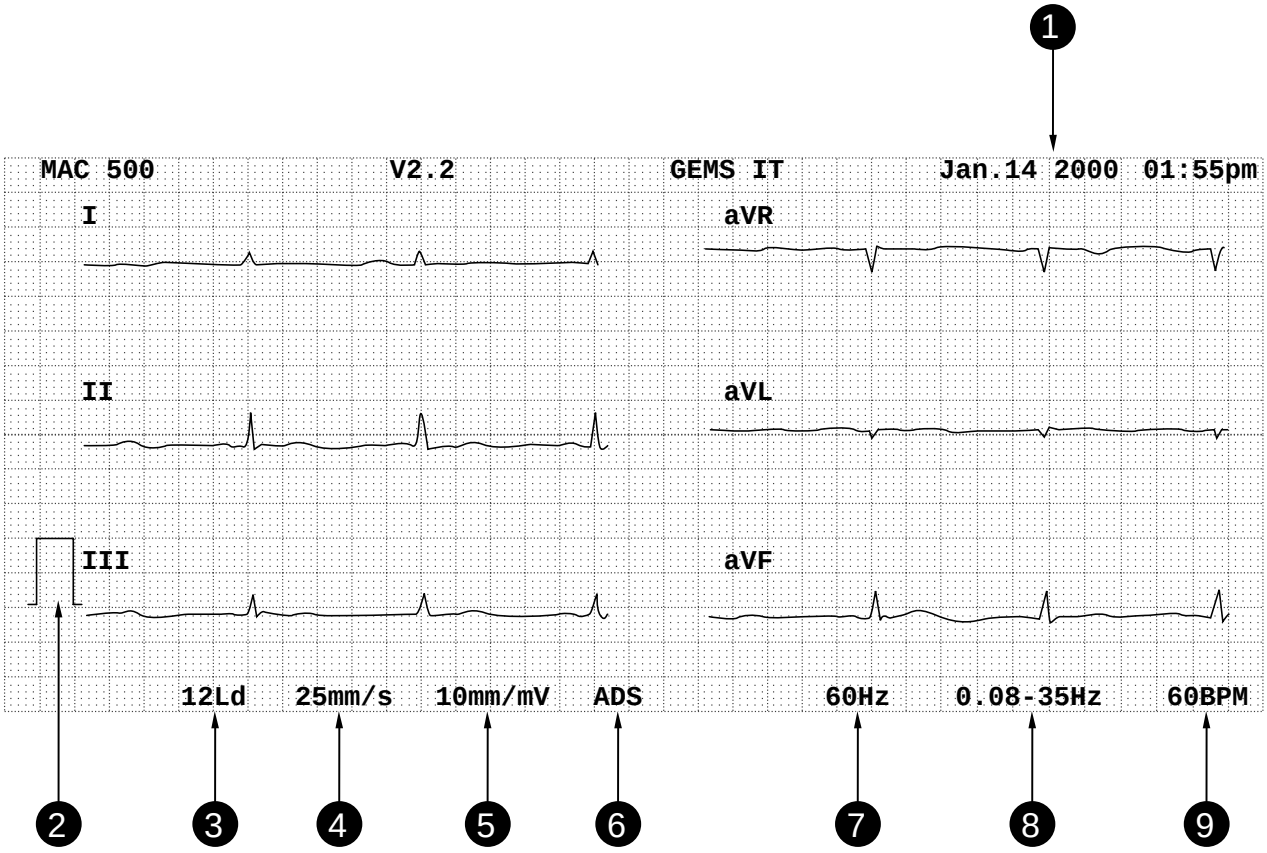


Figure 5-2. ECG recording (12 Lead Mode, factory defaults)

1 *Date/time*
2 *Calibration pulse*
3 *Operating mode*
4 *Paper speed*
5 *Gain*
6 *ADS enabled*
7 *AC filter enabled (60 Hz)*
8 *Signal transmission range (low cut-off frequency at 0.08 Hz - adjustable, high cut-off frequency at 35 Hz - muscle filter enabled)*
9 *Heart rate*

Note

The following parameters cannot be changed before printing out additional report copies

- ***AC line filter***
- ***muscle filter***
- ***ADS.***

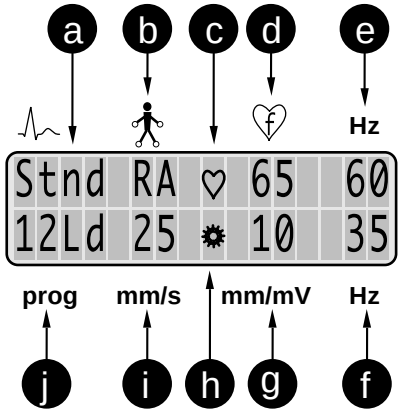


Figure 5-1. 12 Lead mode display (repeated)

- ***a*** *Lead sequence (Stnd = standard, Cab1 = CABRERA)*
- ***b*** *Lead-fail indication*
- ***c*** *QRS indicator*
- ***d*** *Heart rate*
- ***e*** *AC line filter (60 Hz) enabled*
- ***f*** *Muscle filter (35 Hz) enabled*
- ***g*** *Gain*
- ***h*** *"Collecting Data" indicator*
- ***i*** *Paper speed*
- ***j*** *Operating mode*

At the end of the data collection period, the MAC® 500 will record the ECG (Figure 5-2).

- The ECG recording can be stopped at any time with ◇▽.
- Copies of the same ECG can be printed out with copy. Before printing a copy you can
  - change the gain with ***mm/mV***,
  - change the paper speed with ***mm/s***,
  - change the sequence of recorded leads (← →). The display indicates the leads recorded first - **a**, Figure 5-1.

The normal lead sequence is "Standard"
Stnd = standard
Aug = augmented
V1-V3 = V1, V2, V3
V4-V6 = V4, V5, V6

or CABRERA
Cab1 = aVL, I, -aVR
Cab2 = II, aVF, III
V1-V3 = V1, V2, V3
V4-V6 = V4, V5, V6

When starting with the augmented leads, the recording sequence is

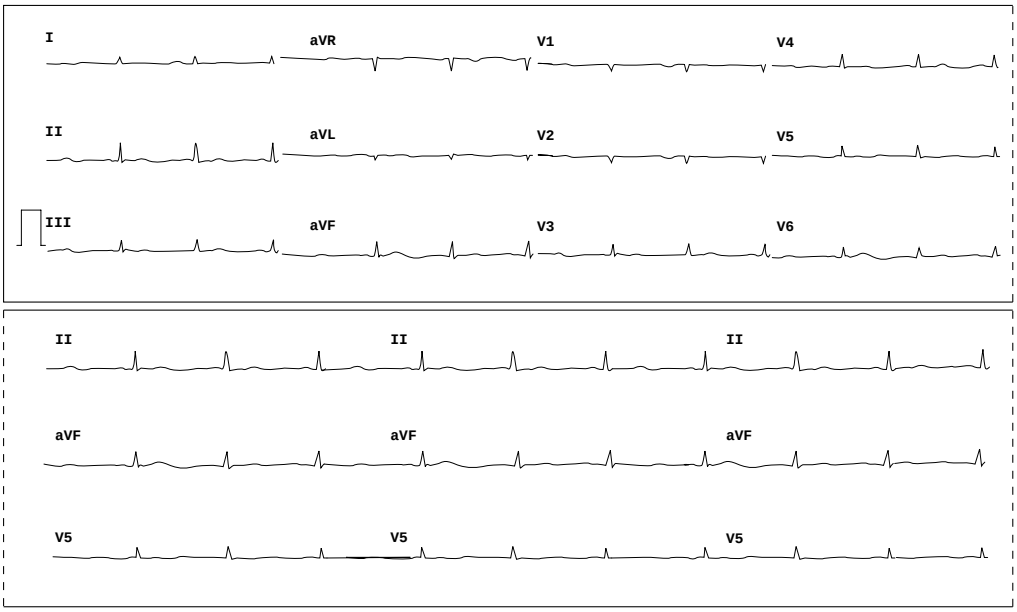
Aug = augmented
V1-V3 = V1, V2, V3
V4-V6 = V4, V5, V6
Stnd = standard

5.3 Report Documents

The length and scope of the reports depends on the selected lead sequence and on the selected report format (chapter 11 "The Setup Menu"). The illustrations below show examples of the default formats.

Sequential Recordings

In sequential recordings the standard leads are followed by the rhythm leads and, if you are using the MAC® 500 with the optional measurement program, the patient data sheet which includes the measurement results (Figure 5-3). Instead of the standard leads, the CABRERA lead sequence can be recorded (aVL, I, -aVR, II, aVF, III).




```
GEMS IT              Jan. 14 00 02:21pm
Serial No       :


Last Name       :
First Name      :
Date of Birth   :
Sex             :

Measurement Results:

QRS     :           108ms
QT/QTC  :     366 / 427ms
PR      :           170ms
P       :           162ms
RR/PP   :     724 / 146ms
P/QRS/T :   67/ 66/  65Degrees


MAC 500             V2.2      12SL V 13
```

Figure 5-3. Lead sequence standard
Report format sequential
(rhythm leads default — can be disabled; measurement results only with the MAC® 500 with optional measurement program)

Simultaneous Recordings

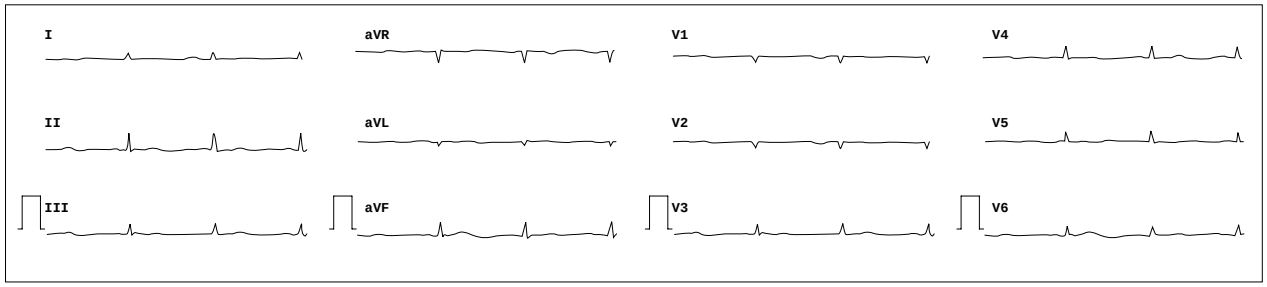


Figure 5-4. Lead sequence standard
Report format simultaneous, short (3 seconds)

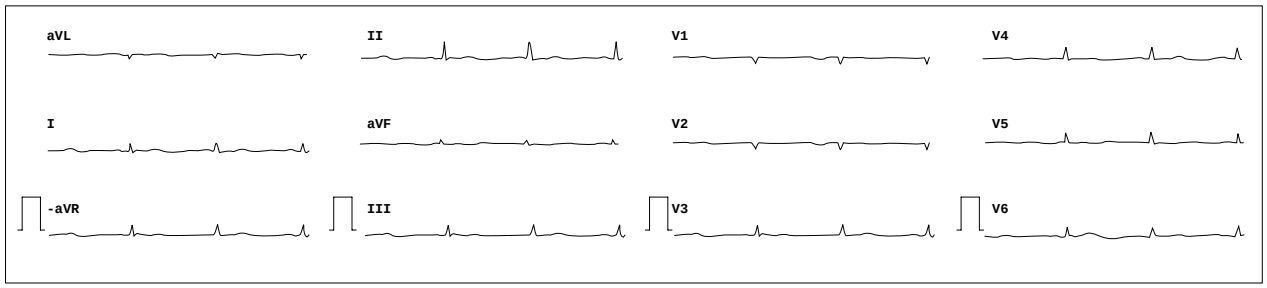


Figure 5-5. Lead sequence CABRERA
Report format simultaneous, short (3 seconds)

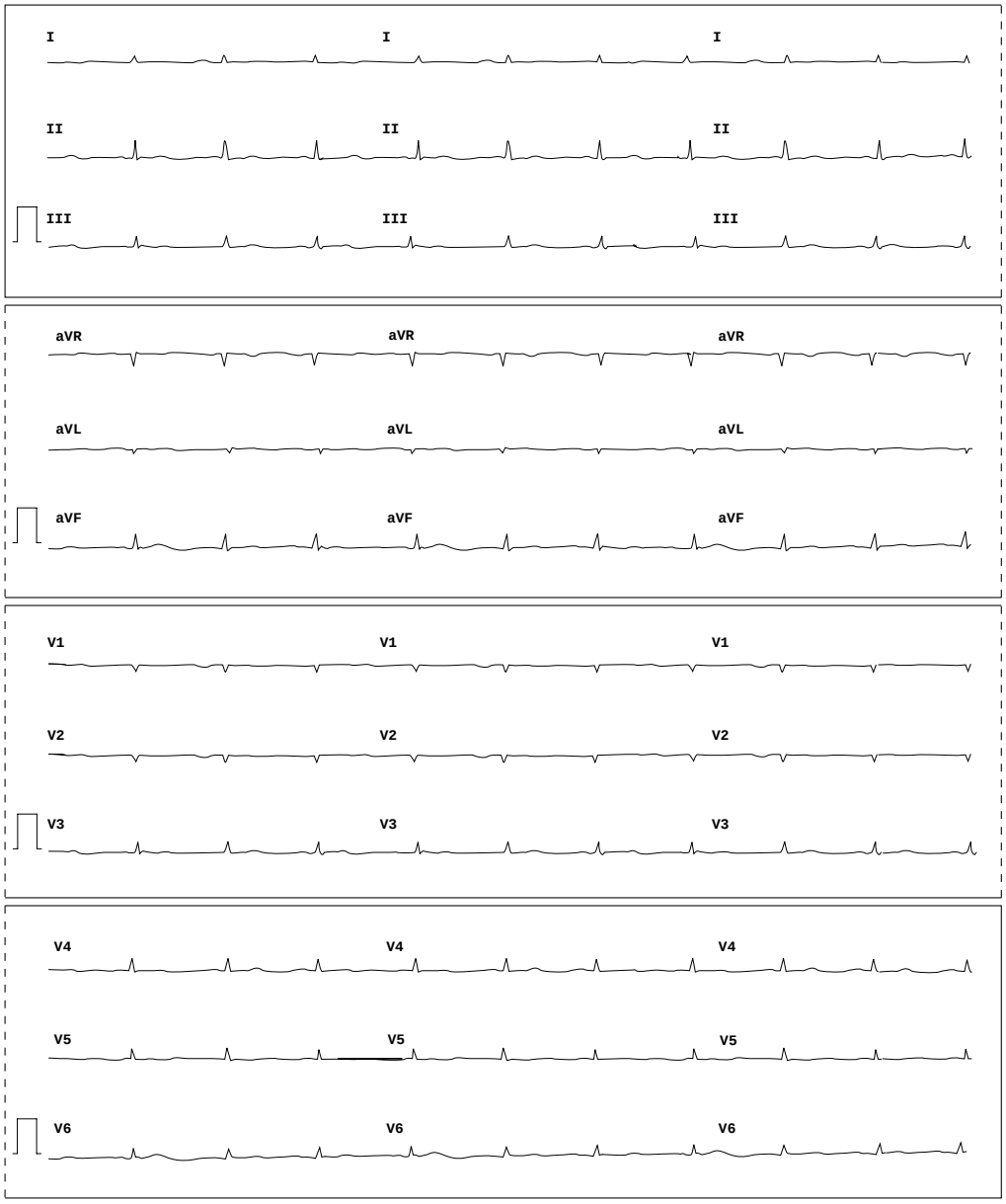


Figure 5-6. Lead sequence standard
Report format simultaneous, long (10 seconds)

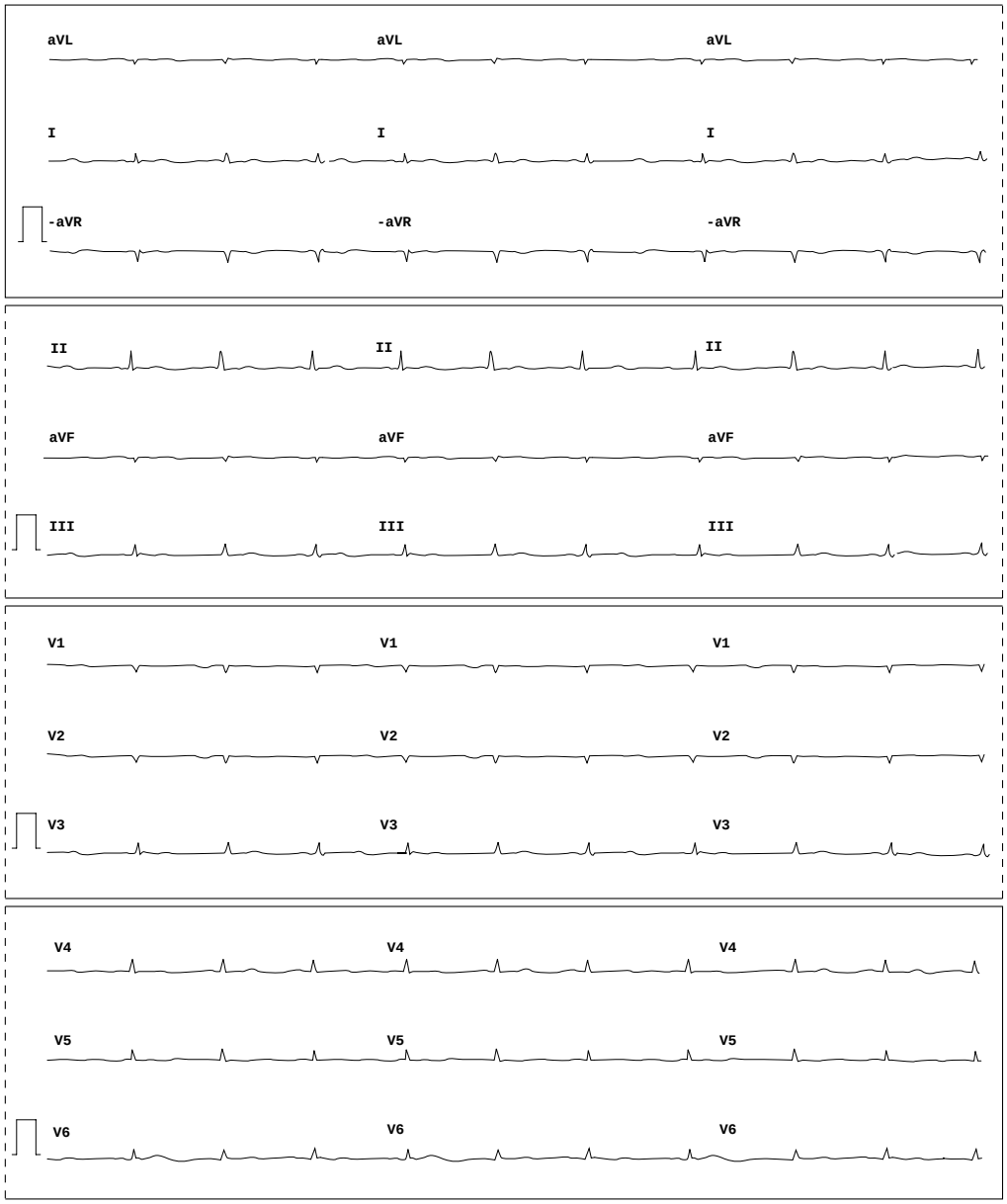


Figure 5-7. Lead sequence *CABRERA*
Report format *simultaneous, long (10 seconds)*

Recording of the Interpretative Statements (Option)

With the **Interpretation** option activated, the MAC® 500 will print the interpretative statements after the measurement results. Since it is not possible to enter the patient's age, the MAC® 500 always interprets data as an adult ECG.
For a detailed description of the ECG measurement and interpretation program, refer to our publication **GE Marquette 12SL Physician's Guide** (part no. 000-90160-010). In chapter 11 "The Setup Menu" you will find detailed information on activating the interpretation option.

```
GEMS IT              Jan.11 00  02:21pm

Interpretation:

Unusual P axis, possible ectopic
 atrial tachycardia
Left axis deviation
Left ventricular hypertrophy with
 QRS widening and repolarization
 abnormality
Inferior infarct, age undetermined
Abnormal ECG




MAC 500           V2.2      12SL V 13
```

Figure 5-8. Interpretation

5.4 Brief Operating Instructions (12 Lead Mode)

- Switch on device and wait for self-test to end
- Apply electrodes to the patient, connect patient cable to device
- Check device settings
  - lead sequence
  - report format

Modify device settings, if required, using the appropriate function key or setup

- Wait for patient to lie motionless
- Start signal acquisition and recording with 

6 3 Lead Mode

6.1 The Basics

Note

With the factory defaults unchanged, the HR indication function is active in all operating modes. The HR limit values are 45 BPM and 130 BPM. These limits can be changed from the setup menu. Further details on this subject can be found in chapter 8 "Heart-Rate Control" and chapter 11 "The Setup Menu".

In the 3 Lead Mode the MAC® 500 simultaneously records 3 leads of ECG in real-time (factory default, the device can also be set up to record one ECG lead). The recording is started and stopped with the key.

Some of the device settings can be customized, either directly with the appropriate key or from the setup menu (chapter 11 "The Setup Menu").

6.2 Recording

Warning

Patient Hazard — The device is not intended for use as a vital-signs physiological monitor.

Switch on the MAC® 500 and select the 3 Lead Mode with .

With the factory defaults unchanged, the MAC® 500 selects the following functions and settings (the most important settings are indicated on the display, Figure 6-1):

– the "Standard" lead sequence (I, II, III, aVR, aVL, aVF, V1 to V6; Stnd = Standard, Cab1 = CABRERA) - **a**

– a gain of 10 mm/mV - **g**, the setting can be changed any time with the gain keys - **9**, Figure 6-2

– a paper speed of 25 mm/s - **h**, the paper speed can be changed any time with the speed keys - **10**, Figure 6-2

– the AC line filter (60 Hz) is active - **e**

– the muscle filter (35 Hz) is active - **f**, it can be disabled any time with the muscle filter key - **8**, Figure 6-2

– the anti-drift system (cubic spline) is enabled

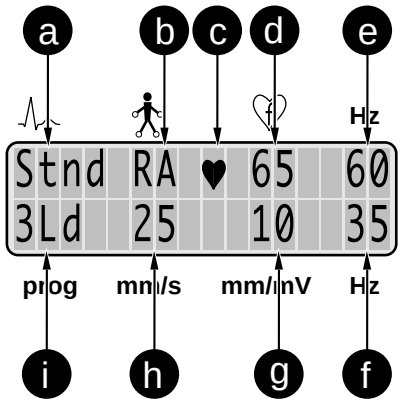


Figure 6-1. 3 Lead mode display

- ***a*** *Lead sequence*
- ***b*** *Lead-fail indication*
- ***c*** *QRS indicator*
- ***d*** *Heart rate*
- ***e*** *AC line filter (60 Hz) enabled*
- ***f*** *Muscle filter (35 Hz) enabled*
- ***g*** *Gain*
- ***h*** *Paper speed*
- ***i*** *Operating mode*

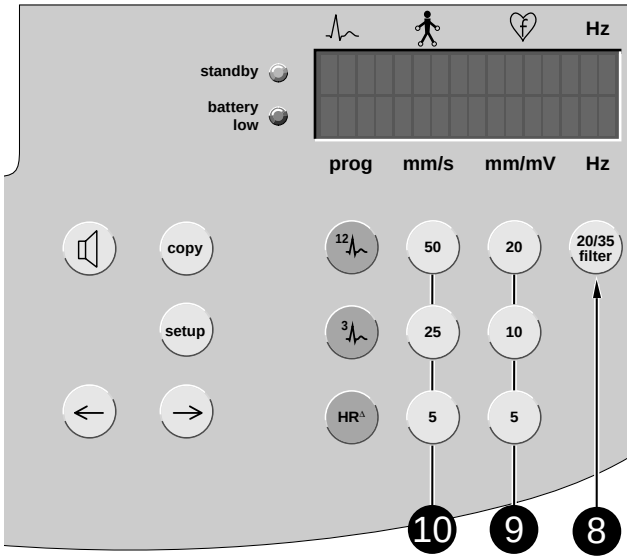


Figure 6-2. Controls and indicators

***RA* right arm electrode disconnected**
***LA* left arm electrode disconnected**
***LL* left leg electrode disconnected**
***RL* right leg electrode disconnected**
***V1* chest electrode V1 disconnected**
***V2* chest electrode V2 disconnected**
***V3* chest electrode V3 disconnected**
***V4* chest electrode V4 disconnected**
***V5* chest electrode V5 disconnected**
***V6* chest electrode V6 disconnected**

Messages indicating disconnected electrodes

– Before starting the recording with ◇▽, check that there is no lead-fail indication on the display - **b**, Figure 6-1. If the lead-fail message persists after you have checked the electrode connections, there could be a break in the patient cable and the cable should be replaced. Also check the paper supply.

- Press ◇▽ to initiate the recording. You can stop the recording by pressing the same key again.

– If you change the paper speed, gain, the lead group or the filter settings during a recording, the MAC® 500 briefly interrupts the recording, advances the paper and then resumes recording with the new settings.

– The arrow keys ← and → can be used to switch to the next 3 leads of the selected sequence.

– If the Anti-Drift System (ADS) is enabled, there will be a short delay before recording starts. The system needs this time to activate the ADS function.

6.3 Brief Operating Instructions (3 Lead Mode)

- Switch on device and wait for self-test to end
- Apply electrodes to the patient, connect patient cable to device
- Select 3 Lead Mode 
- Check device settings
  - lead sequence ()
  - speed (***50***, ***25***, ***5*** mm/s)
  - gain (***20***, ***10***, ***5*** mm/mV)

Modify device settings, if required, using the appropriate function key or  .

- Start recording with 
- Select next lead group with 
- Enable/disable muscle filter with 

7 Auto Rhythm Mode

7.1 The Basics

Warning

Patient Hazard — The MAC® 500 is not intended for use as a vital signs physiological monitor.

In the Auto Rhythm Mode the MAC® 500 continuously scans the ECG and initiates a recording, if it detects specific conditions. The event that triggers the recording is always documented with "context", since the MAC® 500 also records the 5-second segment preceding the event. The recording continues as long as the condition exists. The first 30 seconds are recorded at the selected paper speed, then the recorder selects a speed of 5mm/s.

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.

The default heart-rate limits are 45 BPM and 130 BPM. These limits can be changed from the setup menu. Further details on this subject can be found in chapter 11 "The Setup Menu". The heart-rate indication function can be disabled from the setup menu, but this would only affect the 12 Lead and 3 Lead Modes. The function cannot be disabled for the Auto Rhythm Mode.

The audio signal that the MAC® 500 emits when the heart rate exceeds either limit can be silenced with  (chapter 8 "Heart-Rate Control").

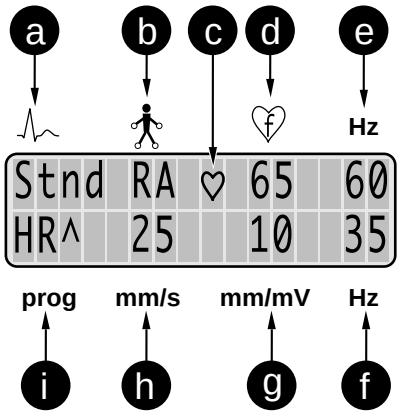


Figure 7-1. Auto Rhythm mode display

- ***a*** *Lead sequence*
- ***b*** *Lead-fail indication*
- ***c*** *QRS indicator*
- ***d*** *Heart rate*
- ***e*** *AC line filter (60 Hz) enabled*
- ***f*** *Muscle filter (35 Hz) enabled*
- ***g*** *Gain*
- ***h*** *Paper speed*
- ***i*** *Operating mode*

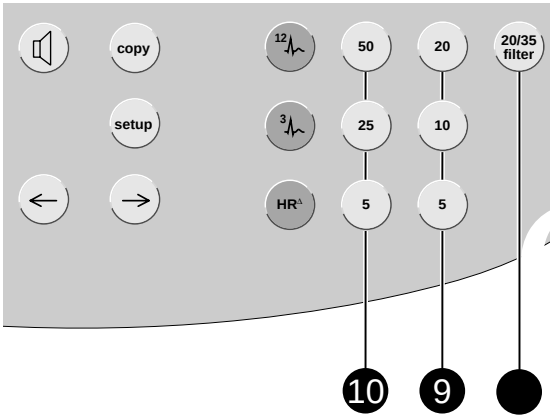


Figure 7-2. Controls and indicators

****RA* right arm electrode disconnected***
****LA* left arm electrode disconnected***
****LL* left leg electrode disconnected***
****RL* right leg electrode disconnected***
****V1* chest electrode V1 disconnected***
****V2* chest electrode V2 disconnected***
****V3* chest electrode V3 disconnected***
****V4* chest electrode V4 disconnected***
****V5* chest electrode V5 disconnected***
****V6* chest electrode V6 disconnected***

Messages indicating disconnected electrodes

7.2 Recording

- Switch on the MAC® 500 and select the Auto Rhythm Mode with HR^.

With the factory defaults unchanged, the MAC® 500 selects the following functions and settings (the most important settings are indicated on the display, Figure 7-1):

– the "Standard" lead sequence (I, II, III, aVR, aVL, aVF, V1 to V6 — as selected; Stnd = Standard, Cab1 = CABRERA) - **a**

– a gain of 10 mm/mV - **g**, the setting can be changed any time with the gain keys - **9**, Figure 7-2)

– a paper speed of 25 mm/s - **h**, the paper speed can be changed any time with the speed keys - **10**, Figure 7-2

– the AC line filter (60 Hz) is active - **e**

– the muscle filter (35 Hz) is active - **f**, it can be disabled any time with the muscle filter key - **8**, Figure 7-2

– the anti-drift system (cubic spline) is enabled

– Before starting the recording with ◇▽, check that there is no lead-fail indication on the display - **b**. If the lead-fail message persists after you have checked the electrode connections, there could be a break in the patient cable and the cable should be replaced. Also check the paper supply.

- Press ◇▽ to initiate the recording. You can stop the recording by pressing the same key again.

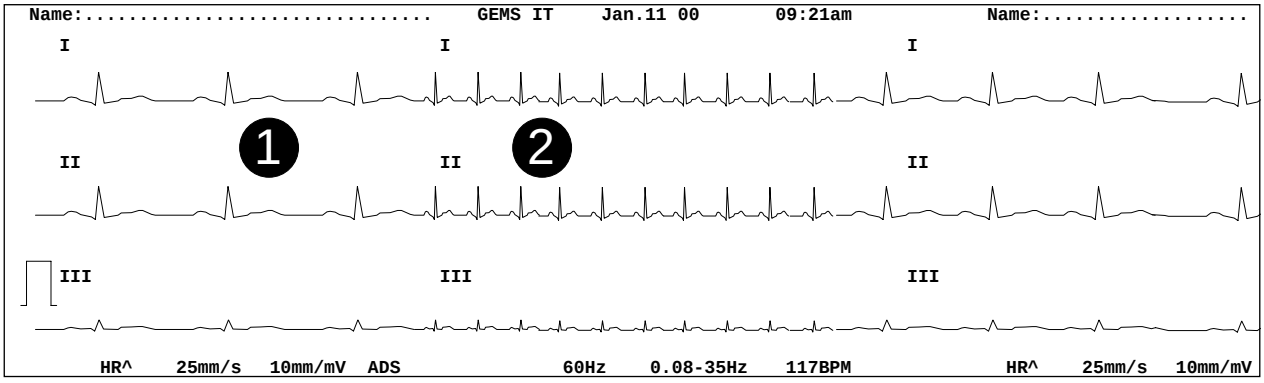


Figure 7-3. Auto Rhythm-recording

1 *History*

2 *Triggering event*

Upon program start, the MAC® 500 writes a 7-inch strip of the selected lead group. Then the recorder stops and starts analyzing the ECG. If the analysis algorithm detects one of the conditions described above, this event is recorded with a history of 5 seconds (Figure 7-3). The recording continues as long as the condition exists. The first 30 seconds are recorded at the selected paper speed, then the recorder selects a speed of 5 mm/s.

The recording can be stopped any time with the key. When there is no paper left in the recorder, the program stops automatically and the recorder will beep at 10-second intervals to alert the user to this condition.

Between events, a 10-second recording of the selected lead group can be initiated with copy .

If the heart rate exceeds one of the set limit values, the MAC® 500 emits an audio signal. This signal can be silenced with .

– If you change the paper speed, gain or the filter settings during a recording, the MAC® 500 briefly interrupts the recording, advances the paper and then resumes recording with the new settings.

– If the Anti-Drift System (ADS) is enabled, there will be a short delay before recording starts.

Note

The recording can be stopped any time with the key.

Warning

Patient Hazard — When there is no paper in the recorder, the program stops automatically and the recorder will beep at 10-second intervals.

Note

Information may be lost due to the pause following a change of the device settings.

7.3 Brief Operating Instructions (Auto Rhythm Mode)

- Switch on device and wait for self-test to end
- Apply electrodes to the patient, connect patient cable to device
- Select Auto Rhythm Mode - HR
- Check device settings
  - lead sequence - setup
  - speed (***50***, ***25***, ***5*** mm/s)
  - gain (***20***, ***10***, ***5*** mm/mV)

Modify device settings, if required, using the appropriate function key or setup

- Start program with ◇| and ▽
- Select lead group with ← →
- Enable/disable muscle filter with 20/35 filter

8 Heart-Rate Control

Warning

Patient Hazard — The MAC® 500 is not intended for use as a vital signs physiological monitor.

The Basics

The MAC® 500 will control the heart rate in all operating modes, even when not recording. This automatic control function can be disabled from the setup menu (chapter 11 "The Setup Menu"). It is also possible to modify the heart-rate limits. The factory defaults are 45 and 130 BPM.

If the heart rate exceeds one of the set limit values, the MAC® 500 will emit an audio signal (alternating beep).

This audio signal will cease

– automatically when the heart rate returns to the permitted range

– when you press the key.

The audio signal will not recur if it was silenced with . Only when the heart rate exceeds one of the limit values anew, will the audio signal recur.

Selecting HR Limit Values

- Press setup.

Figure 8-1 will appear.

- Keep pressing until the display shown in Figure 8-2 appears.

The cursor flashes on the low limit value. Using the cursor keys ← →, you can change this value in steps of 5 BPM between 30 and 120 BPM.

- Press to confirm your selection, or to skip this menu option.
- Adjust the high limit value in the same way (between 80 and 240 BPM).
- Again, confirm the entry with .
- Press setup to exit the menu.

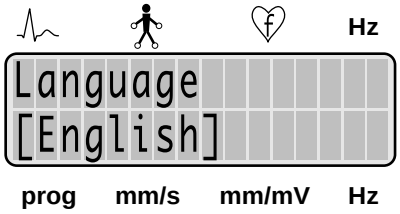


Figure 8-1. Language selection menu

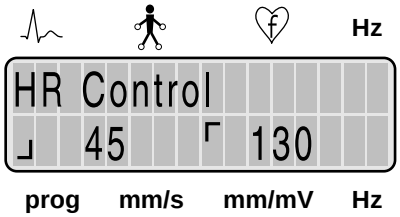


Figure 8-2. HR limit menu

9 ECG Recording During Defibrillation / ECGs of Pacemaker Patients

ECG Recording During Defibrillation

The patient signal input is defibrillation-proof. Therefore it is not necessary to remove the patient cable during defibrillation.

When using stainless steel or silver electrodes, however, the defibrillator discharge current may cause complete polarization at the electrode/skin interface. This will block acquisition of the ECG signal for several minutes. You can avoid this effect by using silver/silver-chloride electrodes.

Select the 3 Lead Mode, if defibrillation is carried out during ECG recording and disable the anti-drift system as it causes a signal delay of approx. 4 seconds (chapter 11 "The Setup Menu").

If electrodes made of other materials are used, we recommend disconnecting the patient cable from the recorder while the shock is delivered.

Warning

- ***Shock Hazard — For safety reasons, use only the original GEMS IT patient cables. Before connecting the cable to the device, check it for signs of mechanical damage. Do not use a damaged cable.***
- ***Shock Hazard — Observe the safety information given in the operator manual of the defibrillator used.***
- ***Shock Hazard — During defibrillation, do not touch the patient, the electrodes or the leadwires.***

Caution

Patient Hazard, Equipment Damage — The patient signal input of the device is protected against damage from defibrillation voltages. Nevertheless, caution is advised when using defibrillators at the same time as other equipment connected to the patient.

ECGs of Pacemaker Patients

Due to the slow paper speed it is not possible to display pacing pulses directly on the ECG recording. At a paper speed of 50 mm/s and a pulse duration of just 0.5 ms, the width of the recorded pacing pulse would be a mere 0.025 mm.

For this reason the MAC® 500 adapts the pulse amplitude and pulse width for recording, so that the pacing pulse is easier to identify. The MAC® 500 records the pulse with the correct polarity and a width of 5 ms. The pulse amplitude is the same in all leads (depending on the polarity of the pacing pulse in leads I and II, the pacing pulse in lead III may be suppressed). The charge reversal waveform may differ slightly between leads. Figure 9-1 shows an ECG recording with pacing pulses.

Warning

Patient Hazard — If several adverse conditions exist at once, the possibility that the pacer pulses are interpreted (and counted) as QRS complexes should be considered. At the same time, however, QRS complexes might be suppressed in certain situations. Therefore, pacemaker patients should always be watched closely.

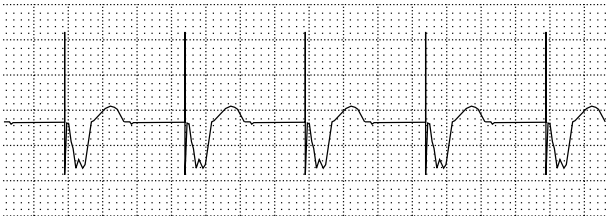


Figure 9-1. ECG recording with pacing pulses

10 Loading Writer Paper

Note

Use only the original GEMS IT writer paper. This paper is specifically designed to prevent electrostatic build up and debris collection on the thermal array printhead. Using other papers may result in recordings of poor quality and/or premature wear of the printhead. Use of other paper may void the warranty.

Caution

Risk of Skin Burns — Take care not to touch the thermal printhead when inserting the paper. After prolonged periods of recording there is a risk of skin burns.

- Switch on the device.
- Press on the spring lock of the paper compartment to open the door (Figure 10-1).
- Remove the sleeve of the previous paper roll and the plastic axle.
- Slide new roll on axle and insert as shown in Figure 10-2.
- Unroll a length of paper and close the door (Figure 10-3), taking care that the paper is exactly positioned on the pressure roller and that the door locks into place on both sides.

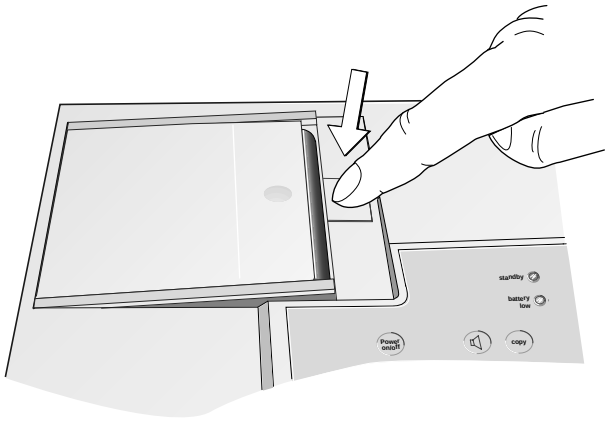


Figure 10-1. Opening the paper compartment

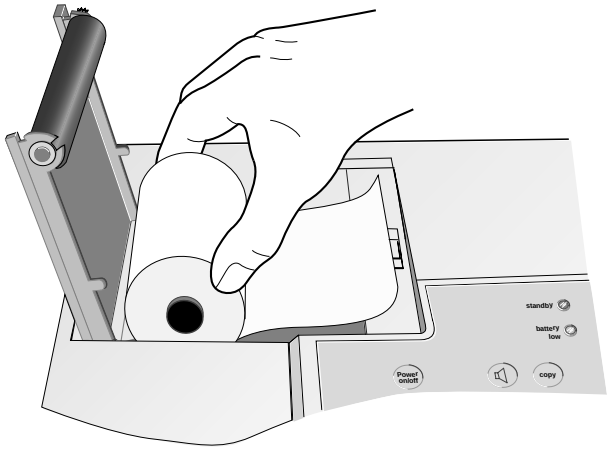


Figure 10-2. Inserting the new pad

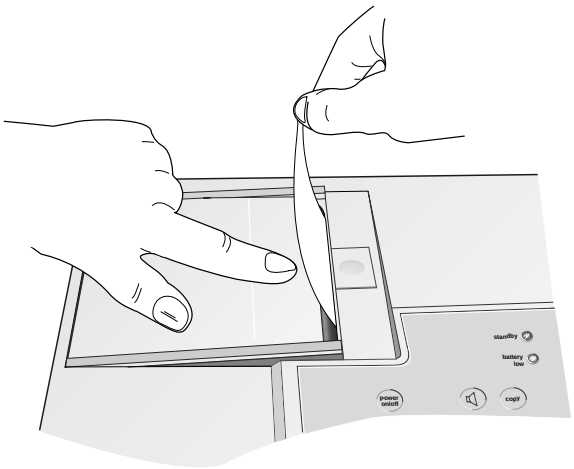


Figure 10-3. Closing the paper compartment

End-of-Paper Indication

The last 10 feet of the paper roll are marked.

Aging Stability

The standard ECG writer paper CONTRAST® is designed to guarantee full contrast for a period between 3 and 5 years if it is handled as described below before and after recording:

- Store the paper in suitable rooms at a temperature between 18 °C and 24 °C/65 °F and 75 °F and a relative humidity between 40 % and 60 %.
- Avoid direct contact of the paper with
  - carbon and carbonless forms
  - chart papers and adhesives containing tributyl phosphate, dibutyl phthalate, or any other organic solvents
  - document protectors, envelopes, and sheet separators containing plasticizers.
    Caution: The above components may also be found in recycled papers.
  - solvents or solvent-based products containing alcohols, ketones, esters, or other substances from this chemical group.
- We recommend archiving ECG recordings on our ECG filing cards only (P/N 217 043 03).
- If longer storage periods are required, we suggest using our ARCHIVIST 30 writer paper (image legibility up to 30 years) or other image storage technologies.

Error Message

When the message "Paper Problem" appears

- press  to clear the message
- verify the paper supply and check that the paper compartment is correctly closed

Parameter	Default	Options
Language	[English]	further languages
Notation	[AAMI]	IEC
Leads	[Standard]	Cabrera
Report format	[Sequential]	Simultaneous
- when choosing "sequential" Rhythm lead	[Yes]	No
- when choosing "simultaneous"	[Short]	Long
Override Mode	[On]	Off
Patient Data sheet*	[No]	Yes
Leads	[3]	1
Speed	[25]	50
Sensitivity	[10]	5, 20
AC Filter	[60]	50, off
Muscle Filter	[On]	Off
Muscle Filter	[35]	20
ADS (cubic spline)	[On]	Off
HR Control	[On]	Off
HR-Control	[45], [130]	30 to 120, 80 to 240
Cut-off Frequency	[0.08]	0.04; 0.16
Contrast		< reduce, > increase
QRS Beep	[2] (medium)	0 (off), 1 (low), 3 (loud)
Date		
Time		
Option no.**	for "Interpretation" option	
Factory Defaults	[No]	Yes
Print	[No]	Yes (printout of all settings)

Figure 11-1. The setup menu and menu options

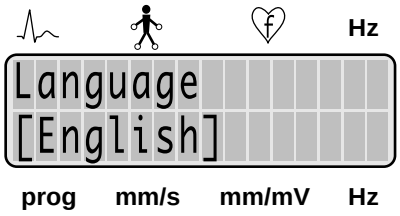


Figure 11-2. Language selection menu

* not part of MAC® 500 with measurement program

** only for MAC® 500 with measurement program

11 The Setup Menu

From the setup menu many of the MAC® 500 settings can be customized. The MAC® 500 will save these settings as the user defaults and will activate them each time it is switched on. Angular brackets [ ] mark the selected option on the display. Figure 11-1 lists all settings that can be customized and the available options.

- Press setup to display the setup menu.

The first menu item is the language (Figure 11-2).

Selection of a setting is always done in the same way:

- use the cursor keys ← → to move the cursor to the desired setting and
- confirm your selection with ◇▽.

The cursor moves automatically to the next menu item. You can also press ◇▽ to skip a menu item. You can exit the setup menu with setup .

Language
lets you select the language

Notation (Electrode Designation)
AAMI: RA, LA, RL, LL, V1 to V6
IEC: R, L, F, N, C1 to C6

Leads

standard (10-lead cable):	I, II, III, aVR, aVL, aVF, V1 to V6
CABRERA (10-lead cable):	aVL, I, -aVR, II, aVF, III, V1 to V6

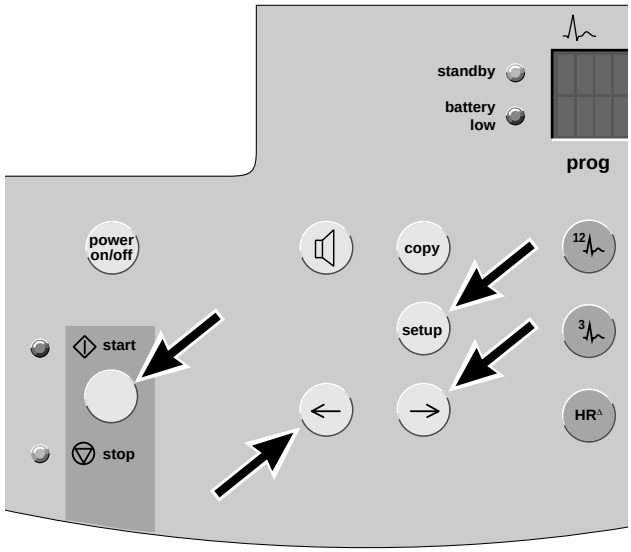


Figure 11-3. Recorder setup keys

Report Format

The MAC® 500 collects the 12 standard leads for 10 seconds and saves them. Then the leads are recorded in 4 groups of 3 leads each. For the simultaneous report format, all recorded leads reflect the same period of time: long format = 10 seconds, short format = 3seconds. On the sequential reports, the 10-second period is divided into 4 segments of 2.5 seconds each: the first 3 leads reflect the first quarter of the 10-second period, the second group of 3 leads, the second quarter and so on. The sequential report is followed by the rhythm leads (II, aVF, V5) and by the patient data sheet which includes the measurement results.

Override

After actication of the START key, the MAC® 500 will record a resting ECG, even if one or more ECG leads are impaired by lead failure. Lead failure may be caused by disconnected electrodes or inadequate electrode application. When the system detects lead failure, a message informing the user of poor signal quality will be annotated on the recording. Furthermore, system with interpretation capability will print a message indicating that the measuring results and interpretation may be incorrect.

Patient Data Sheet

In the 12 Lead Mode, a patient data sheet which is without measurement results can be added to the report. You can measure the ECG manually and annotate the measuring values on the patient data sheet.

Leads

Number of leads recorded in 3 Lead Mode: 1 or 3

Speed

Paper speed 25 or 50 mm/s

Sensitivity (gain)

5, 10 or 20 mm/mV

AC Filter
Suppression of AC line interference:
50 Hz = AC line filter Europe
60 Hz = AC line filter USA

Muscle Filter
Suppression of muscle artifact: filter on or off

Muscle Filter
Selection of the muscle filter frequency:
20 Hz or 35 Hz

> **Note**
>
> ***Please note that filters may suppress diagnostically relevant portions of the signal. Filters should therefore only be enabled if necessary.***

ADS (anti-drift system – cubic spline)
In case of wandering baselines the anti-drift system restores the baseline to its original position. ADS causes a signal delay of 4 seconds.

HR-Control
Enables/disables the HR indication function. When the function is disabled, the MAC® 500 switches off automatically when no key is activated for 5 minutes.

HR-Control
For selection of the heart-rate limit values (in steps of 5 BPM). ← reduces the value, → increases it. Adjustment ranges: 30 to 120 BPM and 80 to 240 BPM.

Cut-off Frequency
For selection of the lower cut-off frequency of the signal transmission range: 0.04, 0.08 or 0.16 Hz.

Contrast
→ : increases contrast

← : reduces contrast

Date
Adjust date with ← →, confirm with 

Time
Adjust time with ← →, confirm with 

Option no.
In order to activate the optional "Interpretation" function, enter the option code shown on the option code sheet. Do not enter any blanks. If the number is correct the option will be activated and the menu item will not appear any more.

Factory Defaults
Allows you to restore the factory default settings (Yes)

Print
To obtain a printout of all device settings (Yes)

12 Cleaning, Disinfection and Maintenance

Cleaning and Disinfecting the Recorder Housing

Warning

Shock Hazard — Disconnect the device from the power line before cleaning or disinfecting its surface.

Caution

Equipment Damage — Liquids must not be allowed to enter the device. Devices into which liquids have entered must be immediately cleaned and checked by a service technician, before they can be reused.

Equipment Damage — The MAC® 500 has no additional protection against ingress of water.

- Wipe the monitor clean with a moist cloth. Do not let liquid enter the monitor. All cleaning agents and disinfectants that contain alcohol and are commonly used in hospitals are suitable (exception: disinfectants on a phenol base or peroxide compounds).

Cleaning and Disinfecting the Patient Cable

- Disconnect the cable from the recorder before cleaning or disinfecting it. When disconnecting the cable, be sure to pull on the connector, not on the cable.
- **Clean** the cable by rubbing it down with a cloth moistened with soap water. Use a disinfectant for **disinfection**. Do not immerse the cable in liquid.

Handling Electrodes

- Discard disposable electrodes immediately after use to prevent that they are reused.

Maintenance

Checks before each use

Before each use, visually inspect the device, the leads and electrodes for signs of mechanical damage.

If you detect damages or impaired functions that may adversely affect the safety of the patient or user, do not use the device before it has been repaired.

Technical Inspections

For safety, the devices require regular maintenance. To ensure functional and operational safety of the MAC® 500 units, Technical Inspections should be carried out on an annual basis.

These checks should be performed by persons with adequate training and experience.

The checks can be carried out by *GEMS IT* within the framework of a service agreement. The inspections include the following checks:

- Visually inspect the device and the accessories for signs of mechanical damage that may impair the device functions.
- Check that all device labeling relevant for safety is legible.
- Run a performance test as described in the operator's manual.
- Measure the resistance of the non-fused, earthed conductor and the equivalent leakage current as per local regulations.

The device does not require any other maintenance.

13 Troubleshooting

Symptom	Cause	Remedy
Periodic superimposition of AC line interference (60 Hz) (Figure 13-1)	Interference from the power line	Ground bed, verify position of the leadwires, switch on AC line filter
Superimposition of irregular interference signals (Figure 13-2)	Muscle artifact caused by patient movements, hiccup, coughing	The patient should be warm enough and resting comfortably (place cushions under arms and knees). Comfort or distract patient, enable muscle filter (20 Hz / 35 Hz), if necessary.
The printed date and time are incorrect	Built-in lithium battery is depleted. The battery has a life of approx. 5 years.	Notify service to check and/or replace battery
The green "standby" indicator **6** does not light up, although the recorder is connected to the power line	Defective AC power adapter or fuse	Notify service to check and/or replace fuse
The recorder does not write over the entire paper width	Paper compartment not properly closed	Paper 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 writer paper was inserted the wrong way round, so that the queue mark cannot be identified.	Insert the paper as instructed (chapter 10).
Message "Paper Problem"	The MAC® 500 is out of paper Paper jam Paper compartment not properly closed	Check paper supply Remove jammed paper Close paper compartment correctly Acknowledge message with

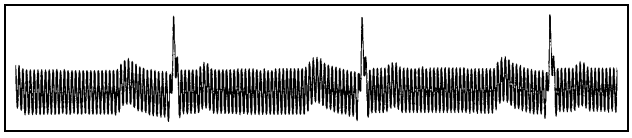


Figure 13-1. Regular AC interference

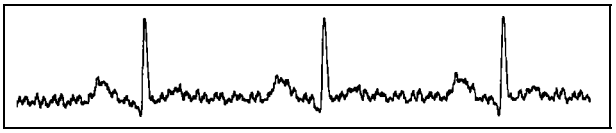


Figure 13-2. Irregular interference signals

Note

In the presence of very strong AC line interference in all leads, the thermal printhead may interrupt the recording. Activate the AC line filter in these situations.

14 Technical Specifications

Recording
Direct recording of waveforms and alphanumeric characters with rectangular coordinates by means of thermal-array printhead printing on thermosensitive paper.

- recording channels: 3, in manual mode 1 or 3, overlapping is possible
- baseline pitch: 25 mm with 3 leads (manual)
- writing width: 80 mm maximum
- annotation of device settings, date and time in the margin of recording strip
- documentation of analysis results on separate page
- resolution of the recording:

  vertically 8 dots/mm

  horizontally 25 µm at 25 mm/s

Writer paper
CONTRAST® thermal roll paper
paper width 90 mm/0.35 inches
length 35 m/115 feet

To prevent debris from collecting on the printhead, use the original writer paper only!

Chart transport
- paper speed
  5-25-50 mm/s (key-selectable)
  error limit: typically ±1%, max. ±10%
- when supply of writer paper is depleted, recorder switches off and sounds an audible indicator; end-of-paper indication by red stripe in upper paper margin

Membrane keypad
Membrane keys with tactile feedback
- function keys for all important routine operations

Display
Alphanumeric LCD, 2 x 16 characters, contrast adjustable

Indicators (LEDs)
For mains supply, battery charge level and start/stop function

Automatic functions
Assisting and facilitating device operation:
- automatic amplifier blocking
- automatic lead sequencing, paper feed, calibration
- report formatting
- automatic baseline adjustment
- anti-drift system compensating for polarization voltage fluctuation (cubic spline)

Detection of pacing pulses
- pulse duration between 0.1 and 2 ms
- pulse amplitude between ±5 mV and ±700 mV
- marks with correct pulse polarity in all leads

Heart-rate display
Derivation of the heart rate from all ECG signals
- display range 30 to 300 BPM ±1BPM
- display update with every heart beat, maximum every 2 seconds

Signal inputs
Isolated patient signal input, type CF according to IEC, high-voltage protection for all lead connections and neutral electrode RL (only in conjunction with the original *GEMS IT* patient cables), interference compensation via neutral electrode (RL), monitoring for detection of open leads
- electrode connections for RA, LA, LL, RL, V1 to V6

- input impedance for differential signals applied between any two electrode connections >10 MOhms for 10 Hz
- input impedance for common-mode signals referred to RL >50 MOhms for up to 60 Hz
- dynamic range for differential signals between any two electrode connections for AC voltage ±10 mV, for superimposed DC voltage (polarization voltage) ±600mV
- dynamic range for common-mode signals referred to RL±1V, referred to chassis 263 V AC voltage (rms)
- quiescent input current via any electrode connection for 1-kOhm termination referred to RL <50 nA
- patient leakage current (rms values) according to IEC class CF: under normal conditions <10 µA, in single-fault condition (e.g., patient in contact with line voltage) <20 µA
- non-destructive range for lead-electrode connections and the RL-connection referred to RL ±50 V, referred to chassis ±1500 V
- pulse voltage resistance of all lead-electrode connections and of the N-connection referred to chassis (e.g., defibrillation) 5000 V
- monitoring of each electrode for disconnection: RA, LA, LL, RL, V1 to V6
  audible indicator signal upon detection of disconnected leads

Signal transmission

Patient signal input to recording

After lead formation and digitization simultaneous transmission of all electrode signals to the digital processing system; muscle filter, AC filter, pacing pulse identification, automatic or manual gain adjustment, automatic baseline adjustment and drift compensation by means of the anti-drift system (A.D.S.) can be enabled or disabled simultaneously for all channels; digital output of processed signals via thermal-array printhead

- low cut-off frequency (-3-dB limits) 0.04 Hz, 0.08 Hz or 0.16 Hz
  equivalent to a time constant of 4 s, 2s or 1 s
- high cut-off frequency (-3-dB limit) 150 Hz (IEC/AHA)
- signal sampling rate 1000 Hz
- resolution, referred to the input, 5 µV
- output rate to recorder 1000/s
- for all leads gain adjustment in three steps: 20 - 10 -5mm/mV, max. error limits ±5%
- with muscle filter (low-pass characteristic) switched on, 3-dB drop of the amplitude frequency response at approx. 35 Hz or 20 Hz
- with AC filter switched on, identification and compensation of periodic 50 or 60-Hz frequency components: attenuation > 40 dB
- non-linear distortion below values specified in IEC and AHA recommendations
- coincidence error limits between any two channels ±0.5mm
- identification of pacing pulses in V2 or other V-leads and marking in all channels for signals referred to patient input: duration ≥ 0.1 ms, amplitude > 5 mV
- noise in the signal-transmission path below values specified in IEC and AHA recommendations: ≤ 2,5 µV rms
- common-mode rejection for 50 or 60-Hz signals (depending on recorder model) with AC filter switched on > 140 dB

ECG calibration

Automatic recording of a defined voltage step, valid for all channels

- calibration voltage of 1 mV ± 1%, referred to ECG signal input

calibration pulse width approx. 200 ms, irrespective of paper speed

Baseline
Automatic adjustment of the baseline to the optimal recording range, in dependence of the signal amplitude

Anti-Drift System (A.D.S) — Cubic Spline
Automatic compensation of baseline fluctuations caused by polarization voltage fluctuations at the lead electrodes (recording delayed 4.2 s)

Blocking
Rapid charge reversal of the coupling capacitors in the preamplifiers after electrode application

Lead-fail indication
Audible and visual indication on the LCD of disconnected electrodes or line break; each single electrode is monitored

Copy function
In 12 Lead Mode, after ECG recording, additional copies of the ECG can be printed from memory

Test
Automatic performance test upon power up, including verification of the signal path starting at the signal input

Power
From the power line or from a built-in rechargeable battery, automatic switchover; automatic battery charging via built-in charger during line-power operation

Line-power operation

- instrument design in protection class I according to IEC60601-1
- rated voltage range 100 to 240 V
- operating voltage range 90 to 264 V; 49 to 65 Hz
- rated current 0.12 to 0.3 A
- typical power consumption:
  during battery charging 13 W
  device turned on + battery charging 17 W
  recording + battery charging 22 W

Battery-power operation

- battery type: lead-acid
- rated battery voltage 12 V
- rated battery capacity 1.2 Ah
- fully charged battery sufficient for up to 50 "automatic" ECGs, if device is switched on only for recording
- operating time without recording:
  approx. 4. hours
- battery charge time approx. 6 hours (100%)
  approx. 4 hours (90%)
- min. charge time for one 12-Lead ECG
  20 minutes
- battery service life approx. 3 years, replacement only by *GEMS IT* service
- Lithium battery for built-in clock: battery service life approx. 5 years, replacement only by *GEMS IT* service

Automatic Switch-Off
Device switches off automatically when the battery voltage drops below a given level.

Device switches off automatically when no controls are activated for 5 minutes (if HR control is set to "OFF")

Operational readiness
After successful self-test within 5 seconds of power-up

Operating position
Horizontal

Environment

Operation

- ambient temperature between +10 and +40 °C/50 and 104 °F
- rel. humidity between 25 and 95% (no condensation)
- atmospheric pressure between 700 and 1060 hPa

Storage and transport

- ambient temperature
  between -20 and +60 °C/-4 and 140 °F (without battery)
  between -15 and +50 °C/5 and 122 °F (with battery)
- rel. humidity between 20 and 95% (no condensation)
- atmospheric pressure between 500 and 1060 hPa

Case dimensions

- width 290 mm/11.4 in.
- height 80 mm/3.1 in.
- depth 200 mm/7.8 in.

Weight

MAC® 500 with battery approx. 2.2 kg/4.84 lbs

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W

GE Medical Systems
Information Technologies

gemedicalsystems.com

European Headquarters
GE Medical Systems
Information Technologies GmbH
Postfach 60 02 65
D-79032 Freiburg • Germany
Tel. +49 761 45 43 - 0
Fax +49 761 45 43 - 233

World Headquarters
GE Medical Systems
Information Technologies, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 • USA
Tel. +1 414 355 5000
Fax +1 414 355 3790

Asia Pacific
GE Medical Systems Hong Kong Ltd.
11th Floor, The Lee Gardens
33 Hysan Avenue
Causeway Bay Hong Kong
Tel: +852.2100.6300
Fax: +852.2100.6292