

User manual



CARDIO**MAX**
Cardioverter/Biphasic Defibrillator Monitor

I N S T R A **M** E D

Manufacturer

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For information about warranty or technical assistance, please contact Instramed's technical support.

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CardioMax User Manual English R14.0 2021-07-08

Battery use

ATTENTION: observe the battery charge maintenance instructions.

First use

Before first use the equipment should receive a full battery charge. For this it needs to be connected to the electric current for at least four and a half hours (for 4Ah) and seven hours and twenty minutes (for 6Ah).

Occasional use

Even when disconnected (stand-by), the CardioMax executes internal routines checking the status of the equipment. In spite of this procedure entailing a low power consumption, the battery charge may be consumed.

Therefore, whenever the device has not been connected to an electric current for more than 20 days, it is advisable to execute a full battery charge. If this procedure is not performed, there is a risk of draining the battery and consequently being unable to use the CardioMax in its portable configuration (not connected to the electric current).

Storage

The battery must be removed from the equipment in case it is stored or not used.

Replacement

Every battery has a determined lifetime, which is the possible quantity of full charge and discharge cycles, without loss of performance (check out the specifications of the battery on page 171). When the appliance has a drop in performance of the battery, with low autonomy, request a new unit from Instramed technical assistance.

The battery can be replaced following the procedures described on the chapter “Care and maintenance”.

Battery replacement is recommended every 02 (two) years or when the runtime is less than 01 (one) hour.

Package contents

Included items

When opening the package, please check whether all items below are present:

- The CardioMax Monitor Cardioverter/Biphasic Defibrillator.
- Instruction Manual.
- 3-pin electric power cable.
- Removable battery.
- External defibrillation pads - Adult and child.
- 5-lead ECG cable.

When the NIBP optional parameter is present:

- Adult armband.
- Armband extensor.

When the oximetry optional parameter is present:

- Oximetry sensor.
- Oxymetry sensor extensor.

When the printer optional parameter is present:

- Paper bobbin for the printer.

When the EtCO₂ optional parameter is present:

- Non reusable EtCO₂ sampling line kit, including:
 - Tracheal sample line (adult).
 - Tracheal sample line (children).
 - Nasal sample line (adult).

When the pacemaker/AED parameter is present:

- MP trunk cable.
- Multifunction adhesive pads.
- SoftDEA installation CD.

When the central RTC optional parameter is present:

- USB cable.

Replacement parts

You can call Instramed for replacements of consumable items, parts and accessories.

Consult Instramed for prices.

Shipping may apply.

To request parts and services, contact your local representative (the list can be found at www.instramed.com.br) or directly contact Instramed by telephone at: +55 (51) 3073 8200.

The items already included may be acquired for replacement as extra items.

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Purpose and application

The CardioMax uses electrical defibrillation and cardioversion therapy to reverse ventricular fibrillation arrhythmia or ventricular tachycardia without a pulse in adult and pediatric patients. Cardioversion of arrhythmias is also used when necessary.

In the external pacemaker mode, the CardioMax uses monophasic electrical stimulation in order to reproduce or regulate the cardiac rhythm.

The equipment is also used for monitoring vital signs in adult, pediatric and natal patients.

The ECG/Monitor mode shows the ECG signal and the heart rate value on the screen.

The NIBP/Monitor mode indicates the blood pressure value measured by a Non-Invasive method on the screen.

The SpO₂/Monitor mode measures the oxygen saturation of blood by a Non-Invasive method.

The EtCO₂/Monitor mode presents the partial pressure of exhaled CO₂ at the end of expiration as well as inhaled value.

The RESP/Monitor mode displays the respiratory rate measured by ECG electrodes or by the capnograph.

CPR Maestro is an accessory from Cardiomax, created to help rescuers perform compressions in accordance with the latest CPR recommendations. Its sensors measure the frequency and depth of chest compressions, providing the user with real-time feedback. These information are displayed on CPR Maestro and Cardiomax screens and through sound recommendations.

Characteristics

The CardioMax is a modern, practical, lightweight, compact and portable device that can be used in emergency situations.

The CardioMax offers the following parameters and/or characteristics (some parameters are optional):

- Exhaled carbon dioxide (CO₂) monitoring.
- Respiratory rate monitoring (RESP).
- ECG and cardiac frequency monitoring.
- Functional artery oxygen saturation monitoring (SpO₂).

- Non-Invasive pacemaker.
- Pressure monitoring (Non-Invasive method - NIBP).
- Biphasic Defibrillator.
- Automatic defibrillator mode (AED).
- Sudden Death Prevention Mode (SDP).
- ST segment value monitoring.
- Exhaled carbon dioxide monitoring (EtCO₂).
- Real Time Check (RTC).
- Charge Auto-Sequencing mode (CAS).
- Printer.
- Removable battery.

Optional items



This manual refers to all of CardioMax's functions, however, some of them are optional and may not be present in your equipment. The icon beside will appear next to the text, whenever an optional characteristic is mentioned.



WARNING: the CardioMax must be used by qualified professionals on patients who need defibrillation therapy or as a complement in assessing the patient's physiological conditions. It must be accompanied by constant analysis of the patient's clinical status and symptoms.

About the manual

This guide explains the functioning of the CardioMax defibrillator/monitor series, alerting the user to possible safety risks. This manual is part of the CardioMax and must be kept for further reference.

The information contained in this manual belongs to Instramed and cannot be copied fully, or in part, without expressed written consent.

Instramed has the right to make any changes to improve this guide as well as the product without prior notice.

Attention



The following factors can cause ECG misinterpretation:

- Wrongly placed pads.
- Patient's movements.
- Pacemaker (it may lessen the precision of the cardiac arrest detector).
- Radio frequency interference, including mobile phones.
- Excessive hair or wet skin in the application area of the electrodes.
- Pieces of clothing between skin and pads.

CardioMax does not have support system and its carrying handle must not be used for this purpose.

This equipment does not have reminder signals.

Warnings



IMPORTANT: this device must only be operated by qualified technical personnel. Before using, read the manual attentively.

WARNING: for defibrillation, cardioversion, pacing and AED modes, we do not recommend the use in patients under 01 (one) year old. For monitoring modes such as ECG, SpO₂, NIBP and EtCO₂, it's use is possible with suitable accessories to these patients.

WARNING: CardioMax can be used by patients over 01 (one) year old, regardless of their weight.

WARNING: risk of explosion if the equipment is operated in the presence of flammable liquids or gases.

ELECTRICAL SHOCK HAZARD: NEVER OPEN THE DEVICE. Each and every repair must be performed by Instramed's authorized technical centers.

WARNING: THE PATIENT MUST BE PLACED ON NON CONDUCTIVE SURFACES. DO NOT USE WET OR METALLIC SURFACES AND, IF NECESSARY, DRY THE CHEST BEFORE APPLYING THE SHOCK.

WARNING: DO NOT TOUCH THE PATIENT, THE EQUIPMENT, THE ACCESSORIES NOR ANY METALLIC OR CONDUCTIVE SURFACE WHICH IS IN CONTACT WITH THE PATIENT DURING THE DEFIBRILLATION.

WARNING: THE PATIENT MUST BE COMPLETELY STILL DURING THE CARDIAC RHYTHM ANALYSIS PHASE (AED MODE). DO NOT GIVE CARDIAC MASSAGE AT THIS POINT.

ATTENTION: do not use CardioMax or its accessories in the presence of MRI equipment.

This equipment was projected to offer resistance to electromagnetic interferences. However, the functioning of this device can be affected in the present of strong sources of electromagnetic-interference or radio-frequency, such as mobile phones, communicator radios, etc.

If the precision of measurements seems to be incorrect, first check the vital signs of the patient and then check the functioning of the CardioMax.

WARNING: always check the general state of the equipment, the battery and the accessories before using it.

Before installing the equipment verify if there are any abnormalities or damage caused by mishandling during transportation.

NOTICE: the CardioMax must only be used as a complement to assess the patient's physiological conditions. It must be accompanied by constant analysis of the patient's clinical status and symptoms.

WARNING: the use of the CardioMax is restricted to one patient at a time.

NOTICE: the applied parts (electrodes, sensors, armbands, etc.) are protected against defibrillation discharge; during discharge there may be baseline variation.

WARNING: when the CardioMax is operated in monitor mode, it can be used with other electromedical equipment simultaneously connected to the patient, provided that the other equipment are in compliance with the safety standards.

WARNING: the conductive parts of the electrodes and connectors associated with the applied parts, including the neutral electrode, must not come into contact with other conductive parts, including the ground wire.

NOTICE: avoid connecting the patient to several items of equipment at the same time. The limits of current leakage may be exceeded.

NOTICE: the applied parts intended to come into contact with the patient have been evaluated and comply with the directives and principles of ISO 10993-1.

WARNING: CardioMax should not be used too close to or over other equipment. If this is necessary, it is recommended that the equipment or system be observed to verify the normal operation in the configuration in which it will be used.

NOTICE: when removing the equipment from its package, carefully verify if there is any abnormality or visible damage in the device or its accessories, caused by impact or mishandling during transportation. In case of irregularities, please contact Instramed.

NOTICE: disposable accessories and any other components must be disposed of according to the norms of hospital waste disposal.

WARNING: do not modify this equipment without authorization from Instramed.

ATTENTION: patient movements can confuse correct rhythm detection and delay therapy. Do not move the patient and keep the patient still during rhythm analysis.

Adverse or side effects

Superficial burns may occur on the patient's skin in the area in contact with the electrodes. To minimize the effect of the disposable paddles, apply them directly after removal from the protection envelope and attach them firmly to the patient's skin.

The skin must be dry, or electric current leakage may occur, increasing the burn's area and reducing the efficiency of the treatment.

Possibility of reddish skin at the defibrillation electrodes exposition place, due to the high voltage applied.

Possibility of superficial skin burns. To minimize the effect, in the case of adhesive pads, apply them immediately after removal of the protective envelope and securely attach to the patient's skin. The patient's skin must be dry.

Possibility of reduction of treatment efficiency. The patient's skin must be dry, otherwise the electric discharge may leak.

Do not apply conductive gel outside the area of contact with the pads to avoid electrical leakage.

Possibility of erythematous skin at the pacemaker electrodes exposition place, especially during prolonged use.

Possibility of discomfort and pain, with the use of high levels of pacemaker current. In case of high levels of current, it is recommended that the patient is anesthetized or unconscious.

Possibility of eczematous skin, due to the use of non-biocompatible electrodes (non-compliance with the ISO 10993 standard). Always use accessories with technical recommendation described in this User Guide.

It is recommended for cases of resuscitation maneuvers of long duration, the use of a gauze between the skin and the CPR MAESTRO.

Possible DISCOMFORT and REDUCED BLOOD CIRCULATION in NIBP measuring. The operator should always ensure that the applied pressure or the quantity of measures did not effect in the blood circulation or discomfort to the user. In this case, the quantity of measures should be decreased and the arm should be changed.

DISCOMFORT or COMPLICATIONS DUE TO THE PRODUCT SMELL in EtCO₂ monitoring. Some patients have been with nausea or headaches due to the cannula smell or discomfort with the cannula positioning. In this cases, it's reversible with just changing the cannula or readjusting the positioning.

Classification and symbols

Symbol	Description
	CF applied part - defibrillation proof.
	Follow the instructions for use.
	General warning symbol.
	Warning: dangerous voltage.
	Terminal for equalization of potential.
	Terminal for general ground.
Off	Disconnects the equipment.
	Alternate current.
	Direct current.
	Non-ionizing radiation
	Input and output connection.
	Maintain this side upwards.
	Fragile equipment.
	Maximum stacking of 4 units.
	Maintain protected from the rain.
	Minimum and maximum atmospheric pressure.
	Minimum and maximum relative humidity.
	Recyclable paper.

	Remains of electrical and electronic equipment - Separate disposal from other objects.
	Mark of conformity according to the European Community. "2460" stands for the number of the Notified Body.
	Manufacturer.
	Manufacturing date.
	European representative.
	Serial number. The manufacturing date of Cardiomax is located in its serial number, from the third to the sixth digit (inclusive).
	Português.
	English.
	Español.
	Storage temperature limits. The norms EN 60601-1 (IEC 60601-1) and ISO 15223 are used as reference to the symbols.
	Operation temperature limits. The norms EN 60601-1 (IEC 60601-1) and ISO 15223 are used as reference to the symbols.
	Inmetro conformity identification labelling.
IPX1	Protected against water drops falling vertically (default).
IP44	Protected against solid foreign objects 1mm in diameter or larger. Protected against splashing water (optional).
	Do not reuse.
	Does not contain natural rubber LATEX.
	Non-sterile.
	Do not use if the packaging is damaged.
	Keep away from sunlight.
	Adhesive pads operation temperature limits.
	Check instructions for use.
	Lot code.
	Catalog number.
	Date after which the product cannot be used.

Standards

CardioMax was designed following performance and safety national and international standards. Among them are:

- NBR IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- NBR IEC 60601-1-2 - Medical electrical equipment - Part 1-2: General requirement for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and test.
- NBR IEC 60601-1-4 - Medical electrical equipment - Part 1-4: General requirements for the safety - Collateral Standard: Programmable electrical medical systems

NBR IEC 60601-1-6 - Medical Electrical Equipment - Part 1-6: General requirements for basic safety - Collateral Standard: Usability.

-
- NBR IEC 60601-1-8 - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standards: General requirements, testes and guidance for alarm systems in medical electrical equipment and medical electrical systems.
 - NBR IEC 60601-2-4 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators.
 - NBR IEC 60601-2-27 - Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.
 - NBR IEC 80601-2-30 - Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
 - NBR IEC 60601-2-49 - Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment or equivalent IECs.

The current versions of the Standards can be verified in the Certificate of Conformity of the product, available at www.instramed.com.br.

Device care

- Do not place the equipment where it may fall on the patient. Do not lift the equipment by its cables or connections.

- Place cables connected to the patient in order to restrict the possibility of strangulation.
- Keep the defibrillator in a dry environment, avoiding places that allow liquids to spill over the monitor. Do not use the defibrillator if it is wet or excessively humid.
- Always keep the equipment and its accessories clean and well maintained.
- If you suspect a fall or external damage, do not use the equipment.

Connection to other equipment.

When connecting the CardioMax to any device, ensure that the equipment is operating correctly before clinical use. The equipment or accessories connected to the device must be certified according to the IEC 950 standard for data processing equipment or according to the IEC 60601-1-1 for medical equipment.



GROUNDING IS ESSENTIAL TO PROTECT THE OPERATOR AND PATIENT AGAINST ELECTRICAL DISCHARGE ACCIDENTS. IN THE ABSENCE OF ADEQUATE GROUNDING, DANGEROUS CURRENTS MAY CIRCULATE FROM THE EQUIPMENT BOX IF THERE IS AN INTERNAL ELECTRICAL DEFECT. GROUNDING MUST BE PERFORMED ACCORDING TO ABNT NORMS FOR ELECTRICAL INSTALLATIONS (NBR 13534/1995).

The potential equalization is performed by the Mains Supply cable connector with 3 pins (accompanying the product) and / or with the earthing cable (optional).

Electromagnetic compatibility

The installation of the CardioMax requires special precautions concerning Electromagnetic Compatibility in compliance with the information contained in this manual (see the chapter Care and maintenance).

Disposing of the device

Avoid contamination of the environment, humans, or other equipment by making sure to properly sterilize and decontaminate the equipment before disposing of it.

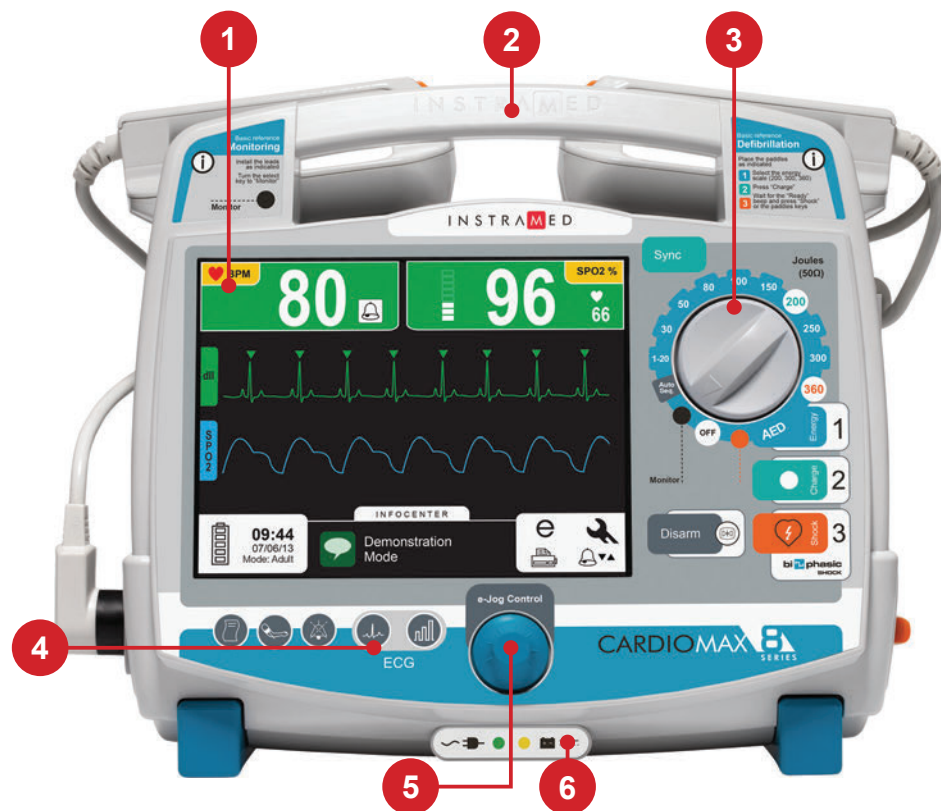


Refer to local regulations for the proper disposal of trash in your area. For countries that follow European Guidelines, refer to 2002/96/CE.Grounding.

The equipment

3

Front panel



1. LCD screen.
2. Transport handle.
3. Selector switch: turns the equipment on and off. Selects the operation mode (see following chapters).
4. Quick access buttons (see “quick access buttons” in this chapter).
5. E-Jog Control: equipment general configuration.
6. Power and battery charging indicators (see “power and charging indicators” in this chapter).

Screen

The LCD screen displays graphic and numeric information used in ECG and SpO₂, defibrillation and others. For more information about the configurations and screen information, see the “Screen and operation” section.

e-Jog Control

The e-Jog Control is used to access all of the CardioMax's functions, such as set alarms, define information displayed on the screen, alter parameters, etc.

ROTATE: rotating allows the user to select or change information and navigate all menus. It operates similarly to a computer mouse.

PRESS: works similarly to the enter button on a computer, confirming the selection.



Selector switch

Scale from 1 to 360 J: allows the user to select the desired energy charge.

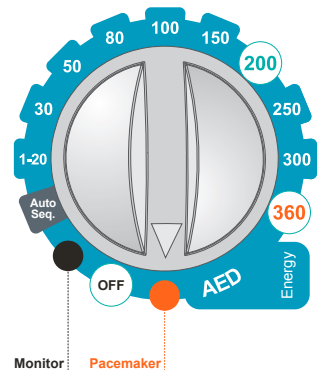
Monitor mode: used to monitor ECG, SpO₂, NIBP, EtCO₂ and RESP parameters, as in a multiparametric monitor.

Pacemaker mode (*): enables external pacemaker.

Off: turns off the equipment.

AED Position: enables external automatic defibrillator mode.

Auto Seq Mode: enables charge auto-sequencing.



NOTE: the equipment does not defibrillate in pacemaker and monitor modes. The pacemaker will only work in pacemaker mode.



(*) Check your equipment's configuration. This item is optional and may not be present in all commercialized equipment.

Quick access buttons



Fast Lead Change: enables quick access to change ECG leads.



Fast Sensitivity Change: enables quick change of ECG sensitivity.



Print: press once to print a quick report. For continuous printing, simply press the button for 3 seconds. For further information, see the “Printing” section.



Pause audio: press the button quickly to deactivate ALL sound alarms for a period of 60 seconds. For more information, see the “Alarms and limits” section.



NIBP (when available): starts or suspends the functionality of the Non-Invasive Blood Pressure Measurement. *When the NIBP (optional) parameter is not present in the device, this button has no function.*



Freeze: Freezes graphic screen signals for a closer examination (same Cancel button).

Power and battery charging indications

1. Power Connected: when the LED is on, it indicates that the equipment is connected to a power source or an external battery.

2. Battery Charging: when the LED is on, it indicates that the battery is charging.



NOTE: when the equipment is connected to an electric current, the LEDs will light up indicating the beginning of charging, even if the CardioMax is inoperative.

Side view



The photos in this manual are merely illustrative. The connections are placed correctly according to the images. The art on the labels may be altered in accordance with the requirements of the applicable standards.

1 - SpO₂ connector



BCI standard oximetry connector. Adult and child oximetry sensors.

2 - USB connector



USB connector for access to data stored by the AED mode. It can be plugged directly to a Windows PC.

3 - NIBP connector



Connector for direct use with the armband.

4 - ECG connector

Connector for ECG cables. Depending on the parameters present in the equipment, it may be available in the following settings:

- 3 or 5-wire - AAMI standard. Protected against defibrillation.
- 10-wire (optional) - allows up to 12 simultaneous leads. This connector substitutes the standard connector and is not compatible with the 3 or 5-wire cables.

5 - Printer



Printer for thermosensitive paper. It prints electrocardiograms and events. For more information view the "Printing" chapter.

6 - CPR Maestro connector



Connector for the CPR Maestro accessory.

7 - Connector for defibrillation electrodes (pads)

Multi-functional: adhesive pads for defibrillation, pacemaker and monitoring.

Adult/child external: included with the equipment, may be used on adults and/or children. **Cannot be used in pacemaker mode.**

8 - Capnography exhaust connector



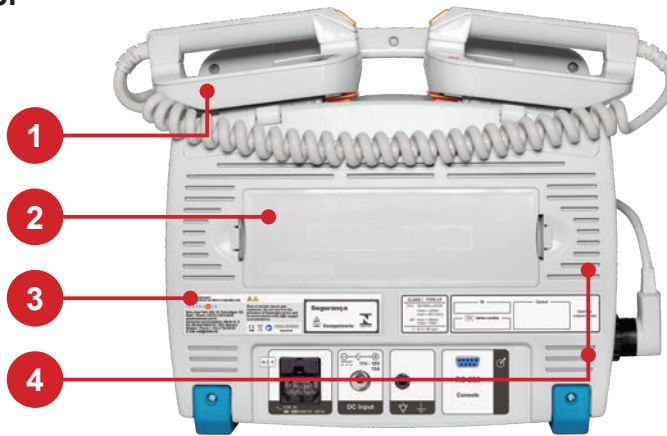
Connector used for the removal of the gases collected by capnography. For more information, see chapter 12 - "Capnography".

9 - Capnography connector



Connector for the capnography sampling line.

Rear panel



1 - Pads

The pads accompanying the CardioMax must be placed on top of the equipment and must be properly connected to the adult adapter.

2 - Removable battery

The battery can be easily replaced by simply pressing both side tabs one against the other. The battery will unlock and automatically detach itself from the equipment.

NOTE: do not remove the battery when the equipment is operating in battery mode. Connect it to an electric current first.

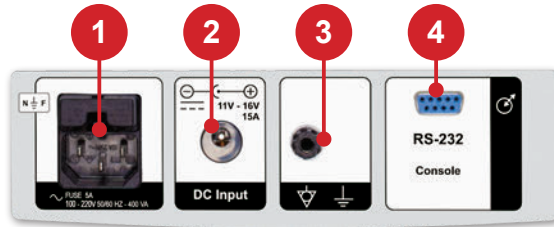
3 - Identification tags

The identification tags have important information about the product, such as the model, serial number and manufacturer information. This information may be requested if technical assistance is needed. Therefore, do not remove or damage the identification tags.

4 - Ventilation

Do not block ventilation slots. Keep the equipment positioned in order to facilitate airflow. These slots are raised to reduce the accidental entry of liquids, as well as to prevent against spills or drips.

Rear connectors



1 - 3-pin power connector

Input of 100 to 220 VAC, with central pin for grounding.
5 A fuse (20 mm 20 AG F5A GLASS FUSE).

2 - External DC socket

For battery connection or external DC source connection in a range of 11 to 16 VDC.

3 - Grounding and potential equalizer

Potential equalization and general grounding connector.

4 - RS-232 output

Cable socket for updating software (reserved for authorized technical personnel).

4

Use selector switch (1) for turning CardioMax on and off. When turning on, the operator must immediately select an operation mode (defibrillator, monitor or pacemaker).



Turn clockwise or counter-clockwise to select the operation mode. On "Off" position the equipment is turned off.

Enables to set the time of the automated internal discharge of the energy stored in the device.

3 - Auto Seq. mode

In this mode, it is possible to deliver shocks in a sequence of energy levels preset by the user. (See the “Defibrillator mode” chapter).

4 - Monitor mode

Used to monitor the patient's ECG, SpO₂, NIBP, EtCO₂ and RESP. In this position the CardioMax works as a multiparametric monitor.

ECG and SpO₂ limit alarms continue operating. ECG and SpO₂ messages are enabled.

5 - Turns equipment off

In this position, the CardioMax is turned off. After the device is turned off, only the circuit that charges the battery remains in operation. (This is indicated by a green LED in the base of the equipment's front).

6 - AED mode

Enables the Automated External Defibrillator (AED).



In this situation, the CardioMax is capable of assessing, through sophisticated sensors, the patient's state, consider the clinical variables and apply, automatically, the most indicated shock therapy. At the same time, the device guides the user by verbal commands and screen indications which can be warnings, instructions or status messages.

The CardioMax's Automated External Defibrillator will only function if the multifunctional pads (adhesive) are connected to the equipment.

7 - Pacemaker mode

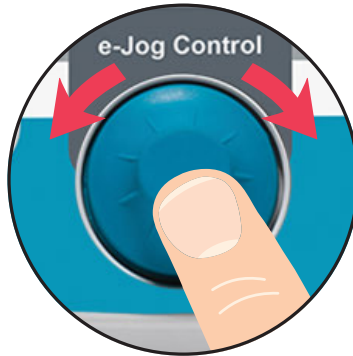


Enables the external pacemaker.

The external pacemaker will only work if the multifunction pads (adhesives) are connected to the equipment.

Operating the e-Jog Control

To access the configuration menus and equipment operation use the rotating e-Jog Control as indicated below:



STEP 1

ROTATE: Rotate the button to the desired item observing the highlighted icons on the equipment screen.



STEP 2

PRESS: Press to select the highlighted item. The menu for the chosen function will appear.

STEP 3

ROTATE: Rotate the button to the corresponding value desired in the selected item's menu.

STEP 4

PRESS: Press to confirm the new selected value.

Startup screen

The startup screen is displayed whenever the device is turned on. It displays a list of all parameters available to CardioMax by showing the corresponding status next to each item:

[OK] - Parameter has been installed and runs accordingly.

[Fail] - Parameter has been installed, but failure is detected. Contact Instramed assistance.

[Not present] - Parameter has not been originally installed or has been removed from device.

Software versions for each internal module are also presented.

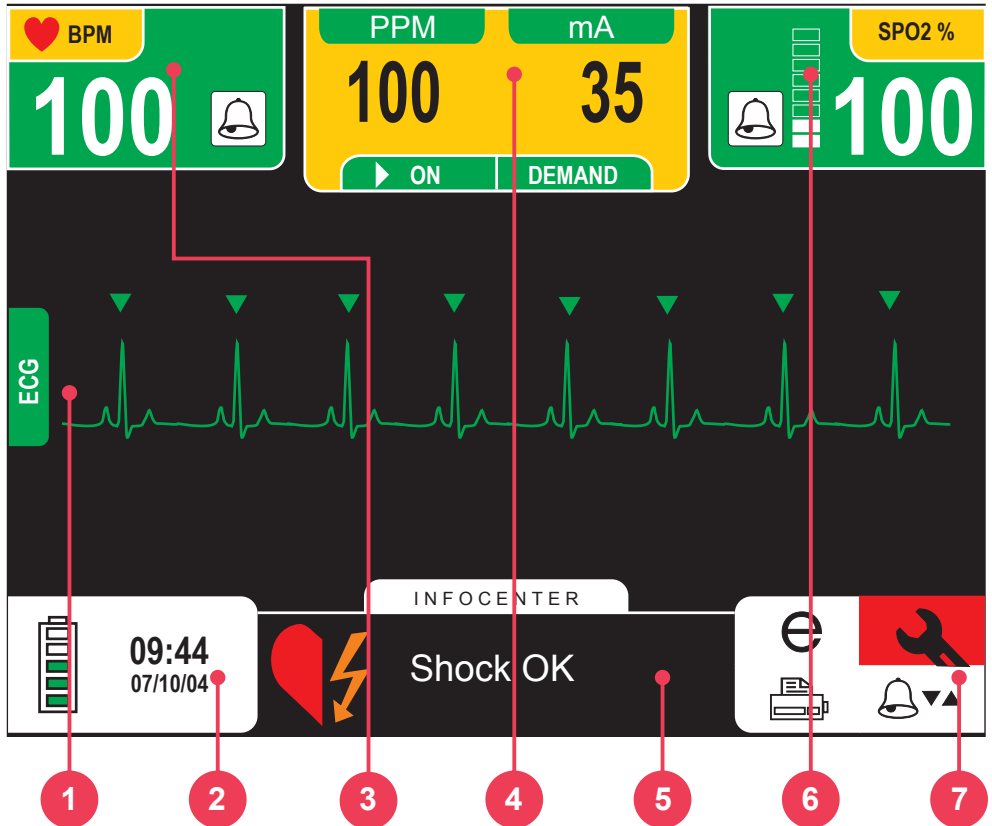
I N S T R A  E D

CARDIO**MAX**  **SERIES**


ECG/Resp/DEA/PMS/12D	[OK]
SPO ₂	[OK]
NIBP	[OK]
Defibrillator	[OK]
Pacemaker	[OK]
Printer	[OK]
EtCO ₂	[not present]

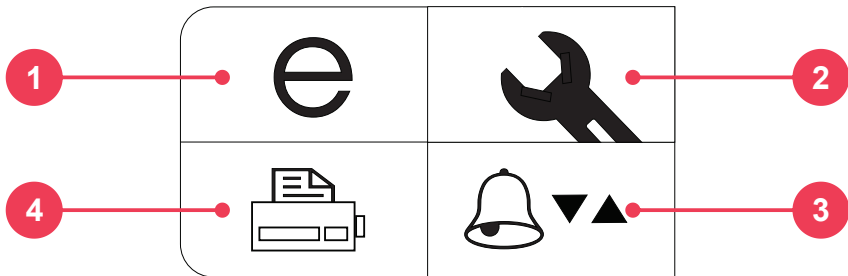
Firmware Version CPU:	SWCPURX_CMXXXRX
Firmware Version ECG:	SWECGDSP_CMXXX
Firmware Version CTBF:	SWCTBFARM7_CMXXX

Parameters visualization screen



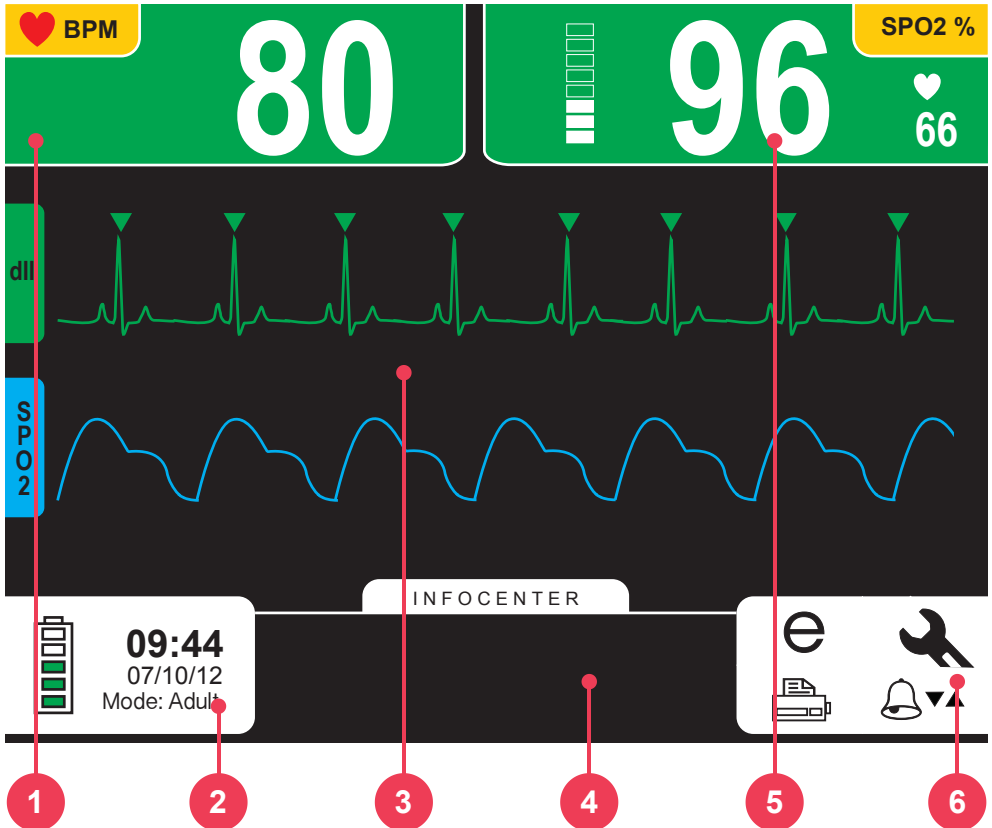
1. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
2. Time, date, battery and mode status.
3. ECG: ECG measurements and ECG alarms.
4. Pacemaker or defibrillation modes: area for the defibrillation or pacemaker modes.
5. Infocenter: information on the equipment and its operation. This is how the device communicates with the user.
6. SpO₂ : oximetry measurements and oximetry alarms.
7. Access icons for event and configuration functions: check it on the next page.

Access icons for events and configuration functions



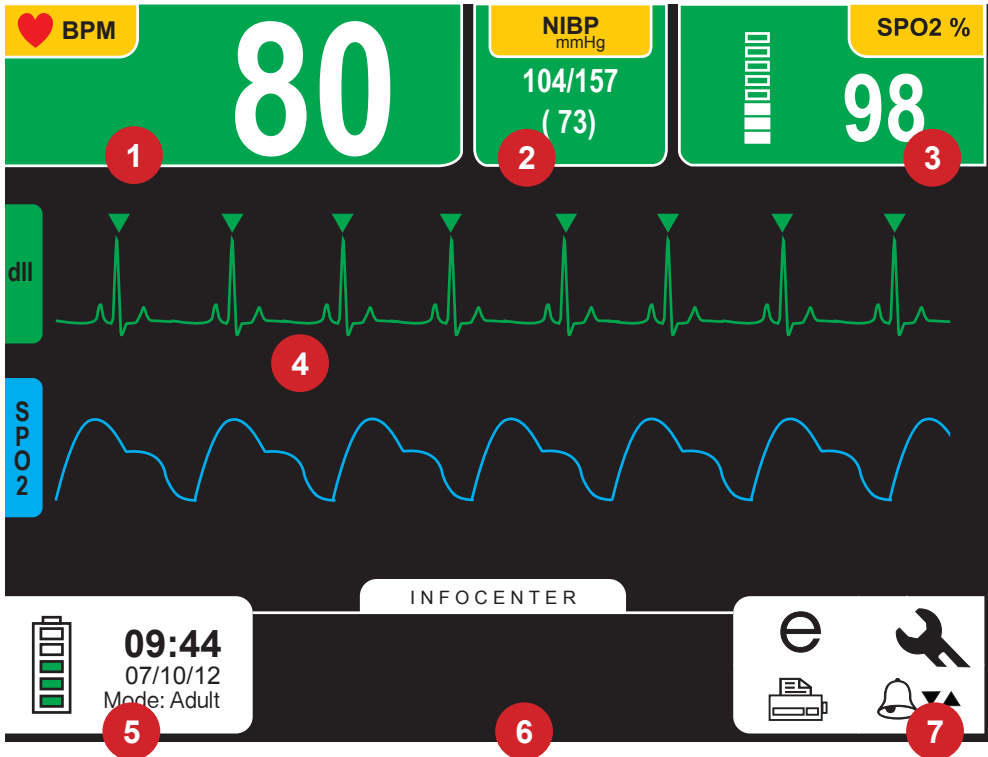
1. **Events menu:** views events stored in the CardioMax.
2. **Configuration menu:** enables the configuration of all the parameters of the equipment. See the “Configuration menu” in this chapter.
3. **Alarms menu shortcut:** configures ECG and SpO₂ alarms.
4. **Printer menu shortcut:** prints and configures the printing parameters.

The equipment screen will display different segments and parameters according to the mode defined using the selector switch. See examples on the following pictures.

Monitor mode screen – variation A (ECG and SpO₂ present)

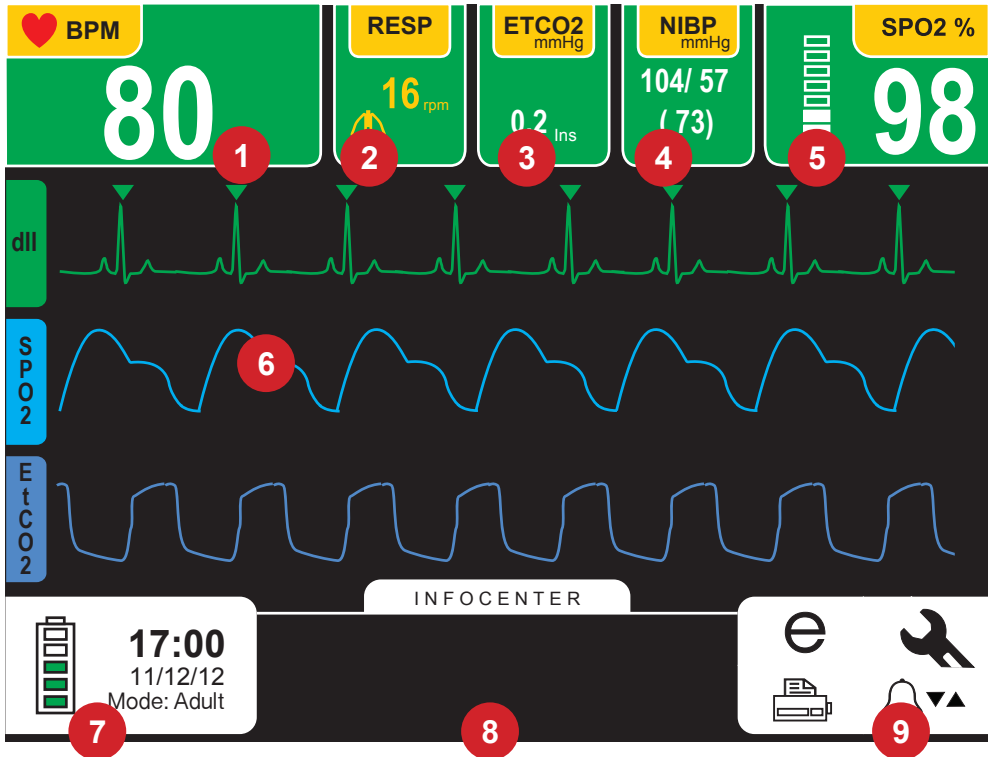
1. ECG: ECG measurements and ECG alarms.
2. Time, date, battery and mode status.
3. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
4. Infocenter: information on the equipment and its operation. This is how the device communicates with the user.
5. SpO₂: oximetry measurements and oximetry alarms.
6. Access icons for event and configuration functions.

Monitor mode Screen – variation B (ECG, SpO₂, and NIBP present)



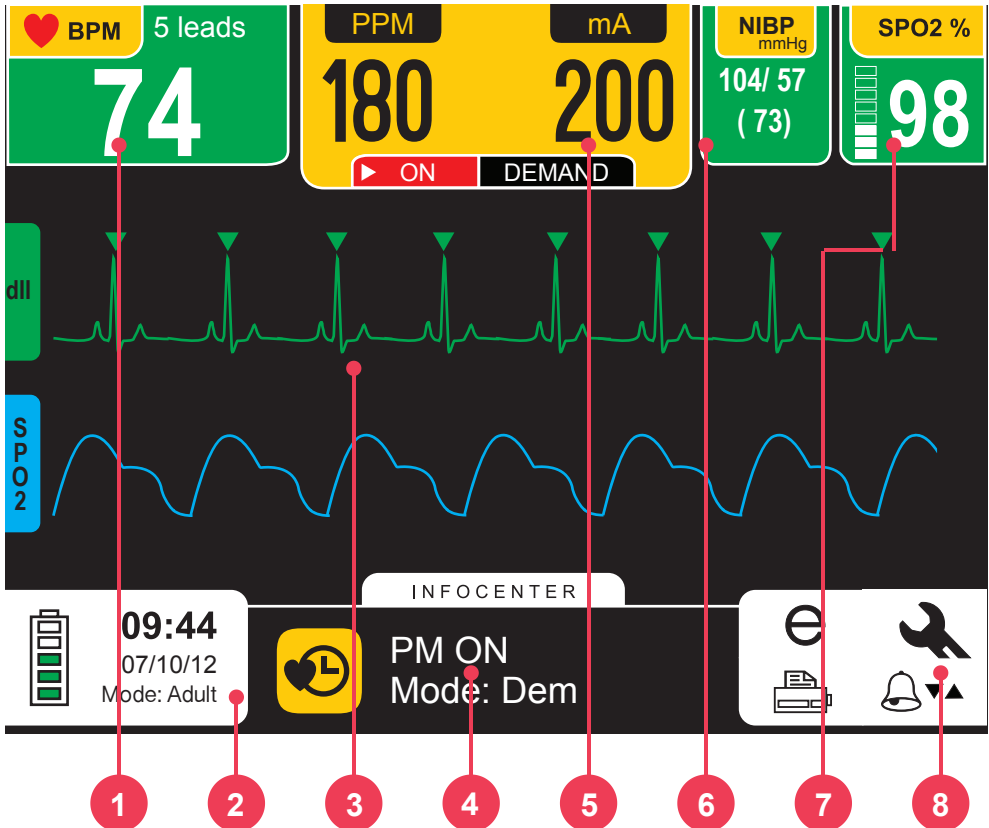
1. ECG: ECG measurements and ECG alarms.
2. NIBP: measurement values for systolic, diastolic and mean Non-Invasive Blood Pressure.
3. SpO₂: oximetry measurements and oximetry alarms.
4. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
5. Time, date, battery and mode status.
6. Infocenter: information on the equipment and its operation. This is how the device communicates with the user.
7. Access icons for event and configuration functions.

Monitor mode screen – variation C (all parameters present)



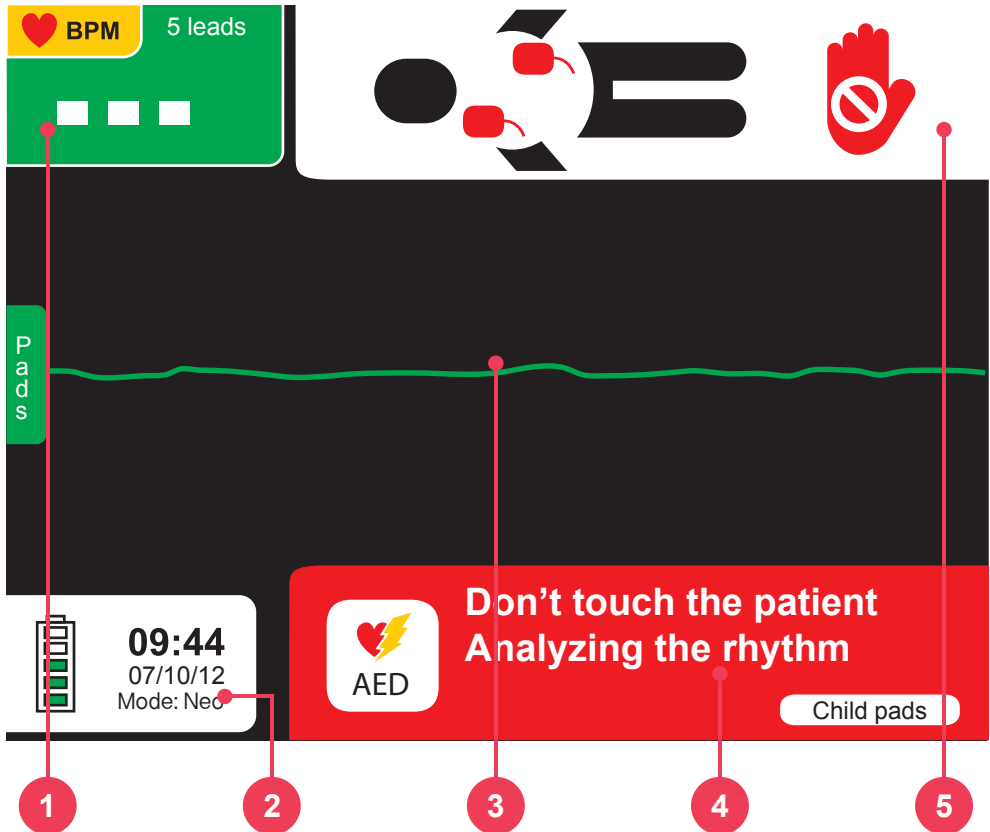
1. ECG: ECG measurements and ECG alarms.
2. RESP: respiration measurements and respiration alarms.
3. EtCO₂: EtCO₂ measurements and alarms.
4. NIBP: measurement values for systolic, diastolic and mean Non-Invasive Blood Pressure.
5. SpO₂: oximetry measurements and oximetry alarms.
6. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
7. Time, date, battery and mode status.
8. Infocenter: information on the equipment and its operation. This is how the device communicates with the user.
9. Access icons for event and configuration functions.

Pacemaker mode screen

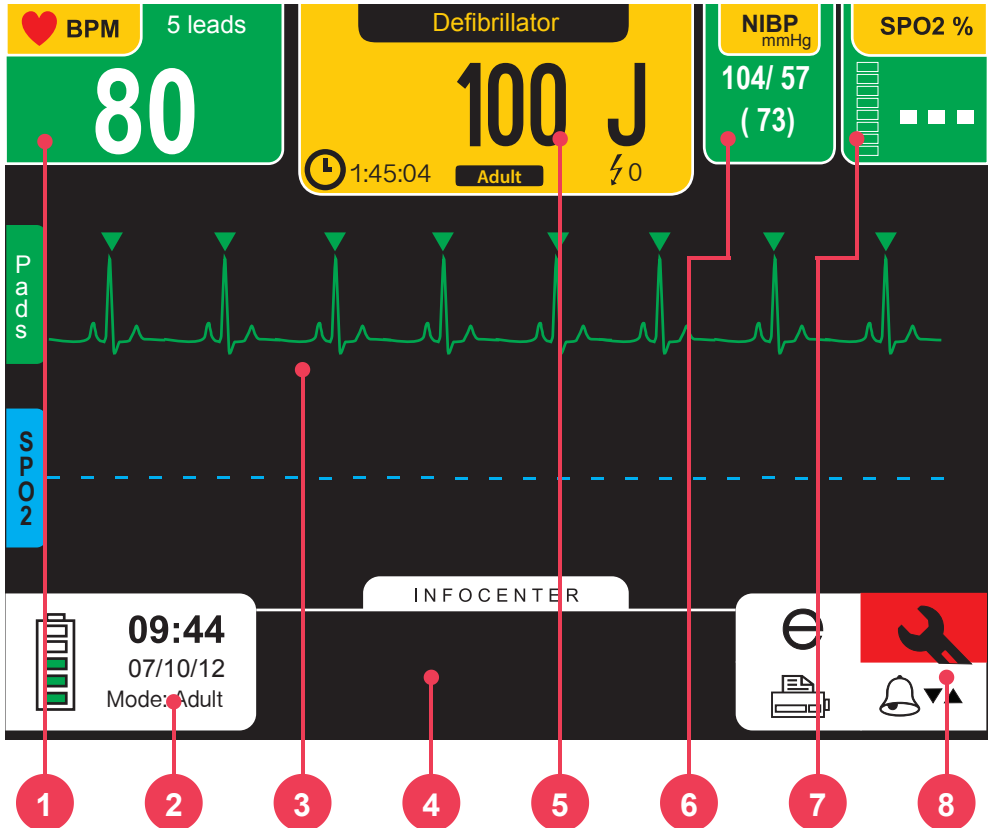


1. ECG: ECG measurements and ECG alarms.
2. Time, date, battery and mode status.
3. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
4. Infocenter: information on the equipment and its operation. This is how the device communicates with the user.
5. Information on the pacemaker mode.
6. NIBP: measurement values for systolic, diastolic and mean Non-Invasive Blood Pressure.
7. SpO₂: Oximetry measurements and oximetry alarms.
8. Access icons for event and configuration functions.

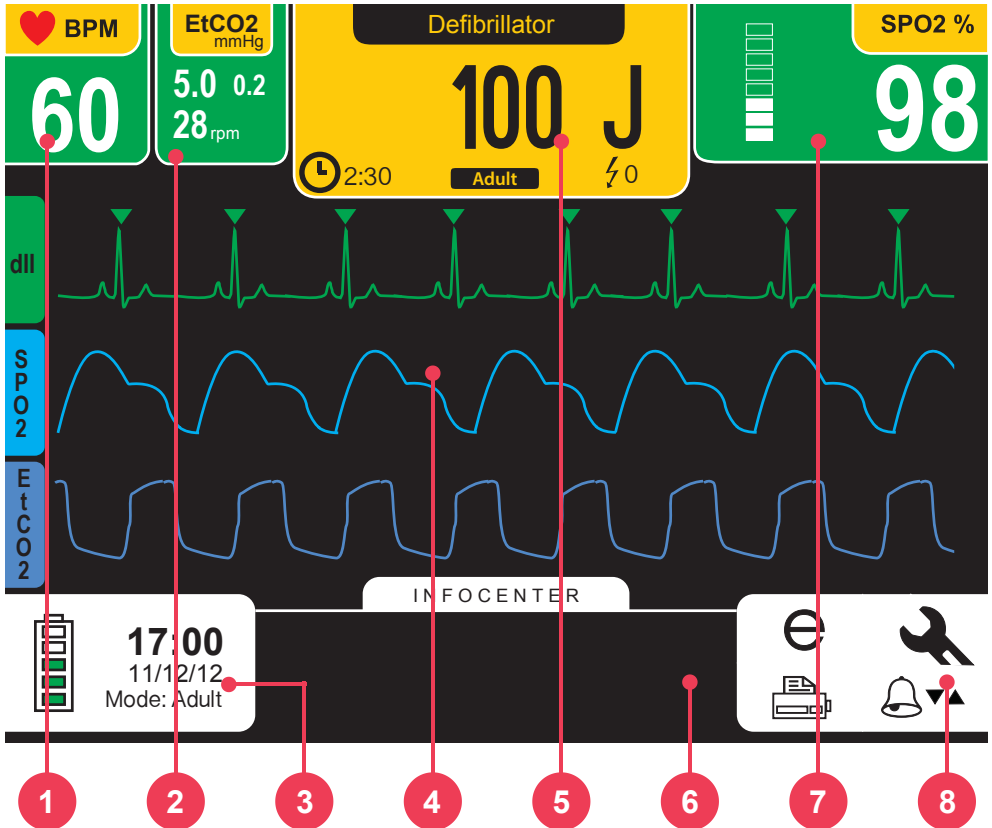
AED mode screen



1. ECG: ECG measurements and ECG alarms.
2. Time, date, battery and mode status.
3. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
4. Visual representation of the instruction given by the CardioMax to the user when in AED mode.
5. Transcription of the instruction given by the CardioMax to the user when in AED mode.

Defibrillator mode - variation A (ECG, SpO₂ and NIBP present)

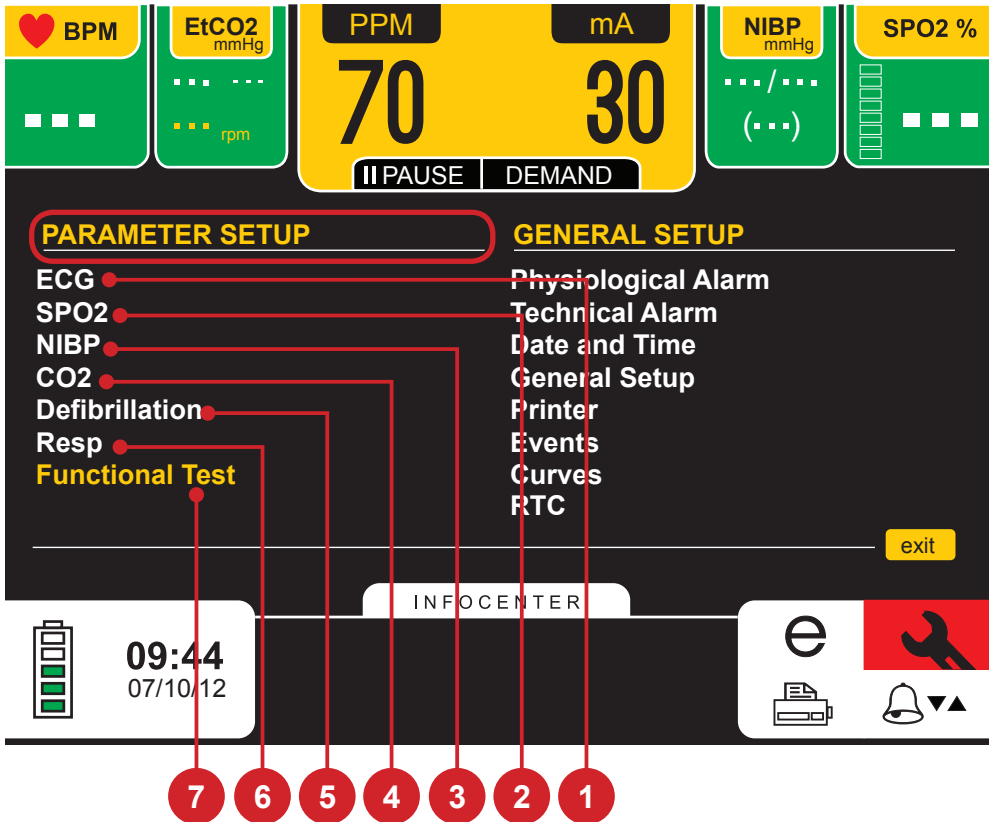
1. ECG: ECG measurements and ECG alarms.
2. Time, date, battery and mode status.
3. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
4. Infocenter: Information on the equipment and its operation. This is how the device communicates with the user.
5. Information on the defibrillation mode.
6. NIBP: measurement values for systolic, diastolic and mean Non-Invasive Blood Pressure.
7. SpO₂: oximetry measurements and oximetry alarms.
8. Access icons for event and configuration functions.

Defibrillator mode - variation B (ECG, SPO₂ and EtCO₂ present)

1. ECG: ECG measurements and ECG alarms.
2. EtCO₂: EtCO₂ measurements and alarms.
3. Time, date, battery and mode status.
4. Graph area for oximetry, ECG and EtCO₂ waveforms. Also used for configurations.
5. Information on the defibrillation mode.
6. Infocenter: Information on the equipment and its operation. This is how the device communicates with the user.
7. SpO₂: oximetry measurements and oximetry alarms.
8. Access icons for event and configuration functions.

Configuration menu

Parameter setup



1 - ECG

It allows you to manually set the ECG parameters of CardioMax (see chapter "Monitor mode - ECG").

2 - SpO₂



Enables manual configuration of SpO₂ parameters (see: "Monitor mode - SpO₂" chapter).

3 - NIBP



Enables manual configuration of NIBP parameters
(see: “Monitor mode - NIBP” chapter).

4 - CO₂



Enables manual configuration of CO₂ parameters
(see: “Monitor mode - capnography” chapter).

5 - Defibrillator mode

Enables to set the time of the automated internal discharge of the energy stored in the CardioMax (See the “Defibrillator mode” chapter).

6 - RESP

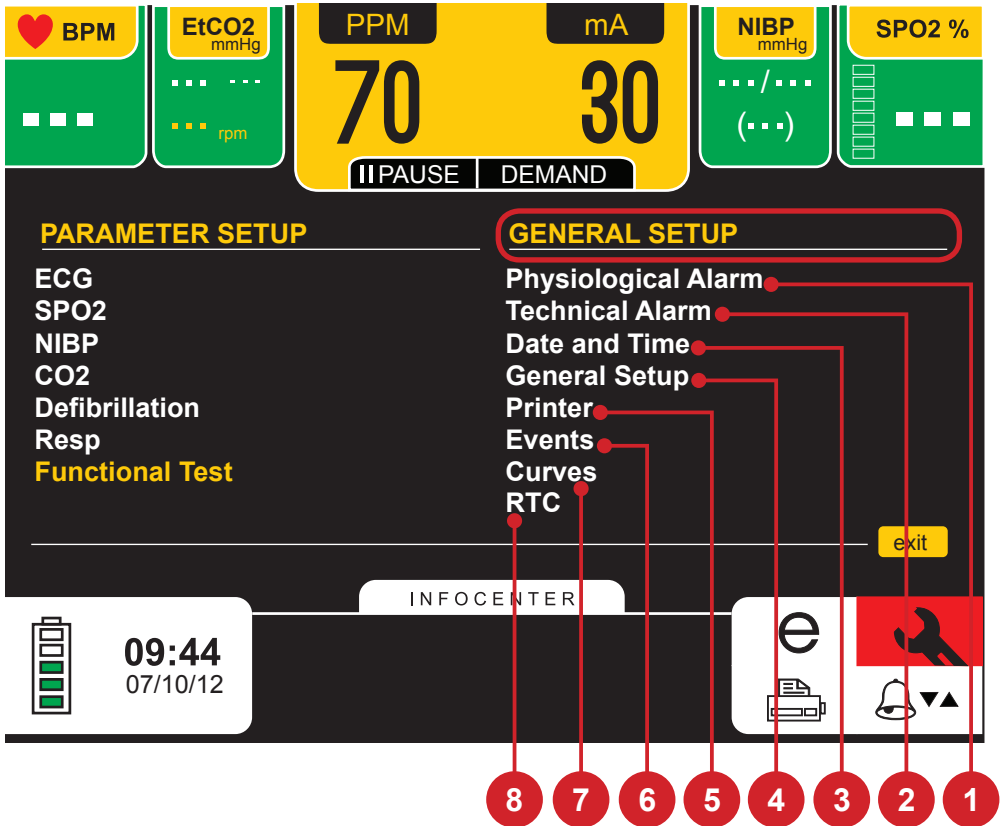
Enables manual configuration of RESP parameters
(see the “Monitor mode – respiration” chapter).

7 - Functional test

Enables to perform the CardioMax’s functional test
(see the “Defibrillator mode” chapter).

Configuration menu

General setup



1 - Physiological Alarm

It allows you to set the alarm for each of the parameters (see section "Alarms and limits").

2 - Technical Alarm

It allows you to turn on or off different technical alarms (see section "Alarms and limits").

2 - Time and date

TIME AND DATE SETUP

Date: **08** / 02 / 07
Time: 08 : 45

backexit

The “Time and date” menu adjusts the CardioMax’s calendar and time. You can opt for international or North-American standards of date and time. It is very important to keep time and date well adjusted because this information will appear on all printed reports.

You can adjust the time and the date using the e-Jog Control.

3 - General setup

GENERAL SETUP

BIP Volume	[Off]	Off		10
Alarm Volume	[1]	1		10
Defibrillator Volume	[1]	1		10
Language	[Port]	Port		Span
Mode	[Adult]	Neo		Adult
Cardiac Freq.	[ECG]	SpO2		Auto
Restore original setup				

backexit

The “General setup” menu allows you to configure four items and perform two actions.

BEEP Volume - Turns off or adjusts BEEP volume (BEEP is the audio indication of QRS).

Alarm Volume - Alarm volume adjustment.

Defibrillator Volume - Adjusts the volume of the defibrillator's audio information (charge, charge ready, shock disarmed and shock delivered).

Language - Choose the language in which menus will be displayed.

Mode - Enables to select Non-Invasive pressure monitoring in adult, pediatric or neonatal patients. In neonatal mode, the armband's initial pressure is limited to 60mmHg and in pediatric mode, the armband's initial pressure is limited to 140mmHg.

Cardiac Frequency - Enables to select the heart rate by the SpO₂ sensor, ECG electrodes or automatic mode. In the automatic mode, priority is given to ECG electrodes.

Restores original setup - Restores original factory settings.

4 - Printer

Print and configure printing parameters
(see the "Printing" chapter).

5 - Events

View and manage events saved in the CardioMax
(see the "Events" chapter).

6 - Waveforms

In this menu, you may select which waveform will be presented on the screen (ECG, SpO₂, EtCO₂ or RESP waveforms) or you may view up to 3 waveforms (the EtCO₂ and RESP waveforms cannot be shown at the same time). It is also possible to select the waveform scan speed. The possible speeds are 12.5 mm/s, 25.0 mm/s e 50.0 mm/s for ECG and SpO₂ and 6.25 mm/s, 12.5 mm/s and 25.0 mm/s for EtCO₂ and RESP waveforms.

OBS: if all waveforms are disabled simultaneously, the CardioMax will automatically select the "DII" lead. The EtCO₂ curve will only be enabled if the module is on.

See the picture on the next page.

WAVEFORMS SETUP

Waveform 1	[dll]	Off		Pads
Waveform 2	[Off]	Off		SPO2
Waveform 3	[Off]	Off		EtCO2
ECG/SPO2 speed	[25,0]	12,5		50,0
12-lead ECG	[Off]	Off		On
Initial derivation - Monitor	[dll]	dll		Pads
Initial derivation - Def	[Pads]	dll		Pads

back

exit

8 - RTC

Allow access to RTC function configurations
(see the chapter RTC - Real Time Check).

The CardioMax has audio and visual indications of physiological and technical alarm conditions.

Physiological Alarm

There are two ways to enable the physiological alarm indications:

ECG - Asistoly - The CardioMax cannot detect valid heartbeats for over 4 seconds.

SDP - Shock indicated - When the CardioMax identifies a rhythm that is liable to shock.

RESP - Apnea - When the CardioMax identifies lack of respiration for a period of time longer than that set in the Adjustments menu.

SpO2 - Pulse loss - When the CardioMax identifies that it has lost the pulse in the SPO2 sensor.

Violation of MAXIMUM or MINIMUM limits - When the Oximetry, ECG, NIBP, EtCO₂ or RESP maximum or minimum alarm limits are not within the equipment's preset range.

The visual indications of physiological alarms will occur in any mode except on AED mode, as well as audible indication.

FEATURES

- ECG, SpO₂, NIBP, RESP or EtCO₂ (except AED mode): Alarm indicator: numerical value in white alternating with a red arrow. The direction of the arrow indicates (up or down) which limit has been exceeded.
- Maximum alarm delay (includes the delay of the alarm status and the signal generation delay):
 - Heart rate: 3 seconds.
 - SpO₂ Saturation: 4 seconds.
 - EtCO₂: 11 seconds.
 - NIBP (systolic, diastolic, average): 1 second.
- Visual frequency: 2 Hz

STANDARD ALARM VALUE

The following tables provide the factory default values for the alarm limits:

ECG	
Answer	Normal
Sensitivity	20 mm/mV
Filter 60Hz	On
Network Filter	On
Detector Mp	Off
BPM Max	160 BPM
BPM Min	40 BPM
Cable	5 Leads

PANI	
Max systole	200 mmHg
Min systole	90 mmHg
Max Diastole	150 mmHg
Min Diastole	50 mmHg
Max mean	170 mmHg
Min mean	50 mmHg
Initial pressure	160 mmHg

Capnografia	
CO ₂ Max	60 mmHg
CO ₂ Min	21 mmHg

ST	
Max	10.0
Min	-10.0

Respiration	
Max	45
Min	6

SpO ₂	
Answer	Normal
SPO ₂ Max	100%
SPO ₂ Min	85%

Technical Alarm

Sound and visual signals indicate that the CardioMax is not able to accurately monitor the patient's status. The technical alarm indications are shown in the Infocenter area. See below a detailed list:

ECG or RESP - Loose Electrode: loose ECG electrode, poor contact between electrode and skin, or broken ECG conductor.

SpO₂ - No finger on sensor: sensor connected to the device, but cannot detect the patient's finger.

SpO₂ - Searching for signal: monitor searching for valid SpO₂ signal.

SpO₂ - Disconnected sensor: the SpO₂ sensor or extension is disconnected or badly placed.

SpO₂ - Artifact: muscular spasm detected.

SpO₂ - Weak signal: the CardioMax cannot identify the signal. Weak signal means the patient probably has low perfusion.

SpO₂ - Lost pulse: no beats for more than 4 seconds.

Printer - Printer without paper: printer out of paper.

NIBP - Excessive pressure: the armband's maximum pressure has been exceeded.

NIBP - Armband problems: the armband has been wrongly placed or has a leak in its measurement circuit.

NIBP - Weak signal: pulse too weak for NIBP measurements. Check the armband's position and tightening.

NIBP - Excessive movement: there is noise due to the patient's moving.

NIBP - Long measurement: the pressure measurement is too long and possibly inaccurate.

EtCO₂ - No Filterline: the capnography sampling line is not connected.

EtCO₂ - Occlusion: there is no airflow in the EtCO₂ sensor. Change the sampling line (Filterline).

EtCO₂ - Starting sensor: the EtCO₂ module is heating up its internal sensors (this occurs during the beginning of capnography and lasts about 15 seconds).

RESP - Apnea alarm: the alarm will emit a sound when a suspension of breathing is detected (apnea) in the specified times of 5, 10, 15, 20, 25, 30, 35 or 40 seconds (set in Menu > RESP > Apnea Alarm).

These indications will be enabled when CardioMax is in any mode except in AED Mode.

FEATURES

Maximum alarm delay (includes the delay of the alarm status and the signal generation delay):

- Heart rate: 3 seconds.
- SpO₂ Saturation: 4 seconds.
- EtCO₂: 11 seconds.
- NIBP (systolic, diastolic, average): 1 second.
- For other parameters: 5 seconds.
- Frequency of verification of the Technical Alarms System by the user: monthly.

It is possible for the operator to visualize the alarms from a 1 meter distance from the equipment.

CardioMax has audible and visual indications of physiological alarm conditions (HIGH PRIORITY) and technical alarm (MEDIUM PRIORITY).

The alarms will sound according to their priority:

- High Priority Alarm (Physiological Alarms): Indicates the physiological changes of the patient and will be triggered when the value measured by the equipment exceeds the minimum or maximum limits set previously on the machine by the operator.
- Medium Priority Alarm (Technical Alarm): indicates that the equipment is not able to monitor the patient's condition.
- Information Messages: they are displayed on equipment screen (in white or cyan colors). This messages are only indications and do not require immediate action from the operator.
- Sings and warning do not emit beeps; they are just visual changing its color to cyan.

If the equipment has different alarm priorities simultaneously occurring, the high priority alarm will overlap the medium priority.

The CardioMax maintains the previous alarm settings in case of shutdown for a period of 30 seconds or less. After this time, the equipment returns automatically to the factory default settings to ensure safety in the event of patient exchange.

Alarm Priority	Alarm description or audible alert	Alarm Volume or audible alert
Physiological – High Priority	Two sets of five tons of short beeps, repeated at 2.6 second intervals.	74 dB (A).
Technical – Medium Priority	One sets of three tons of longs beeps, repeated at 6 second intervals.	67 dB (A).

Characteristics of alarm messages:

ECG			
Alarm	Priority	Color	Possible cause
Electrode loose	MEDIUM PRIORITY		Electrode disconnected .
Searching ECG sign	MEDIUM PRIORITY	YELLOW	Low ECG amplitude or saturated ECG signal.
PACEMAKER detected	MEDIUM PRIORITY	YELLOW	Pacemaker pulses detected.
Bradycardia (↓)	HIGH PRIORITY	RED	When the BPM is below the value set on the alarm configuration.
Tachycardia (↑)	HIGH PRIORITY	RED	When the bpm is above the value set on the alarm configuration.
Asystole	HIGH PRIORITY	RED	CardioMax cannot detect valid beats for more than 4 seconds.
Shock Indicated	HIGH PRIORITY	RED	Ventricular fibrillation / ventricular tachycardia (VF / VT) was identified.

RESPIRATION			
Alarm	Priority	Color	Possible cause
Apnea Alarm	HIGH PRIORITY	RED	When detected the suspension of breathing (apnea) on specified times 5, 10, 15, 20, 25, 30, 35 or 40 seconds (set at Menu > RESP > Apnea Alarm).
RPM High (↑)	HIGH PRIORITY	RED	When the RPM is above the value defined on the alarm configuration.
RPM Low (↓)	HIGH PRIORITY	RED	When the BPM is below the value defined on the alarm configuration.

ST Segment

Alarm	Priority	Color	Possible cause
(↑) ECG - ST XX above the limit.	HIGH PRIORITY	RED	ST segment is above the value defined in the alarm configuration. XX represents the possible derivation shown.
(↓) ECG - ST XX below the limit.	HIGH PRIORITY	RED	ST segment is below the value defined in the alarm configuration. XX represents the possible derivation shown.

SpO₂

Alarm	Priority	Color	Possible cause
No finger on the sensor	MEDIUM PRIORITY	YELLOW	Connected sensor on the equipment, but without detection of patient's finger.
Searching signal	MEDIUM PRIORITY	YELLOW	The monitor is searching for valid SpO ₂ signal.
SpO ₂ - Disconn. Sensor	MEDIUM PRIORITY	YELLOW	Sensor or SpO ₂ extension disconnected or incorrectly placed.
Too long search.	MEDIUM PRIORITY	YELLOW	The equipment is searching a valid signal of SpO ₂ of more than 20 seconds.
SpO ₂ - Artifact	MEDIUM PRIORITY	YELLOW	Muscle tremor detected.
Weak signal	MEDIUM PRIORITY	YELLOW	CardioMax cannot identify the signal. Weak signal, possibly patient with low perfusion.
Loss of pulse	HIGH PRIORITY	RED	Patient without heartbeats for more than 4 seconds
SPO ₂ - Sat above the limit (↑)	HIGH PRIORITY	RED	Saturation is above the value defined on the alarm configuration.
SPO ₂ - Sat below the limit (↓).	HIGH PRIORITY	RED	Saturation is below the value defined on the alarm configuration.
SPO ₂ - BPM above the limit (↑)	HIGH PRIORITY	RED	Pulse value is above the value defined in the alarm configuration.
SPO ₂ - BPM below the limit (↓)	HIGH PRIORITY	RED	Pulse value is below the value defined in the alarm configuration.

NIBP

Alarm	Priority	Color	Possible cause
Excessive Pressure	MEDIUM PRIORITY	YELLOW	The cuff's maximum pressure has been exceeded.
Cuff problems	MEDIUM PRIORITY	YELLOW	The cuff is misplaced or there is leakage on measure circuit.
Weak signal	MEDIUM PRIORITY	YELLOW	Pulse too weak for NIBP measurements. Check the cuff's position and tightening.
Excessive movement	MEDIUM PRIORITY	YELLOW	There is noise due to the patient's movement.
Long measurement	MEDIUM PRIORITY	YELLOW	The measurement of pressure is too long with possibility of inaccuracy.
Sys above the limit (↑)	HIGH PRIORITY	RED	Systolic pressure value is above the value set in the alarm setting.
Sys below the limit (↓)	HIGH PRIORITY	RED	Systolic pressure value is below the value set in the alarm setting.
Dia above the limit (↑)	HIGH PRIORITY	RED	Diastolic pressure value is above the value set in the alarm setting.
Dia below the limit (↓)	HIGH PRIORITY	RED	Diastolic pressure value is below the value set in the alarm setting.
Mea above the limit (↑)	HIGH PRIORITY	RED	Mean pressure value is above the value set in the alarm setting.
Mea below the limit (↓)	HIGH PRIORITY	RED	Mean pressure value is below the value set in the alarm setting.

EtCO₂

Alarm	Priority	Color	Possible cause
No Filterline	MEDIUM PRIORITY	YELLOW	The capnography sampling line is not connected.
Occlusion	MEDIUM PRIORITY	YELLOW	There is no airflow in the EtCO ₂ sensor. Change the sampling line (Filterline).
Starting sensor	MEDIUM PRIORITY	YELLOW	The EtCO ₂ module is heating up its internal sensors (this occurs during the beginning of capnography and lasts about 15 seconds).
Auto-Zero	MEDIUM PRIORITY	YELLOW	Necessary procedure for proper functioning of the equipment.

CO ₂ EXP High (↑)	HIGH PRIORITY	RED	CO ₂ EXP is above the value defined on the alarm configuration.
CO ₂ EXP Low (↓)	HIGH PRIORITY	RED	CO ₂ EXP is below the value defined on the alarm configuration.
Communication failure	HIGH PRIORITY	RED	Communication failure of EtCO ₂ module.

Defibrillator

Alarm	Priority	Color	Possible cause
Connect pads	MEDIUM PRIORITY	YELLOW	Pads are not connected.
Ready load	HIGH PRIORITY	RED	It indicates that the load is complete and ready to be delivered.
Defibrillator failure	HIGH PRIORITY	RED	Defibrillator module failure.

INFORMATIVE MESSAGES

Adhesive pads - CardioMax detected Adhesive pads connected.

Adult pads - CardioMax detected Adult pads connected.

Children pads - CardioMax detected paddles connected, but the adult electrode is disconnected. The same message is also exhibited when CardioMax detects Children Adhesive pads.

Charging – The load is not yet complete.

Shock delivered - The energy was delivered to the patient.

Shock disarmed – The energy was canceled by the operator.

Shock disarmed (automatic internal discharge) - The energy was automatically canceled because the shock button was not pressed before the internal discharge time selected by the operator.

Shock disarmed (bad contact) – The energy was canceled because the impedance of the patient is not satisfying the applicable shock conditions.

Bad contact – Patient impedance measurement is not satisfying the applicable shock conditions.

Pacemaker

Alarm	Priority	Color	Possible cause
Connect adhesive pads	MEDIUM PRIORITY	YELLOW	Adhesive paddles are disconnected.
INFORMATIVE MESSAGES			
PM: Pause – The outbreak of pacemaker pulses is paused.			
PM: On – The outbreak of pacemaker pulses is on.			
Mode: Asynch – The pacemaker is in asynchronous mode.			
Mode: Dem – The pacemaker is in demand mode.			

Printer

INFORMATIVE MESSAGES
Without paper – Printer is out of paper.
Printing – Printer is printing.

ATTENTION

There is a risk possibility if the alarm limits do not follow a pattern in the equipment or area, it means, if it is changed for each patient, or it is different for more than one equipment.

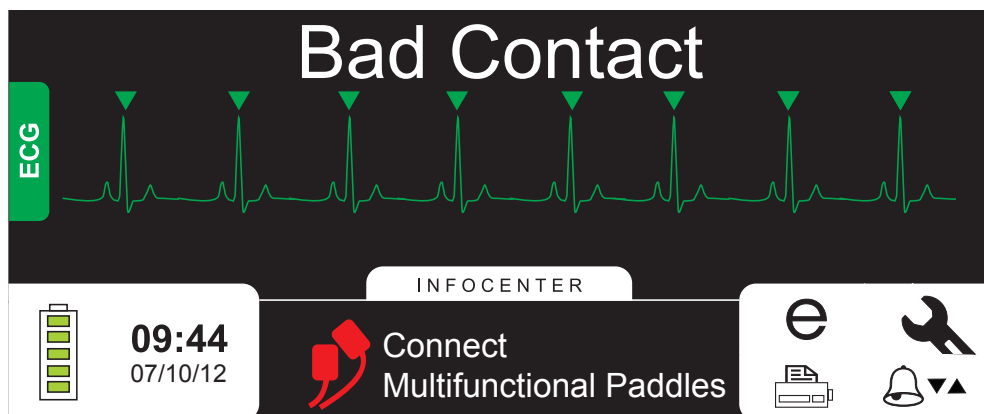
Confirm that the alarm limits are appropriate for the patient each time there is a new case of patient.

Do not set alarm limits to such extreme values that make the alarm system useless.

For simultaneous alarms of the same priority, the CardioMax will intercalate the alarm signals and messages.

Bad contact

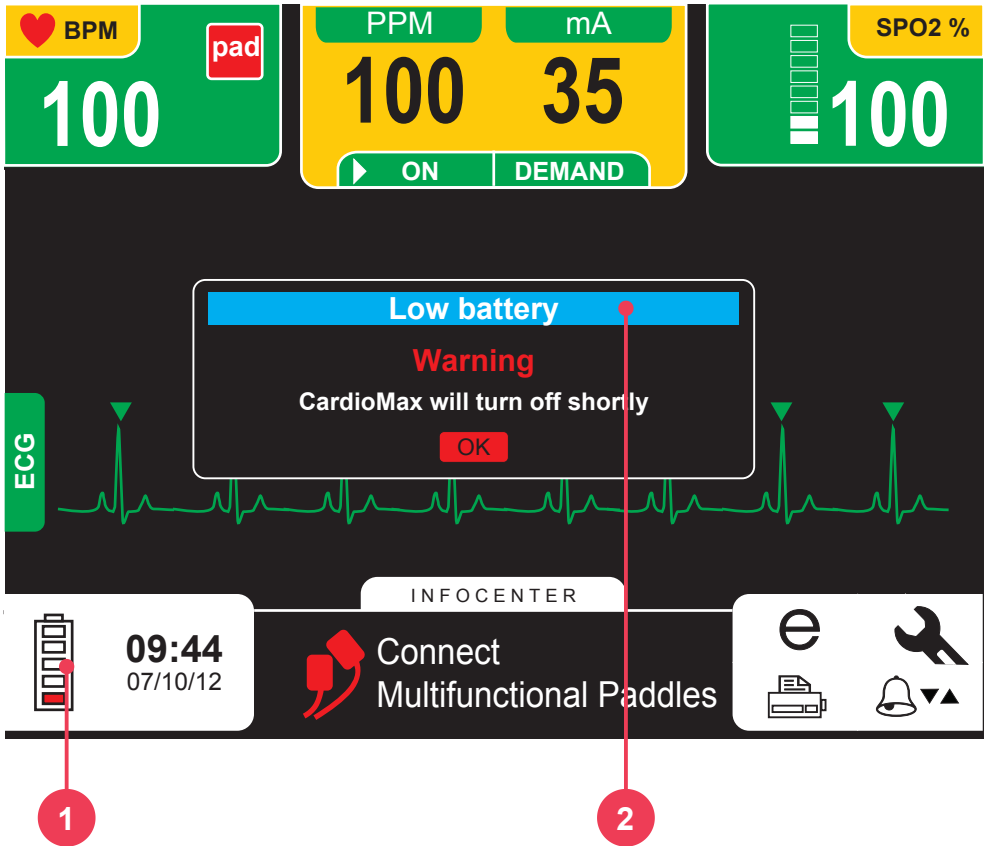
Informs when the patient's impedance measurement does not satisfy the necessary shock delivery conditions. This information is presented in the Infocenter.



Battery charge level

Indication	Battery status*	Device operating conditions
	100% charged	- 6Ah: it will allow approximately 6 hours and 30 minutes of monitoring, if the battery is installed. - 4Ah: it will allow approximately 3 hours of monitoring, if the battery is installed.
	80% charged	- 6Ah: it will allow approximately 5 hours and 10 minutes of monitoring, if the battery is installed. - 4Ah: it will allow approximately 2 hours and 50 minutes of monitoring, if the battery is installed.
	60% charged	- 6Ah: it will allow approximately 3 hours and 50 minutes of monitoring, if the battery is installed. - 4Ah: it will allow approximately 1 hours and 40 minutes of monitoring, if the battery is installed.
	40% charged	- 6Ah: it will allow approximately 2 hours and 30 minutes of monitoring, if the battery is installed. - 4Ah: it will allow approximately 1 hours and 10 minutes of monitoring, if the battery is installed.
	20% charged	- 6Ah: it will allow approximately 1 hours and 10 minutes of monitoring, if the battery is installed. - 4Ah: it will allow approximately 40 minutes of monitoring, if the battery is installed.

*Battery status when the AC power supply cable is not connected.



See the indication for low battery above:

1 - One red battery bar and four white bars.

2 - Dialogue box shows: "low battery".

When you see these indications on screen, this means the equipment will turn off shortly.

Pause audio



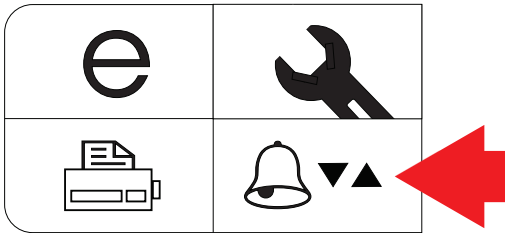
By pressing the Pause Audio button **RAPIDLY** (less than 3 seconds), ALL sound alarms are silenced for a period pre-determined by the operator.

Its visual indication is the "audio paused" icon in all parameters.

Configuration of alarm limits

Whenever the CardioMax is started, it returns to the last limits and configurations set by the user.

To alter alarm limits, the user must select the ALARM menu.



ALARM SETUP

Auto set

[180]

30  180



Auto set

The AUTO SET function configures alarm limits taking into account the physiological parameter values that are instantly measured on the patient by calculating a deviation of the minimum and maximum limits. See the table below:

Parameter	Minimum	Maximum
ECG	X 0.8	X 1.6
SpO ₂	Default	Default
NIBP - Systole	X 0.7 + 10	X 0.9 + 40
NIBP - Diastole	X 0.7 + 6	X 0.9 + 34
NIBP - Mean	X 0.7 + 6	X 0.9 + 35
Respiration	Default	Default
EtCO ₂	Default	Default

For instance, if a patient registers a cardiac frequency of 60 BPM, the values for the AUTO-ADJUSTMENT function will be: Minimum = 48 and Maximum = 96.

Minimum/maximum limit

100



85

The adjustment of minimum and maximum values is done individually on each parameter by using the e-Jog Control. The operator must first select the limit and the parameter to be modified and then press it. Next, the desired value must be adjusted and then pressed again.

ECG: It is possible to adjust the minimum ECG alarm to levels between 30 and 100 BPMs with intervals of 5 BPMs in "adult" mode and intervals of 1 BPMs in "neo" mode. It is possible to adjust the maximum ECG alarm to levels between 100 and 250 BPMs with intervals of 5 BPMs in "adult" mode and intervals of 1 BPMs in "neo" mode.

SpO2: It is possible to adjust the minimum SpO2 alarm to levels between 40 and 99 BPMs with intervals of 5 BPMs in "adult" mode and intervals of 1 BPMs in "neo" mode. It is possible to adjust the maximum ECG alarm to levels between 41 and 100 BPMs with intervals of 5BPMs in "adult" mode and intervals of 1 BPMs in "neo" mode.

NIBP: It is possible to adjust the minimum NIBP alarm to levels between 50 and 290 mmHg to systolic, diastolic and mean pressure with intervals of 5 mmHg. It is possible to adjust the maximum NIBP alarm to levels between 60 and 300 mmHg to systolic, diastolic and mean pressure with intervals of 5 mmHg.

CO2: It is possible to adjust the minimum CO2 alarm to levels between 18 and 96 mmHg, with intervals of 3 mmHg in "adult" mode and intervals of 1 mmHg in "neo" mode. It is possible to set the maximum CO2 alarm to levels between 21 and 99 mmHg, with intervals of 3 mmHg in "adult" mode and intervals of 1 mmHg in "neo" mode.

RESP: It is possible to adjust the minimum respiration alarm to levels between 3 and 147 rpm, with intervals of 3 rpm in "adult" mode and intervals of 1 rpm in "neo" mode. It is possible to set the maximum respiration alarm to levels between 6 and 150 rpm, with intervals of 3 rpm in "adult" mode and intervals of 1 rpm in "neo" mode.

Technical alarm test

To perform the alarm test do the following steps:

1 - Turn the equipment on, without cables or sensors connected. It should occur indication of technical alarm (text messages in Infocenter) disconnected sensor.

2 - After confirming the visual indication, connect the sensor correctly. If the indication disappears, the alarm is working properly.

Otherwise, change the sensor and repeat the test. If the result is the same, the alarm will probably be defective.

3 - Repeat this procedure for the other modules, remembering to test with their respective sensor and parameters.

4 - With the indication of an active technical alarm, press the button PAUSE AUDIO  for 1 s and check on screen the suspended alarm indication for all parameters.

Wait for 60 seconds and the alarm will activate. On the screen, the suspended alarm signal disappears, indicating the return of the alarm sound.

The time the alarm stays turned off is 60 s.

To turn the alarm sound on again, press the PAUSE AUDIO button  for 1 second.

The sound of the parameters of alarm can be turned on and off individually in the "Alarm" menu and in parameter menus.

Physiological alarm test

To perform the alarm test do the following steps:

- 1 - Turn on the equipment, with the electrodes properly connected. Verify the BPM value on the equipment screen and that there are no alarms.
- 2 - Through the e-Jog Control key on the panel, navigate to: PARAMETER CONFIGURATION > ECG CONFIGURATION > ALARM. With this same key, select one of the limits and then change its value so that the initially measured value is outside the range. Then go back to the main screen.
- 3 - Having done this, the alarm should sound. If it does not, the alarm is probably defective.
- 4 - Repeat this procedure for the other modules, remembering to test with their respective sensor and parameters.
- 5 - With the indication of an active technical alarm, press the button PAUSE AUDIO  for 1s and check on screen the suspended alarm indication for all parameters.

Wait for 60 seconds and the alarm will activate. On the screen, the suspended alarm signal disappears, indicating the return of the alarm sound.

The time the alarm stays turned off is 60 seconds.

To turn the alarm sound on again, press the PAUSE AUDIO button  for 1 second.

The sound of the parameters of alarm can be turned on and off individually in the "Alarm" menu and in parameter menus.

ATTENTION

By default, alarm sound is turned on when the monitor is turned on and the alarm sound is turned off when entering other mode: PACEMAKER, AED, DEFIBRILLATION (1 to 360 J) or AUTO SEQUENCE. Individual settings remain unchanged due to mode switches, so the user-selected setting prevails until a new patient is added, or a power interruption/shutdown occurs that lasts longer than 30 seconds.

In AED mode, the sound of all parameter alarms remains off since they can confuse or distract the operator, once the operation of this mode is guided by voice instructions.

Physics principle used

The biphasic cardiac defibrillator is an instrument that delivers energy previously stored in a capacitor to a patient. The defibrillation is external (when the capacitor's discharge is delivered through the patient's thorax).

The CardioMax uses biphasic shock technology, which is characterized by a current liberated in one direction and, after a brief period of time, reverted in the opposite direction.

During the defibrillation the myocardium is briefly depolarized by a strong positive and negative impulse of adjustable intensity (Truncated Exponential Biphasic Shock). These impulses are used to eliminate arterial, ventricular fibrillation, and ventricular disturbances.



Warnings

The CardioMax has a patient impedance meter that delivers shocks in 25 to 300 Ohms impedances.

If a cable or conductor is suspected of being ruptured, avoid using the equipment due to possible risk to the operator.

Ensure that the defibrillation electrodes of the CardioMax are at an appropriate distance from other electrodes so that the power applied does not flow through these electrodes.

Disconnect all equipment devoid of protection against the discharge of defibrillators.

Ensure that the patient does not come into contact with any metallic parts.

Use criteria

In defibrillation mode, the CardioMax must only be used if the following circumstances, as a whole, are presented:

- 1 - Unconscious victim.
- 2 - No breathing.
- 3 - No pulse.

Other important considerations regarding the use of the CardioMax:

- 1 - Not recommended for children under one year old.
- 2 - Pacemakers may affect the device's efficiency.
- 3 - Medicines in adhesive form must be removed before starting defibrillation.
- 4 - Hypothermic patients may not respond well to defibrillation.
- 5 - Once the removal of the patient is started, the defibrillation must be interrupted.

Qualified users

Shall be considered qualified users those who have a degree in Medicine.

External pads use

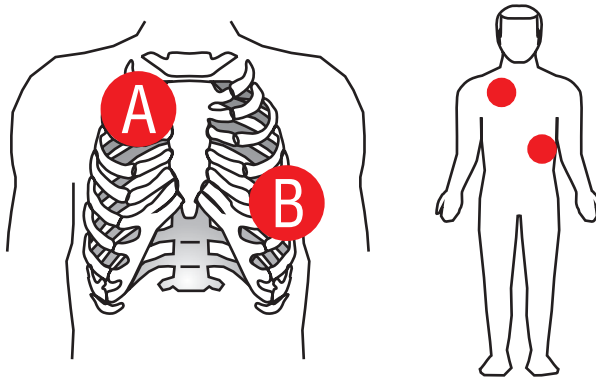
1 - Check if the pads are connected to the CardioMax. If they are not, connect the defibrillation cable to the pads socket located on the equipment's side (as show in the image below).



2 - Take both pads from their base pulling them up and out.

3 - Apply the conductive material to the pads' electrodes.

4 - Place pads as shown in the image below:



A - Sternum

B - Apex

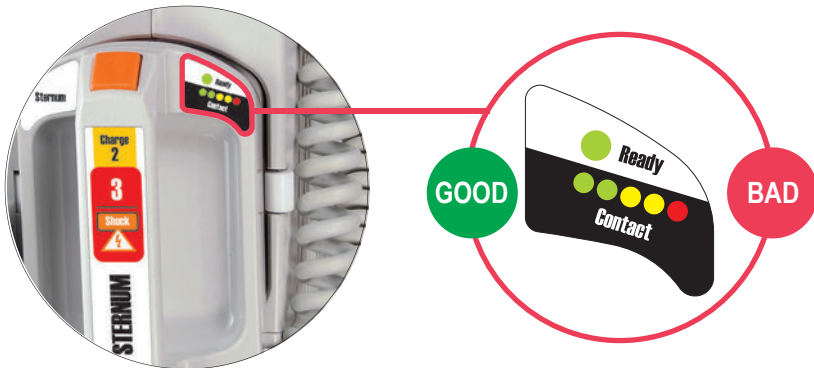
The electrodes must be placed in a position which will maximize the current that passes through the myocardium. The standard position is:

- a) **Electrode identified as “STERNUM”** on the right second intercostal space, mid-clavicular line.
- b) **Electrode identified as “APEX”** positioned on the left sixth intercostal space, midaxillary line.



ENSURE that the electrodes are away from each other. **DO NOT** apply paste or gel to the thorax between the pads or the current may follow a superficial route along the thorax wall and not reach the heart.

5 - Check contact with the patient.



The STERNUM pad has a patient contact indicator.

The indicator goes from BAD contact (red flashing LED) to GOOD contact (at least one LED on).

Make sure to adjust the pressure and the pads' placement to optimize contact with the patient, so that AT LEAST ONE GREEN LED remains on.

About shock delivery

Aligning the pressure of the pads and the conductive material applied to the electrodes, different patient impedances are obtained.

The table below indicates the conditions in which the CardioMax offers or inhibits the delivery of energy.

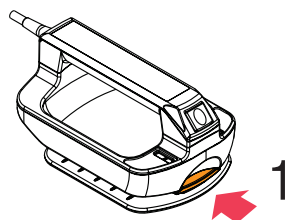
Patient's impedance	Shock	Message on screen after "Charge" key pressed	Values indicated on bargraph
Short circuit	Shock inhibited	Bad contact	All LEDs blinking
< 25 Ohms	Shock inhibited	Bad contact	All LEDs blinking
>25 Ohms e < 300 Ohms	Shock delivered and the waveform is adjusted according to the patient's impedance	No message	LEDs lit up indicating contact level
> 300 Ohms	Shock inhibited	Bad contact	Only the red LED is blinking
Short - open	Shock inhibited	Bad contact	Only the red LED is blinking

When all LEDs blink simultaneously the pads have a short circuit, and shock delivery will not be permitted.

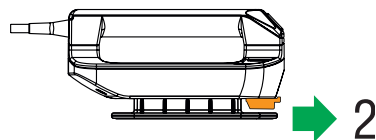
When only the RED LED is blinking, shock delivery will not be allowed.

Child pads use

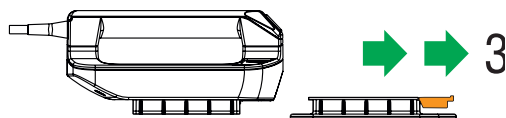
1 - Fasten the lock in the front of the adult external pads.



2 - Pull the pads base forward to remove them.



3 - This exposes the smaller electrode for children



The CardioMax will automatically identify that it is operating in pediatric mode. Energy is limited to 50 J in the pediatric mode.

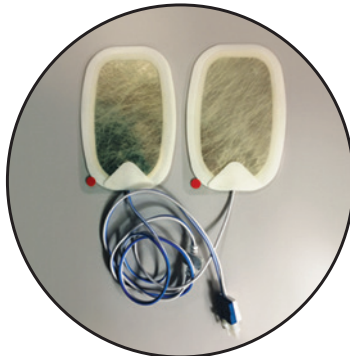
Using multifunction pads

The use of the multifunction pads (disposable) requires that the operator uses the adapter provided (extension cable) in order to connect them to the standard socket of the external pads, as described below:

- 1 - Connect the AED/pacemaker extension cable to the equipment.



- 2 - Connect the adhesive multifunction pads to the extension cable.



- 3 - Remove the multifunction pads' protective film and apply them to the patient, using the same positions recommended for the external pads (Sternum and Apex).





ATTENTION: the pads are disposable and for single-use, cannot be reused under any circumstances.

ATTENTION: after opening the wrapping, the pads should be used within 24 hours.

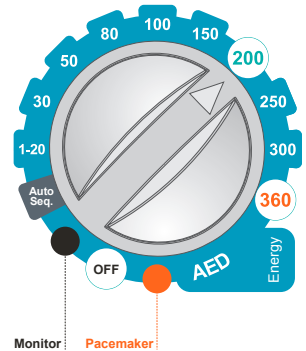
ATTENTION: in case of use for long periods, the pads should be replaced every 24 hours.

Defibrillation

Follow the steps 1-2-3

Step 1 - Select energy

Rotate the selection switch until you reach the energy desired. Energy options go from 1 to 360 J. In most cases, 200 J is recommended for adult use.



Step 2 - Charge



Press the “Charge” button (green) in the front panel or use the charge button in the external pads (orange).

While the CardioMax is charging, a sound will be emitted and the measurement of the charged energy will appear on the display.

The energy selected can be increased or decreased at any time just by rotating the selector switch to the new charge.

To cancel the shock press “Disarm”.

When the charge is complete, the device sends a sound signal and displays “Charge Ready” on the screen.

Step 3 - Shock



After the “Charge Ready” warning, press the “Shock” 3 button (orange) in the front panel or use **the two buttons** (orange) in the external paddles.

It is only possible to defibrillate using the pad buttons with the adult/child external pads.



CAUTION: make sure nobody is touching the patient! Tell passersby to stand clear of the patient!

The number of shocks and length of operation are indicated on the screen.

Synchronism - Synchronized discharge - Cardioversion

Remember: The function “Synchronized Shock” is disabled after the shock is delivered.



Monitor the patient with 3 or 5-leads ECG cables or with the defibrillation electrodes.

Press the “Sync” button in the front panel. Ensure that the synchronization marker is red and lined up with the “R” wave and the “SYNC” indication is displayed next to the selected energy value.

Follow steps 1-2-3 for defibrillation.



IMPORTANT: Keep key 3 (shock) or the two shock pads’ buttons pressed until the next “R” wave is identified. The CardioMax will deliver the shock when the next “R” wave is identified.

IMPORTANT: If CardioMax does not identify a valid QRS it will not trigger the shock! For this reason, do not use the cardioversion in Ventricular Fibrillation rhythms.

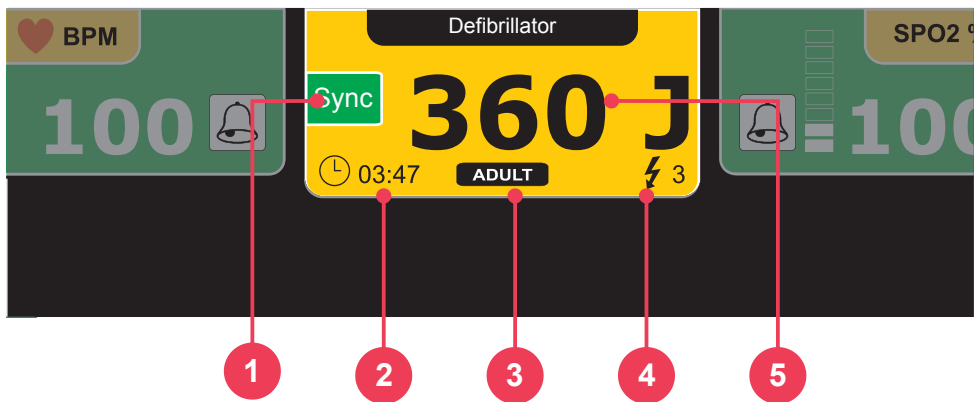
Cardioversion can cause discomfort to the patient, as well as skin redness.

Disarm key

Disarm

Disarm the stored charge. Charge may be disarmed at any time, whether the charge is ready or not.

Defibrillation display



1 - Synchronism

Indicates if sync is on or off. When it is turned on, the symbol blinks indicating the function is activated.

2 - Elapsed time

Indicates how long the equipment has been used for. The marker returns to zero if the equipment is turned off.

3 - Defibrillation electrode type

Shows which defibrillation electrode is connected to the equipment: ADULT (adult external pads), CHILD (child external pads) or ADHESIVE.

4 - Number of shocks

Shows number of shocks delivered. The counter is set to zero when the equipment is turned off.

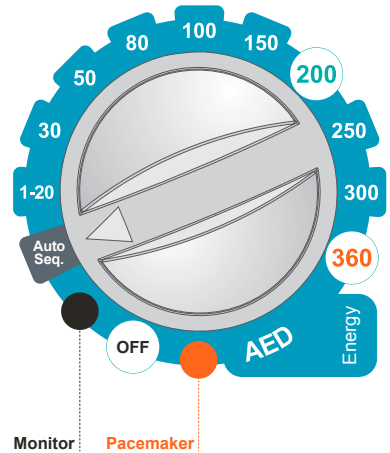
5 - Selected and charged energy

The energy SELECTED by the user is shown in this display area in BLACK numbers.

During the equipment's charging cycle, the value of the energy that has already been stored is displayed in RED. When the charge is complete the numbers are displayed in RED and blink, indicating the equipment is ready and the shock can be delivered.

Auto-Sequencing mode (Auto Seq)

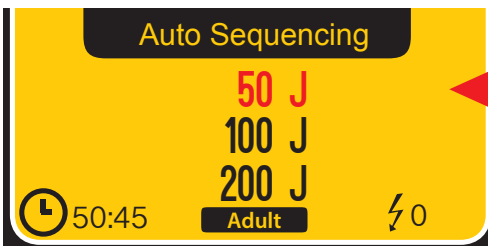
In the Auto Seq mode, the shock energy levels will follow the order previously set by the user in: "Defibrillation > Auto Sequencing Charge" (See "Defibrillation setup" below).



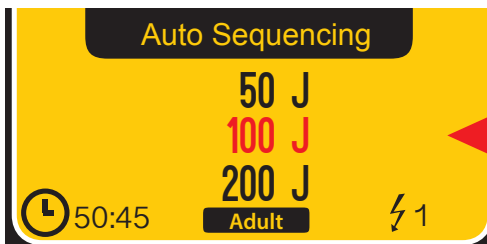
There are three sequential energy levels, being that, from the third shock on all subsequent shocks will use the same discharge value of the latter. The preset sequence will be interrupted in the following conditions:

- Equipment shutdown.
- Auto Seq mode exit.
- Reconfiguration of the Auto-Sequencing mode energy levels (available after the delivery of the third shock).

If child pads are used, the equipment will automatically limit the charge value to 50 J.



The energy to be charged is indicated in red



After shock delivery, the energy is updated with the next energy level

Defibrillation setup

DEFIBRILLATION SETUP

Internal discharge time	[30]	30		120
Sudden Death Prev.	[Off]	Off		On

CHARGE AUTO-SEQUENCING

First Shock	[50]	10		360
Second Shock	[100]	10		360
Third Shock	[200]	10		360

back
exit

1 - Internal discharge time

Determines how long the equipment keeps the charge ready before discharging it internally.

2 - Sudden Death Prevention (SDP)



Turn on or off the Sudden Death Prevention mode. When on adhesive pads or electrodes monitoring, the equipment sets off the alarm and shows “Shock Indicated” if ventricular fibrillation/ventricular tachycardia (VF/VT) is identified.

3 - Charge Auto-Sequencing

Sets energy levels for the Auto Seq mode. The user can select energy levels of 10 to 360 J for the first, second and third shocks. Preset values are 150 J for the first shock and 200 J for the next shocks.

If child pads are used, the equipment limits energy levels to 50 J. When using child pads followed by use of adult pads, the last values set for adult pads are recovered.

The charge and shock delivery processes are operated manually. After every delivery, the energy levels are updated.

4 - Back/Exit

“BACK” to configuration menu or “EXIT” to go to the monitoring screen.

Functional test



WARNING: the functional test must be executed daily in order to guarantee that the equipment is in working order and ready to use.

FUNCTIONAL TEST

Put the Paddles on the support ☒

Select 100J ☒

Press CHARGE ☐

Press SHOCK ☐

back

exit

Step 1

Place pads on their base located on top of the equipment.

Step 2

Select 100 J of energy.

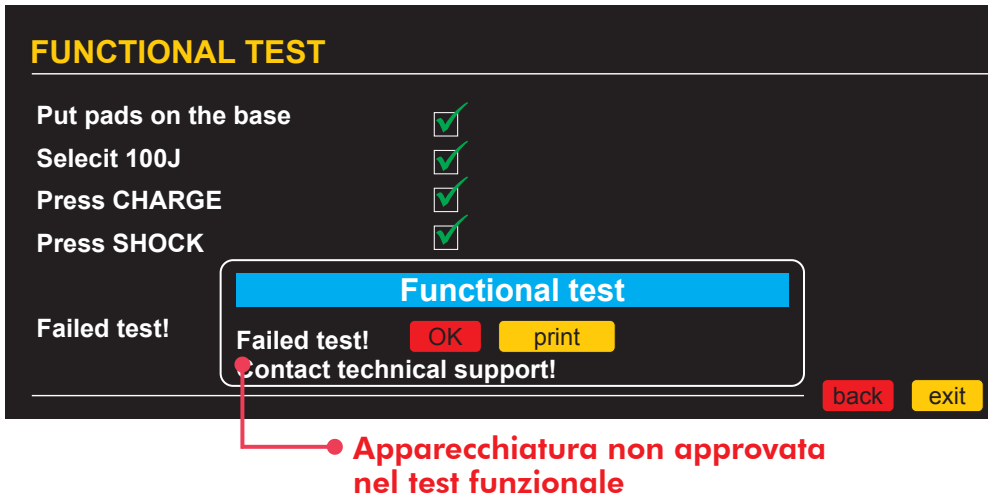
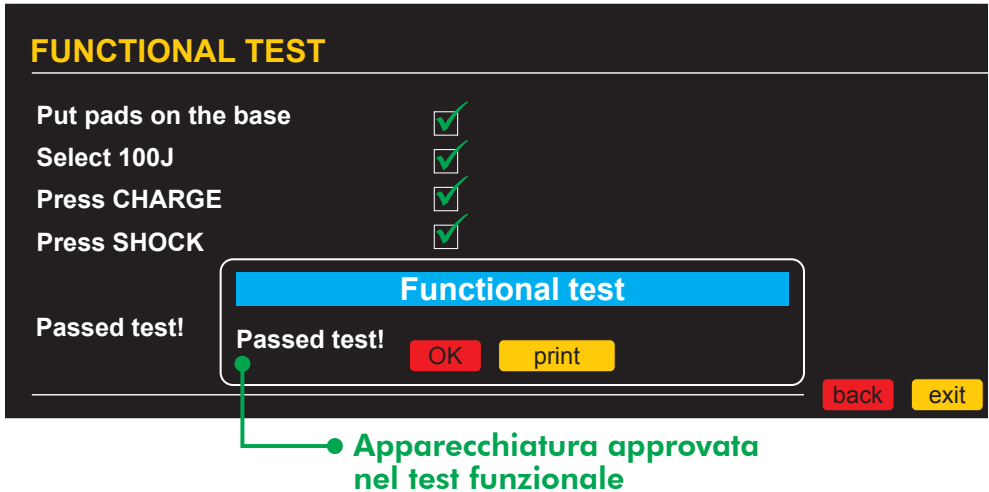
Step 3

Press the “charge” key and wait until the equipment sends the charge ready signal.

Step 4

Press the “shock” key.

Result screens for functional tests



Remember: if CardioMax fails the functional test, contact technical support IMMEDIATELY.

NOTE: printouts of test results will only be available in the CardioMax units equipped with a thermal printer.

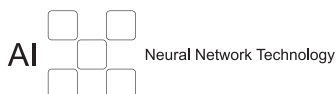
NOTE: the CardioMax indicates failure in the functional test when there is a failure in one of the 4 steps of the functional test or when the power delivered has an energy exceeding that allowed by health standards.

Introduction

Given the complexity of clinical variables involved, for many years only doctors and experienced paramedics could use defibrillators to reverse a cardiac arrest.

Nowadays, however, with the evolution of artificial intelligence (AI), the CardioMax, using its Neural Network Technology, is capable of assessing, via sophisticated sensors, the patient's state, consider the clinical variables and deliver automatically the most indicated shock therapy.

This allows any individual with adequate training, to perform assistance to a victim in fibrillation process, facilitating and multiplying lifesaving possibilities.



Characteristics

- Artificial Intelligence: accurate diagnosis of the patient's conditions, indicating shock delivery or not.
- Safety safeguards: avoids accidental use, in cases in which shock treatment is not indicated or in healthy people.
- Voice orientation and screen indications.
- Internal recording of events.
- PC connection via USB.
- Connection software, data download and management via PC.
- Biphasic shock.
- Automatic self-test.
- Use in hospital or out-of-hospital environment including emergency rescue units.

Physics principle used

The biphasic cardiac defibrillator is an instrument that delivers energy previously stored in a capacitor to a patient. The defibrillation can be external (when the capacitor's discharge is delivered through the patient's thorax) or internal (applying the capacitor's discharge directly to the heart with an open thorax and during surgical procedure).

The CardioMax uses biphasic shock technology, which is characterized by a current liberated in one direction and, after a brief period of time, reverted in the opposite direction.

During the defibrillation the myocardium is briefly depolarized by a strong positive and negative impulse of adjustable intensity (Truncated Exponential Biphasic Shock). These impulses are used to eliminate arterial, ventricular fibrillation, and ventricular disturbances.



Warnings

The CardioMax has a patient impedance meter that delivers shocks in 25 to 300 Ohms impedances.

If a cable or conductor is suspected of being ruptured, avoid using the equipment due to possible risk to the operator.

Ensure that the defibrillation electrodes of the CardioMax are at an appropriate distance from other electrodes so that the power applied does not flow through these electrodes.

Disconnect all equipment devoid of protection against the discharge of defibrillators.

Ensure that the patient does not come into contact with any metallic parts.

In this AED mode, all of the HIGH PRIORITY and MEDIUM PRIORITY alarms are disabled, keeping only the VISUAL ALARM of the ECG HIGH PRIORITY and MEDIUM PRIORITY ALARM.

Use criteria

In defibrillation mode, the CardioMax must only be used if the following circumstances, as a whole, are presented:

- 1 - Unconscious victim.
- 2 - No breathing.
- 3 - No pulse.

Other important considerations regarding the use of the CardioMax:

- 1 - Not recommended for children under one year old.
- 2 - Pacemakers may affect the device's efficiency.
- 3 - Medicines in adhesive form must be removed before starting defibrillation.
- 4 - Hypothermic patients may not respond well to defibrillation.
- 5 - Once the removal of the patient is started, the defibrillation must be interrupted.

Qualified users

Shall be considered qualified users those who have a degree in Medicine.

Operation

Before starting the operation, call the emergency service.

Step 1 - Connect disposable pads to the CardioMax



If the disposable pads have not been connected to the CardioMax yet, attach the connector to the plug on the right side of the equipment.

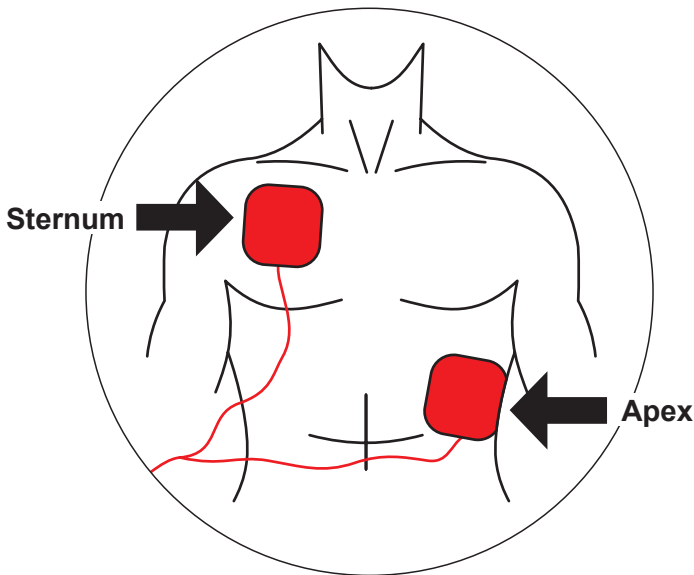
After disposing of used pads, always leave a replacement pair already connected to the equipment, avoiding having to replace them at the moment of the emergency.

ATTENTION: this device has electronic safeguards and will not operate in inadvisable situations.

Check patient's condition. Only use the equipment if the patient is not breathing.

NOTE: When using child pads, the shock will be set in 50 J.

Step 2 – Apply pads to patient



Remove pads from their wrapping and peel off the film protecting the adhesive.

Place pads on the patient according to the picture above, keeping adhesive area in contact with the skin.

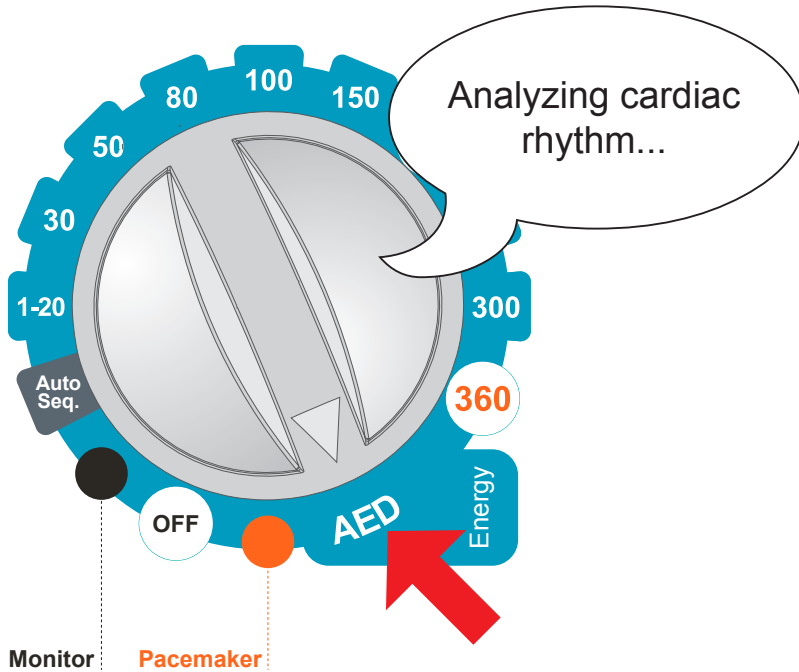
This position allows the electric current to circulate from one pad to the other, thus reaching the whole thoracic cage.

ATTENTION: the area in contact with the pads must be dry.

he presence of too much hair in the contact area may affect scanning. In this case, shave hair.

ATTENTION: the pads must be applied directly over the skin. DO NOT place pads over clothes.

Step 3 - Select AED



Rotate the selector switch to the AED position.

The CardioMax will automatically enter cardiac rhythm analysis mode and will start giving vocal instructions clearly and pausedly, so that the user can perfectly understand them.

ATTENTION: the patient must be on a steady surface. Any movement during the process of clinical analysis will result in mistaken scans.

ATTENTION: the pads are disposable and can be used in only one patient at a time. Remember to always keep extra ones with the equipment. For replacements, please contact Instramed.

Step 4 - Deliver shock



If the need for shock is detected, the shock symbol will blink and the device will ask the user to press the shock button again.

Press “SHOCK” button again.

The shock will be delivered

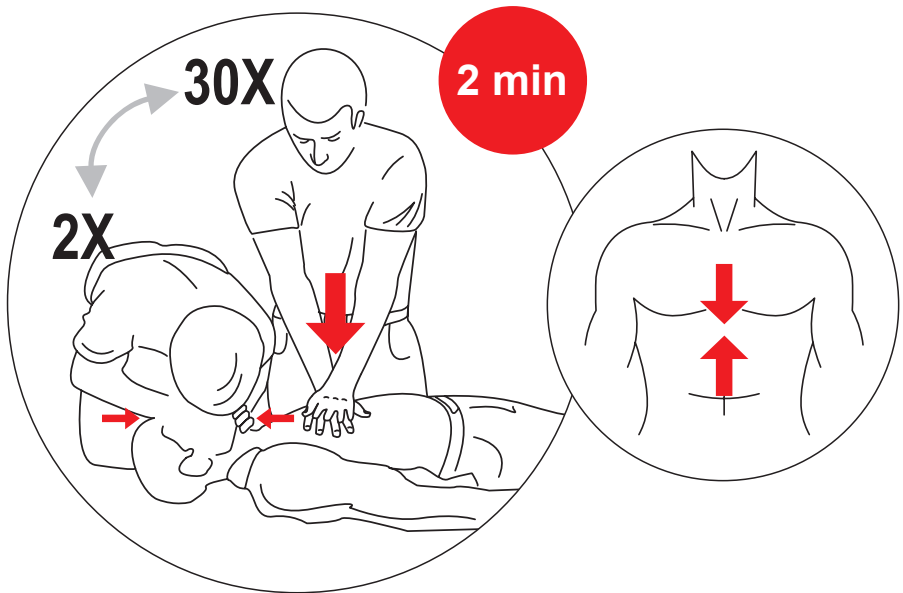
ATTENTION: the user must not touch the patient or conductive surfaces in contact with him/her during shock delivery, under risk of suffering a powerful electric discharge.

NOTE: The energy delivered is pre-adjusted. The user cannot alter this protocol. For adult electrodes: 1st shock is 150 J and the following are 200 J; for child electrodes, all shocks are 50 J.

If clinical scans show that defibrillation is not recommended, the CardioMax will announce: “TREATMENT NOT RECOMMENDED”.

Check if there was no movement of the patient during the analysis. If so, restart the process. If not, remove pads and start the CPR (cardiopulmonary resuscitation) procedure. Details on the next section.

Step 5 - Start CPR



After the shock, start the CPR procedure.

CPR (cardiopulmonary resuscitation) is a technique which consists in mechanical stimulation of the lungs and heart. Through simple actions, it aims to maintain the oxygenation of the brain, avoiding irreversible damage.

Applying CPR

- 1) Lay the victim on his back on a hard flat surface.
- 2) Run your fingers from the center of the victim's thorax, descending until finding a bone that comes to a tip in the middle of the chest (Sternum), right above the stomach.
- 3) Keep two fingers right below this point.
- 4) Place the palm of your other hand above the two fingers that indicate the base of the Sternum bone. This is the correct spot for the massage.

CONTINUES>

5) Put one palm on top of the other, keeping your fingers curled up without touching the thorax. In small children, however, use only your fingers. Apply force according to the victim's size.

6) Keep your arms stretched. Put pressure on the victim's thorax, compressing the chest and then releasing it. Follow the BEEPS emitted by the CardioMax, which mark the rhythm of the compressions. Every 30 compressions, apply 2 mouth-to-mouth ventilations.

7) Performing mouth-to-mouth breathing:

- Place one hand on the back of the victim's neck and lift it; place your other hand on the victim's forehead and force the head back, in order to let the air through.
- Close the victim's nostrils with the fingers which are on the forehead.
- Take a deep breath, and place your open mouth on the victim's mouth (if it is a child, also cover the nose with your mouth).
- Force air inside the victim's lungs, until the thorax inflates, as in normal breathing.
- Allow the person to release the air by removing your mouth.

8) At every interval to perform mouth-to-mouth breathing, check if the patient's pulse is back.

The massage and ventilation cycle must be done for two minutes. If the patient's pulse does not return, restart shock procedure with the CardioMax.

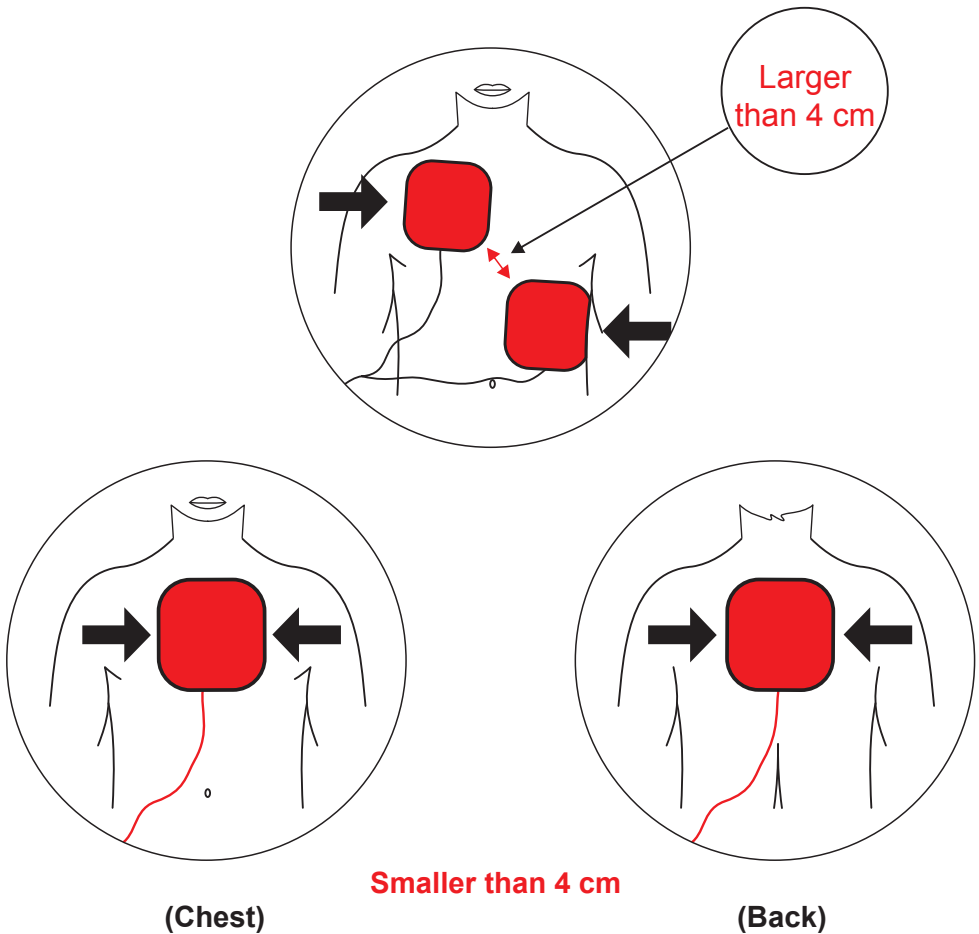
After the third complete CPR and shock cycle, chances of the patient's resuscitation are very slim.

The CardioMax also has the CPR Maestro accessory, to help in the efficient application of CPR. For more information, see the chapter "CPR Maestro".

Using the CardioMax on children under 8 years old

The CardioMax can be used on children from the age of one year onwards. However, on patients from one year of age to eight years of age or patients who weigh less than 40 Kg, some precautions must be taken:

- **Use child pads;**
- **If the pads cannot be placed within the minimal distance of 4 centimeters between them, place one of them on the child's chest and another on his back.**



Alarm system

The alarm system in AED mode consists of a single alarm, as the table below:

ALARM CONDITION	The equipment is ready to shock the patient with the energy previously established in the algorithm, just waiting for the operator to press the shock button.
ALARM PRIORITY	High.
VISUAL ALARM SIGN	Messages in Infocenter flashes red at a frequency of 2 Hz which active cycle of 50%.
VERBAL ALARM SIGN	Voice statement with the following text: "press the button to treat the patient".
POWER SOUND	85 dB.
DELAY ON ALARM SIGNAL GENERATION	Less than 5 seconds.
OPERATOR POSITION	The operator should be at the frontal face of the equipment, a maximum distance of 1 m.

Pause or inactivation of warning signs

According to NBR IEC 60601-2-4, it is not possible for the operator to pause or disable the alarm signals to the device **ALARM CONDITION**.

Alarm Checking

You can check the operation of alarm signals using an ECG simulator device, capable of generating signals of ventricular fibrillation. It is recommended that this check is done by a qualified technician, during preventative maintenance (see "Inspection and maintenance").

Information signals

CardioMax AED mode has information signals that can be visual, audio and verbal.

VISUAL INFORMATION SIGNAL	DESCRIPTION
Patient BPM	Number of heart beats per minute of the patient detected by the equipment.
ECG waveform	ECG waveform of the patient detected by the equipment.
CPR interval counter	Informs the elapsed time since the recommendation of the CPR procedure. In manual mode, reports the elapsed time since the entry on this mode.
Illustrative picture of the current procedure step	Picture illustrating to the operator which stage of the automatic procedure the equipment is performing at the moment.

AUDITIVE INFORMATION SIGNAL (BEEP)	DESCRIPTION
Metronome for CPR compressions	The equipment beeps at a frequency of 100 beeps per minute, helping the user in performing the cardiac compressions.

The equipment also has verbal information signals. The differentiation of verbal information signals and verbal alarm signal is given in two ways:

Sound power

Verbal information signals will always be at least 6dB(A) below the set to the alarm signal.

Messages content

Verbal information signals have the following messages:

- Analyzing heart rhythm.
- Perform CPR for two minutes.
- Treatment recommended – do not touch the patient.
- Shock is not recommended.
- Put the paddles on the patient's chest.
- Energy is being discharged internally.
- Don't touch the patient
- Children's paddles.
- Treatment successfully
- Give two breaths
- Check the patient respiration or pulse if you cannot detect either, perform CPR for two minutes.

Physics principle used

The external pacemaker applies a squared waveform of variable frequency and intensity to the heart in order to stimulate heartbeats. In a normal heart, the heart beats as follows: the sinoatrial node, located in the right atrium, stimulates the heart's contraction. It is controlled by the parasympathetic system that by freeing acetylcholine, performs a depressor effect while a sympathetic innervation, when stimulated, produces noradrenaline, which accelerates the rhythm. This potential is then propagated through the atrial myocardium and then reaches the second most important system center, the atrium-ventricular node, also located in the right atrium, which transmits the potential to the ventricles through the atrium-ventricular and its branches.

The pacemaker uses electrical stimulation to reproduce or regulate the heart's rhythm.

Its function is to supply pulses in order to stimulate the heart. These pulses have two characteristics that must be adjusted: The number of pulses per minute (PPM) and the strength of the current (mA). The pacemaker works in two modes: fixed or on demand (synchronous).



Warnings

The CardioMax has a patient impedance meter that delivers shocks in 25 to 300 Ohms impedances.

If a cable or conductor is suspected of being ruptured, avoid using the equipment due to possible risk to the operator.

Prolonged use of external pacemaker may cause erythematous skin.

In this Pacemaker mode, only the SOUND of the HIGH PRIORITY AND MEDIUM PRIORITY alarms are disabled.

Fixed mode

In this mode, the pacemaker does not consider the patient's heart frequency and applies the PPM number defined by the user.

Demand mode (synchronous)

In this mode the CardioMax assesses the patient's heart rate, applying the PPM number selected in the panel only when the heart rate is lower than the PPM value indicated. It must be within at least 5 BPM (the security margin) for the pacemaker to work.

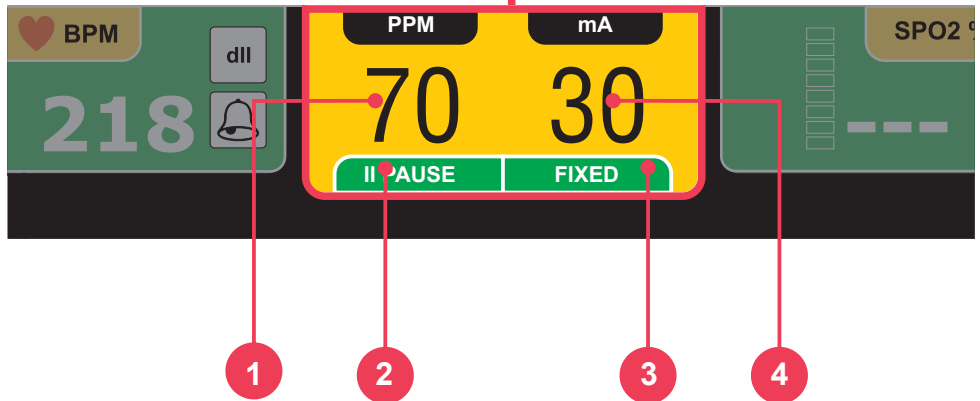
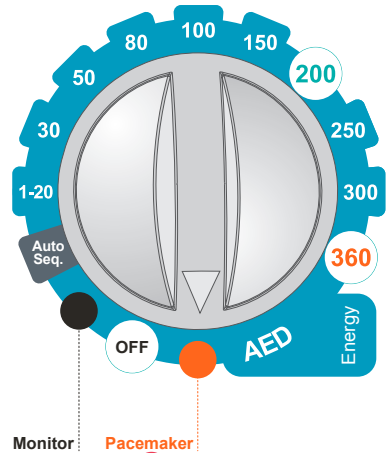
In this mode, the pacemaker uses the ECG signal captured by the electrodes (patient cable), synchronizing the pulses in order to prevent the heart's vulnerable phase.

Operating in pacemaker mode

Place the selector switch on pacemaker mode.

The screen below will appear.

With the e-Jog, navigate on the yellow area to configure the pacemaker's parameters.



1 - PPM: selection of the pacemaker's stimulation frequency. The user alters the "Pulses Per Minute" (PPM) value.

2 - Changes between "PAUSE" and "ON" in the Pacemaker mode. In "PAUSE" mode, it does not emit any stimulation.

3 - Allows the change between "FIXED" and "DEMAND" modes.

4 - mA: alters the stimulation current in milliamperes.

Starting stimulation

- 1 - If it not yet connected, connect the adhesive pads cable to the CardioMax.
 - 2 - Check if the multifunction adhesive pads package is intact and within the expiration date.
 - 3 - Insert the adhesive pads connector into the equipment's extension cable.
 - 4 - Put the adhesive pads on the patient according to package instructions.
 - 5 - In case of demand mode stimulation, apply ECG monitoring electrodes.
-

Fixed stimulation

- 1 - Rotate the dial to the pacemaker mode.

The pacemaker starts in PAUSE, without stimulation pulses.

The mode must be changed to FIXED.

- 2 - Select the leads for ECG viewing.
- 3 - With the e-Jog, adjust the initial current and frequency (PPM) values (see the previous page). The current value must be as low as possible.
- 4 - Go to "ON" with the e-Jog, in order to start stimulation. A message in the "Infocenter" will inform the pacemaker is active.
- 5 - Check if the pacemaker's pulse meter appears on the screen.
- 6 - Increase the stimulation current until the heart rate is captured. This is indicated by the presence of the QRS complex (Q, R and S waveforms) right after the pacemaker marker.

Under demand stimulation

- 1** - Rotate the selector switch to the pacemaker mode. The pacemaker starts in PAUSE, without stimulation pulses.
- 2** - Select the leads for viewing the ECG. Check if the “R” wave indicators mark every “R” wave present on the screen. If not change the derivation.
- 3** - Adjust the initial current values and frequency (PPM) with the e-jog. The current value must be as low as possible.
- 4** - With the e-Jog, go to “ON” to start stimulation. A message in the “Infocenter” will warn that the pacemaker is active.
- 5** - Check if the pacemaker's pulse meter appears on the screen.
- 6** - Increase the stimulation current until cardiac capture occurs. The capturing is indicated by the presence of a QRS straight after the pacemaker marker.

NOTES

There may be spontaneous beatings not related to the application of stimulation. If the patient's heart frequency is above the pulse's frequency, the stimulation pulses will not be applied and the stimulation markers will not appear.

Stimulation will not start if there is a problem with the multifunction (adhesive) paddles or contact with the patient.

The stimulated pulses will be applied in the asynchronous mode if there is a connection problem with the ECG monitoring electrodes or if the CardioMax does not identify a valid QRS.

Defibrillation

If defibrillation is necessary, turn the switch to defibrillation mode. The CardioMax automatically inhibits the pacemaker's stimulation pulse.

Physics principle used

ECG is the measurement of electrical potential generated by the depolarization and re-polarization of heart cells, generating the bioelectrical impulse responsible for the heart's contraction. Heart impulses are detectable on the body surface by applying electrodes. Each electrode's potential is amplified and processed by the heart monitor, displayed on the screen and then used to calculate the heart's frequency (BPM).

The heart cycle period is the elapsed time from any point in the ECG cycle to the corresponding point in the next cycle. For example, the interval "R-R" is the time between two successive "R" waves. Using this measurement, it is possible to determine the beats per minute (BPM).



Warnings

Use only original Instramed cables and conductors. Other ECG cables may impede defibrillation or not work correctly.

If you suspect a cable or conductor is ruptured, avoid its use due to possible risk to operator.

If the patient has a pacemaker, do not rely solely on the equipment alarms. Keep the patient under observation.

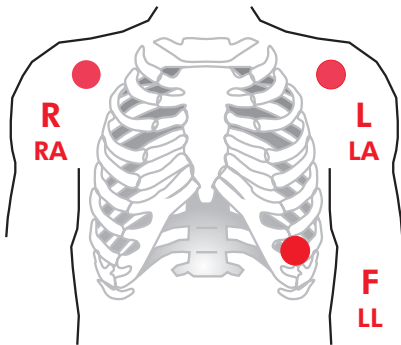
The cardiac frequency measurement can be affected in the presence of a transcutaneous pacemaker.

The ECG electrodes are disposable and single-use and cannot be reused under any circumstances.

Monitoring ECG

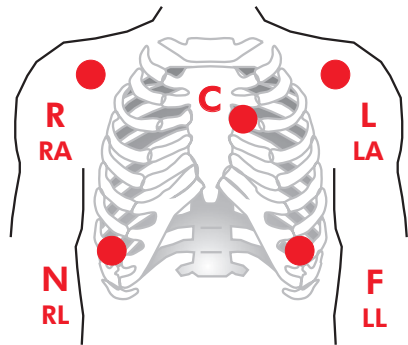
- 1 - Connect the ECG cable into the ECG socket in the equipment's side panel.
- 2 - Select the electrodes to be used on the patient. Use only one kind or brand of electrode. The electrodes must follow AAMI standards for electrode performance.
- 3 - Prepare the application area according to the manufacturer instructions.
- 4 - Apply the electrodes according to the images below, following the color pattern on the table on the following page.
- 5 - Connect the patient's ECG cable to the electrodes.

3-wire cable



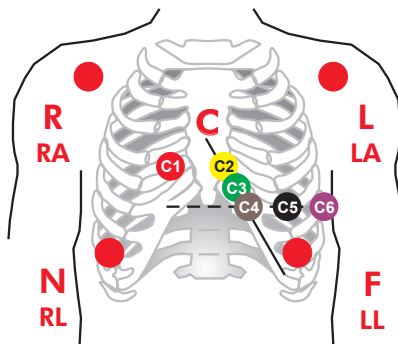
(3 derivations)

5-wire cable



(7 derivations)

10-wire cable



(12 derivations)

Leads

Lead	Electrode differential	Reference
DI	LA - RA	LL
DII	LL - RA	LA
DIII	LL - LA	RA
aVR	RA - (LL+LA)	RL
aVL	LA - (LL+RA)	RL
aVF	LL - (LA+RA)	RL
C (V1 - V6)	C - (RA+LA+LL)	RL

Color patterns

There are two color patterns for ECG cables. The CardioMax uses the IEC pattern. See the table below.

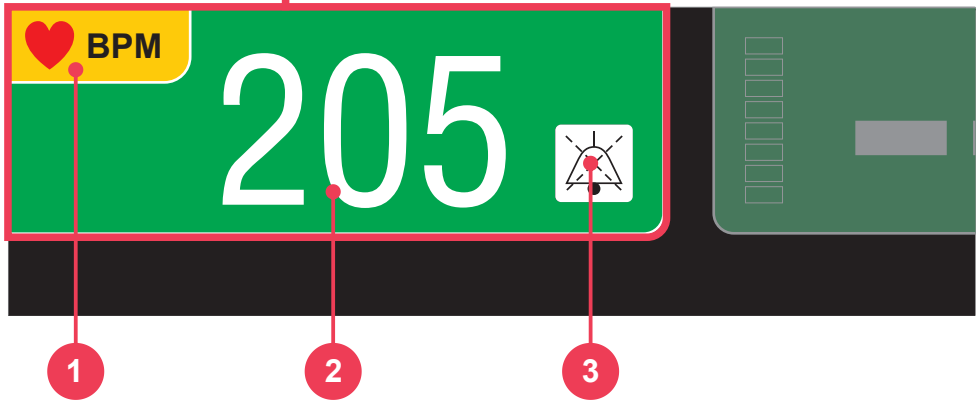
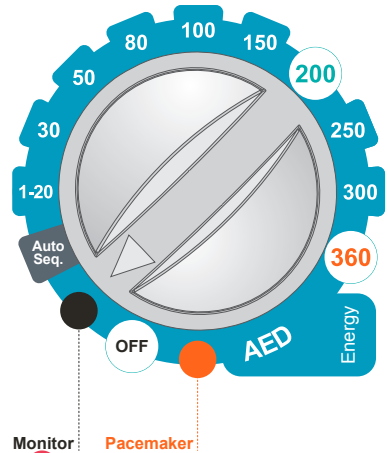
Position	IEC (European)	AHA (American)
Right Arm	R - Red	RA - White
Left Arm	L - Yellow	LA - Black
Left Leg	F - Green	LL - Red
Right Leg	N - Black	RL - Green
Thorax	C - White	V - Brown

Operating in monitor mode - ECG

Turn the selector switch to the Monitor mode.

All ECG and SpO₂ alarms will be enabled.

The next screen will be displayed.

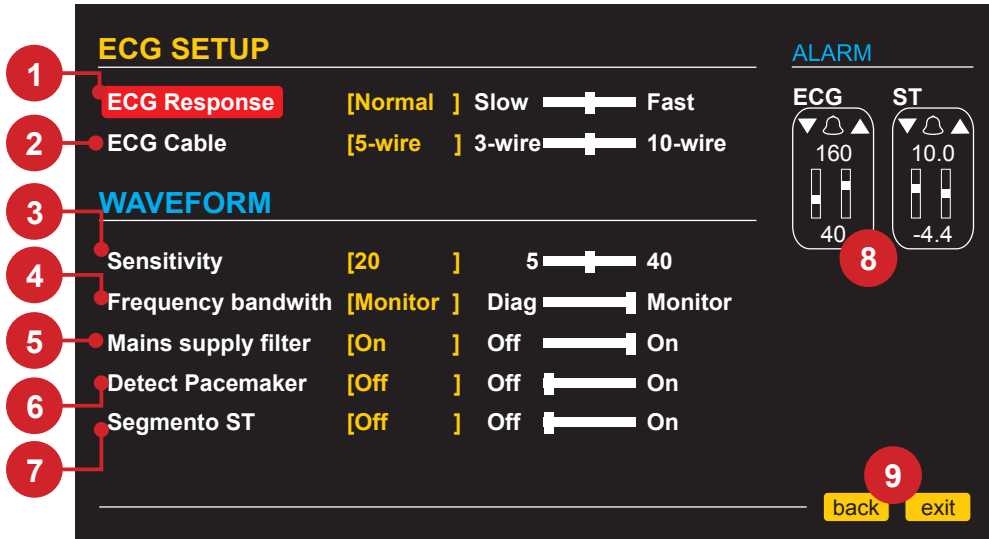


1 - ECG Symbol. The ECG icon represents an expanding heart that indicates that the ECG's "R" wave peak has been detected.

2 - ECG numeric value and BPM measuring unit.

3 - The "BELL" Icon - Indicates audio in pause or off.

ECG Setup



1 - ECG response

Select the ECG numeric update response. You can select from “SLOW”, “NORMAL” and “FAST” responses.

NORMAL: used for most patients, this mode uses 16 beats to define the average.

FAST: used when the operator needs faster responses. It is affected by the patient's movements, using 8 beats to define the average.

SLOW: less affected by the patient's movements. However, you must pay attention to the slow response of the heart rate variation. This mode uses 32 beats to define the average.

2 - ECG cable

It allows selecting the ECG monitoring by cable with 3 lead, 5-lead or 10-lead.

Using the 3-wire ECG cable in the SDP (Sudden Death Prevention) makes it functional only in the DII lead.

3 - Sensitivity

Select the ECG amplification gain. You can select from 5, 10, 15, 20, 30 or 40 mm/mV.

4 - Frequency bandwidth selection

Filter selection for power interference. "Diag" or "Monitor".

5 - Mains supply filter

Enables to turn filter on or off to reduce mains supply interference with the ECG signal.

6 - Detect pacemaker

Enables to turn the pacemaker detection mode on or off. When on, the equipment indicates on the screen the pacemaker's pulse moment. Detect pacemaker mode must only be used on patients with pacemaker.

7 - ST segment

Enables/disables the presentation of the ST segment. The visual indication will occur in the column at the end of the parameter curves, before the numerical values.

8 - Alarm

The "BELL" icon indicates audio "OFF", "ON" or "PAUSED".
Alarm limits configuration "MINIMUM" and "MAXIMUM".

9 - Back/Exit

"Back" to Configuration menu and "Exit" to monitoring screen.

Relation between ST elevation and myocardial infarction

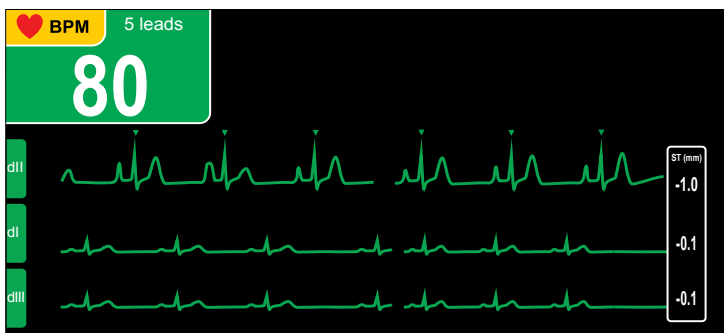
Acute myocardial infarction is a necrosis process of part of the cardiac muscle due to the interruption of blood flow in the coronary arteries. Early diagnosis is a key factor in reducing mortality and possible sequelae for the patient.

One of the most precise forms for this diagnosis is the identification of anomalies on ST elevation, which can be identified in the electrocardiogram (ECG) evaluation.

When a ST elevation bigger than 2 mm is detected, the patient may be suffering the acute phase of a myocardial infarction.

When a ST depression of more than 2 mm is detected, the patient may be suffering from myocardial ischemia (malnutrition of a certain part of the myocardium).

Ranges up to ± 2 mm are frequent and normal in healthy patients.



ST elevation characterization

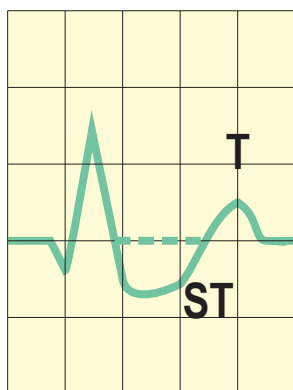
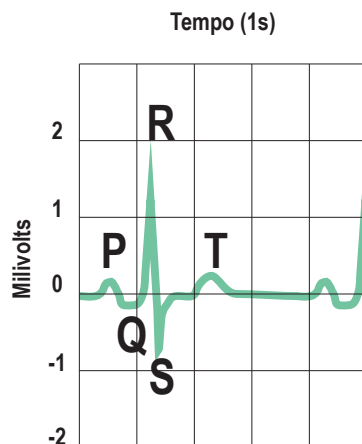
The waves recorded on the ECG are identified by the points ranging from P to T, as shown in figure 1.

The ST segment begins at the point at which the set Q-R-S ends, presenting upward curve in a normal situation.

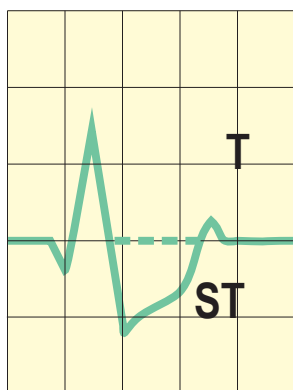
The indication of possible acute myocardial infarction is an evident decrease of the ST segment, represented by the decrease or inversion of the concavity of this region of the curve (other figures).

Segment ST normale

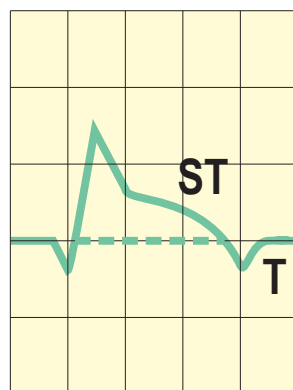
(Figure 1)



Sottolivellamento di ST



Sottolivellamento di ST



Sopraslivellamento di ST

ST levels detection

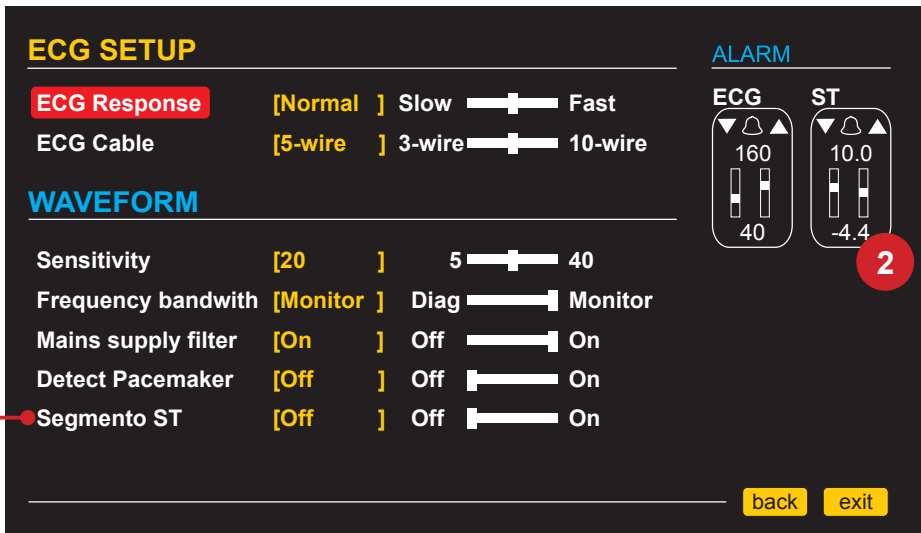
The CardioMax has internal algorithms for measuring ST levels.

It will be measured seven ST segments of DI, DII, DIII, aVR, aVL, aVF and C derivations. These 7 ST gradients will be shown on the screen at the right end of each curve.

ST segment configuration

Using the e-Jog, in the main menu, select the ECG parameter and in its submenu, the "ST Segment" function to turn on or off this analysis function.

See figure bellow



1 - ST segment

Location of the power switch for displaying the "ST Segment" on the main screen of CardioMax.

2 - Alarm

Bell icon - Indicates sound alarm off or on. Minimum and maximum alarm limits configuration both in the ECG menu and in the alarm menu.

Physics principle used

CardioMax uses oscillometric mode to calculate Non-Invasive blood pressure. A armband is used to convey arterial pressure changes caused by blood flow. The armband is inflated to a pressure higher than systolic pressure in order to occlude blood flow in extremities. Gradually, armband pressure is reduced generating little pulses or oscillations.

Mean pressure is the lowest pressure in the armband, in which detected oscillation peaks have higher amplitude. Systolic pressure occurs when oscillation increases quickly and diastolic pressure occurs when oscillation decreases in the same intensity. As a characteristic of oscillometric mode, mean pressure is the most precise one.



Warnings

If you suspect a cable or conductor is ruptured, avoid using the equipment due to possible risk to the operator.

The armband must not be applied on the same limb or extremity where the SpO₂ sensor is. When inflating the armband, SpO₂ monitoring may be affected.

Do not place armband on limb or extremity which is being used for intravenous infusion, or in any area where circulation is compromised.

The CardioMax shows the results of the last NIBP measurement until a new measurement is obtained. If the patient's conditions change between measurements, the monitor will not detect it.

Patient's excessive movements may cause imprecise measurements.

During NIBP monitoring, avoid compression or restriction of the pressure tubes.

The NIBP connection is protected against defibrillation discharges. It is not necessary to remove the armband from the patient or disconnect it in case of defibrillation.

In case the equipment is accidentally wet, dry it with a clean cloth.

A doctor should be consulted to interpret the non-invasive blood pressure measures.

Non-invasive Blood Pressure measurements are not intended for use during procedures with High Frequency surgical equipment such as electro bistoury.

Non-invasive Blood Pressure measures are not intended for use during patient transportation, out of the medical environment.

Harmful injury to the patient may be caused by the continuous pressure of the ARMBAND and resulting from twists in the connecting tubing.

Very frequent measurements of blood pressure can cause injury to the patient, because of interference with blood flow.

Injury to the patient can be caused if the ARMBAND is positioned on top of a WOUND.

Injury to the patient and temporary interference in blood flow may be caused in the event of pressurization of the ARMBAND where there is an intravascular access or arteriovenous connection.

Measuring blood pressure in the arm on the same side of a mastectomy can cause measurements to be inaccurate. In this case, use the contralateral arm.

Pressurization of the ARMBAND may cause temporary loss of function of the equipment being used on the same limb.

In patients where the measurement is FREQUENT, it must be checked if there is a prolonged reduction of blood circulation in the patient.

For a blood pressure measurement with greater precision, it is necessary:

- Patient at rest.
- User adjust pressure reduction rate when necessary.
- Patient must be:
 - Comfortably seated.
 - With legs uncrossed.
 - With feet flat on the floor.
 - With the middle of the ARMBAND in the right atrium level of the heart.
 - Patient relaxed and avoiding speaking.
 - It is recommended that there be a 5-minute pause before the first reading is taken.
 - Operator position in NORMAL USE.

Any reading of blood pressure may be affected by the location of the measurement, patient position, exercise or physiological condition of the patient.

If the operator notices unexpected readings, he must check the positioning of the ARMBAND, the position of the patient, check if the patient's clothing sleeve is in the way and take a 5-minute break before the next measurement.

Monitoring Non-Invasive Pressure

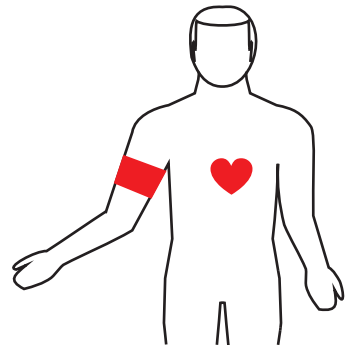
- 1 - Connect the extremity of the extension hose to the equipment's front panel.
- 2 - Measure the limb in which the armband will be applied to and select an adequate type. See the chart below.
- 3 - Place the armband according to the "Placing the armband" item.
- 4 - Connect the armband to the extension hose.
- 5 - Select one of the measurement modes: manual, automatic or stat.

ARMBAND SELECTION

Armband	Limb circumference (arm/leg)
Child	10 to 19 cm
Pediatric	18 to 26 cm
Adult	25 to 35 cm
Extra Large	33 to 47 cm

PLACING THE ARMBAND

- 1 - Select the measurement place. Choose a place with good blood circulation, without skin problems and in which armband use does not harm the patient. Because of convenience and because of the fact that standard values are based on this location, give preference to the upper arm.
- 2 - Check the armband's appropriate size for the chosen area according to the previous chart.
- 3 - Make sure the limb is supported to guarantee that the armband is at the heart's level. Due to the hydrostatic effect, placement above or below the heart's level may cause incorrect measurements.
- 4 - Ensure the ARTERY Mark is above the brachial artery.



Measurement modes

1 - Manual: Instantaneous measurement of systolic, diastolic and mean pressure.

To activate the manual mode, press NIBP MANUAL MEASUREMENT in the front panel or in the NIBP Menu Setup, select the Manual Measurement item.

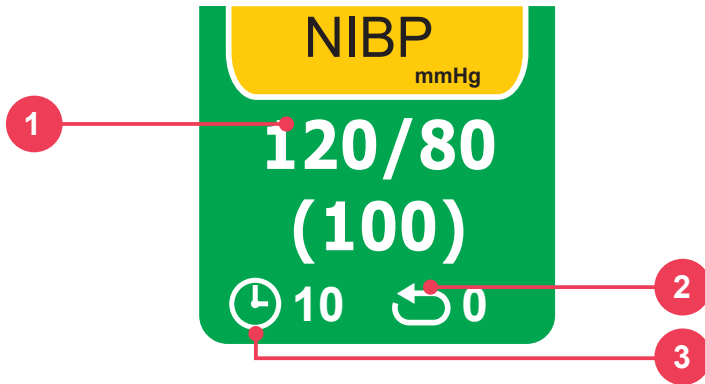
When pressing the NIBP MANUAL MEASUREMENT button while the monitor is exerting the NIBP measurement, it will immediately interrupt the measurement.

2 - Long-term automatic: Automatic measurements of systolic, diastolic and mean pressures. Measurements are automatically repeated during the time set by the operator.

To activate the automatic mode select the desired time in the Configuration Menu > NIBP. Interval between measurements can be selected to: 1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes.

Interrupting NIBP measurements: To cancel an ongoing pressure measurement, press “NIBP MANUAL MEASUREMENT”, located in the equipment’s front panel. The CardioMax does not offer a short-term automatic measurement option.

NIBP numeric indicator



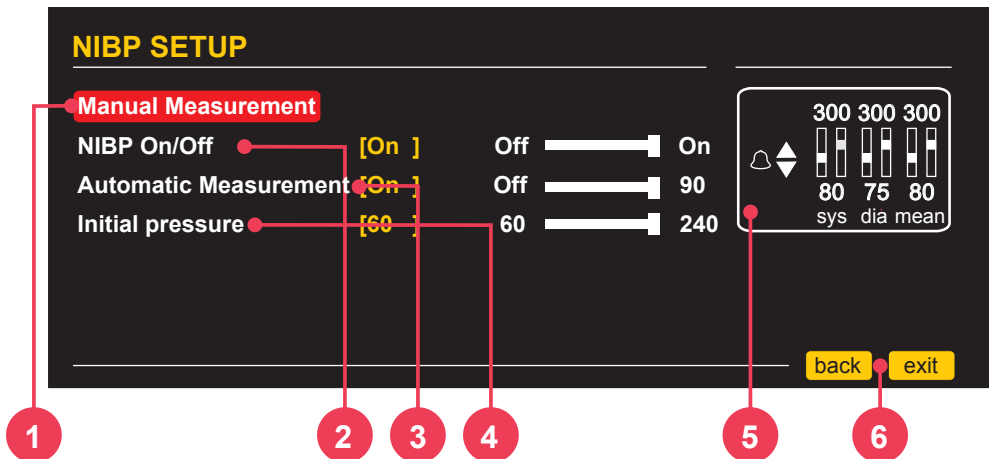
1 - Numeric values for systolic/diastolic and mean pressures.

3 - Time interval between measurements (used in automatic measurements).

2 - Number of measurements exerted (used in automatic measurements).

NIBP setup

Using the e-Jog select the NIBP function in the setup menu to access the NIBP setup sub-menu.



1 - Manual measurement

Start a NIBP manual measurement.

2 - NIBP ON/OFF

Enables or disables the CardioMax's NIBP function.

3 - Automatic measurement

Starts the NIBP automatic measurement mode. When selecting this function, a measurement is immediately exerted. Posterior measurements will be exerted in the time set by the user. Time can be selected to OFF, 1, 2, 3, 4, 5, 10, 15, 30, 60, 90 minutes.

4 - Initial pressure

Select the initial pressure for the armband's insufflation.

5 - Alarm

The "BELL" icon indicates audio "OFF", "ON" or "PAUSED".
Alarm limits configuration "MINIMUM" and "MAXIMUM".

6 - Back/Exit

"BACK" to configuration menu or "EXIT" to monitoring screen.

Physics principle used

The CardioMax measures oxygen saturation on arterial blood by the passage of two light wavelengths through the body tissue, a red one and an infrared one which are detected by a photo-sensor.

The oximeter processes these signals, separating invariable parameters (thickness of tissue, skin color, light intensity and venous blood) from the variable parameters (arterial volume and SpO₂) in order to identify pulse frequency and calculate oxygen saturation. Calculation of oxygen saturation is precise due to the fact that blood saturated with oxygen absorbs less red light than blood with less oxygen.

The CardioMax measures functional saturation, not detecting significant quantities of dysfunctional hemoglobins, such as carboxyhemoglobin or methemoglobin.



Warnings

Use only original SpO₂ sensors manufactured by Instramed. Other sensors may cause inadequate performance.

If you suspect a cable or conductor is ruptured, avoid using the equipment due to possible risk to the operator.

Before using the sensor carefully read instructions which accompany it.

Do not wet the SpO₂ sensor.

When handling the SpO₂ cable, be careful not to strangle the patient.

The SpO₂ sensor should be repositioned every 4 hours, alternating its location.

Any condition that may restrict blood circulation, such as the armband of the arterial pressure device or extremes of systemic vascular resistance may affect the precision of the pulse frequency and SpO₂ readings.

Position the SPO₂ sensor so that the cable rests against the palm of your hand. This places the light source on the side of the nail and the detector on the underside of the finger.

Remove nail polish, or artificial nails, if present.

The presence of too much ambient light may affect the operation of the sensor. In this case, block sunlight (with a surgical towel) if necessary.

Prolonged use or the condition of the patient may require replacement of the sensor. Replace the sensor every 4 hours and often check the integrity and circulatory condition of the skin as well as the correct alignment of the sensor.

If the finger cannot be positioned correctly, choose a smaller finger or use another sensor.

Factors which affect the SpO₂ measurement's precision

- Incorrect use of the sensor.
- Anemia.
- Use of vasoactive drugs.
- Patient in shock or cardiac arrest.
- Significant number of dysfunctional hemoglobins.
- Intravascular contrasts such as indocyanine green and methylene blue.
- Exposure to excessive lighting.
- Arterial occlusion next to the sensor.

Sensor selection

Choose an appropriate sensor in the chart below. Check the instructions which accompany the sensor for application instructions.

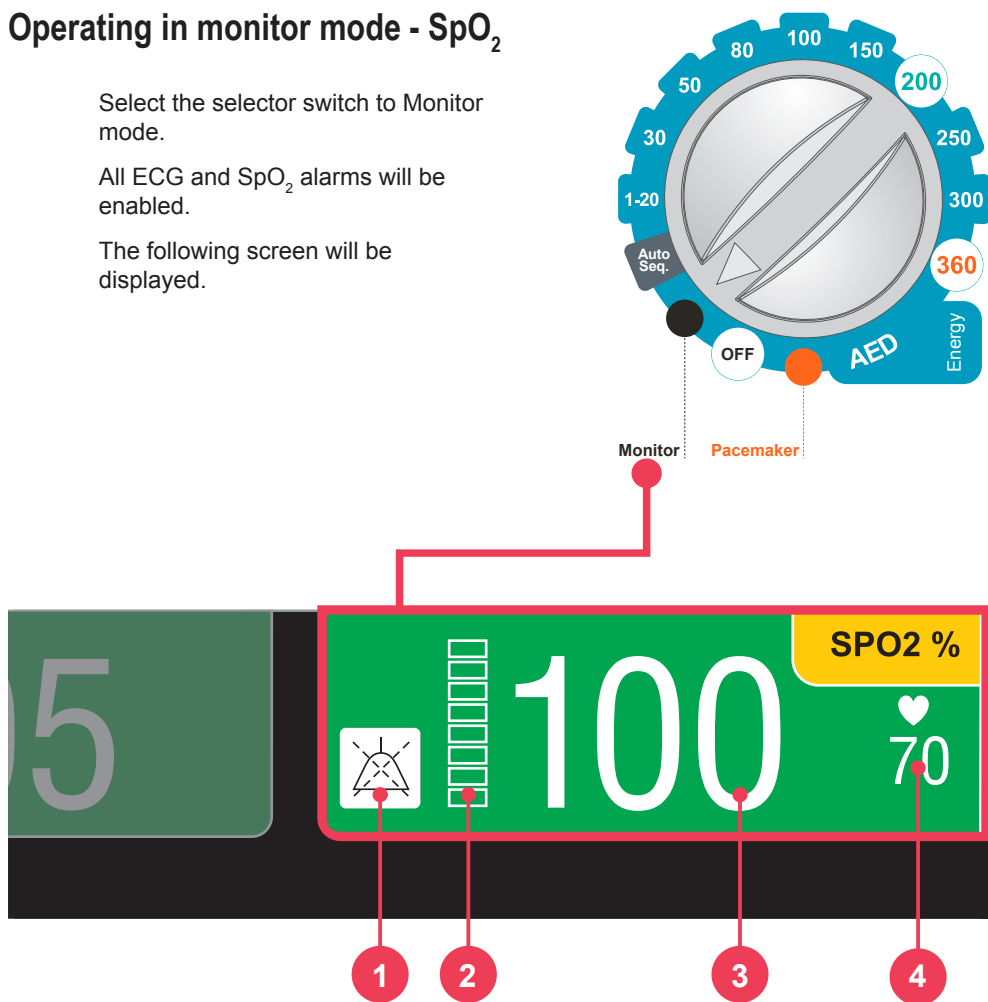
Patient	Place	Description
Adult/ Pediatric	Finger (hand). Finger or toe (hand or foot).	12556: Sensor, adult. Ref: 3044. 12475: Sensor, "Y" universal. Ref: 3043.
Child	Finger or foot.	12475: Sensor, "Y" universal. Ref: 3043.

Operating in monitor mode - SpO₂

Select the selector switch to Monitor mode.

All ECG and SpO₂ alarms will be enabled.

The following screen will be displayed.



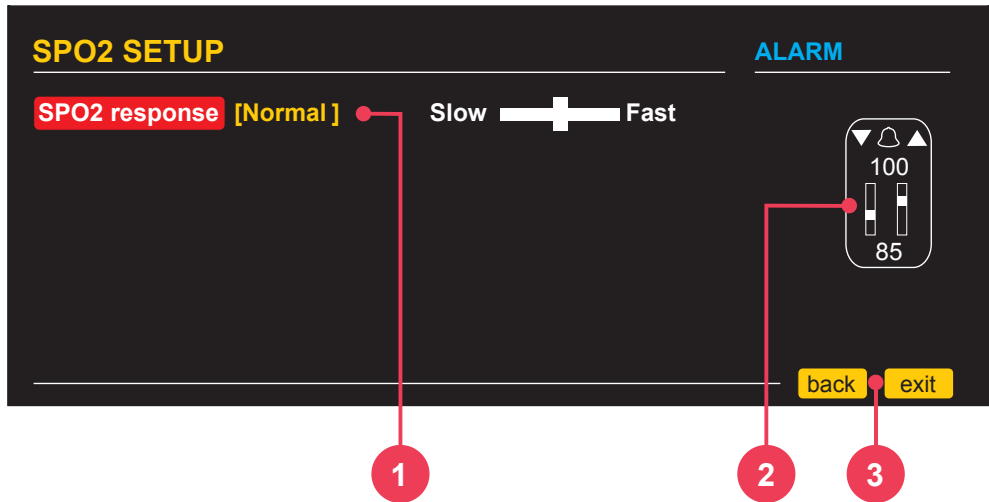
1 - The “BELL” Icon – Indicates audio in pause or off.

2 - Digital scale indicating pulse amplitude.

3 - SpO₂ numeric value.

4 - Patient's pulse frequency value, obtained by the oximetry sensor.

SpO₂ setup



1 - SpO₂ response

Selects the SpO₂ numeric update response. You can select among the SLOW, NORMAL and FAST options.

NORMAL: Used for most patients.

FAST: Used when the operator needs faster answers. The response is affected by the patient's movements.

SLOW: Less affected by the patient's movements. However, you must pay attention to the SpO₂ slow response variations.

2 - Alarm

The "BELL" icon indicates audio "OFF", "ON" or "PAUSED". Alarm limits configuration "MINIMUM" and "MAXIMUM".

3 - Back/Exit

BACK to the Configuration menu or EXIT to the monitoring screen.

Physics principle used

Capnography is a Non-Invasive measurement usually presented by a graph of expiratory CO₂ plotted against time.

The Microstream method is used in intubated or non-intubated patients. A sample of the gas exhaled by the patient is collected by cannulas and sent to the Microstream chamber and sensor inside the CardioMax. CO₂ measurement is based on the characteristics of laser absorption by CO₂ molecules.

Capnography consists of measuring and registering the carbon dioxide released at the end of expiration (EtCO₂). The capnograph is an EtCO₂ analyzer which displays its concentration or partial pressure both digitally and in graph record. The main information given by the capnograph are the exhaled CO₂ partial pressure at the end of expiration, respiratory frequency and the capnogram.



Warnings

Never cut or bend the EtCO₂ sample line. The use of folded or cut sample line can damage the equipment and prevent proper operation of the module.

The EtCO₂ sample line is disposable and single-use and cannot be reused under any circumstances.

Capnography monitoring

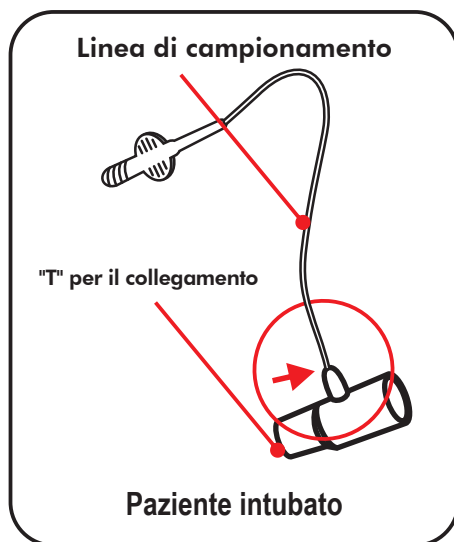
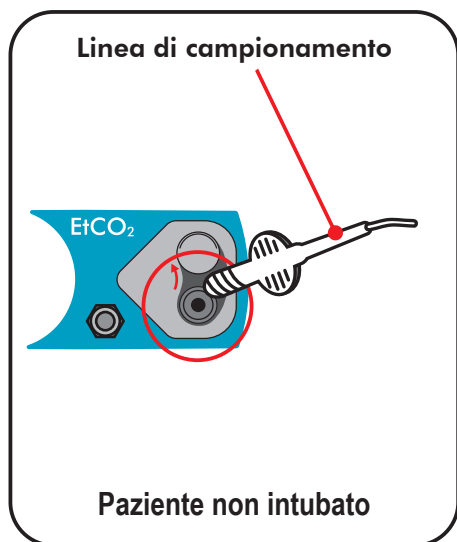
To start the EtCO₂ measurement, navigate through the “Configuration Menu – CO₂” – and set the “CO₂ – On/Off” item to ON.

Right after the start, the EtCO₂ module performs a procedure called “auto-zero”, which is necessary for the proper functioning of the equipment. During this procedure, no measurements are exerted.

The CardioMax can monitor EtCO₂ in intubated or non-intubated patients. To do so, you just need to change the following accessories.

Connect the following accessories:

- **Intubated patient:** sampling line and “T” connector.
- **Non-intubated patient:** sampling line and nasal cannula.



Sampling line

The sampling line collects a sample of the gas released by the patient.

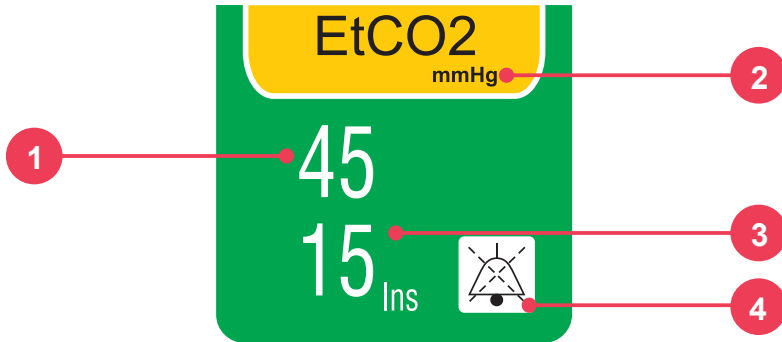
In intubated patients the sampling line is directly connected into the circuit via the “T” connector.

In non-intubated patients the sampling line is connected to the cannula and positioned on the patient.

“T” connector

Connects the sampling line into the main ventilation circuit.

The sampling lines are disposable and non-washable.

EtCO₂ numeric indicator

1 - Numeric value for the EtCO₂ expiration. The value of the EtCO₂ measured at the end of expiration is informed in mmHg or percents.

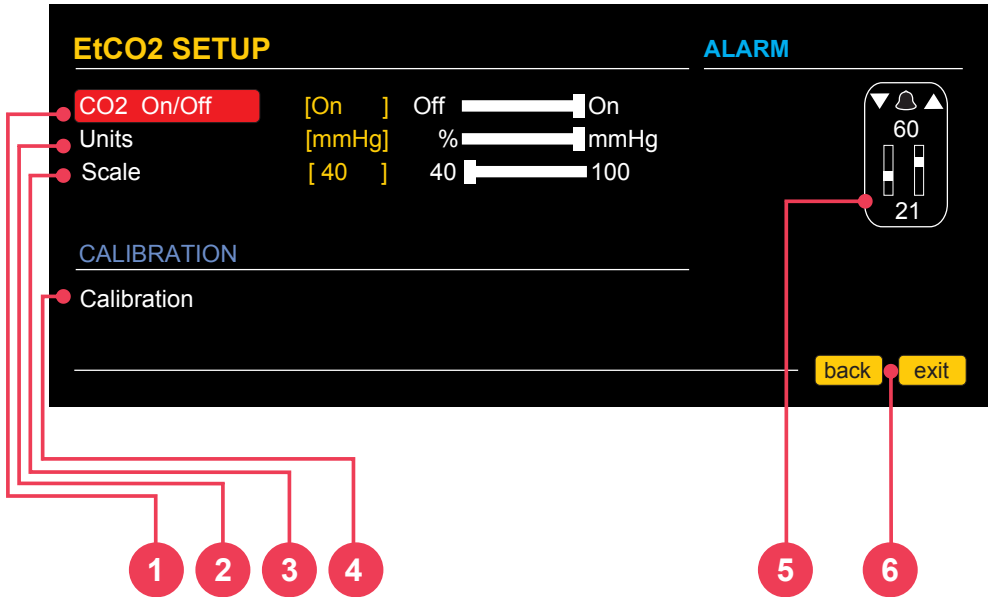
2 - EtCO₂ measuring units. They can be displayed in mmHg (mercury millimeters) or % (the relative percent of the value measured in mmHg divided by the atmospheric pressure in mmHg).

3 - Inspiration numerical value. Informs, in mmHg or percentage, the value of CO₂ measured at the end of inspiration.

4 - The “BELL” Icon – Indicates audio in pause.

EtCO₂ setup

Using the e-Jog select the EtCO₂ function in the setup menu to access the EtCO₂ setup sub-menu.



1 - CO₂ On/Off

Turns the CO₂ module on or off. When on, the sampling pump is also operating. The numeric values, graphs and CO₂ alarms will be activated.

2 - Units

Selects the measuring units of the CO₂ values. They can be displayed in mmHg (mercury millimeters) or % (the relative percent of the value measured in mmHg divided by the atmospheric pressure in mmHg).

3 - Scale

Alters the CO₂ gain graph on the screen.

4 - Calibration

The equipment is calibrated using a known gas sample, thus configuring its measuring curve.

IMPORTANT: calibration must be performed when the equipment shows a message requiring this procedure during initialization. Calibration must be performed by QUALIFIED TECHNICAL PERSONNEL.

5 - EtCO₂ alarm

The “BELL” icon indicates audio “OFF”, “ON” or “PAUSED”. Alarm limits configuration “MINIMUM” and “MAXIMUM”.

Is it possible to adjust the EtCO₂ minimum alarm to levels between 18 and 96 mmHg, with a 3 mmHg interval when in “Adult” mode and a 1 mmHg interval when in “Neo” mode. It is possible to adjust the EtCO₂ maximum alarm to levels between 21 and 99 mmHg, with a 3 mmHg interval when in “Adult” mode and a 1 mmHg interval when in “Neo” mode.

6 - Back/Exit

“BACK” to Configuration menu or “EXIT” to monitoring screen.

Physics principle used

The respiration waveform is generated by the measurement of the patient's bioimpedance. By means of a high frequency signal, which is applied to two electrodes (RA and LA), the thoracic impedance variation caused by the effort of breathing is detected and displayed on the monitor, in graph and numeric forms.



Warnings

If you suspect a cable or conductor is ruptured, avoid using them.

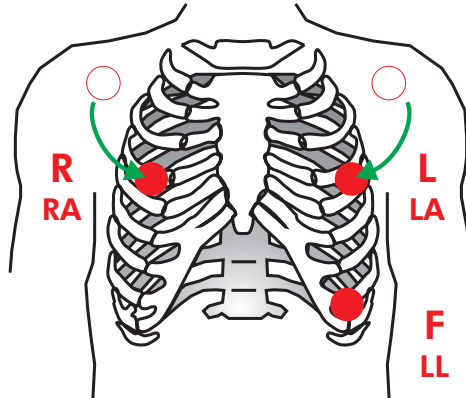
The respiratory rhythm must be used to detect apnea.

Patient's excessive movements may cause imprecise measurements.

Respiration monitoring

The breathing signal is obtained by ECG electrodes. For more information on connections see the “ECG monitoring” chapter.

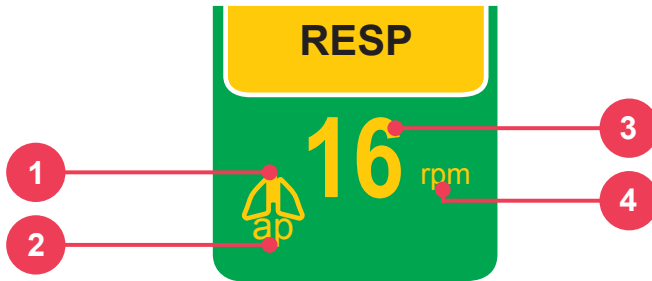
In order to improve breathing performance, you can change the position of the ECG electrodes, opting for alternative places. You must reposition RA and LA in a way so that they are applied below the nipples, as shown in the picture below:



WARNING: when repositioning the electrodes, the ECG waveform and amplitude may change.

WARNING: only the respiration numeric value is obtained by the CO₂ module. The waveform is not.

Capnography: the monitor can also show the respiratory frequency calculated by the Capnography module. In order to this, set the function in the Configuration Menu (Menu > RESP > RESP Freq).

Respiration numeric indicator

1 - Respiration symbol.

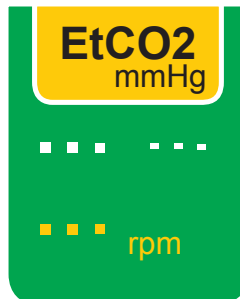
2 - Apnea alarm – Displayed when breathing suspension is detected.

3 - Respiration numeric value.

4 - Measuring unit(respirations per minute).

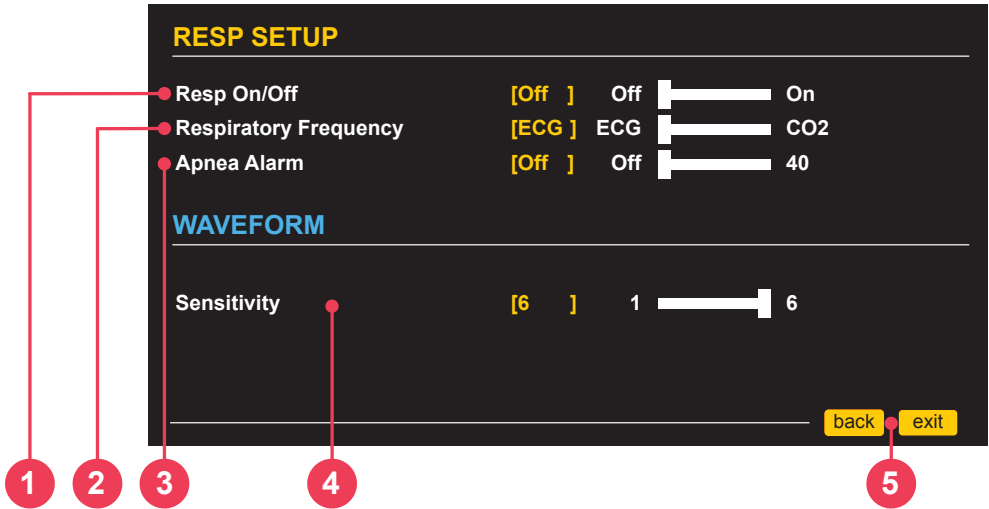
Yellow indicators show that the respiratory frequency is originated via ECG cable, blue indicators show that the respiratory frequency is originated via capnography.

If the EtCO₂ and respiration are on in the defibrillator and pacemaker modes, the respiration numeric indicator will be shown in the EtCO₂ window, with the same color indications (check picture below).



Respiration setup

Using the e-Jog select the respiration function in the setup menu to access the respiration setup sub-menu.



1 - Respiration monitoring On/Off

When turned off, all visual and sound alarms will be inhibited and there will be no numeric indication for respiration.

2 - Respiratory frequency

Determines if the frequency shown by the equipment will be obtained by thoracic impedance (ECG cable) or by capnography (CO₂).

3 - Apnea alarm

The alarm emits a sound when a suspension of breathing is detected (apnea) in the specified times of 5, 10, 15, 20, 25, 30, 35 or 40 seconds.

4 - Respiration sensitivity

You can select among the following values:1, 2, 3, 4, 5 and 6.

5 - Back/Exit

“BACK” to Configuration menu or “EXIT” to monitoring screen.

Data storage

The CardioMax creates an event list for each patient observing the following criteria:

Automatically - if CardioMax stays turned off for 30 seconds more.

Manually - via the events setup menu.

The quantity of events the equipment can store will vary according to how long each patient has used the equipment and the type of therapy used. The CardioMax has a 2 Mb memory.

The last two hours of continuous ECG will be stored in the equipment's memory.

ATTENTION: whenever the internal memory capacity reaches its limits, events prior to 100 will be replaced with new information.

CardioMax does not store patient's personal data, and does not allow the entrance of external data.

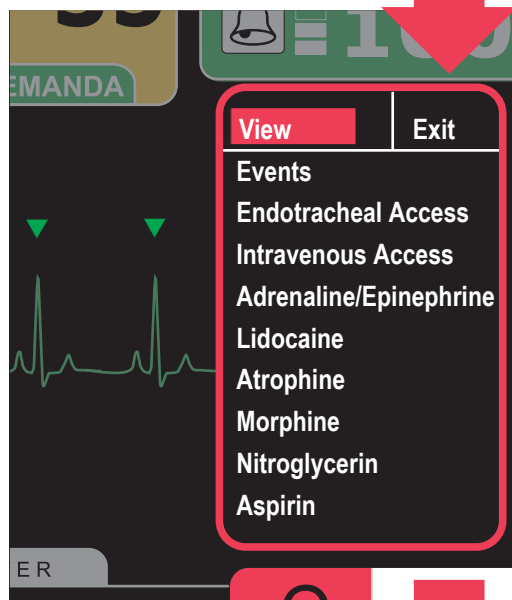
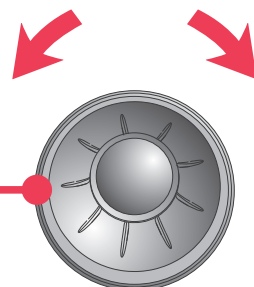
The CardioMax does not record occurrences of ALARM CONDITIONS.

Events stored

The CardioMax stores date, time, heart frequency and saturation of the following events:

- Pads change.
- Charge values.
- Number of shocks.
- Turn equipment on/off.
- Loose electrode/bad contact in the pads.
- Failure in module initialization.
- Functional test stimulation.
- Synchronism.
- Operation mode (monitor, pacemaker, monitoring).
- Stimulation - pacemaker on/off.
- Turning on the "pause audio" button.
- Shock failure.
- Internal discharge.
- "Event setting" key activation.
- Printing.
- Low battery/equipment turning off.
- Pacemaker stimulus change.

Viewing and managing events



Event setting works on defibrillator, monitor and pacemaker mode and allows you to manually mark the following items:

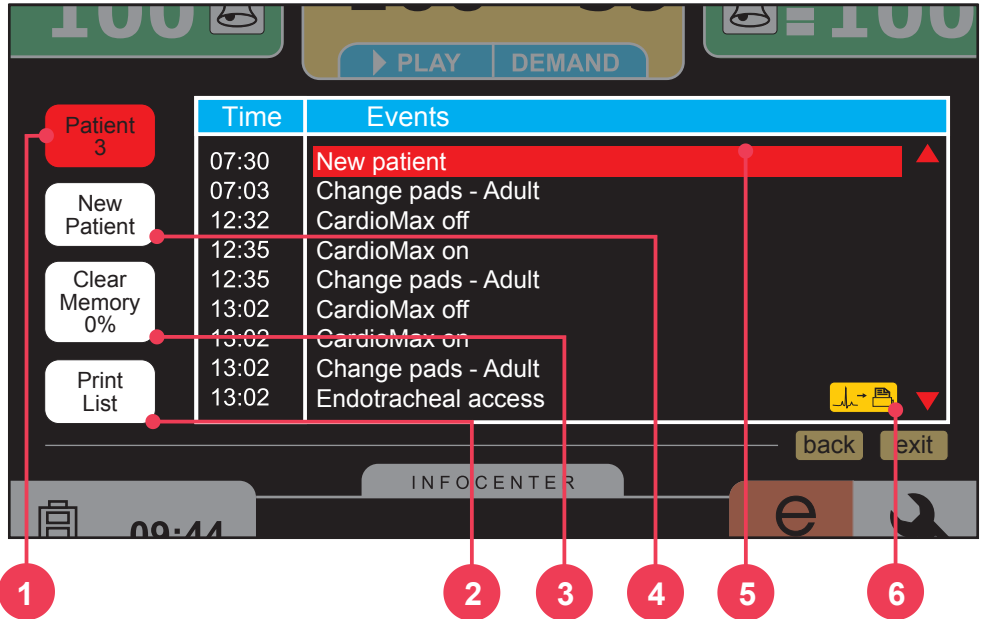
Events, Endotracheal Access, Intravenous Access, Adrenaline/Epinephrine, Lidocaine, Atrophine, Morphine, Nitroglycerin and Aspirin.

To view, manage and print stored events use the e-Jog control to select the “e” icon in the main screen’s configuration menu.

Also use the e-jog to navigate through events and available settings.



Visualizing events is also possible by accessing the Events option in the configuration menu.



1 - Patient

Indicates the number of the active patient and enables changing patients.

2 - Print list

Prints a list of events associated with a specific patient, including related events and the moment when each event occurred.

3 - Delete memory/used memory

Deletes every event from the memory. It Indicates the percentage of memory that has already been used (2 Mb limit).

NOTE: When 100% of the memory has been used, the contents of the event memory must be deleted.

4 - New patient

Creates a new patient, starting a new event table. When it is done the alarms limits are restored to the original factory values.

5 - Events list

Presents the selected patient's events.

6 - Printing icon

When present next to an event, this icon indicates that printing the ECG waveform associated with that event is available. 15 seconds of an ECG curve are stored for each event which displays this icon.

To print the curve, the table must be selected by browsing the table of events using the e-Jog Control. After selecting an event, quickly press the printing button in the front panel to print it.

15 seconds of the ECG wave related to the selected event will be printed, 5 seconds before the event and 10 seconds after the event.

General

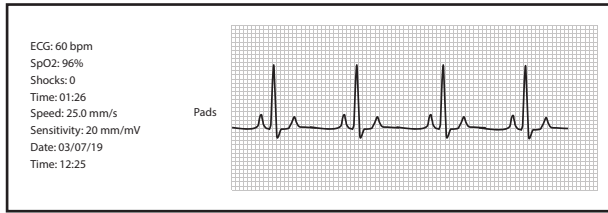
The thermal printer (optional item) allows you to manually or automatically print events, shock or electrocardiogram reports. To activate the printer, press the print button, located in the equipment's front panel or use the e-Jog control to enter the printing menu.



Instant printing

When the print button is pressed for LESS than three seconds, the CardioMax prints a fast report. The fast report prints the same curves being displayed at the moment. The numeric indicators for the following parameters are: date/time, trace speed and number of shocks. In the ECG report, the leads and corresponding amplitude will be printed.



*Instant printing*

Continuous printing

When the print button is pressed for MORE than three seconds, the CardioMax prints a continuous report for an indeterminate period of time or until printing is interrupted. The data in the continuous report is identical to the data in the quick printing. See the instructions below for more information on use.

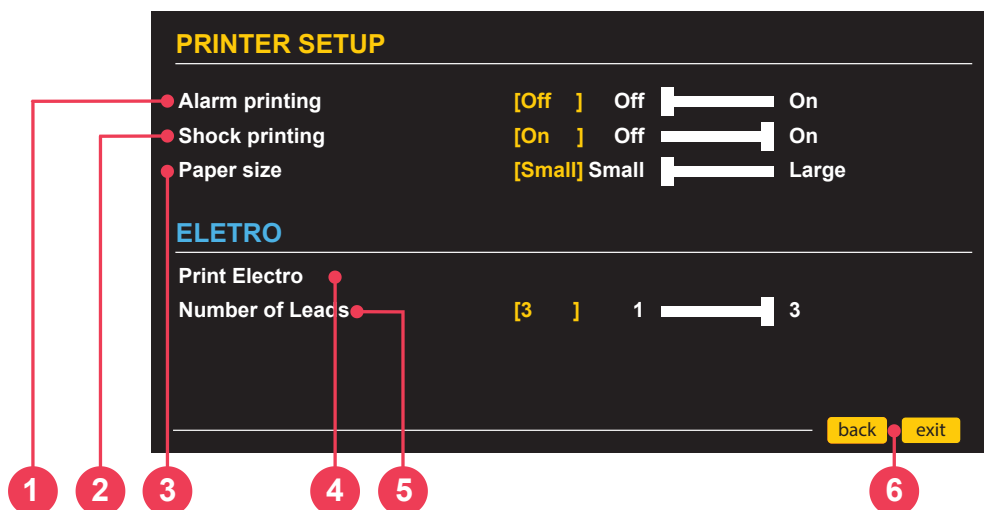


Stop printing

To interrupt continuous printing or instant printing, press the print key again.



Configurations

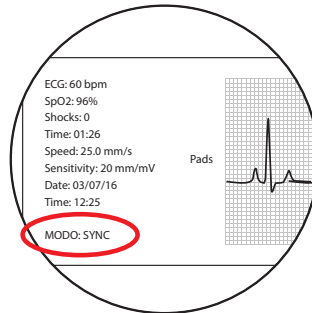


1 - Alarm printing

When the “alarm printing” option is enabled (in the printing setup menu), the CardioMax prints an instant report whenever an alarm goes off.

2 - Shock printing

When the shock printing option is enabled (in the printing setup menu), the CardioMax prints an instant report whenever the equipment identifies shock delivery. In this report you can see the equipment’s operation mode at the moment of the defibrillation: MANUAL mode, SYNC mode and AED mode. See the pictures below.

*Report*

3 - Paper size

Shows the selected size of the report to be printed.

- Large = 30 cm.
- Medium = 23 cm.
- Small = 15 cm.

4 - Electrocardiograph function

To print a 7-lead electrocardiogram use the print Electro function, in the printing setup menu. When this function is selected, the equipment begins monitoring and printing the leads, starting by the DI lead. At the end of printing, it returns to its normal monitoring mode.

5 - Number of leads

Select the number of leads to be printed simultaneously, in the electrocardiograph function. The DI, DII, DIII, AVR, AVL, AVF and C leads will be printed sequentially, individually or in groups, in this same sequence, according to the defined value. The C lead is always printed individually. In case the ECG cable used is a 3-wire one, it is not possible to print more than one lead simultaneously.

6 - Back/Exit

“Back” to configuration menu or “EXIT” to go to the monitoring screen.

General

This function allows you to program up to three different times for the device to carry out a self-diagnosis of defibrillation, battery level, connected paddles, and verification of the device's connection to the power outlet. The results of the diagnosis are sent to the computer that has the RTC system software installed on it and is within reach of the network.

When the RTC Central module is not acquired, the equipment will not have communication with PC central, but it will be enable on the menu (details on page 142).

RTC Operation on the CardioMax 8 with transmitter

The configurations for the RTC function can be accessed through the menu CONFIGURATION > GENERAL CONFIGURATIONS > RTC (see chapter Screen and Operation).

The configurations screen of the RTC function allows you to define the number of automatic daily tests to be performed, configurable in values from 1 to 3 tests. It is also possible to configure the time for each of these daily tests, carry out a manual test, or check the status of the last test carried out.

RTC

Daily tests quantity

First Schedule

Second Schedule

Third Schedule

Perform test manually

Last test status

3
06:00
12:00
20:00

back

exit



1. Number of automatic daily tests. It can be configured with values of 1 to 3 tests daily.
2. Time for performing the first daily test. Configured by the user.
3. Time for performing the second daily test. Configured by the user. This item will be disabled when the number of daily tests is 1.
4. Time for performing the third daily test. Configured by the user. This item will be disabled when the number of daily tests is less than 3.
5. Carry out a manual test, without the need for prior configuration.
6. Displays the data from the last test performed.

Automatic test

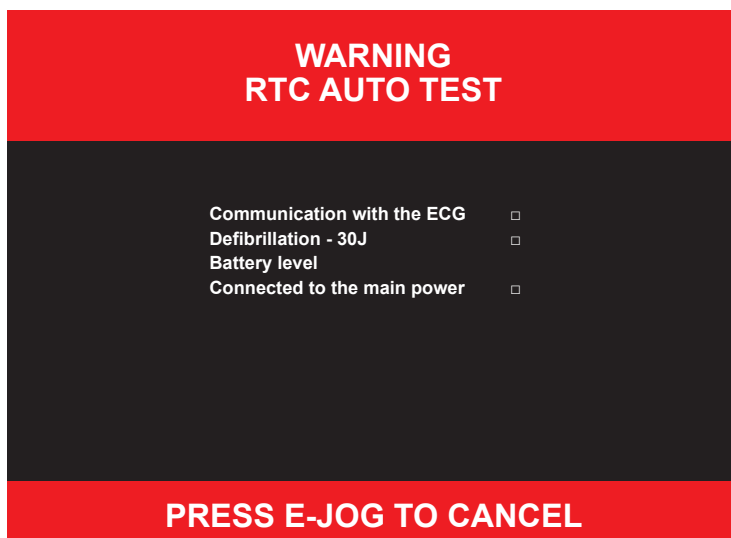
The automatic test can be programmed through the menu **CONFIGURATION > GENERAL CONFIGURATIONS > RTC**. To perform the automatic test, the equipment should be turned off at the programmed time.

At the configured time, the CardioMax will automatically turn on and begin the test, composed of the following steps:

- Test of the connection with the ECG board.
- Test of the defibrillator module.
- Check of the battery level.
- Check of the connection with the power outlet.

It is possible to interrupt the test with a click on the e-Jog button.

It is possible to interrupt the test with a click on the e-Jog button.



After completing the test, the equipment will send the collected data to the RTC Control Center. At this time, it is not possible to turn off the device. If the connection with the RTC Control Center cannot be established, the device will cancel sending the data after 10 seconds. After this procedure, the device will save the collected data and turn off automatically.



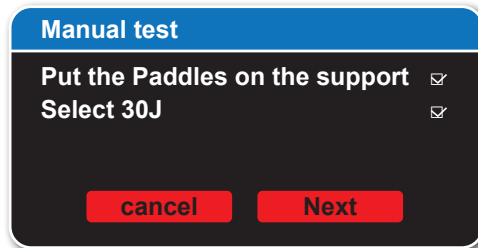
Note: the test of the defibrillator module will not be carried out if:

- The equipment is connected to the computer by USB cable.
- The paddles are not on the support or are disconnected from the device (External Adult Paddles).

The battery has a charge of less than 10% and the equipment is not connected to a power outlet.

Manual test

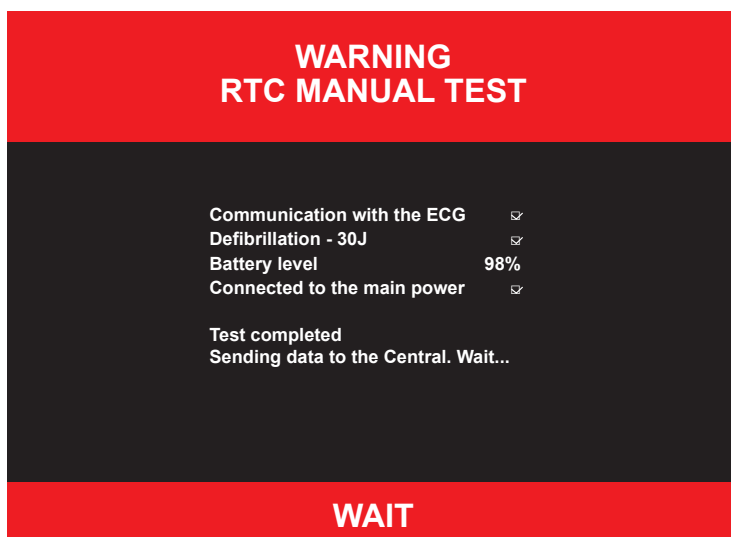
To open the dialog box for the manual test, access CONFIGURATION > GENERAL CONFIGURATIONS > RTC > PERFORM TEST MANUALLY.



Follow the instructions on the screen and click on "next" to start the test. Or click on "cancel" to close the dialog box and return to the RTC menu.

Once started, the manual test goes through the following steps:

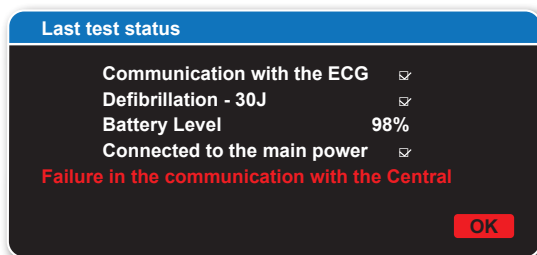
- Test of the connection with the ECG board.
- Test of the defibrillator module.
- Check of the battery level.
- Check of the connection with the power outlet.



It is not possible to interrupt the manual test. After completing the test, the equipment will send the collected data to the RTC Control Center. At this time, it is not possible to turn off the device. If the connection with the RTC Control Center cannot be established, the device will cancel sending the data after 10 seconds. After this procedure, the device will save the collected data and return to the mode defined by the rotating switch on the CardioMax.

Status of the last test

To see the data from the last test performed, access CONFIGURATION > GENERAL CONFIGURATIONS > RTC > STATUS OF THE LAST TEST. In this window, the information regarding the last test is available, including possible failures.



To return to the RTC menu, just click on the "OK" button.

Error BIPS

When there is an error in the last RTC test, the equipment sends three "beeps" per minute that can be remotely identified by the user.

The CPR Maestro is an accessory from CardioMax, created to help rescuers perform compressions in accordance with the latest CPR recommendations. Its sensors measure the frequency and depth of chest compressions, providing the user with real-time feedback. These information are displayed on CPR Maestro and CardioMax screens and through sound recommendations.

Note: because it is an accessory, it can not be used by itself. Only connected to CardioMax.

The CPR Maestro parameter must work on DEFRIBRILLATION, CHARGE AUTO SEQUENCE and AED modes. On AED mode, the messages on screen and the audible ones will only be presented after the orientation “Perform CPR for 2 minutes”.

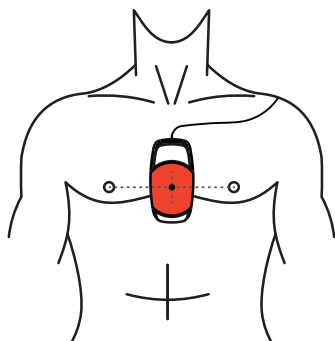
To turn off the equipment, simply press the ON/OFF button for 3 seconds. The parameter will be automatically turned off on the CardioMax screen.

Using the CPR Maestro

1 – Connect the CPR Maestro to CardioMax, using the input indicated below, located on the side of the equipment.



2 – Place the device on the patient's chest, according to the image below.

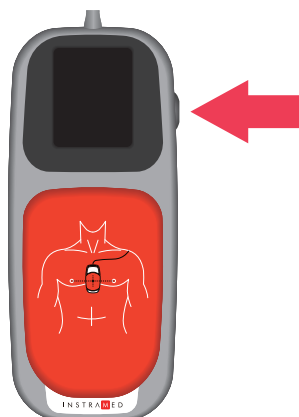


This step is important and must always be followed. When the equipment is initialized, the CPR sensors are calibrated, enabling the evaluation of the compressions. The initialization with the device out of the recommended position may cause incorrect evaluations.

CAUTION: for long-lasting CPR in naked chest, place a gauze between the skin and the CPR MAESTRO to avoid risk of skin abrasion.

ATTENTION: do not use CPR Maestro in NEONATES. The recommended for NEONATES is the resuscitation maneuver using 2 fingers (without the use of CPR Maestro accessory).

3 – Press the ON/OFF button, on the side of the equipment. At this moment, the equipment is not ready to be used yet.

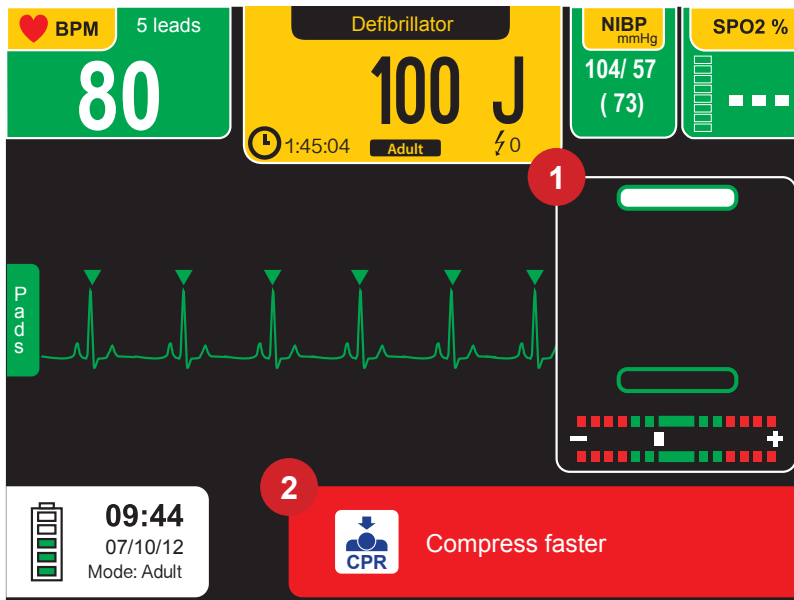


4 - A message will be displayed to confirm if the device is correctly placed on the patient's chest, where the compressions will be performed. If yes, press the ON/OFF button again and start the compressions.

Feedback

The user receives CPR feedback in the following ways:

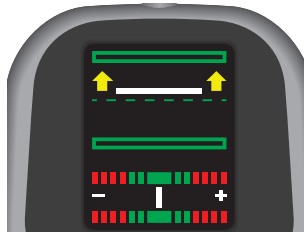
- Message and CPR image on CardioMax screen.



1. CPR indicative graphic.

2. Messages.

- CPR indicative graphic on the CPR Maestro screen.



- Audio message.

Messages

The following messages can be displayed during the CPR Maestro use:

Compress harder: the rescuer did not reach the minimum depth required which is of 50 mm.

Allow full chest expansion: the rescuer is not allowing the patient's chest to return to total relief position.

Compress softer: the rescuer exceeded the limit of chest compression which is of 60 mm.

Compress faster: the rescuer is performing the compressions at a frequency below the ideal limit, which is of 100 to 120 compressions per minute.

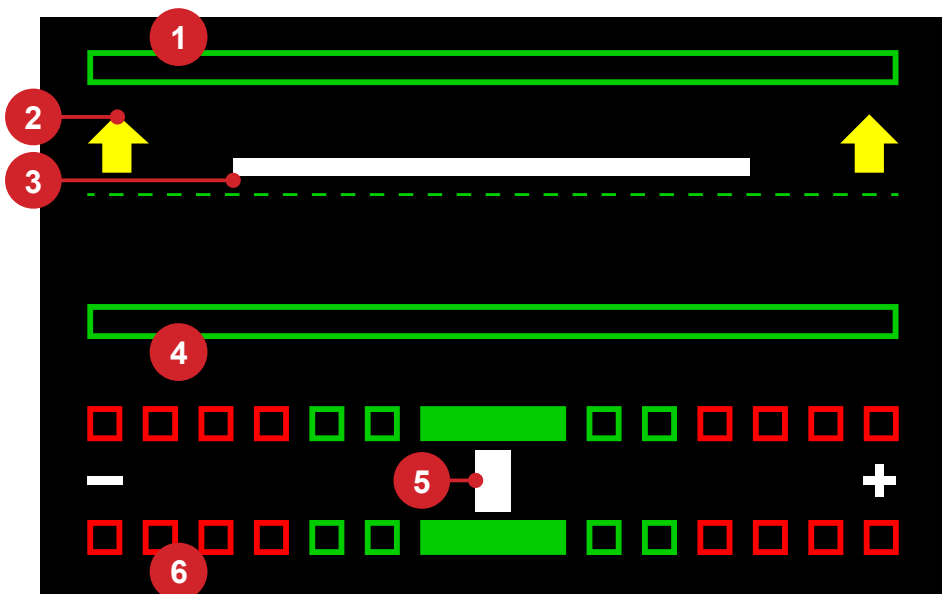
Compress slower: the rescuer is performing the compressions at a frequency beyond the limit.

Good compressions: the rescuer is performing a perfect massage.

Start CPR: the rescuer stopped doing the massages.

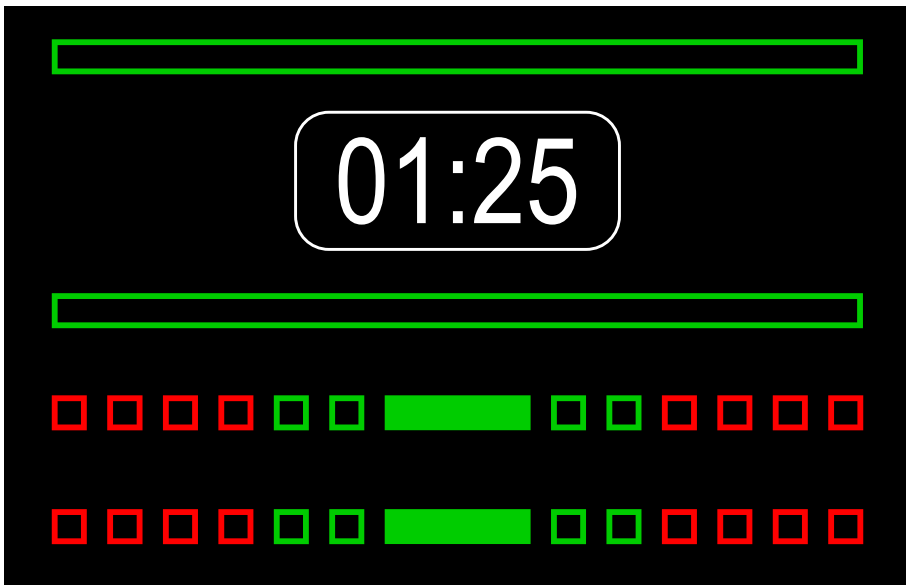
CPR Graphic

The CPR graphic displays information about the frequency and depth of the compressions.



3. Chest full expansion indicator: When filled with the color green indicates that the chest returned to the initial position of the compressions.
4. Indicative arrows of correction: When present, the arrows indicate that the movement must be wider in the indicated direction.
5. Depth indicative bar: Indicates the current depth of the compression.
6. Maximum depth indicator: When filled with the color green, indicates that the compression reached the ideal depth. When filled with the color red, indicates too hard compression.
7. Frequency indicative bar: Indicated the frequency of the compressions. When aligned with the red rectangles, indicates need of frequency adjustments.
8. Frequency indicators: The red rectangles indicate very low (on the left) or very high (on the right) frequency. The green rectangles indicate appropriate frequency.

When the rescuer stops the compressions, a chronometer is automatically displayed on the graphic area.



Introduction

The CardioMax can be connected to a PC, allowing the user access to new functions as:

- View, save in external media or print list of the last 100 events.
- View, save in external media and print ECG activity of the last two hours.
- Change the operational configurations of the CardioMax (only for authorized technical personnel).
- Check and update firmware version of the equipment (only for authorized technical personnel).
- Real Time Check: self-diagnosis of defibrillation, battery level, connected pads, and verification of the device's connection to the mains supply.

Requirements

The CardioMax can be connected to a computer through the installation of two pieces of software: The SoftDEA application and the RTC application. This software is found on the CD that comes with the device.

To install the SoftDEA application and/or the RTC application, observe the following requirements:

- Windows XP, Windows Vista or Windows 7 operating system.
- CPU of 300 MHz or faster.
- 02 GB free hard disk space.
- Minimum 512 MB RAM (1 GB recommended).
- CD or DVD ROM reader unit.

For physical connection to the PC:

- An available USB port.

SoftDEA installation

- Insert the program CD in the CD/DVD ROM drive.
- If the autorun does not start automatically, find the “softdeasetup.exe” file in the CD and double-click it.
- Follow the installation instructions which will show up on the screen.

Connecting the CardioMax to a PC

- Connect the equipment only after installing SoftDEA.
- After the installation connect the device through an USB cable.
- The location of the device drivers to be installed will be required. They can be found in this folder: C:\Program Files\Instramed\SoftDEA\DRIVERS.
- Start the SoftDEA application.
- On the language selection screen, choose among Spanish, English or Portuguese. You only have to select a language the first time you start the software.
- Start the list of events and ECG waveform display following the steps in the next section.

Startup Screen

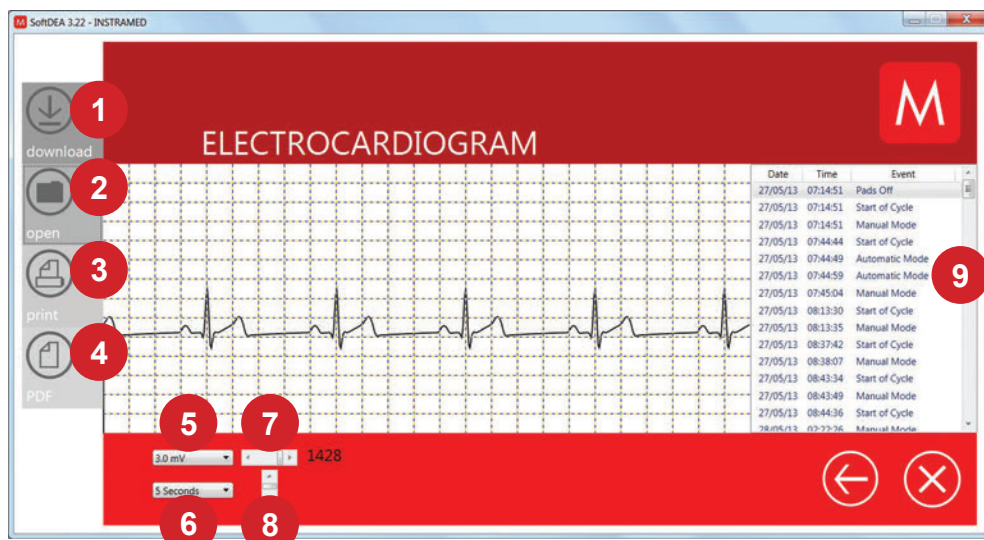


1 - Graphic display button

Click this button to display the ECG waveforms and event list stored on the device. The displayed interval corresponds to the user-defined time frame (see item 7 on page 128 of this manual).



Graphic display screen



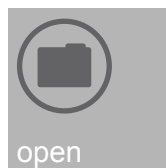
1 - Download

The set of information that is currently being viewed can be saved on the PC by clicking this button. A window will open enabling the user to select the desired location in which to store the file.



2 - Open

Click this button to open a ".dea" file that was previously saved on the computer.



3 - Print

Click this button to print the set of information that is currently displayed on the screen. Use the printer driver dialog box to set printing options.



4 - PDF

Click this button to generate a file showing the set of information that is currently displayed on the screen in pdf format. The user must select the desired directory in which to save the file.



5 - Amplitude selection

Allows the user to vary the ECG amplitude from 0.5 mV to 3.0 mV.

6 - Time frame

Allows the ECG to be viewed in time frames from 1 second to 60 seconds.

7 - Time frame scroll

Allows the ECG to be viewed throughout its time scale.

8 - Amplitude scroll

Allows the ECG to be viewed throughout its amplitude scale.

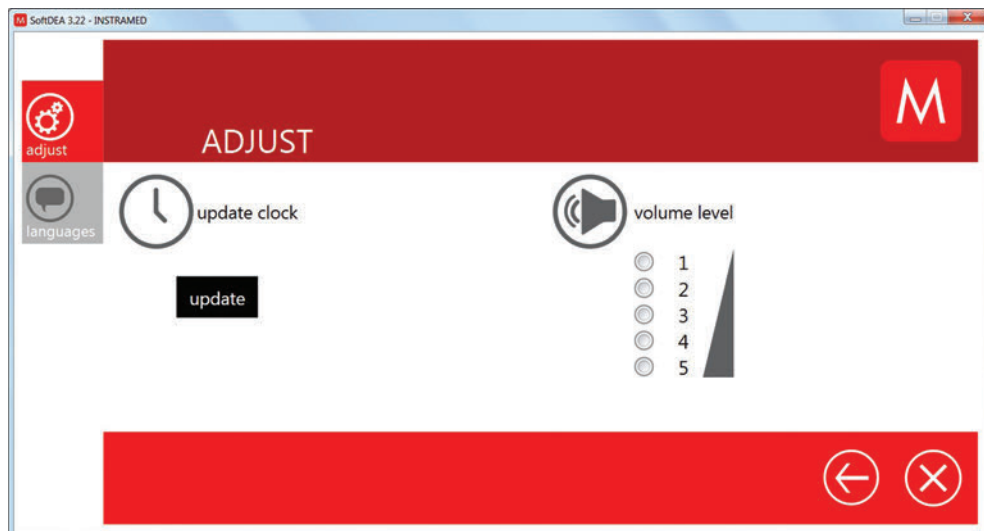
9 - Event viewer window

After downloading the information contained in the CardioMax memory, the list of events stored by the device will be displayed in this area in chronological order. Double click on an event to view it on the main screen.

Definition of events displayed in AED mode

- INTERNAL DISCHARGE - Power discharged internally due to pressing the start button for an excessive amount of time.
- TREATMENT PERFORMED - A shock was delivered to the patient.
- SHOCK INDICATED - Shock indicated due to the patient's ventricular fibrillation or ventricular tachycardia pattern.
- SHOCK NOT INDICATED - Shock not indicated on account of the electrocardiogram pattern not requiring a shock.
- ANALYZING AED - Analyzing heart rhythm.
- ASYSTOLE - Asystole detected.
- PADS DISCONNECTED - The pads were disconnected.
- CHILD PADS - Child pads were connected to the device.
- ADULT PADS - Adult pads were connected to the device.
- TURNED ON - The equipment was turned on.
- CPR - Equipment indicating the CPR procedure.

Settings



Volume and clock adjustments via SoftDEA are made via the device's own settings menu, as described on page 49 in the "Screen and operation" chapter.

Changing languages



- **Under the "in the SoftDEA" option:** Change the language of the software interface. Does not require a device to be connected.
- **Under the "in the device" option (when a CardioMax device is connected):** Change the language of voice prompts emitted by the speaker on the device to the selected language.
- **Under the "in the device" option (when a CardioMax device is connected):** The CardioMax language can be changed through the device's settings menu (see page 48 - "General setup"). However, if the voice prompts emitted by the CardioMax device show signs of degradation or defects, this function can be used to restore the equipment's speech synthesis files.

Other buttons

1 - Back

Click this button to return to the previous page/menu.



2 - Exit

Click this button to close SoftDEA 3.



RTC software installation

- Insert the program CD in the CD/DVD ROM drive.
- If the installer does not initiate automatically, locate the "RTC" file or "Real Time Check" on the program CD and double click on it.
- Follow the installation instructions that appear on the screen.

NOTE: check that the "Wireless Reception Unit" is connected to the computer by USB prior to installing the software. After completing the installation, links will be created to run the program on the Windows start menu and on the desktop. Equipment that do not have the transmitter installed, will not have communication with the central station installed on the PC.

RTC software operation

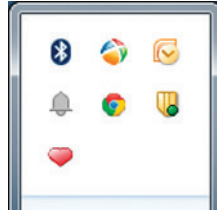
The RTC software runs in the background, with the minimized system awaiting a device to communicate with the "Real Time Check Control Center".

The CardioMax can be configured to perform self tests at times specifically configured by the user. The device will send the results of the following tests to the RTC system:

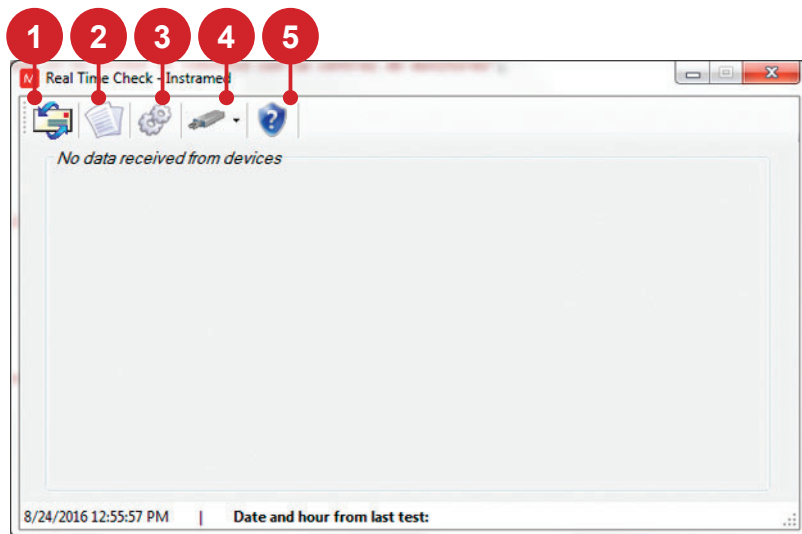
- Test of the connection with the ECG board.
- Test of the defibrillator module.
- Check of the battery level.
- Check of the connection with the power outlet.

Upon receiving the test results, the RTC software will open a screen showing this data. This information will also be stored in a log storage file. Optionally, the program can be set up to send e-mails with this data to determined recipients.

After the program is run for the first time, the software will be configured to automatically run after Windows starts up. The RTC icon is in the shape of a heart and will be shown on the task bar, next to the clock of the operating system, as shown in the figure below:



To see the software's main window, just click on the heart icon. This window will also be shown when receiving data via USB.



1 - E-mail configurations

Click on this icon to open the e-mail configurations screen.

On this screen, it is possible to configure the sender, recipient and enable or disable sending e-mails when the software receives equipment tests.

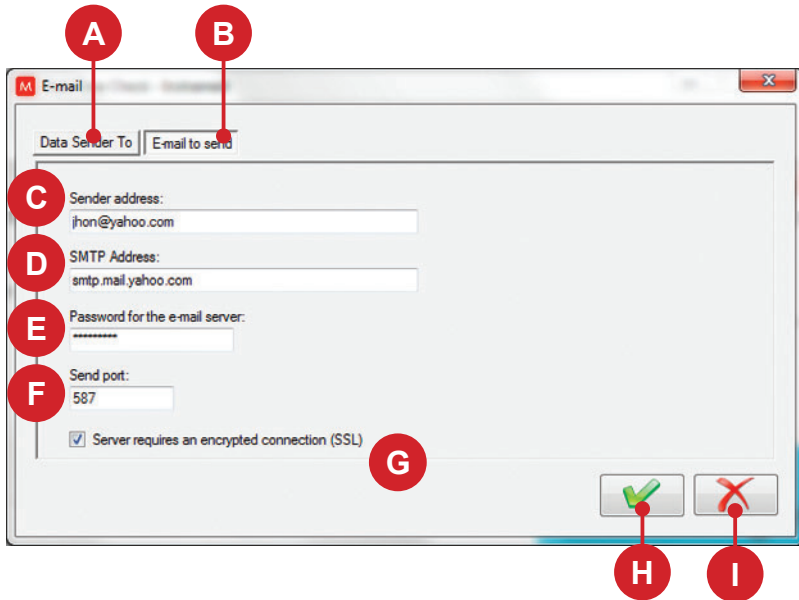
ATTENTION: when sending e-mails is enabled, the system will try to send 3 times, with intervals of 15 minutes between attempts. If sending is not possible, the e-mail will be discarded by the system after the third attempt.

"E-mail to send" Tab

The screenshot shows a window titled "E-mail" with two tabs: "Data Sender To" and "E-mail to send". The "E-mail to send" tab is active. It contains the following elements:

- A:** Points to the "E-mail to send" tab.
- B:** Points to the "Data Sender To" tab.
- C:** Points to the "Recipient address:" field, which contains the text "engsuporte@instramed.com.br".
- D:** Points to the "with copy:" field.
- E:** Points to the checkbox labeled "Send e-mail to the recipient when receiving test equipment.", which is checked.
- F:** Points to the green checkmark button at the bottom right.
- G:** Points to the red X button at the bottom right.

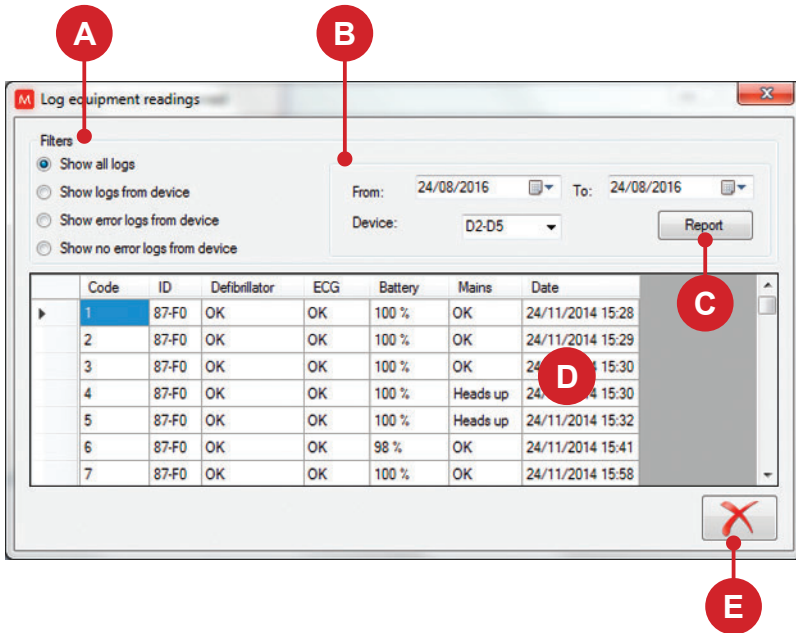
- | | |
|--|--|
| <p>A. Selected tab.</p> <p>B. Opens the sender data tab.</p> <p>C. Field for entering the recipient's address.</p> <p>D. Field for entering the carbon copy recipients' addresses.</p> | <p>E. Enables or disables sending of the e-mail when new tests are received.</p> <p>F. Confirms and saves the completed data.</p> <p>G. Cancels changes and closes the e-mail configurations window.</p> |
|--|--|

"Sender Data" Tab

- | | |
|--|--|
| <p>A. Opens the "E-mail to send" tab.</p> <p>B. Selected tab.</p> <p>C. Field for entering the sender's address.</p> <p>D. Field for entering the SMTP address.</p> <p>E. Field for entering the e-mail server password.</p> | <p>F. Field for entering the sending portal.</p> <p>G. Select if the server requires an encrypted connection (SSL) or not.</p> <p>H. Confirms and saves the completed data.</p> <p>I. Cancels changes and closes the e-mail configurations window.</p> |
|--|--|

2 - Reading log of the equipment

Click on this icon to check the test logs stored in the system.



A. Filter selection area. Allows you to select the criteria for displaying logs.

B. Data selection and equipment ID area. Allows you to limit the log display to a time period and/or specific equipment.

C. Opens a new screen with a detailed report of the selected log.

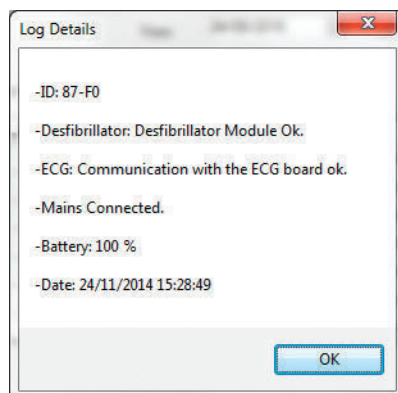
D. Log display area. This contains information about the tests conducted with the filters applied. A double-click on the content of a log will open a new screen with detailed information.

E. Closes the equipment reading log window.

NOTE: the equipment code is the ID value printed on the equipment.

Log details

Double-clicking on any line of the log will open a second window with more details.



Report

To open this screen, click on the "Report" button. A complete report of the selected log will be generated. It is possible to save the content in Word or Excel, as well as print it.

The 'Log Report's' window displays a table of log entries. The table has the following columns: ID, Defibrillator, ECG, Battery, Mains, and Date. The data is as follows:

ID	Defibrillator	ECG	Battery	Mains	Date
87-F0	OK	OK	100 %	OK	24/11/2014 15:28:49
87-F0	OK	OK	100 %	OK	24/11/2014 15:29:23
87-F0	OK	OK	100 %	OK	24/11/2014 15:30:09
87-F0	OK	OK	100 %	Attention	24/11/2014 15:30:22
87-F0	OK	OK	100 %	Attention	24/11/2014 15:32:06
87-F0	OK	OK	98 %	OK	24/11/2014 15:41:13
87-F0	OK	OK	100 %	OK	24/11/2014 15:58:40
87-F0	OK	OK	100 %	OK	24/11/2014 16:10:38

3 - Options

Click to open the options screen.

On this screen, it is possible to change the RTC software language and program the device communication check.

NOTE: the system should be restarted for the changes to take effect.

"Language" tab



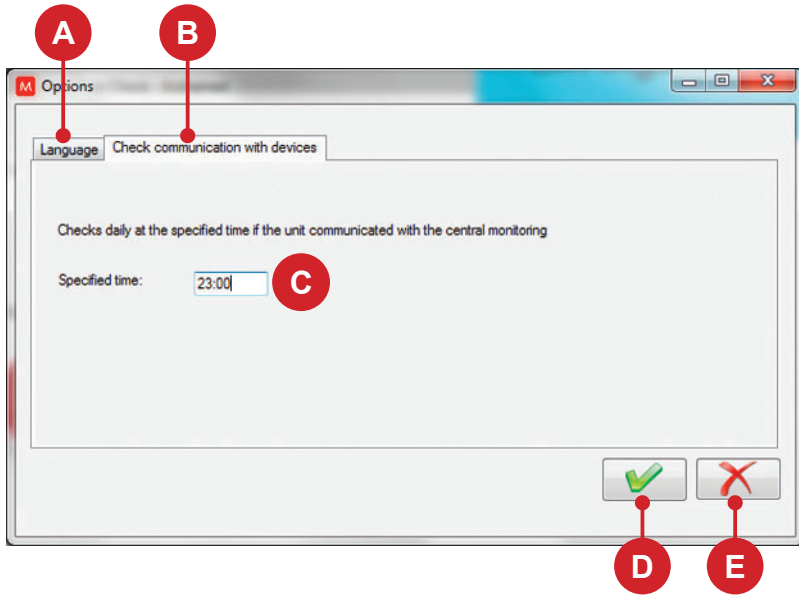
A. Selected tab.

B. Opens the "Check device communication" tab.

C. Selects the software language.

D. Confirms and saves the configurations.

E. Cancels changes and closes the window.

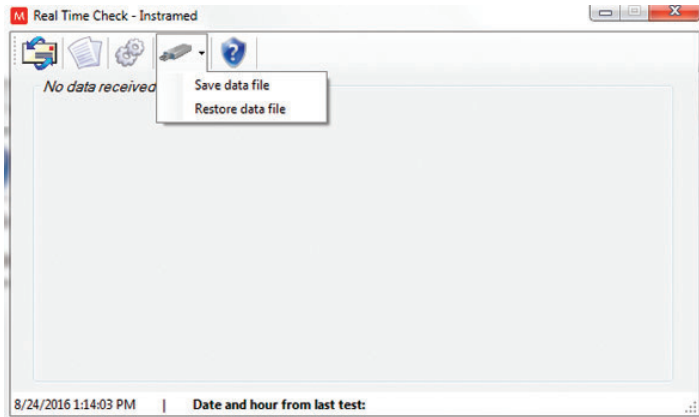
"Check device communication" tab.

- | | |
|---|---|
| A. Opens the "Language" tab. | D. Confirms and saves the configurations. |
| B. Selected tab. | E. Cancels changes and closes the window. |
| C. Field for entering the time to perform the device communication check. | |

The system will perform a check at the selected time. If a device has not communicated with the control center for more than 24 hours, a notification will be shown on the screen.

4 - Backup

Click on this icon to select between the options "Save data files" and "Restore data files."

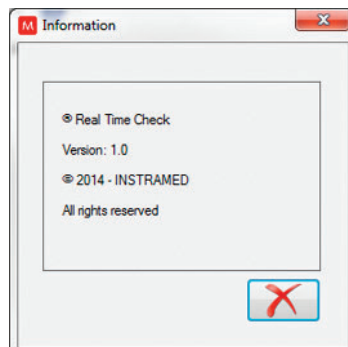


If a data file is lost, it is possible to restore the information from the last saved file. When restoring, all of the data obtained after the last backup file was saved will be lost.

ATTENTION: it is the full responsibility of the final user to make data file backups.

5 - Information

Click to see version and software developer information.

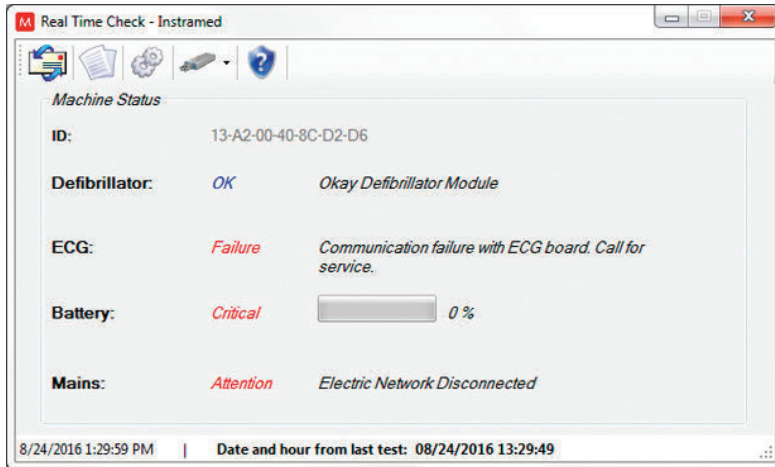




WARNING: accessories connected to the data interface must be certified according to the IEC 60950 standard for data processing equipment.

Receiving data

When the CardioMax performs the RTC test, the results will be sent to the control center and shown on the screen, along with the MAC ID code of the device.



Closing the application

To close the RTC software, access the initial program screen and type "S".

Preventive maintenance

Instramed recommends that the CardioMax be examined by a qualified technician every 12 months. We recommend that you contact the manufacturer for more information about qualified and trained personnel in your area to perform preventive maintenance.

It is recommended that periodic inspections be performed on the equipment's power supply charger, cables and connectors in order to determine possible isolation or internal conductor ruptures.

Functional tests must be performed at the beginning of every work shift.

Corrective maintenance

If the equipment needs repair, this can only be done by Instramed or its authorized representative, otherwise this Warranty certificate may no longer be valid.

No internal parts are to be fixed by the user.

Cleaning

Instramed recommends cleaning and disinfecting the equipment and its accessories every three months, or shorter periods whenever excessive dirt or contamination is noticed.

CLEANING THE EQUIPMENT

- Disconnect the equipment from the mains supply before cleaning it.
 - Wipe the external part of the device with a cloth moistened with water (almost dry) and neutral liquid soap until the entire surface is free of dirt. Never allow cleaning agents or water to enter the cabinet slits, display, and openings for connectors.
 - Repeat the procedure only with the cloth moistened with water (almost dry) to remove soap residue.
 - Dry the equipment with a clean and dry cloth.
 - Perform the procedure in room temperature.
-

CLEANING THE ACCESSORIES

For the ECG cable

- Clean the cable, the connection box and the surfaces of contact with the patient with a soft cloth moistened with water or neutral disinfection solution, dry the cable to use again.
- The cleaning must be periodic.
- Keep the cable plugs dry, since a wet plug may cause some kind of failure.

For the SPO₂ sensor and cable

- The cleaning process is specified in the accompanying instructions.

For the NIBP cuff and connection

- The cleaning process is specified in the accompanying instructions.

For the CPR MAESTRO

- Moisten a cloth with clean water and neutral detergent and clean the device until all dirty is removed.
- Use a second dry cloth to remove excess of liquid and/or foam.
- Moisten a third cloth with Alcohol 70° and pass lightly on the product.

For the DEFIBRILLATION PADDLES set

- Dampen a cloth with clean water and mild detergent and wipe any accessories until all dirt is removed.
- Use a second dry cloth to remove excess liquid and / or foam.
- Moisten a third cloth with 70° alcohol and lightly wipe the product.



IMPORTANT RECOMMENDATIONS

- Never immerse in liquid and never spill liquid of any kind on any part of the equipment.
- Do not use any other cleaning products not recommended by this manual.

NEVER sterilize any parts of the equipment, regardless of the sterilization method, as this would damage the mechanical structure and compromise the product's operation.

The recommendations above will ensure that the device will withstand, without damage or deterioration of safety factors, the necessary cleaning process.

Removable battery

Even when disconnected (stand-by), the CardioMax executes internal routines checking the status of the equipment. In spite of this procedure entailing a low power consumption, the battery charge may be consumed. Therefore, whenever the device has not been connected to an electric current for more than 20 days, it is advisable to execute a full battery charge. If this procedure is not performed, there is a risk of draining the battery and consequently being unable to use the CardioMax in its portable configuration (not connected to the electric current). To recharge the battery, connect the monitor to an AC power source (110 or 220 V outlet) or a DC power source.

There are no restrictions or limitations for using the CardioMax while its battery is being recharged by an AC source or DC External source.

Every battery has a determined lifetime, which is the possible quantity of full charge and discharge cycles, without loss of performance (see battery specifications in chapter 8). If the equipment presents a loss in battery performance, please request a new set to Instramed's technical assistance. To request pieces and services, please contact Instramed at +55 (51) 3073-8200.

Battery replacement is recommended every 02 (two) years or when the runtime is less than 01 (one) hour.

Removable battery replacement

The battery will automatically detach itself from the equipment as shown in the picture below.



1 - Press the side tabs to unlock the removable battery.



2 - Manually remove the battery from the equipment.

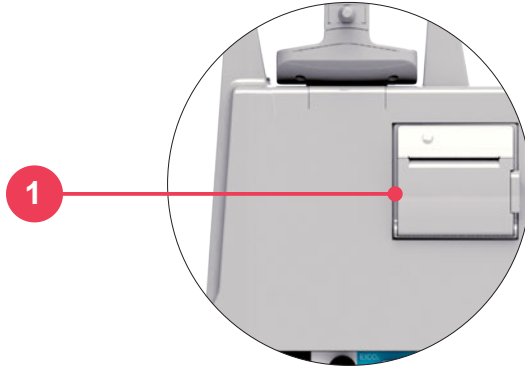
3 - Correctly position the new battery, as shown in the picture below.



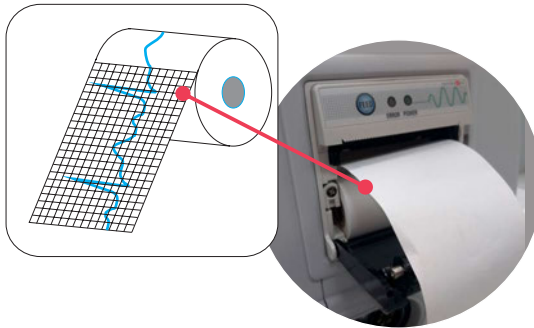
4 - Push the new battery until it firmly locks into the cabinet.

Replacing the thermal paper of the printer

1 - Pull the lever to open the printer door.



2 - Remove the old paper roll.



3 - Insert the new paper roll between the side clips. The paper roll should be positioned as shown above. The side with thermal sensitivity, which corresponds to the marking with millimeter lines, must be side up.

4 - Pull out the paper to unroll approximately 10 cm.

5 - Align the paper with the printer door.

6 - Close the printer door. The printer is ready for operation.

Returning components

If CardioMax must be returned for repair, call Instramed for shipping instructions. To facilitate assistance be prepared to provide the equipment's series number.

If possible, use the original equipment's packaging. If this is not possible, use an equivalent box that provides adequate protection for the monitor.

Repairs

Please contact Instramed at +55 (51) 3073 8200 or at assistencia@instramed.com.br or suporte@instramed.com.br in case of repairs or further doubts.

In order to help us assist you, please be ready to inform the equipment's serial number.

In case you send us the equipment for repairs, try to use its original packaging. If it is not possible, use proper packaging and protect the monitor well. Precautions, restrictions and warnings

The CardioMax is a device built according to NBR and IEC standards and therefore offers total safety for patient and operator. However, all safety precautions described below must be followed.



The monitor's operation can be affected by the presence of electromagnetic power sources, such as electrosurgical equipment and computer tomography (CT).

Precautions, restrictions and warnings

Cardiomax is a device built according to NBR and IEC standards and therefore is completely safe for the patient and the user. However, all safety precautions described below must be followed.



This equipment was designed to be resistant to electromagnetic interference. However, monitor performance can be affected if in the presence of strong sources of electromagnetic interference, such as electrosurgical equipment and computed tomography.

1 - ECG

1 - To guarantee protection against the effects of a defibrillation, use only the patient cable that accompanies the equipment.

2 - If the monitor is used simultaneously with an electric scalpel, position the ECG electrodes as far as possible from the RF current route, between the surgical field and the neutral card. Do not use needle type ECG electrode during surgical procedures.

2 - SpO₂

1 - The operation of this device may be affected by the presence of electromagnetic energy sources, such as electrosurgical or CT equipment. It also may be damaged by the presence of strong ambient light. If necessary, protect the area of the sensor with a surgical towel.

2 - Any dyes injected into the blood stream, such as methylene blue, indocaine green, indigo carmine and fluorescein, may affect the SpO₂ reading precision. The presence of dyshemoglobin, such as carboxyhemoglobin (in consequence of carbon monoxide poisoning) or methemoglobin (in consequence of sulfonamide's treatment) may affect the SpO₂ reading precision.

3 - Electromagnetic compatibility



Warning

Installing the CardioMax requires special precautions concerning electromagnetic compatibility according to the information contained in this manual.

Mobile and portable RF communications equipment, such as mobile phones, can affect the CardioMax's functioning.

Maximum length of accessories cables - in compliance with electromagnetic compatibility requirements:

ECG cable 5 leads (code 7900-5) 2.5 m.

Set of external defibrillation pads (code 27009) 2.5 m.

SpO₂ finger sensor cable (code 12556) + SpO₂ finger cable extensor (code 21176) 2.5 m.

Pacemaker cable (code 80208) 2.5 m.



Warning

Using cables, transducers and accessories different from the ones specified above, except for the ones sold by Instramed as replacement pieces, may result in emission increase or immunity decrease of the equipment.

The CardioMax must not be used too close to or piled over other equipment.

When the equipment is used in a surgical procedure simultaneously with an electric scalpel, there is a risk of burnouts if a defect in the connection of the neutral electrode of the high frequency equipment matches a defect in the CardioMax's ECG socket. This type of accident will only occur when the defects occur simultaneously, as the CardioMax's ECG socket is electrically protected against risks of burnouts, being completely insulated.

Electromagnetic emissions

Directives and manufacturer declaration - electromagnetic emissions		
The CardioMax is intended for use in the specific electromagnetic environment below. The customer or user of the defibrillator is advised to ensure that it is used in such an environment.		
Tests	Compliance	Electromagnetic environment - directives
RF Emissions ABNT NBR IEC CISPR11	Group 1	The CardioMax only uses RF power for its internal functions. Nevertheless, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The CardioMax is suited for use in any establishment. This includes residential establishments and those directly connected to the public network of distribution of low voltage electricity which supply domestic use buildings.
RF Emissions ABNT NBR IEC CISPR11	Class B	
Harmonics Emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	
NOTE: It is of paramount importance that the true efficacy of the RF shielding and the true attenuation of the RF filter of the shielded location are checked to ensure that they meet or exceed the minimum values specified.		

WARNING: CardioMax is suitable for use in professional healthcare environments.

WARNING: do not use the equipment in the presence of MRI devices. Measures should be taken to minimize interference from high frequency surgical equipment.

The actions to be taken to prevent adverse events to the patient and the operator

due to electromagnetic disturbances, during the useful life are

- Ensure minimum distance, according to the table on page 68, of an RF emitting source.
- The cables and accessories must also keep this distance.
- Do not use this product in conjunction with electrical scalpel.
- Do not use this product in conjunction with MRI devices.

The essential performance of the CardioMax is understood as the ANALYSIS of the patient's heart rate, the DEFIBRILLATION, CARDIOVERSION and PACEMAKER applied to the patient, and the monitoring of the PATIENT in electrocardiogram, oximetry, non-invasive pressure, respiration, and invasive pressure, The performance of the CardioMax is designed and verified for the absence of an unacceptable risk.

If performance is lost or degraded due to electromagnetic disturbances:

- The ECG signal may be interfered with and cardiac rhythm analysis may be compromised as long as electromagnetic disturbances persist.
- The SPO₂ curve can be disturbed, besides the possibility of alteration in the measured value.
- Non-invasive pressure measurement may suffer alterations on the measured values.
- The Invasive pressure curve may suffer interferences.
- If performance is lost or degraded due to electromagnetic disturbances, the ECG signal may be interfered with and cardiac rhythm analysis may be compromised as long as electromagnetic disturbances persist.

WARNING: portable RF communication equipment (including peripherals such as cables and external antennas) should not be used within 30 cm of any part of CardioMax, including cables specified by Instrumed. Failure to do so may cause performance degradation.

Electromagnetic immunity - General

Directives and declaration of the manufacturer - Electromagnetic emissions			
The CardioMax is intended to be used in the specific electromagnetic environment below, The user or customer of the defibrillator should ensure that it is used in such an environment,			
Immunity test	Test level EN 60601	Compliance level	Electromagnetic environment Directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact, ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be made of wood, concrete or tiles, If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient Burst IEC61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	The quality of the power supply should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode (phase - phase) ± 2 kV common mode (phase - ground)	± 1 kV differential mode (phase - phase) ± 2 kV common mode (phase - ground)	The quality of the power supply should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T (> 95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles < 5% U_T (> 95% dip in U_T) For cycle of 5 seconds	< 5% U_T (> 95% dip in U_T) For 0,5 cycle 40% U_T (60% dip in U_T) For 5 cycles 70% U_T (30% dip in U_T) For 25 cycles < 5% U_T (> 95% dip in U_T) For cycle of 5 seconds	The quality of supply power should be that from a hospital or commercial environment, During power outage, it is recommended that CardioMax is recharged by an uninterruptible power supply, Because the equipment does not operate when connected to the charger.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m and 30 A/m	3 A/m and 30 A/m	Power frequency magnetic fields should be at characteristic levels of a typical commercial or hospital environment.
NOTE: U_T is the ac mains voltage prior to application of the test level.			

Electromagnetic immunity - Equipment with life support functions

Advisable separation distances between mobile and portable RF communications equipment and the CardioMax			
The CardioMax is intended to be used in the electromagnetic environment specified below. The customer or user of the defibrillator should ensure that it is used in such an environment.			
Immunity test	Test level of EN 60601	Compliance level	Electromagnetic environment Directive
			Portable and mobile RF communications equipment should not be used near any part of the CardioMax, including cables, with a separation distance less than the one advised, calculated using the equation applicable to the frequency of the transmitter. Advisable distance of separation:
Conducted RF IEC 61000-4-6	3 Vrms 150 KHz up to 80 MHz outside bands ^a ISM.	3 Vrms 150 KHz up to 80 MHz outside bands ^a ISM.	$d = 1.2 \sqrt{P}$
	10 Vrms 150 KHz up to 80 MHz outside bands ^a ISM.	10 Vrms 150 KHz up to 80 MHz outside bands ^a ISM.	$d = 1.2 \sqrt{P}$
Conducted RF IEC 61000-4-3	10 V/m 80 MHz up to 2.5 GHz.	10 V/m 80 MHz up to 2.5 GHz.	$d = 1.2 \sqrt{P}$ 80% AM to 1 KHz. $d = 2.3 \sqrt{P}$ 80% AM to 1 KHz.
			Where "P" is the maximum output power of the transmitter in watts (W), according to the transmitter manufacturer, and "d" is the advisable separation distance in meters (m)^b. Field strengths established by RF transmitters, as determined by an electromagnetic site survey,^c should be less than the compliance level in each frequency range^d. Interference can occur around equipment marked with the following symbol:
NOTE 1: at 80 MHz and 800 MHz, the highest frequency range is applied. NOTE 2: these directives may not be applicable in all situations, electromagnetic transmission is affected by the absorption and reflection of structures, objects and people.			
^a ISM bands (industrial, medical and scientific) between 150 KHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.6 MHz to 40.70 MHz. ^b The compliance levels in the ISM frequency bands between 150 KHz and 80 MHz and in the frequency range between 80 MHz and 2.5 GHz are intended to reduce the likelihood of mobile and portable communications equipment causing interference if inadvertently brought into the patient areas. Therefore, an additional factor of 10/3 is used in calculating the advisable separation distance for transmitters in these frequency ranges. ^c Field strengths established by fixed transmitters, such as base stations for radio, telephones (cell phone/wireless) mobile land radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with any accuracy. In order to evaluate the electromagnetic environment due to fixed RF transmitters, it is advisable to consider an electromagnetic site survey. If the measured field strength in the site where the CardioMax is used exceeds the level of RF compliance used above, the CardioMax should be observed to check if operation is normal. If abnormal performance is observed, additional procedures may be required, such as reorienting or repositioning the CardioMax. ^d Over the frequency range 150 KHz to 80 MHz, the field intensity should be less than V1 (3 V/m).			



Electromagnetic immunity - Equipment with life support functions

Advisable separation distances between mobile and portable RF communications equipment and the CardioMax

The CardioMax is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the defibrillator can help to prevent electromagnetic interference by maintaining a minimum distance between the mobile and portable RF communications equipment (transmitters) and the CardioMax as recommended below, according to the maximum output power of the communication equipment.

Maximum output power of the transmitter (W)	Distance of separation according to the frequency of the transmitter (m)			
	150 KHz to 80 MHz outside ISM bands	150 KHz to 80 MHz outside ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d=1.2.\sqrt{P}$	$d=1.2.\sqrt{P}$	$d=1.2.\sqrt{P}$	$d=2.3.\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters with a maximum output power not listed above, the advisable separation distance "d" in meters (m) can be determined by using the equation applicable to the frequency of the transmitter, where "P" is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: at 80 MHz and 800 MHz, the separation distance for the highest frequency range is applied.

NOTE 2: the ISM (industrial, medical and scientific) frequency bands between 150 KHz to 80MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3: an additional factor of 10/3 is used in calculating the advisable separation distance for transmitters in the ISM frequency bands between 150 KHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to reduce the likelihood of interference that mobile/portable communications equipment could cause if taken inadvertently to patient areas.

NOTE 4: these directives may not be applicable in all situation. Electromagnetic transmission is affected by the absorption and reflection of structures, objects and people.

The CardioMax was designed to provide **basic safety** with RF equipment by the following table:

Testing specifications for cabinet interface immunity to RF wire communications equipment						
The CardioMax was designed to provide Basic Security with RF equipment by the following table:						
Testing frequency (MHz)	Band ^a (MHz)	Service ^a	Modulation ^b	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation ^b 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 FRS 460	FM ^c deviation of ± 5 kHz Sinusoidal 1 kHz	2	0.3	28
710	704-787	Band LTE 13, 17	Pulse modulation ^b 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900 TETRA 800 iDEN 920 CDMA 850 Band LTE 5	Pulse modulation ^b 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800 CDMA 1900 GSM 1900 DECT Band LTE 1, 3, 4, 25 UMTS	Pulse modulation ^b 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth WLAN, 802.11 b/g/n RFID 2450 Band LTE 7	Pulse modulation ^b 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation ^b 217 Hz	0.2	0.3	9
5500						
5785						
NOTE: If necessary, to reach the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the EM EQUIPMENT or EM SYSTEM may be reduced to 1 m. The test distance of 1 m is allowed by ABNT NBR IEC 61000-4-3.						
^a For some services, only the terminal's transmission frequencies are included. ^b The carrier must be modulated using a 50% service cycle square wave signal. ^c As an alternative to FM modulation, 50% to 18 Hz pulse modulation can be used because, although it does not represent actual modulation, this would be the worst case.						

Symptom	Probable cause	Probable solution
The CardioMax does not turn on.	There is no electricity.	- Check connections: the CardioMax/Power Cable/Plug.
Does not select energy > 50 J.	Adult pads identification.	- Check if is adult pads are connected to the equipment and if adult electrodes are properly connected.
Does not deliver shock.	Impedance measuring.	- Check the graph bar for the patient's impedance indication.
Does not capture ECG via electrodes.	Lead selection.	- Select a lead other than the "pads" lead.
No tracing.	Unstable since last shutdown.	- Restore initial configuration.
Low battery autonomy.	Defective battery.	- Turn off battery.
No QRS audio indication.	BEEP volume.	- Turn on BEEP's volume in the configuration menu.
No alarm sound indications.	Operation mode.	- Alarm indications are only active in the monitor mode.
No SpO ₂ curve.	SpO ₂ curve turned off.	- Turn on SpO ₂ curve in Waveform setup.
Pacemaker does not start.	Multifunction/Adhesive pads.	- Check if multifunction pads are connected. - Check if there is a "bad contact" message. - Check gel in multifunction pads.
Does not print .	No paper in the printer.	- Check if there is paper in the printer. - Check if paper is positioned properly.
Printer makes noises and does not print.	Too much paper on roll.	- Change roll's size.

Included items list

Básic		
Quantity	Description	Code
01	Mains supply power cable (3 pins)	5550
01	Removable battery (Li-Ion 14.4 VDC 4 A/h)	11113
01	Reference Guide	10011

Defibrillator (accessory included when this parameter is available)		
Quantity	Description	Code
01	A set of adult/child external defibrillation paddles	27009

ECG (accessory included when this parameter is available)		
Quantity	Description	Code
01	5-lead ECG cable	79005

NIBP (accessories included when this parameter is available)		
Quantity	Description	Code
01	Adult armband (cuff)	25671
01	Armband (cuff) extensor	25900

SpO ₂ (accessories included when this parameter is available)		
Quantity	Description	Code
01	Oximetry sensor	12556
01	Oximetry sensor extensor	21176

EtCO ₂ (accessories included when this parameter is available)		
Description: non reusable EtCO ₂ sampling line kit, including:		Code
01	Tracheal sample line - Adult	22686
01	Tracheal sample line - Childre	22687
01	Nasal sample line	22688

Pacemaker (accessory included when this parameter is available)		
Quantity	Description	Code
01	Trunk cable connection.	80208
01	Multifunctional pads.	79047

Optional items list

Description	Code
Y 3043 type oximetry sensor. Description: to use SPO ₂ in pediatrics or in case of a body part in which can not use the finger sensor.	12475
Disposable adult ECG electrodes. Description: package (check quantity availability per package) with adult non reusable ECG electrode.	21669
Bixelon printer paper. Description: 58 mm width printer paper.	11858
Removable battery (Li-Ion 14.4 VDC 6 A/h)	15257
CPR Maestro. Description: CPR feedback device to provide visual and audio informations about the quality of the CPR in the moment with purpose of increase the CPR's performance.	13542
Oridion capnography board - EtCO₂. Description: ETCO ₂ measurement module.	22684
WW3711 BCI board for neonatal SPO₂. Description: SPO ₂ measurement module.	20759
Pressure board MODEL 2 OEM NIBP (92-0033-58). Description: NIBP measurement module.	22766
CPR Maestro holder	15308
Adult 10-wire patient cable	80202
A-B USB cable	10985
Grounding cable	5495
Battery cable	79004
Disposable adhesive pads - Children	79048
Transport bag	22095

General specifications

Dimension with pads:	30.0 cm (W). 21.5 cm (D). 28.0 cm (H).
Weight:	Device - 5.15 kg (11.35 lbs). Li-Ion battery - 0.60 kg (1.32 lbs). External pads - 0.85 kg (1.87 lbs). Complete set (Li-Ion battery) - 6.60 kg (15.66 lbs) (except NIBP).
Power:	AC: 100 to 220 VAC, 50/60 Hz. DC external: 11 to 16 VDC.
Removable rechargeable battery:	- Li-Ion, 14.4 VDC 4 A/h. Battery life: 3 hours in monitor mode, without the printer or a minimum of 140 shocks at 360 J or a minimum of 200 shocks at 200 J. Time to fully charge the battery (when fully depleted): 4h:30min. - Li-Ion, 14.4 VDC 6 A/h. Battery life: 6.5 hours in monitor mode, without the printer or a minimum of 250 shock at 360 J or a minimum of 400 shocks at 200 J. Time to fully charge the battery (when fully depleted): 7h:20min
Maximum consumption:	AC: 400 W. Battery 15 A.

Fuses:

Location	Marking	Nominal current	Action	Rated voltage	Breaking current
External mains supply	Fuse	5 A	Normal	250 V AC	100 A
External mains supply	F1 and F2	15 A	Normal	250 V AC	100 A
Internal ECG board	F1	2.5 A	Fast	32 V AC	50 A
Internal printing board	F1	3 A	Fast	125 V AC	50 A
Internal battery board	F1	15 A	Fast	125 V AC	50 A

Battery storage:

Storing the battery for a long period of time in temperatures higher than 40°C will reduce its capacity and lifetime.

Memory:

Type: Flash Nand.

Capacity: 2 Mbytes.

Patients stored: >150 patients.

ECG: recording of 2 continuous hours of the ECG curve (when the AED mode is on).

Storage: 15 seconds of ECG when in shock, physiological alarm and panel events.

RTC - Real Time Check (available when equipped with Li-Ion battery):

Defibrillation self-test, battery level, connected pads, power source connection check. Check is performed 3 times which are set in advance. This information is wirelessly transmitted to a PC with RTC System software installed and within range of the network.

Protection index:

IPX1 (default) or IP44 (optional).

Classification:

Class I.

Electrical insulation of the equipment and its applied parts:

CF Type.

Operating mode:

Continuous operation.

Screen:	Size: 128.2 mm x 170.9 mm. Diagonal: 8.4 inches. Type: color LCD TFT. Resolution: 640 x 480 pixels (VGA).
Scan speed:	6.25, 12.5, 25 and 50 mm/s.
Isolating method from mains power supply:	Flexible cable with a mains plug.
Equipment lifetime:	10 years (excluding battery and adhesive pads). NOTE: each accessory has its own useful lifetime (specified by the manufacturers by the number of uses).
Adhesive pads lifetime:	2 years.

Environmental specifications

Temperature:	Operational: 0 to 50°C. Storage: - 20 to 50°C.
Humidity:	Operational: 10 to 95% RH, without condensation. Storage: 10 to 95% RH, without condensation.
Altitude:	Recommended to use in altitudes lower than 2000 meters.



WARNING: if the CardioMax is used outside these conditions, 15 through 30 minutes will be required to stabilize the system so that functioning failures do not occur.

Defibrillator

Waveform:	Biphasic truncated exponential. Wave shaped parameters adjusted according to the patient's impedance.
Shock application:	By means of multifunction pads or external adult/child pads.

Scales for adult/external defibrillation:	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 50, 80, 100, 150, 200, 250, 300 and 360 J. Maximum energy limited to 50 J with child pads.
Charge auto-sequencing:	When enabled, it charges power previously set by the user for the first, second and third shocks, with no need to manually adjust the selector.
Commands:	On/off, charge, shock, sync key.
Energy selection:	Selector switch in front panel.
Charge command:	Button in front panel, buttons in external pads.
Shock command:	Button in front panel, buttons in external pads.
Synchronized command:	Sync key in front panel.
Charge indicators:	Audio indication of equipment being charged, audio indication of charge completed, LED on external pads and charge level indicated on display.
Maximum charge time in maximum energy:	< 6 s with 90% to 100% of the minimum specified voltage. < 6 s with a full charge. < 13 s from equipment initialization.
External pads size:	Adult = 10.3 cm x 8.5 cm (contact area = 81.9 cm ²). Children = 4.5 cm x 4 cm (contact area = 18 cm ²).
Pads cable length:	2 meters. The adhesive pads provided by Instramed have a biocompatibility certificate in accordance with ISO 10993.
Cardioversion:	< 60 ms after the QRS peak.
Maximum output voltage:	2000 V.
Maximum output electric current:	70 A (25 Ω).

AED mode

Functional characteristics:	Voice commands, visual indications, CPR instructions, USB 2.0 for PC connection, multi-languages, SDP (Sudden Death Prevention) technology.
USB:	USB 2.0 for transferring electrocardiogram stored in AED mode to a compatible PC.
SoftDEA:	Software for viewing data transferred to PC.
Waveform:	Truncated exponential biphasic pulse. Waveform parameters adjusted according to the patient's impedance.
Shock delivery:	By means of multifunctional pads (adhesive) or defibrillation pads.
Defibrillation scales:	Adult: 150 and 200 J. Child: 50 J.
Adult/children's selection:	Automatic due to the size of the pads.
Charge command:	Automatic after identifying an arrhythmia.
Shock command:	Frontal panel button, "shock".
Maximum charge time (with 100% of the minimum specified voltage):	200 J: < 6 s. 150 J: < 4 s. 50 J: < 2 s.
Maximum time from rhythm analysis beginning to discharge readiness:	20 s.
Maximum time from beginning of defibrillator operation to discharge readiness in maximum energy:	30 s.

The rhythm detector and recognizer does not continue analyzing ECG after a shockable rhythm is detected.

Size of adhesive pads: Adult = area: 82 cm².
 Child = area: 30 cm².

ECG analysis algorithm

Databases used for the VF/VT recognition algorithm tests

- MIT-BIH Arrhythmia Database.
- MIT-BIH Atrial Fibrillation Database.
- MIT-BIH Supraventricular Arrhythmia Database.
- European Society of Cardiology.
- Creighton University.

Test report

- **Recording methods:** the files were acquired via internet through the MIT-BIH database and used via computer.
- **ECG rhythm sources:** MIT-BIH, on <http://ecg.mit.edu/>
- **Rhythm selection criteria:** rhythms were chosen according to notes present in the MIT-BIH database.
- **Criteria and annotation methods:** the rhythms were recognized and annotated in a separate file. Later they were recognized and compared for sensitivity and specificity calculations.

	VF/VT	Nonshockable rhythms
Shock INDICATED	A	B
NO shock INDICATED	C	D

- Sensitivity = $\frac{A}{A+C}$
- Specificity = $\frac{D}{B+D}$

Sensitivity is the equipment's percent ability to correctly identify a shockable rhythm.

Specificity is the equipment's percent ability to correctly identify a nonshockable rhythm.

A = *True positive.*

B = *False positive.*

C = *False negative.*

D = *True negative.*

A true positive (A) is the equipment's ability, in measurement units, to **correctly** identify a **shockable** rhythm.

A false positive (B) is the equipment's ability, in measurement units, to **wrongly** recognize a **shockable** rhythm.

A false negative (C) is the equipment's ability, in measurement units, to **wrongly** recognize a **nonshockable** rhythm.

A true positive (D) is the equipment's ability, in measurement units, to **correctly** recognize a **nonshockable** rhythm.

Values measured with the AED using the specified database:

	VF/VT	Nonshockable rhythms
Shock INDICATED	329	23
NO shock INDICATED	10	454

- Sensitivity = **97.05%**
- Specificity = **95.18%**

Types of Arrhythmia analyzed

Nonshockable

- Sinus Rhythm/ Sinus Tachycardia/ Sinus Bradycardia.
- Atrial Tachycardia.
- Atrial Fibrillation.
- Atrial Flutter.
- Supraventricular Tachyarrhythmia.
- Normal Rhythm with Extrasystoles.
- Sinus Rhythm with Pacemaker.
- Asystole.

Shockable

- Ventricular Tachycardia with several QRS amplitudes and widenings.
- Ventricular Fibrillation with several amplitudes.

Rhythm classes	Specifications
Shock - VF.	The CardioMax meets IEC 60601-2-4 requirements for sensitivity > 90%.
Shock - VT.	The CardioMax meets IEC 60601-2-4 requirements for sensitivity > 75%.
Nonshockable rhythms.	The CardioMax meets IEC 60601-2-4 requirements for specificity > 95%.

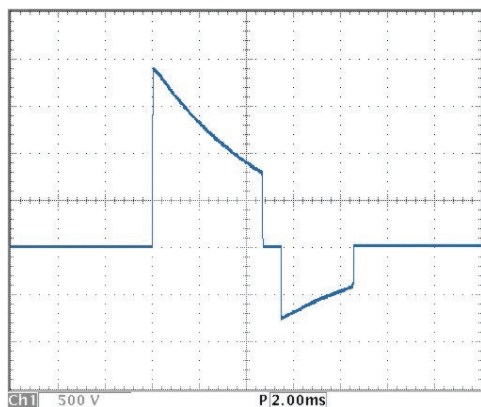
Precision of applied energy:

Energy selected	Impedance							Accuracy
	25	50	75	100	125	150	175	
1	0.9	1.0	1.1	1.1	1.0	0.9	0.8	±1J
2	1.8	1.9	2.0	2.0	2.0	2.0	1.9	±1J
3	2.8	3.0	3.0	3.0	3.1	3.2	3.2	±2J
4	3.6	3.9	3.9	4.0	4.0	3.9	3.9	±2J
5	4.8	5.1	5.1	5.0	5.0	5.0	4.9	±3J
6	5.5	5.8	5.9	6.0	6.0	6.0	6.0	±3J
7	6.5	6.9	7.2	7.2	7.1	7.0	7.0	±3J
8	7.2	7.9	8.1	8.2	8.3	8.1	7.7	±3J
9	7.8	8.6	8.9	9.0	9.0	9.0	8.8	±3J
10	8.8	9.8	10.2	10.4	10.3	10.2	9.8	±3J
20	19.0	20.5	21.0	21.0	20.5	19.5	19.0	±15%
30	27.5	30.0	31.0	31.5	31.0	29.5	27.5	±15%
50	49.0	52.0	53.0	52.5	51.5	48.0	45.5	±15%
80	77.5	81.5	82.5	83.0	80.5	76.5	74.5	±15%
100	96.0	101.0	102.5	103.5	101.0	96.5	92.0	±15%
150	143.0	151.5	155.0	153.0	148.0	141.0	137.0	±15%
200	191.5	201.5	205.5	206.0	203.5	192.0	177.0	±15%
250	240.0	250.5	256.5	256.0	254.0	241.5	224.0	±15%
300	284.0	302.0	305.5	306.0	305.0	290.0	270.0	±15%
360	344.0	363.0	370.5	370.0	363.0	345.0	322.0	±15%

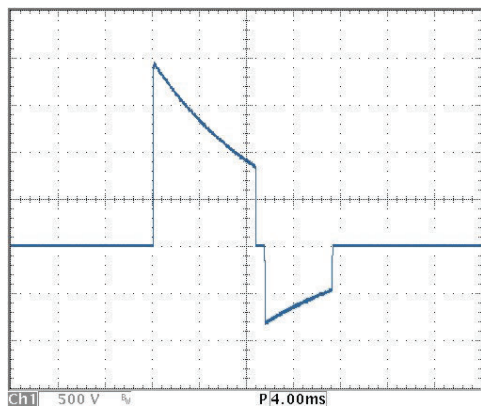
Patient's impedance response table:

Patient Impedance	Shock
Short-circuit.	Shock inhibited.
< 25 Ohms.	Shock inhibited.
> 25 Ohms AND < 300 Ohms.	Shock delivered with a waveform adjusted to the patient's impedance.
> 300 Ohms.	Shock inhibited.
Open circuit.	Shock inhibited.

Values on the Y axis refer to voltage (volts) and values on the X axis refer to time (milliseconds).

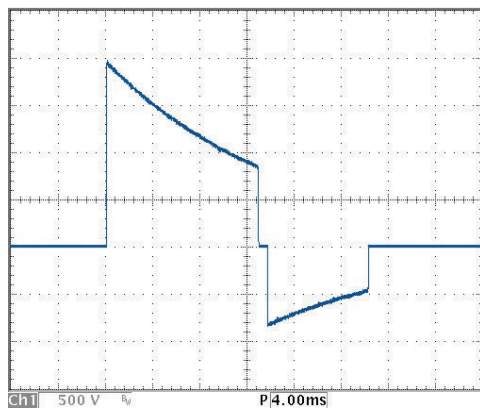


360 J of energy at 25 R impedance.

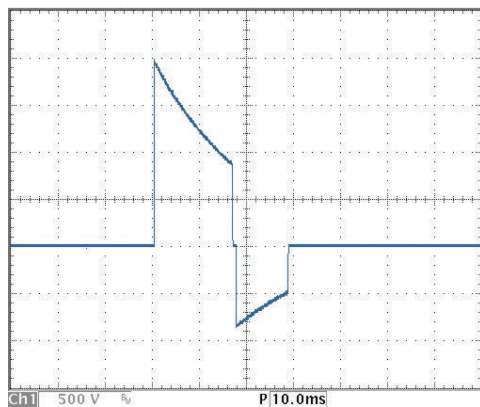


360 J of energy at 50 R impedance.

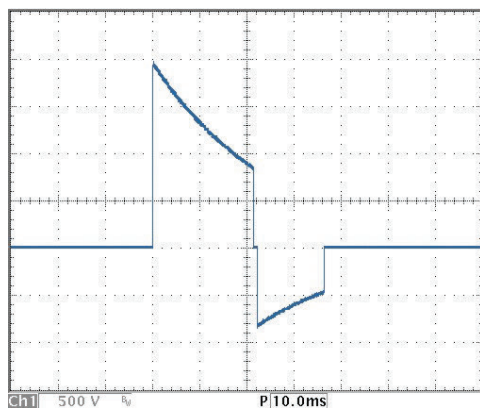
360 J of energy at 75 R impedance.



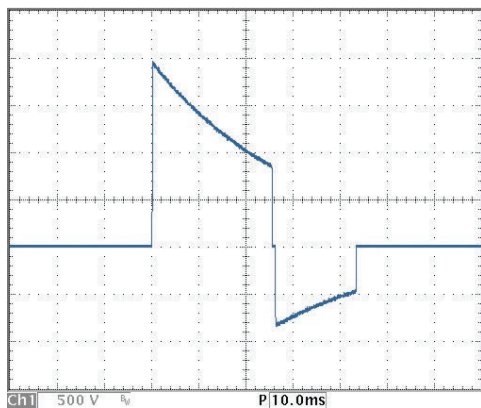
360 J of energy at 100 R impedance.



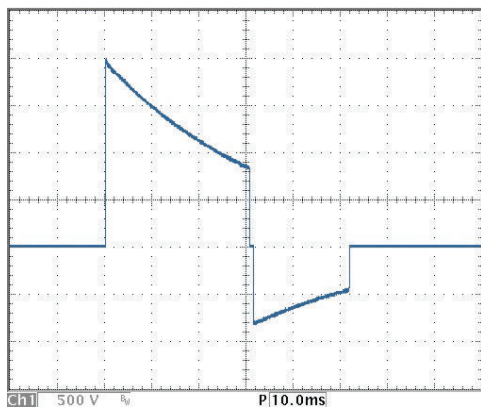
360 J of energy at 125 R impedance.



360 J of energy at 150 R impedance.



360 J of energy at 175 R impedance.



Pacemaker

Waveform:	Single-phase rectangular pulse.
Modes:	Demand or fixed.
Amplitude:	Between 5 mA to 200 mA (resolution of 5 mA). Precision 10%.
Pulse width:	20 ms (tolerance of 10%).
Frequency:	Between 30 ppm to 180 ppm (increments of 5 ppm), precision $\pm 2\%$.
Refractory period:	340 ms (between 30 to 80 ppm), 240 ms (between 90 to 180 ppm).
Maximum output voltage:	350 V.

ECG

Input:	3 or 5 lead ECG cable. 10 lead ECG cable (optional). External pads. Multifunctional pads. Supports up to 12 simultaneous derivations when equipped with optional cable.
Electrode error:	NO ELECTRODES and a trace line will appear on the display if there is a disconnected cable or electrode.
Low ECG amplitude or saturated ECG signal:	The "Searching for ECG Signal" message will appear on the screen or printer (electrocardiograph mode) when the ECG 10 mm/mV amplitude is less than 2.4 mm peak-to peak (or sensitivity proportional).
Multifunction pads error:	If an adhesive pad is disconnected, a trace line will appear on the display.

Range:	15 to 350 BPM.
Precision:	± 1 BPM of 15 to 350 BPM.
Rejection in common mode:	Higher than 90 dB, measurement in compliance with the AAMI standards for heart monitors (EC 13).
Sensitivity:	5, 10, 15, 20, 30 and 40 mm/mV.
AC line filter:	60 Hz or 50 Hz.
ECG response frequency:	Diagnostic mode: 0.05 - 100 Hz. Monitor mode: 1 - 40 Hz.
Patient insulation's (defibrillation proof):	ECG: CF type. SpO ₂ : CF type.
Physiological alarm:	Alarm not locked. Minimum level (30-100). Maximum level (100-250). Visual indication. Sound indication. Suspend sound indication function. Silence sound indication function.
Technical alarm:	Alarm not locked. Visual indication. Sound indication. Suspend sound indication function. Silence sound indication function.
Time to re-establish the ECG baseline after defibrillation:	≤ 3 seconds.
Loose electrode:	Identified and shown with low level alarm.
ECG amplifiers impedance input:	4.7 Mohms (Mega Ohms).

Pacemaker rejection stimulus:	Pacemaker Stimuli with width between 0.1 ms and 2 ms, and amplitude between $\pm 2 \text{ mV}$ e $\pm 700 \text{ mV}$, are rejected in the heart-beat counting. Regarding the overshoot, it meets the method A of the AAMI EC13: 2002 standard. In the range of 15 BPM the 350 BPM the pacemaker pulses are rejected.
Maximum amplitude of the wave:	It meets the minimum recommended value of 1.2 mV for the T wave amplitude rejection.
Accuracy of cardiac frequency in irregular rhythms:	It complies with the AAMI standard for: Ventricular bigeminy (FC = 40 BPM). Slow alternating ventricular bigeminy (FC = 30 BPM). Fast alternating ventricular bigeminy (FC = 120 BPM). Bidirectional systoles (FC = 45 BPM).
Input dynamic range and offset differential voltage:	The equipment complies with 50.102.2 standard IEC 60601-2-27.
50.102.15 standard of IEC 60601-2-27, heart rate range, accuracy and QRS detection range:	To maintain accuracy at low heart rate and high heart rate, the equipment must be in diagnostic mode.
Heart rate response time:	80 to 120 BPM: maximum of 7 s. 80 to 40 BPM: maximum of 9 s.
Tachycardia alarm time:	206 BPM (1 mV): 5 seconds. 206 BPM (0.5 mV): 5 seconds. 206 BPM (2 mV): 5 seconds. 195 BPM (2 mV): 5 seconds. 195 BPM (1 mV): 5 seconds. 195 BPM (4 mV): 5 seconds.
ST segment:	YES (check availability).

ECG electrodes (adult or child):	COMPOSITION: Adhesive conductor with hydrogel and silver sensor (Ag/AgCl), latex free. USE INSTRUCTIONS: 1) Shave hairs, clean the spot and dry with gauze. 2) Before removing the protective film, attach the ECG wire to the electrode. 3) Remove the film from the electrode and put it in place by pressing firmly. PRECAUTIONS: Do not open the packaging before use. Do not apply the electrodes on the nipples, bony protuberance, cuts, lesions, scars, only on intact skin. Store at temperatures between 15°C and 40°C. Non-sterile single-use product. Discard after use.
ECG gel:	It is recommended the use of a gel suitable for medical procedure, indicated for use in electrocardiography, defibrillators and similar. Used as a contact medium for the transmission of electrical impulses by means of an electroconductor. Biocompatible. After each use, clean the accessories according to cleaning recommendations.

NIBP - Non-Invasive Arterial Pressure

Technique:	Oscillometric.
Adult range:	Systolic: 40 to 260 mmHg. Mean: 26 to 220 mmHg. Diastolic: 20 to 200 mmHg.
Pediatric range:	Systolic: 40 to 160 mmHg. Mean: 26 to 133 mmHg. Diastolic: 20 to 120 mmHg.
Neonatal range:	Systolic: 40 to 130 mmHg. Mean: 26 to 110 mmHg. Diastolic: 20 to 100 mmHg.
Overpressure limit per software:	Adult: 290 mmHg max. Neonatal: 145 mmHg max.
Overpressure protection by hardware:	Adult: 300 ± mmHg. Neonate: 150 ± mmHg.

Resolution:	1 mmHg.
Manual mode:	One measurement.
Automatic mode:	1, 2, 3, 4, 5, 10, 15, 30, 60 and 90 minutes.
STAT mode:	Maximum of consecutive measurements in 5 minutes.
Armband:	Use only armband that has connector according to norm ISO 594-1.

SpO₂

SpO ₂ range:	0 to 100%.
Pulse range:	30 to 250 BPM.
SpO ₂ 's precision:	± 2% (70 to 100%). ± 3% (50 a 69%).
Pulse precision:	± 2 BPM.
Physiological alarm:	Alarm not locked. Minimum level (40-95). Maximum level (45-100). Visual indication. Sound indication. Suspend sound indication function. Silence sound indication function.
Technical alarm:	Alarm not locked. Visual indication. Sound indication. Suspend sound indication function. Silence sound indication function.

CPR Maestro (optional)

Accessory for cardiac massage feedback, it presents visual and audible messages guiding the rescuer in relation to the speed and depth of the massage, providing a cardiac massage with greater efficiency.

Precision: Depth = $\pm 2\%$.
 Frequency = $\pm 16\%$.

Minimum number of uses: 100 uses.

Printer

Type: Thermal

Weight: 0.104 Kg.

Speed: 25 or 50 mm/s.

Paper size: 58 mm (width).
 15 m (length).

Respiration

Technique: Transthoracic impedance.

Range: 3 to 150 breaths per minute.

Precision: ± 3 breaths per minute.

Sensitivity: 1, 2, 3, 4, 5 and 6 X.

Electrodes: RA-LA.

The impedance/frequency of the breathing detector signal is of 150 ± 15 KHz at 82 microamps RMS, rectangular wave at 100 Ohms.

Capnography

Weight:	160 gr.
CO ₂ measurement interval:	0 - 99 mmHg.
Precision:	± 2 mmHg (0 - 38 mmHg). $\pm 5\% + 0.08\%$ for each 1 mmHg above 38 mmHg (39 – 99 mHg).
Calibration:	2 points.
Start:	10 seconds to start the CO ₂ curve. Less than a minute for full functioning.
Consumption:	1.5 W.
Format:	Graphic.
Memory:	72 hours - Non-volatile.
Data Interval:	25 seconds.
Graph format:	A graph per vital sign.



WARNING: if the patient's physiological signs are below the specified in the manual, the results presented may be imprecise

Warranty Certificate

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Instramed Indústria Médico Hospitalar Ltda. warrants the equipment described in this Certificate for 12 (twelve) months, starting from the delivery date. This warranty covers manufacturing or material defects that prevents proper functioning according to the specifications stated herein, as long as the conditions presented in this Certificate are respected.

During the warranty period, Instramed Indústria Médico Hospitalar Ltda. or its representative will repair or replace defective parts, at no expense to the equipment's owner.

This warranty will no longer be valid if any damage occurs due to accident, natural disaster, improper connection to a power source, use distinct from that described in the User manual, or irregular working conditions.

Any attempt to violate, adjust or repair this equipment by individuals not authorized by Instramed Indústria Médico Hospitalar Ltda. will automatically invalidate this warranty. This also applies in case of alterations made to this contract, the fiscal receipt, or to the equipment's serial number.

Instramed Indústria Médico Hospitalar Ltda. is not responsible for the improper use of this equipment, by people who are not familiar with its function or the techniques recommend for its proper use.

EQUIPMENT : _____

SERIAL NUMBER: _____

PURCHASE DATE: _____

FISCAL RECEIPT NUMBER: _____

CARDIO**MAX**

Biphasic Monitor Defibrillator



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