
User's Manual



CARDIOMAX

Biphasic Monitor Defibrillator

INSTRAMED

Manufacturer

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**For information about warranty or technical assistance,
contact Instramed Technical Support.**

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Battery use

ATTENTION: Observe the maintenance instructions of the battery charge

First use:

Before the first use the CardioMax should receive a full battery charge. To do this, the equipment needs to be connected to the electric current for at least eight hours.

Possible 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 appliance has not been connected to the 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 electrical network).

Replacement:

Every battery has a determined useful life, which is the possible quantity of full charge and discharge cycles, without loss of performance (check out the specifications of the battery in chapter 15). When the appliance has a drop in performance of the battery, with low autonomy, request a new unit from Instramed technical assistance.

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Introduction

1

Purpose

CardioMax is a biphasic defibrillator, configurable vital signs' monitor and pacemaker. It has been designed and manufactured by INSTRAMED for adult, pediatric and neonatal patients. The parameters monitored are:

- ECG and heart frequency
- Functional arterial oxygen saturation (SpO₂)

CardioMax is a modern, practical, lightweight and compact device that can be used in emergency situations and transported within hospitals or in ambulances.



WARNING: 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 Guide

This guide explains the functioning of the CardioMax defibrillator/monitor series and alerts the user of possible safety risks.

The information contained within, belongs to INSTRAMED and cannot be used 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.

General Warnings

IMPORTANT: This equipment may only be operated by qualified technicians. Read this guide carefully before using equipment.

Verify if there are any abnormalities or damage caused by mishandling during transportation, before installing the equipment.

WARNING: CardioMax should only be used as a complement in assessing the patient's physiological conditions. It must be used along with the patient's symptoms and clinical signs.

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

WARNING: The parts applied are protected against discharge of defibrillation; during the discharge there may be variance of the base line.



















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

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

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

WARNING: 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

Classification and Symbolology

Symbol	Standard	Description
	IEC TR 60878	Defibrillation proof insulated CF type equipment
	IEC TR 60878	Attention: only use as per the instructions of this manual
	IEC TR 60878	Careful: dangerous high electrical voltage
	IEC TR 60878	Terminal for equalization of potential
	IEC TR 60878	Terminal for general ground
Desl	—	Disconnects the Equipment
	IEC TR 60878	Alternate current
	IEC TR 60878	Direct current
	IEC TR 60878	Non-ionizing radiation
	IEC TR 60878	Input and output connection
	ISO 780	Maintain this side upwards
	ISO 780	Fragile equipment
	ISO 780	Maximum stacking of 4 units
	ISO 780	Maintain protected from the rain
	ISO 7000 ISO 780	Minimum and maximum temperature
	ISO 7000	Minimum and maximum atmospheric pressure
	ISO 7000	Minimum and maximum relative humidity
	IEC TR 60878	Recyclable paper
	Diretiva 2002/96/CE	Remains of electrical and electronic equipment – Separate disposal from other objects
CE 0843	Diretiva 93/42/EEC	Mark of compliance with European Community

Standards

CardioMax was designed according to safety and performance standards, such as:

NBR IEC 60601-1:1997, Electrical Medical Equipment- Part 1- General Requirements for Safety.

NBR IEC 60601-1-2:2006, Electrical Medical Equipment -Part1-2 – General Requirements for Safety - Collateral standard: Electromagnetic Compatibility Requirements and Tests.

NBR IEC 60601-2-4:2005, Electrical Medical Equipment –Part 2- Particular Requirements for the Safety of Cardiac Defibrillators.

NBR IEC 60601-2-27:1997, Electrical Medical Equipment –Part 2- Specific Safety Requirements for Electrocardiogram Monitoring Equipment.

NBR IEC 60601-2-49:2003, Electrical Medical Equipment –Part 2- Particular Requirements for the of Multiparametric monitoring equipment.

ANSI/AAMI EC13:2002: Cardiac monitors, Heart Rate Meters and Alarms.

ANSI/AAMI DF80:2003: Part 2-4 - Particular requirements for the safety of cardiac defibrillators (including automated external defibrillators).

NBR IEC/CISPR11:1995, Electromagnetic Compatibility: Radiated and Conducted.

Precautions:



Danger of EXPLOSION: Do not use CardioMax in the presence of flammable anesthetics.



Risk of ELECTRICAL SHOCK: Never take caps off the equipment. If necessary, this must be done by authorized individuals.



Do not use the equipment in the presence of magnetic resonance devices.

This equipment was designed to be resistant to electromagnetic interference. However, equipment performance can be affected if in the presence of strong sources of electromagnetic interference or radio frequencies, such as mobile phones, radio communicators, etc.

If the measurements do not appear to be accurate, first check the patient's vital signs and then CardioMax's performance.

Device care

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

Place cables connected to the patient in a way that limits the possibility of strangulation.

Keep the equipment in a dry place, avoiding the possibility of spilling liquids on the monitor.

Do not use the equipment 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 with other devices

When connecting CardioMax to any instrument, check to 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 of IEC for medical equipment.

Grounding

GROUNDING IS ESSENCIAL 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). In addition to the power cable with a plug and 3-pin connector, there is a cable with a "banana" pin on one side and an "alligator" type clasp on the other, for potential equalization. The potential equalization must be done when the patient is connected to the monitor and directly, or indirectly to another device (for instance, monitoring a child in an incubator). This interconnection should be made with the potential equalization connector and general grounding on the rear panel.

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

To avoid environmental contamination, endangering humans or other equipment, be sure to properly sterilize and decontaminate the equipment before discarding. Follow local laws for disposal of electrical parts and equipment.

To dispose of parts and accessories, follow local regulations regarding hospital waste.

To dispose of the battery, follow local safety regulations.

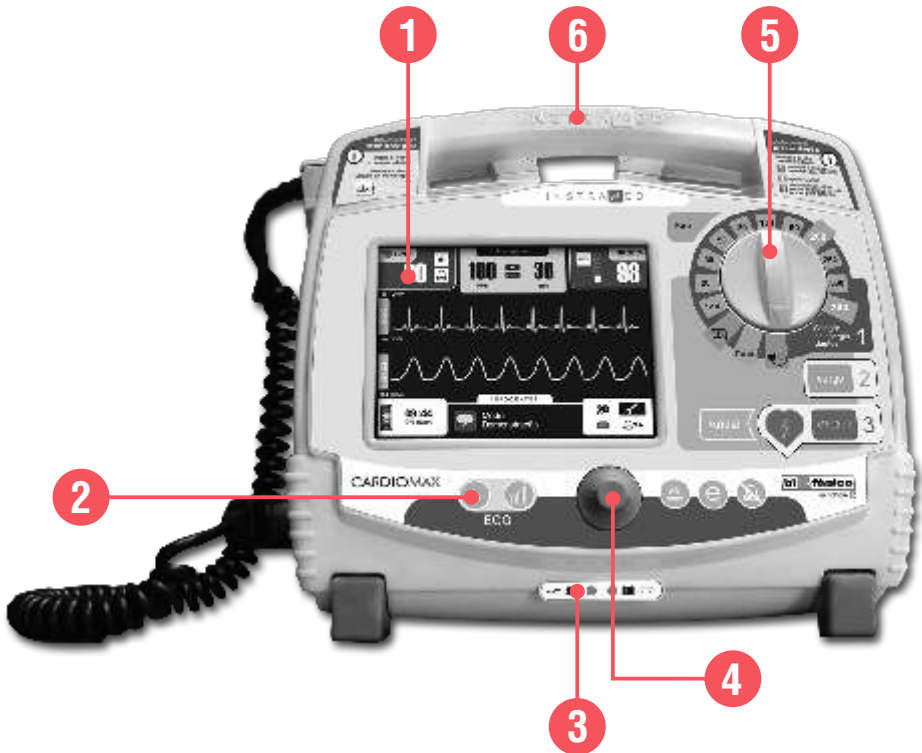


Remains of electrical and electronic equipment. Dispose separately from other objects of the establishment. See the local regulations for trash (follow European Directive 2002/96/CE).

The Equipment

3

Front panel



1 - LCD screen

2 - Quick access buttons

3 - Power and battery charging indicators

4 - E-Jog Control: Equipment's general configurations

5 - Selector Switch: Turns the equipment on and off. Selects defibrillator mode, energy, monitor and pacemaker.

6 - Handle for transportation

Screen

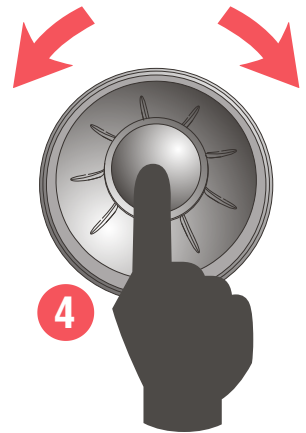
CardioMax's LCD screen displays graphic and numeric information used in ECG and SpO₂, defibrillation and pacemaker monitoring. For more information about the configurations and screen information, see the "Screen and Operation" section.

e-Jog Control

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

ACTION ROTATE: Rotating allows the user to select or change information and navigate all menus. The operation is similar to a computer's mouse.

ACTION PRESS: Works similar to the "enter" button on a computer, confirming the selection.



Selector Switch

A Scale from 1 to 360 Joules: Allows the user to select the desired level of energy.



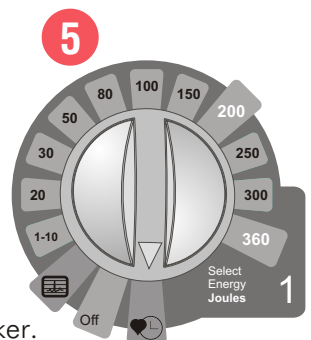
Monitor Mode: Used to monitor ECG and SpO₂ parameters, as in a multiparametric monitor.



Pacemaker Mode: Enables external pacemaker.

Off

"Off": Turns off equipment



NOTE: The equipment does not defibrillate in either pacemaker or monitor mode. Pacemaker will only work in pacemaker mode.

The quick access buttons allow instant access to important equipment functions.



Fast Lead Change: Enables fast access to change ECG leads.

Fast Sensibility Change: Enables fast change of ECG sensibility.



Print: Press once to print a fast 10-second report. For continuous printing, simply press the button for 3 seconds. For further information, see the "Printing" section.

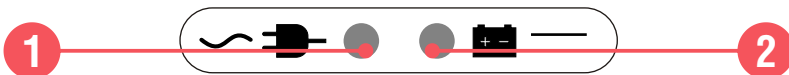


Events: When used along with the e-Jog Control, it allows one to mark an important event and store it in the equipment's memory.



Alarm silence: Press the button rapidly to deactivate ALL audio alarms for a previously programmed period of time. Press for 3 seconds to deactivate all audio alarms for an INDETERMINATE period. For more information, see the "Alarms and limits" section.

Power and battery charging indication



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

2. Battery Charging: When the LED is on it indicates the battery is charging.

NOTE: LEDs turn on even when the screen is off.

Side view



1. Connector for defibrillation electrodes (paddles)

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

Adult/children's external: Included with the equipment, may be used for adult and/or children. *Cannot be used in pacemaker mode.*

Internal: Used for surgery.

2. ECG connector

Connector for 3 or 5-lead ECG cable. AAMI standard. Protected against defibrillation

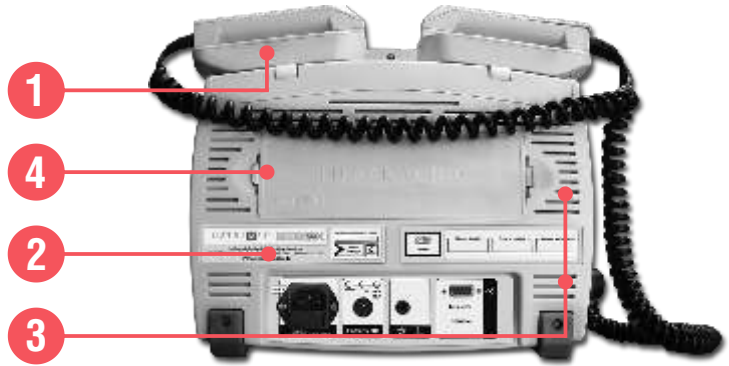
3. Connector

Future use.

4. Printer

Printer uses thermosensitive paper. Prints electrocardiograms and events.

Rear panel



1. Paddles

The paddles accompanying CardioMax must be placed on top of the equipment, with the adult's adaptor connected.

2. Identification Tags

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

3. Ventilation

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

4. Removable battery

CardioMax's battery can be easily replaced, simply press both side tabs and the battery unlocks and automatically detaches from the equipment. *NOTE: Do not remove the battery when the equipment is operating in battery mode. Turn CardioMax off before removing the battery.*

Rear connectors



1. 3-pin power connector

Input of 100 to 265 VAC, with central pin for grounding. 5A fuse (GLASS 20mm 20AG F5A FUSE)

2. External DC Input

For connecting to battery or an external DC source with operating range from 11 to 16 VDC.

3. Grounding and Potential equalizer

Potential equalization connector and general grounding.

4. RS-232 Output

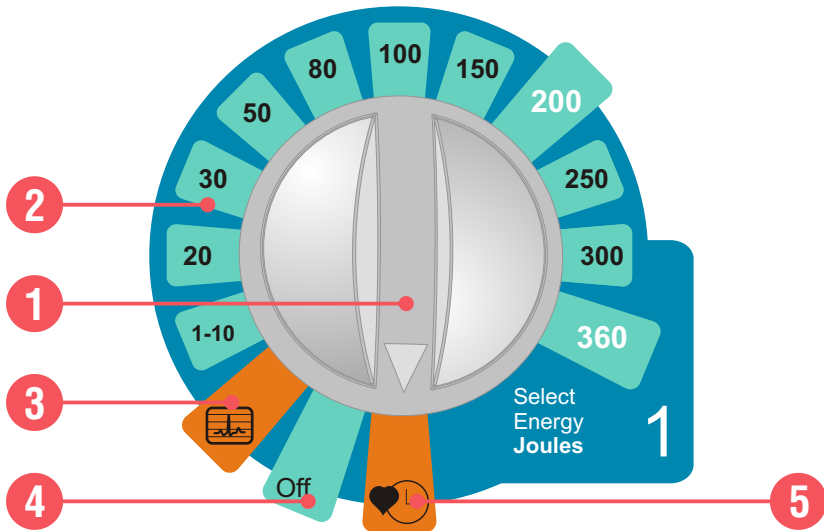
For interconnection with PC and uploading data recorded on the equipment. Programming cable input for updating software.

Screen and Operation

4

Turning on and operating

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).



1. Selector Switch

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

2. Defibrillation mode

Select defibrillator mode. Step 1 for defibrillation is selecting the energy to be stored, from 1 to 360 joules.

3. Monitor mode

Used to monitor patient's ECG and SpO₂ parameters. In this position CardioMax works as a multiparametric monitor.

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

4. Turns equipment off

CardioMax is turned off. Only the circuit that charges the battery operates. (Indication on CardioMax's the front panel).

5. Pacemaker mode

Enables the external pacemaker.

CardioMax's external pacemaker will only work if the multifunctional pads (adhesives) are connected to the equipment.

Operating e-Jog Control

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



STEP 1

ROTATE: Rotate the button to the item to be changed, observing the highlighted icons on the equipment's screen.

STEP 2

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

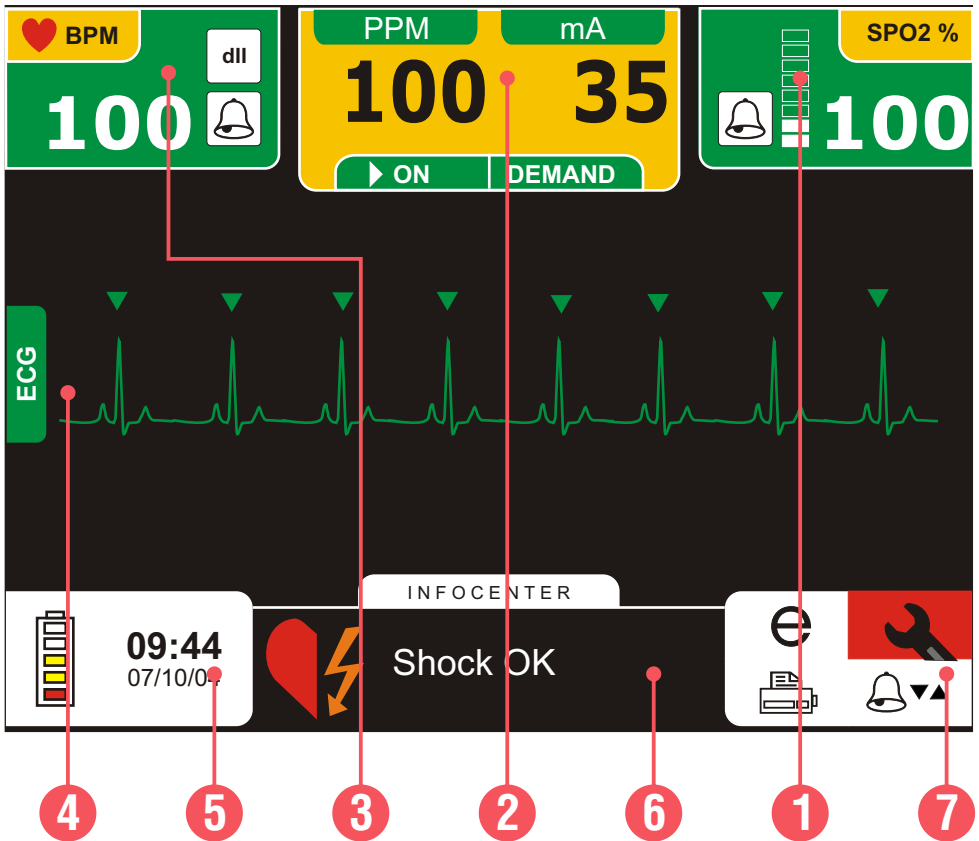
STEP 3

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

STEP 4

PRESS: Press to confirm the new value selected.

Main screen



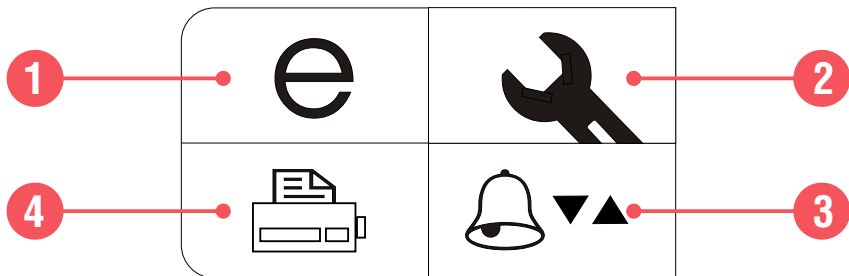
- 1 - SpO₂:** Oximetry measurement values and oximetry alarms.
- 2 - Pacemaker or defibrillation modes:** Indicating defibrillation or pacemaker module.
- 3 - ECG:** ECG measurement values, ECG lead and ECG alarm indications.
- 4 - Graphic area for oximetry and ECG waveforms:** Also used for configurations.

5 - Time, date and battery status.

6 - Infocenter: Equipment and its operational information. It is the device's way of communicating with the user.

7 - Access icons for event and configuration functions: Follow the instructions below.

Access event and configuration function icons



1 - Events Menu: Views events stored in CardioMax.

2 - Configuration Menu: Allows for the configuration of all equipment's parameters.

3 - Alarms Menu: Configures ECG and SpO₂ alarms.

4 - Printer Menu: Prints and configures printing parameters.

See the explanation about configuration functions on the following pages.



Configuration menu

Parameter setup

The screenshot displays the main monitoring screen with three vital signs: BPM (100), PPM (100), and mA (35). The SPO2 % is shown as 100%. Below the vital signs, there are two menu sections: **PARAMETER SETUP** and **GENERAL SETUP**. The **PARAMETER SETUP** section lists ECG, SPO2, Defibrillation, and Functional Test. The **GENERAL SETUP** section lists Alarm, Time and Date, General setup, Printer, Events, and Waveforms. A red box highlights the **PARAMETER SETUP** section. Four red lines connect the items in the **PARAMETER SETUP** section to the **GENERAL SETUP** section: ECG to Alarm, SPO2 to Time and Date, Defibrillation to General setup, and Functional Test to Printer. Below the **PARAMETER SETUP** section, there are four red circles numbered 1, 2, 3, and 4, which correspond to the four red lines. The bottom of the screen shows a status bar with a battery level indicator, the time 09:44 on 07/10/04, a red heart with a lightning bolt icon, the text "Shock OK", and a navigation bar with an "e" icon, a printer icon, a bell icon, and a wrench icon.

1. ECG

Allows manual configuration of Cardiomax's ECG parameters (See: "Monitor Mode-ECG" Chapter).

2. SpO₂

Space for future implementation of the parameter SpO.

3. Defibrillator Mode

Allows configuration of automatic internal discharge time of energy stored on CardioMax (See: "Defibrillator Mode" Chapter).

4. Functional Test

Enables CardioMax's functional test (See "Defibrillator Mode" Chapter).



Configuration menu

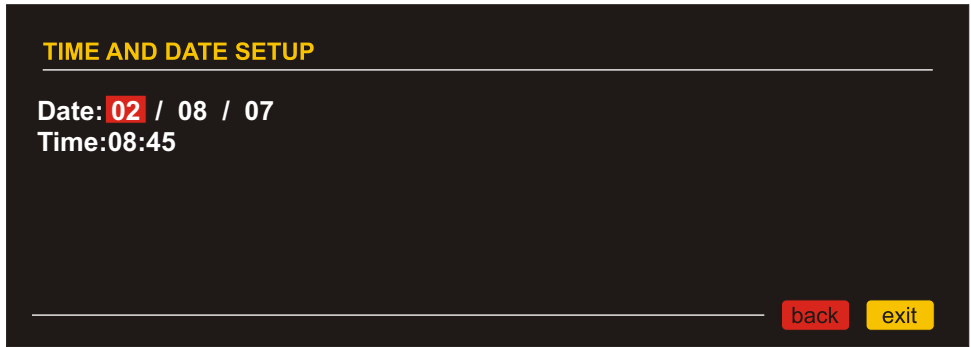
General setup

The screenshot shows the main monitoring screen with three data panels at the top: BPM (100), PPM (100) and mA (35), and SPO2 % (100). Below these is the 'PARAMETERS SETUP' menu with options: ECG, SPO2, Defibrillation, and Functional test. To the right is the 'GENERAL SETUP' menu with options: Alarm, Time and Date, General setup, Printer, Events, and Waveform. At the bottom is the 'INFOCENTER' showing the time (09:44), date (07/10/04), and 'Shock OK' status. A red wrench icon in the bottom right corner is the entry point to the configuration menu. Red lines connect numbered callouts 1 through 6 to the 'GENERAL SETUP' options: 1 points to the wrench icon, 2 to 'Alarm', 3 to 'Time and Date', 4 to 'General setup', 5 to 'Printer', and 6 to 'Events'. An 'exit' button is also visible in the bottom right area.

1. Alarm

Allows adjustment of ECG and SpO₂ alarm values (See: “Alarms and Limits” Chapter).

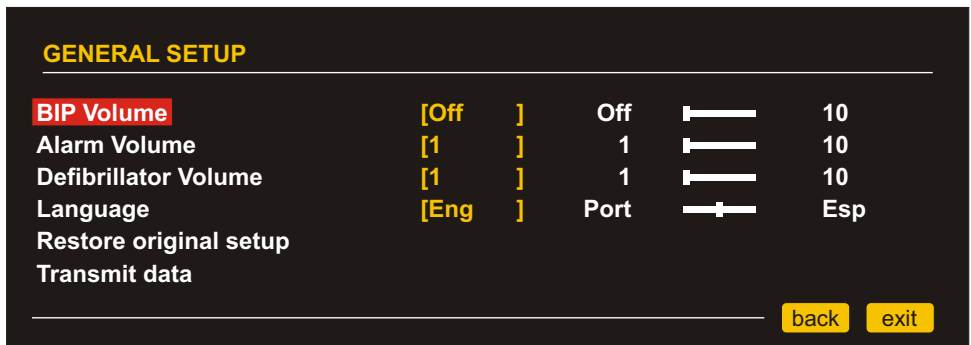
2. Time and Date



The “Date and Time” menu adjusts CardioMax's date and time. You can use international or North-American standards of date and time. It is very important to keep time and date current because this information will appear on all printed reports.

To adjust, use the e-Jog Control.

3. General setup



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

BIP Volume – turns off or adjusts BIP volume (BIP is the audio indication of QRS).

Alarm Volume – alarm volume adjustment.

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

Language – Allows you to choose between CardioMax's available languages.

Restores original setup – Restores original factory configurations.

Data transmission – Allows upload of information stored on CardioMax to a personal computer.

4. Printer

Allows printing and configuration of CardioMax's printing parameters (See: "Printing" Chapter).

5. Events

Allows for viewing and modification of events saved on CardioMax (See: "Events" Chapter).

6. Waveforms

In this menu, you may select which waveform will be presented on the screen or you may view both waveforms.

NOTE: The two waveforms cannot be disabled simultaneously.

WAVEFORM SETUP

ECG Waveform	[On]	On	<input checked="" type="checkbox"/>	Off
SPO2 Waveform	[On]	On	<input checked="" type="checkbox"/>	Off
Trace speed	[12.5]	50.0	<input type="checkbox"/>	25.0

back **exit**

Alarms and limits

5

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

Physiological Alarm

There are two ways to enable the physiological alarm:

Assistoly – CardioMax cannot detect valid heartbeats for over 4 seconds.

Violation of MAXIMUM or MINIMUM limits – When the Oximetry or ECG maximum or minimum alarm limits are not within the equipment's pre-programmed range.

Physiological alarm visual indications will occur on either mode, but the audio indication will only occur when the equipment is on the monitoring mode.

FEATURES:

- ECG (defibrillator mode): White, numerical value of 2 cm x 2 cm
- ECG (monitor mode): White, numerical value of 3 cm x 1.8 cm
- Indicator of alarm: 7 mm x 7 mm
- Visual frequency: 2Hz
- Sound frequency: 440Hz at intervals of 150ms

Technical Alarm

Is an indication that CardioMax is not able to accurately monitor the patient's status. The technical alarm indications are shown in the "Infocenter".

ECG - Loose Electrode: Loose ECG electrode, poor contact

between electrode and skin, or ECG conductor is broken.

Printer – Printer without paper: Printer has no paper.

Printer – Printer door open: Printer door is not duly locked.

NOTE:

These indications will only be enabled when CardioMax is on monitoring mode.

Sound signals are emitted at intervals of 6 seconds whenever there is a technical alarm situation.

Upon disabling the Technical Alarm of the ECG, automatically the technical alarm of the Printer is disabled.

In addition to the advisories indicated in the “Infocenter,” there are two other situations that may occur:

1. Bad Contact

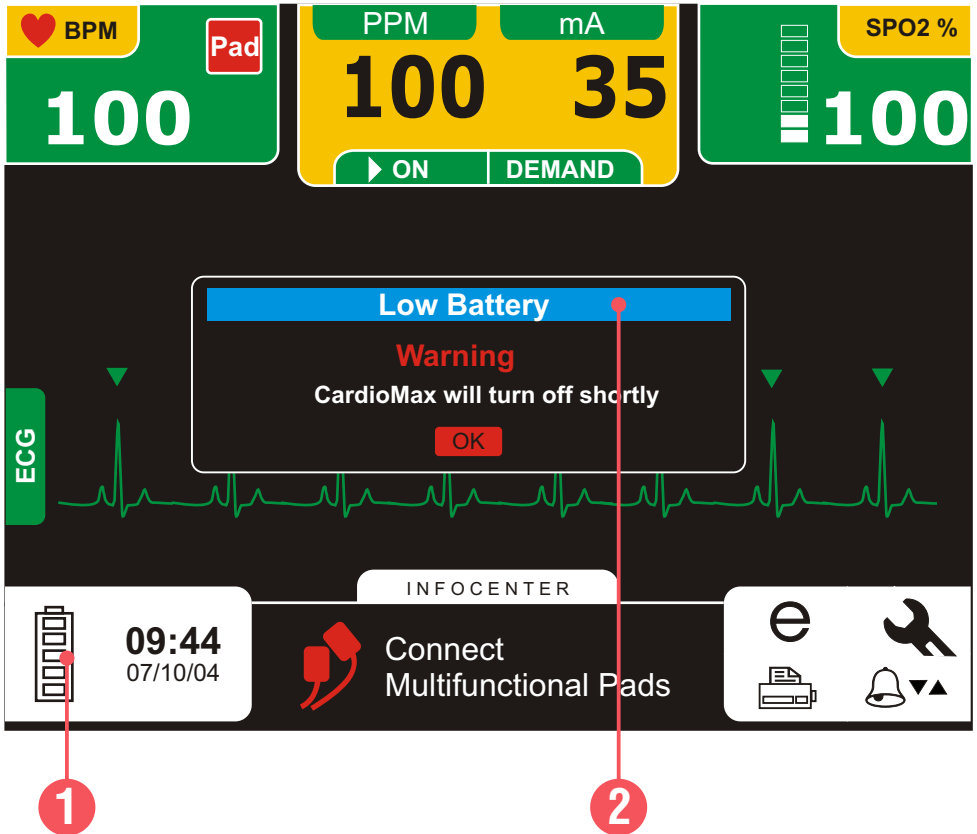
Informs when the patient's impedance measurement doesn't satisfy the conditions necessary to apply shock. This information is presented directly below space reserved for the defibrillator and pacemaker modes on the main screen.



2. Indications of Battery Charge Level:

Indication	Battery status*	Equipment's operating conditions
	100% charged	CardioMax can monitor for about 3 hours and 30 minutes.
	80% charged	CardioMax can monitor for about 2 hours and 50 minutes.
	60% charged	CardioMax can monitor for about 2 hours.
	40% charged	CardioMax can monitor for about 1 hour and 30 minutes.
	20% charged	CardioMax can monitor for about 40 minutes.

*battery status with AC power supply cable disconnected.



Observe the indication for low battery above:

- 1- Five white battery bars.
- 2- Dialogue box states low battery.

In the picture above, the low battery indication is highlighted. When these indications appear on CardioMax's screen, the equipment will soon, automatically, turn off.

Silence/Disarm Alarm

When pressing the ALARM SILENCE button with a FAST touch (shorter than 3 seconds) ALL alarm audio indications are silenced for a period of time predetermined by the operator.



Your visual indication is the “Alarm Silenced” icon in all parameters.

When pressing the ALARM SILENCE button with a LONG touch (longer than 3 seconds) ALL alarm audio indications are silenced for an INDETERMINATE period of time.



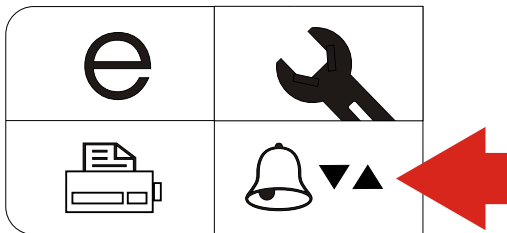
Your visual indication is the “Alarm Disarmed” icon in all parameters.

IMPORTANT: No audio alarm will go off when the alarm is disarmed.

Configuration of alarm limits

Whenever CardioMax is initialized, it returns to the limits and configurations established by the user.

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



CONFIGURAÇÕES DE ALARMES

Auto ajuste

Silencio	[180]	30		180
Alarme Técnico ECG	[Lig]	Desl		Lig
Alarme Técnico SPO2	[Lig]	Desl		Lig

ALARME

♥

SPO2

100

40

100

85

voltar

sair

Silence

It allows the silence time of the physiological and technical alarms to be adjusted with times between 30 and 180 seconds.

ECG technical alarm

It allows the enabling or disabling of the sound indications of the technical alarms of ECG. When this option is enabled and there is a technical alarm situation in the ECG parameter, the equipment will send sound warnings at intervals of approximately 6 seconds.

SpO2 technical alarm

Reserved for future implementation of the parameter SpO2

(the parameter SpO2 is not available and will be implemented in future versions).

Turn audio alarm ON/OFF



For each parameter, the user can turn the audio alarm ON or OFF. An X on top of the bell symbol indicates the audio alarm for that particular parameter is off.



Minimum/Maximum limit

100



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.

85

Next, the desired value must be adjusted and then pressed again.

Note: It is possible to adjust the minimum alarm of ECG at levels between 30 and 100 BPMs with intervals of 5 BPMs. It is possible to adjust the maximum alarm of ECG at levels between 100 and 250 BPMs with intervals of 5 BPMs.

Automatic configuration of alarm limits

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 the deviation, to set the minimum and maximum limits. See the table on the following page:

Parameter	Minimum	Maximum
ECG	X 0.8	X 1.6

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.

Alarm Test

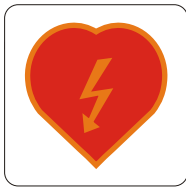
To carry out an alarm test, proceed as follows:

1 – Turn the equipment on without cables and with no sensors connected. **A technical alarm indication, a text messages in the “Infocenter,” must appear.**

2 -Press the “SILENCE ALARM” button for 1 ~~s~~ second and verify that the “disarmed alarm” indication appears on the screen in all parameters. The beep sound will be suspended. Wait 60 seconds and the alarm will turn on again. The disarmed alarm signal is off on the screen and the audio alarm will be reactivated. You can adjust the duration of the alarm on the Alarm Silence menu.

3 -Press the “ALARM SILENCE” button for 3 ~~s~~ seconds and verify, on the screen, that the alarm indication is permanently off. To turn it back on, press the “ALARM SILENCE” button for 1 second.

The audio alarm parameters can be individually turned on and off on the alarm menu as well as on the individual parameter menus. The audio alarm indications can be adjusted on the Alarm Configuration volume menu.



Defibrillator mode

6

Physical principle used

The biphasic cardiac defibrillator is an instrument that applies the energy previously stored in the capacitor, to the patient. It can perform both internal (capacitor charge applied directly to the heart in a surgical procedure) and external (capacitor discharged through the patient's thorax) defibrillation.

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



Warnings:

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△ing 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 by these electrodes.

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

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

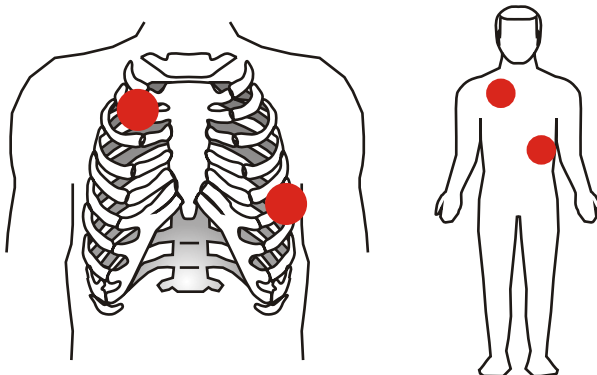
External paddle use

1 - Check that the paddles are connected to CardioMax. If they are not, connect the defibrillation cable to the paddles located on the equipment side (as show in the image below). Rotate the flange until it locks.



- 2** - Take both paddles from the stand pulling them up and out.
- 3** - Apply the conductive material to the paddles' electrodes.
- 4** - Place paddles as shown in the image below.

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



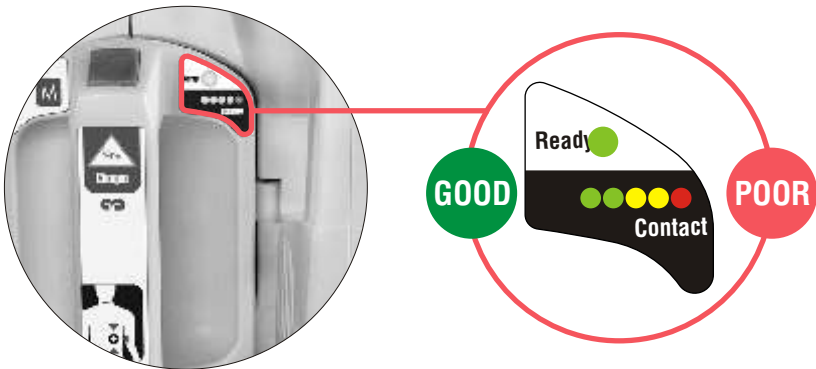
- a) **Electrode identified as "STERNUM"** on the second intercostal space right of the mid-clavicle.
- b) **Electrode identified as "APEX"** positioned on the sixth intercostal space left of the mid-axillary.



MAKE SURE all electrodes are separated. **DO NOT** apply paste or gel to the thorax between the paddles 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 paddle has a patient contact indicator.



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

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

About Shock delivery

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

Below is a table that indicates the conditions in which CardioMax offers or inhibit the delivery of energy.

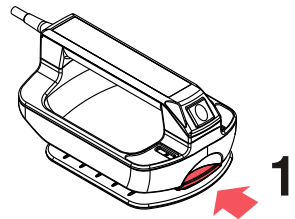
Patient's Impedance	Shock	Msg on screen after "Charge" key pressed	Values indicated on bargraph
Short circuit	Shock inhibited	Bad Contact	All LEDs blinking
< 25 ohm	Shock inhibited	Bad contact	All LEDs blinking
> 25 ohm and < 300 ohm	Shock delivered and the waveform is adjusted according to Patient's impedance	No message	LEDs lit up indicating contact level
> 300 ohm	Shock inhibited	Bad Contact	Only the red LED is blinking
Open Circuit	Shock inhibited	Bad Contact	Only the red LED is blinking

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

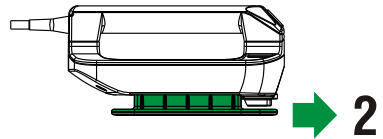
When only the RED LED is blinking, the shock is not allowed.

Children's paddle use

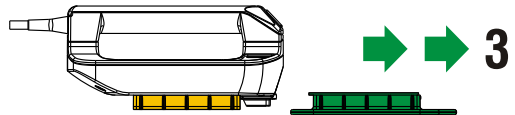
1 - Fasten the lock on the front of the adult external paddles.



2 - Pull the paddle base forward to take it off.



3 - This exposes the smaller electrode for children.



Adult

Children

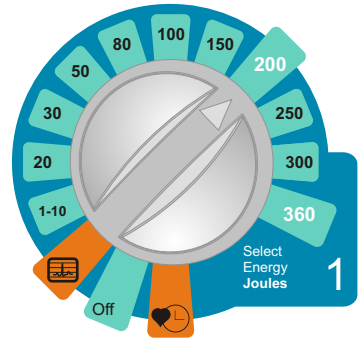
CardioMax states that it is operating in pediatric mode.

Energy is limited to 50 Joules in the pediatric mode.

Defibrillation

Step 1 - Select energy

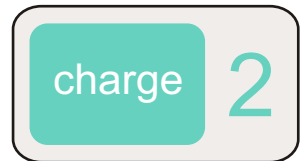
CardioMax limits energy to the pediatric and internal paddles to 50 Joules.



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

When selecting the Joules on a scale from 1 to 10, the value can be changed, with the e-Jog button, to 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 Joules.

Step 2 - Charge



Press Button 2 (Charge) on the front panel or use the charge button on the external paddles. While CardioMax is charging there is a sound and when it is charged it appears in red on the display.

The selected energy can be increased or decreased at any time, just rotate 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 states charge "Ready" on the screen.

Step 3 - Shock



After the warning “Ready” Press Button 3 (Shock) on the front panel or use the **two shock buttons** on the external paddles.

With the adult/children's external paddles it is only possible to defibrillate with the paddle buttons.



CAUTION: Make sure nobody is touching the patient! Everyone needs to be informed to stay away!

The number of shocks and length of operation are indicated on CardioMax's display.

Synchronism-Synchronized Discharge -Cardioversion

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

Sync

Monitor the patient with an ECG 3 or 5-wire cable or by means of the defibrillation electrodes.

Press the synchronism button on the front panel. Check to make sure that the synchronization marker is red and lined up with the “R” wave and the “SYNC” indication next to the selected energy value.

Follow steps 1-2-3 for defibrillation.



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



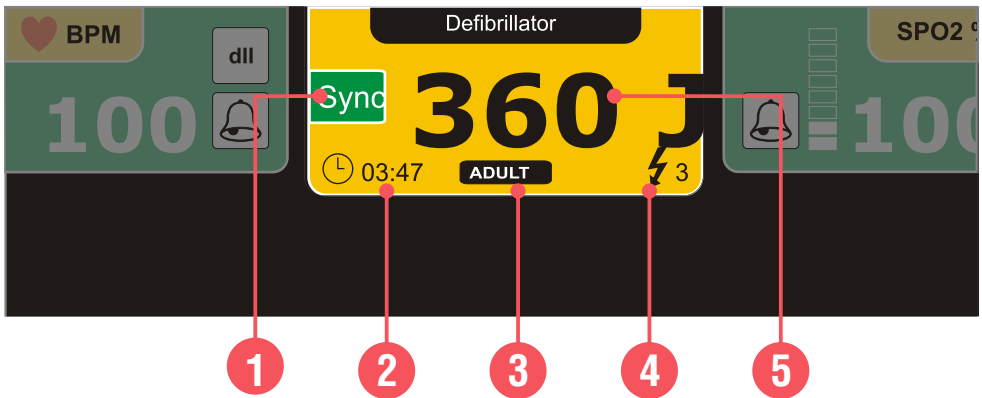
IMPORTANT: If CardioMax does not identify a valid QRS it will not trigger the shock!

Disarm Key



Cancels the stored charge. Charge may be cancelled 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. Length of Use

Indicates the length of time the equipment is being used. The marker returns to zero if the equipment is turned off.

3. Type of defibrillation electrode

Shows which defibrillation electrode is connected to the equipment: ADULT (adult external paddles), CHILDREN (children's external paddles), INTERNAL (internal paddles) or ADHESIVE (multifunctional paddles).

4. Number of shocks

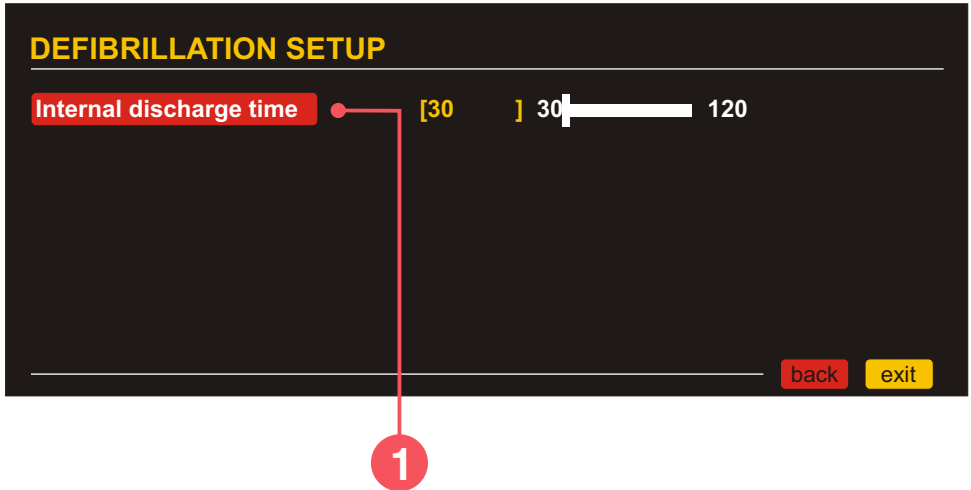
Shows number of shocks applied. The counter is set to zero when the equipment is turned off.

5. Selected and charged energy

The energy SELECTED by the user is shown in the 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 given.

Defibrillation Configuration



1. Internal discharge time

Determines the length of time the equipment keeps the charge before discharging internally.

“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 perfect working order.

FUNCTIONAL TEST

Put the Paddles on the support	<input checked="" type="checkbox"/>
Select 100J	<input checked="" type="checkbox"/>
Press CHARGE	<input type="checkbox"/>
Press SHOCK	<input type="checkbox"/>

[back](#) [exit](#)

Step 1

Place paddles on the support located on the top of the equipment.

Step 2

Select 100J of energy.

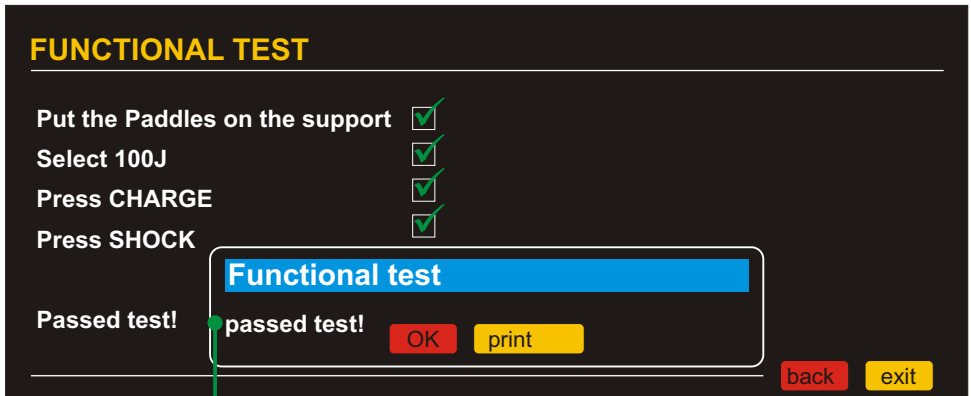
Step 3

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

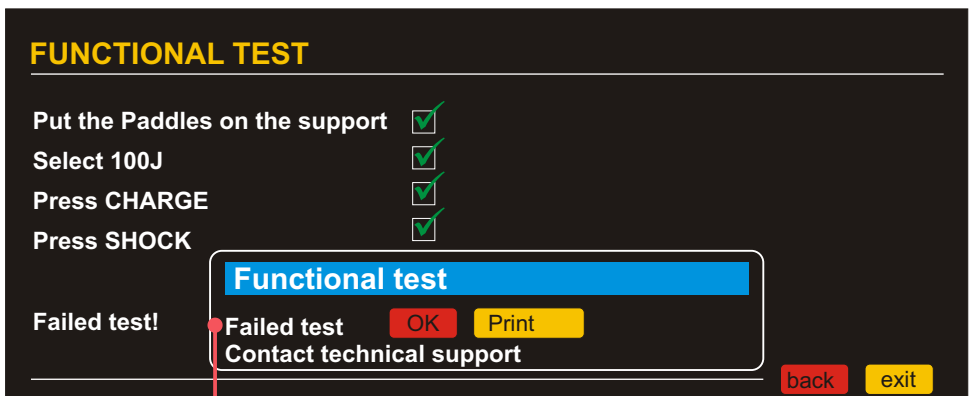
Step 4

Press the "shock" key

Result screen of the functional test



● Equipment passed the functional test

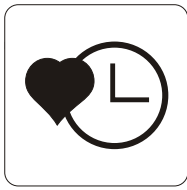


● Equipment failed the functional test

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

NOTE: *printouts of the test results will only be available in 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 the standard.*



Pacemaker mode

7

Physical 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, that is transmitted 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 intensity of the current (mA). The pacemaker works in two modes: fixed or synchronous.

Warnings:



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 equipment due to possible risk to the operator.

Fixed mode

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

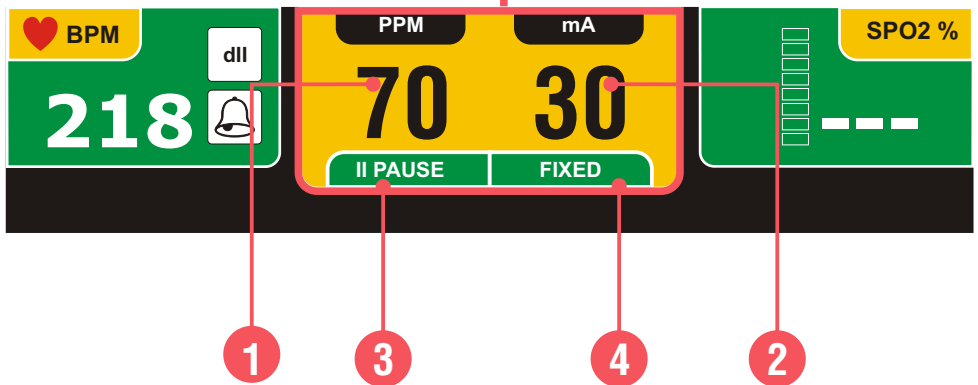
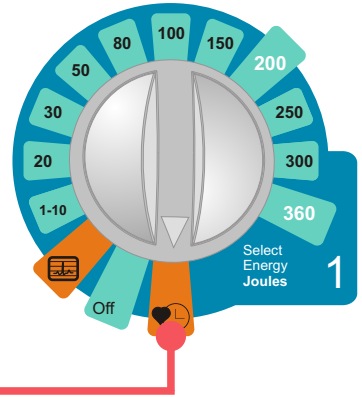
Demand mode (synchronous)

In this mode CardioMax assess the patient's heart frequency, applying the PPM number selected on the panel only when it is smaller 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 placing the heart in a susceptible phase.

Operating on pacemaker mode

- Place 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 pacemaker stimulation frequency, the user alters the equipment "Pulses Per Minute" (PPM) value.

2 - mA: Alters the stimulation current in miliamperes.

3 - Change between "PAUSE" and "ON" modes on Pacemaker. In "PAUSE" mode, it does not send stimulation.

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

Starting stimulation

- 1 - If it not yet connected, connect the adhesive paddles' cable to CardioMax.
- 2 - Verify that the multifunctional adhesive pads' package is intact and valid.
- 3 - Insert the adhesive paddles connector to the equipment's extension cable.
- 4 - Put the adhesive paddles on patient according to the package's instructions.
- 5 - In the 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 warn that the pacemaker is active.
- 6 - Verify that the pacemaker's pulse meter appears on the screen.
- 7 - Increase the stimulation current until the heart is captured. This is indicated by QRS just 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. Verify that 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 the heart is captured. This is indicated by QRS just after the pacemaker marker.

7 - Increase the stimulation current until cardiac capture occurs. The capturing is indicated by the presence of a QRS straight after the pacemaker marker.

NOTES:

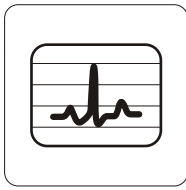
There may be spontaneous beatings not related to the application of stimulation. If the patient's heart frequency is above the pulse's frequency, the stimulation pulses will not be applied and the stimulation markers will not appear.

Stimulation will not start if there is a problem with the multifunctional (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 CardioMax does not identify a valid QRS.

Defibrillation

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



Monitor mode - ECG

8

Physical principle used

ECG is the measurement of electrical potential generated by the depolarization and re-polarization of heart cells, the activity that generates the bioelectrical impulse responsible for the heart's contraction. Heart impulses are detectable on the body's surface by means of the electrode's application. 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 length of 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. From this time measurement, it is possible to determine the beats per minute (BPM).

Warnings:



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



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



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

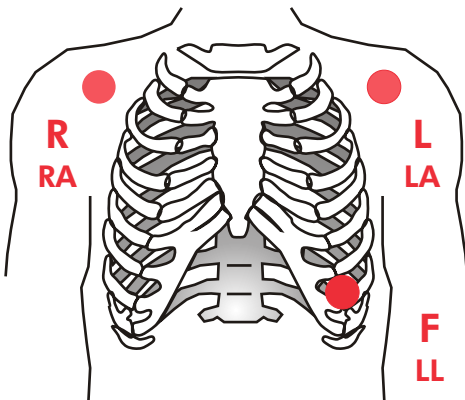


The indication of the cardiac frequency can be affected when using a transcutaneous pacemaker

Monitoring ECG

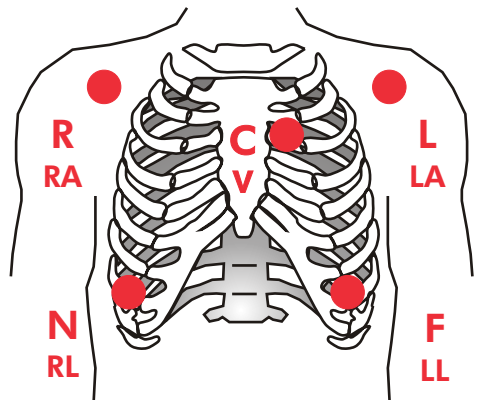
- 1 - Connect ECG cable to the ECG input on the equipment's side panel.
- 2 - Select the electrodes to be used on the patient. Use only one kind or brand of electrode. The electrodes must follow AAMI standards for electrode performance.
- 3 - Prepare the application location according to the manufacturer's 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 leads)

5-wire cable



(7 leads)

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
V	V - (RA+LA+LL)	RL

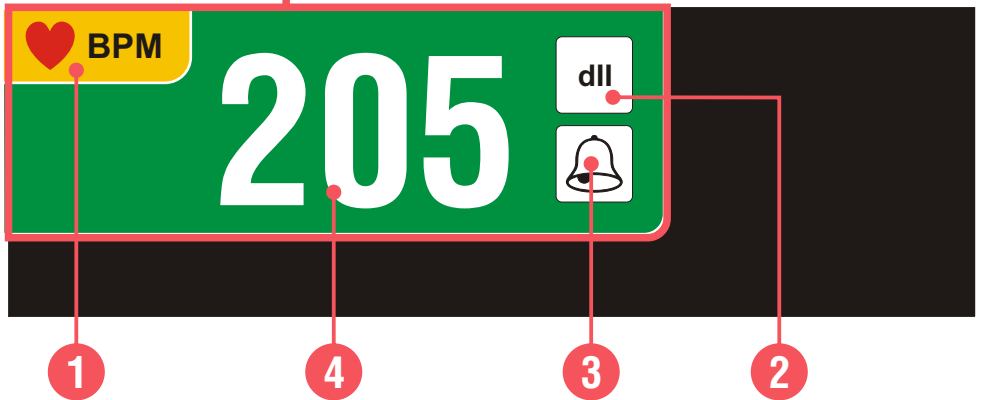
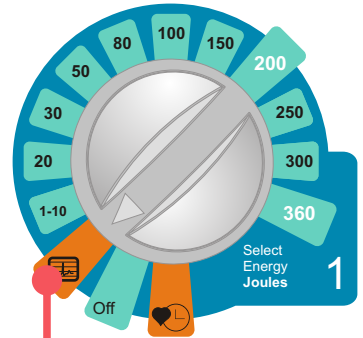
Color patterns

There are two color patterns for ECG cables, CardioMax uses 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 on monitor mode - ECG

- Turn the selector switch to the Monitor mode.
- All ECG and SpO₂ alarms are enabled.
- The next screen starts.



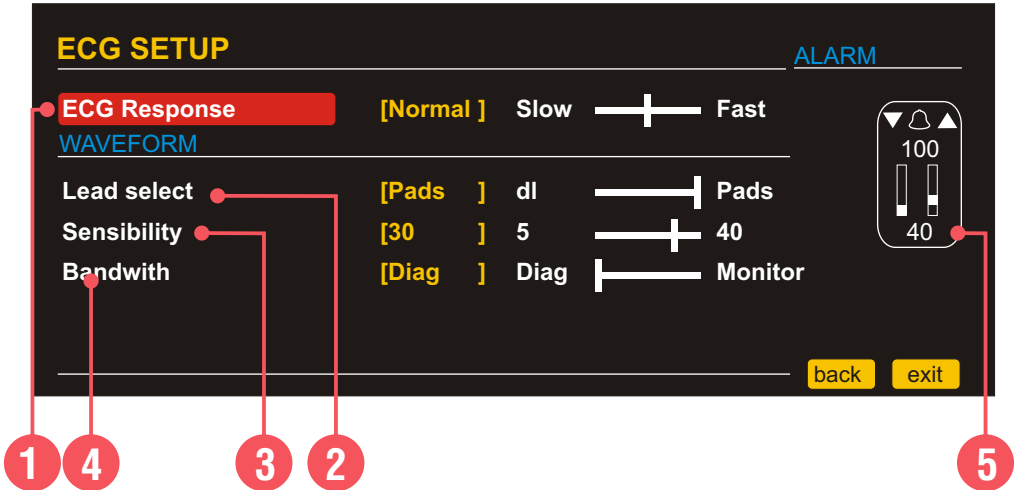
1 - ECG Symbol. The ECG icon represents an expanding heart that indicates that the ECG's "R" wave peak has been detected.

2 - Indicates the lead that is selected.

3 - "BELL" icon indicates that the alarm has been activated, inhibited or suspended.

4 - ECG numeric value and BPM measuring unit.

ECG configurations



1. ECG Response

Select ECG numeric update response, you can select “SLOW”, “NORMAL” and “FAST”.

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

FAST: Is used when the user needs faster responses, it is very affected by the patient's movements, it uses 8 beats to define the average.

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

2. Leads

It indicates the deviation of the ECG module, selectable at dl, dll, dlIII, aVR, aVL, aVF and V. There is also a deviation called CAL, in order to test the heartbeat detector, which must identify the numerical value of 60 bpm.

3. Sensibility

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

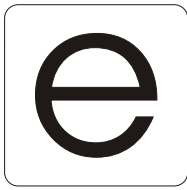
4. Frequency bandwidth Selection

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

5. Alarm

Configures "MINIMUM" and "MAXIMUM" ALARM limits.

"Back" to configuration menu or "EXIT" to the monitoring screen.



Data storage

CardioMax creates an event list for each patient either automatically or manually.

Automatically - a new patient is identified every time the equipment is turned on.

Manually - through the event configuration menu.

The quantity of events the equipment can store varies according to the type of therapy and the length of time each patient has used the device. CardioMax has a 2 Mb memory.

The last two hours of continuous ECG are stored in the memory.

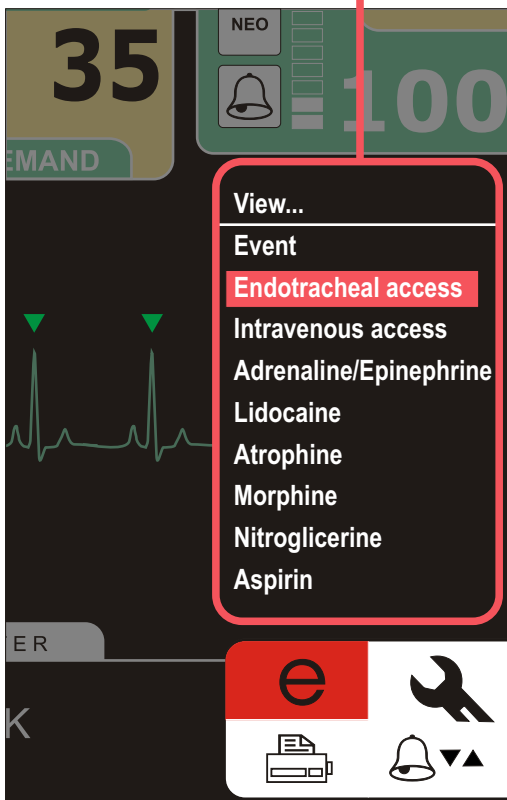
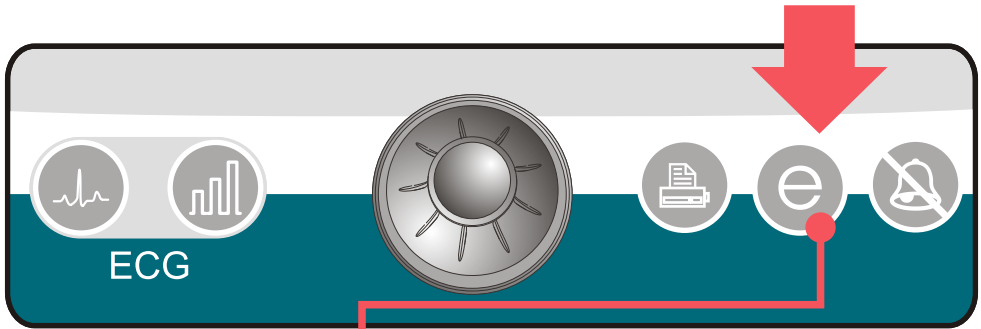
WARNING: When the event memory is completely full, CardioMax cannot store any new events until the memory has been deleted.

Events stored

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

- Paddles changes
- Charge values
- Number of shocks
- Equipment turning on/off
- Loose electrode/poor paddle contact
- Failure in module initialization
- Functional test
- Synchronism
- Operation mode (monitor, pacemaker, monitoring)
- Stimulation pacemaker on/off
- Activation of "silent alarm" key
- Shock failure
- Internal discharge
- Physiological alarm activated
- "Event setting" key activation
- Printing
- Low battery/equipment off
- Change in pacemaker stimulation

Event setting key



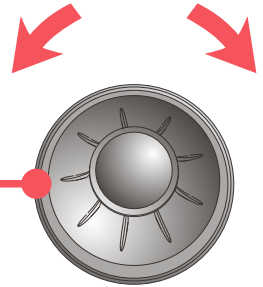
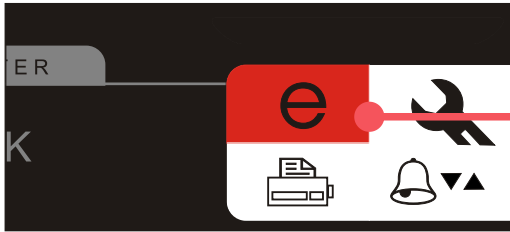
The event setting key is located on the front panel. It works in the defibrillator, monitor and pacemaker modes. When pressed, one can manually set the following items:

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

Once the key is pressed, a sub-menu on the main screen is displayed in order to select the desired event. Use the e-Jog control to choose and confirm an event.

All marked events are stored in the internal memory allowing one to read the stored data in the future.

Viewing and managing events



A screenshot of the CardioMax configuration menu. The top bar shows '100' and 'PLAY DEMAND'. The main area displays a table of events for 'Patient 3'. On the left, there are buttons for 'New Patient', 'Clear Memory 0%', and 'Print List'. At the bottom, there are 'back' and 'exit' buttons. A red arrow points from the physical e-Jog button to the 'e' icon in the bottom right corner of the screen. Six red circles with numbers 1 through 6 are placed at the bottom, with lines pointing to specific elements: 1 to 'Patient 3', 2 to the 'Time' header, 3 to the 'Event' header, 4 to the 'New patient' event, 5 to the 'e' icon, and 6 to the 'exit' button.

Time	Event
07:30	New patient
07:03	Change pads - Adult
12:32	CardioMax off
12:35	CardioMax on
12:35	Change pads - Adult
13:02	CardioMax off
13:02	CardioMax on
13:02	Change pads - Adult
13:02	Endotracheal access

To view, manage and print stored events use the e-Jog control to select the “e” icon on the main screen of CardioMax’s configuration menu. Also use the e-Jog button to navigate between events and functions. In addition, there is a “view” option in the events setting sub-menu.

1. Patient

Indicates the active patient's number and allows one to change 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 all of the event memory's content. Indicates the percentage of memory that has already been used (with a limit of 2Mb).

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 and initiates a new table of events.

5. Events list

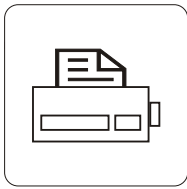
Presents the selected patient's events.

6. Printer icon

When it appears next to an event it indicates that the ECG curve printing associated with that event is available. 15 seconds of an ECG curve is stored for each event with 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, simply press the fast access printing button on the front panel. 15 seconds of the ECG wave related to the selected event will be printed, 5 seconds before and 10 seconds after the event.

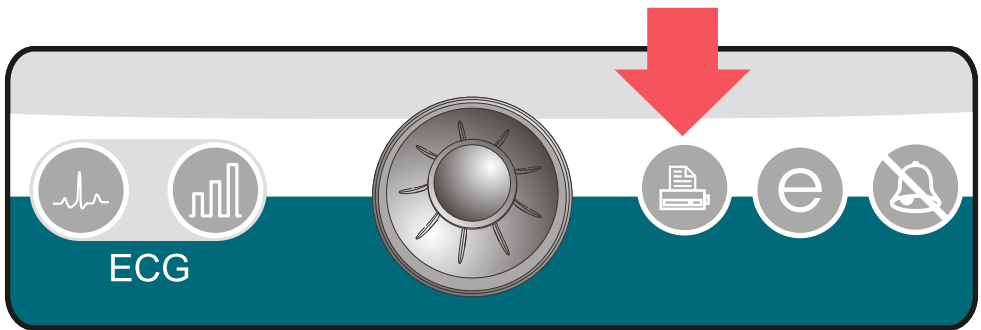


Printing

10

General

Optional thermal printing allows for manual or automatic report printing by event, shock or electrocardiogram. To activate printer, press the print button, located on the equipment's front panel or by using the e-Jog control to enter the "printing" menu.

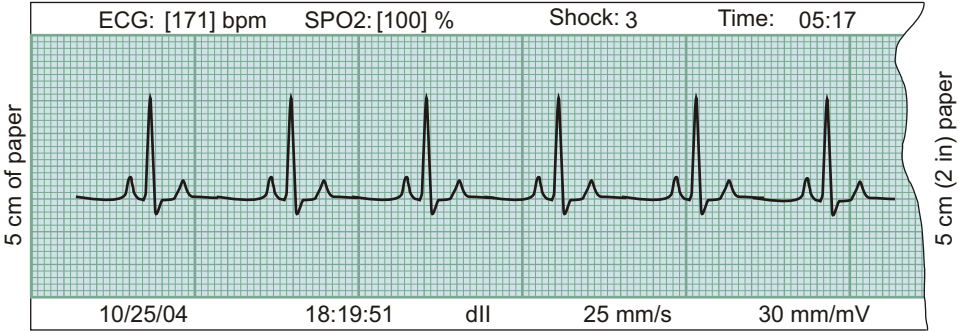


Instant printing

When the print button is pressed for **LESS** than three seconds, CardioMax prints a fast report. The fast report only prints the ECG curve (if ECG and SpO₂ curves are on the screen) or only the SpO₂ curve (if only the SpO₂ curve is on the screen). The date/time, tracing speed and number of shocks are also indicated on the report. In an ECG report, the leads and corresponding amplitude are also printed.



Fast printing (ECG)



Continuous printing

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

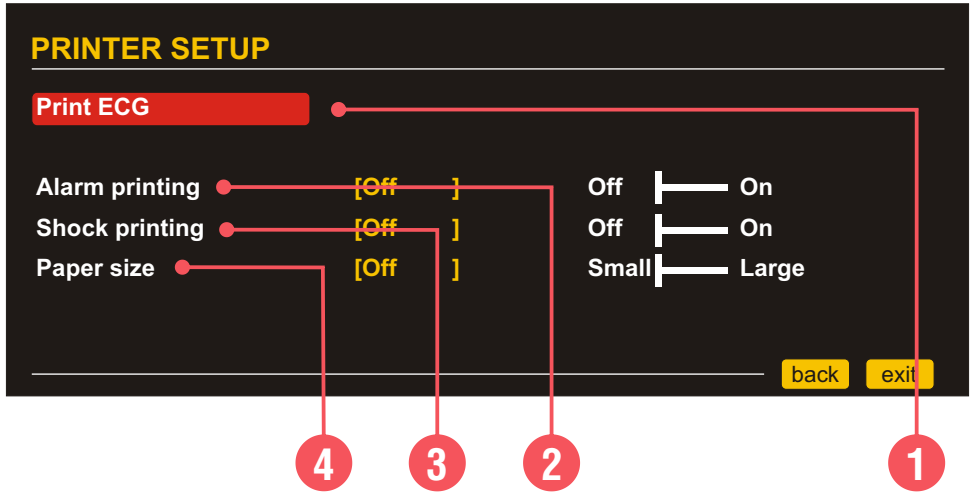


Stop printing

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



Configurations



1. Electrocardiograph function

To print a 7-lead electrocardiogram use the “print ECG” function found in the in the printing configuration menu. When this function is selected, the equipment begins monitoring and printing the leads, starting with dI. At the end of printing, it returns to the normal monitoring mode.

NOTE: To stop printing, press the print key on the equipment's front panel.

NOTE: Simultaneous leads are not printed.

2. Printing in alarm

When the “printing in alarm” option, found in the printing configuration menu, is enabled, CardioMax prints an instant report whenever the equipment sends an alarm.

3. Printing in shock

When the “printing shock” option, found in the printing configuration menu, is enabled, CardioMax prints an instant report whenever the equipment identifies that shocks have been applied to the patient.

4. Paper size

Informs the equipment of the paper size that will be used for printing:

- Large = 30 cm (11.8 in) width
- Medium = 23 cm (9.05 in) width
- Small = 14 cm (5.51 in) width

Preventive Maintenance

INSTRAMED recommends that 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 this preventive maintenance.

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

Functional tests are recommended every time a new work shift starts.

Corrective Maintenance

If the equipment is in need of repair, this can only be done by INSTRAMED or an authorized representative, or the Warranty certificate will no longer be valid.

No internal parts are to be fixed by the user.

Cleaning

Instramed recommends the equipment and its accessories be cleaned at least every three months. This can be done sooner if equipment is clearly dirty or contaminated. The cleaning and sterilization procedure is presented below.

External parts of the Equipment:

- Disconnect the device from the power source before cleaning.
 - Clean the equipment's external parts with a wet cloth and neutral soap.
 - Never immerse it in liquids.
-

Cables:

- Clean them with a cloth that has been wet in warm water and neutral soap.
 - Never immerse them.
 - Do not sterilize them.
-

Removable Battery

If CardioMax has not been used for a long time, the battery will have to be recharged. To charge the battery, connect the monitor to an AC source (110 or 220V outlet) or a DC source.

If a power outage occurs, the battery will support the equipment's functioning for approximately 3.5 hours, according to technical characteristics.

It is advisable to replace the battery every 3 years, or when the autonomy time is less than 1.5 hours.

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

Removable Battery Replacement

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



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



2 – Manually remove the battery from the equipment.

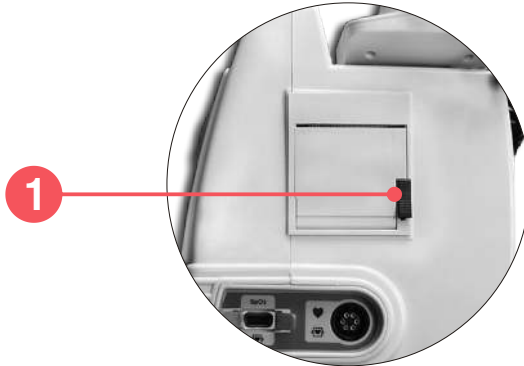
3 – Correctly position the new battery, as shown in the picture below.



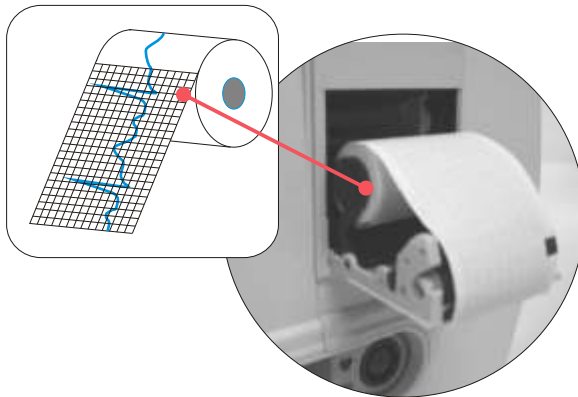
4 – Push the new battery until it firmly locks into the chassis.

Replacement of thermal printer paper

1 - Press the button to open the printer door (see figure below). If the door does not open completely, pull it in your direction.



2 - Remove the old paper bobbin.



3 - Place the new bobbin between the side clasps. The bobbin must be positioned as shown in the picture above, with the thermal-sensitive side (with measurements in millimeters) facing up.

- 4 - Unroll the paper about 10 cm (4 in).
 - 5 - Align the paper with the printer door.
 - 6 - Close the printer door. The printer is ready for use.
-

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

Precautions, Restrictions and Warnings

CardioMax is a device built according to NBR and IEC standards and therefore is completely safe for the 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).

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 electroscapel, position the ECG electrodes as far as possible from the RF current route, between the surgical field and the neutral card. Do not use the needle type ECG electrode during surgical procedures.
-

2 – Electromagnetic compatibility

Warning: The installation of the CardioMax requires special precautions concerning Electromagnetic Compatibility in compliance with the information contained in this manual.

Mobile and portable RF communication equipment, such as a cell phone, can affect the functioning of the CardioMax.

Maximum length of the cables of accessories for complying with the requirements of Electromagnetic Compatibility:

- ECG Cable with 5 channels (code 7900-5) 2.5m
- Set of blades for external defibrillation (code 79001) 2.5m
- Trunk cable (code 19528) 2.5m

Warning: The use of accessories, transducers and cables differing from the ones specified, except for the transducers and cables sold by Instramed as spare parts for internal component, can lead to an increase in emission or decrease in the immunity of the Equipment.

The CardioMax must not be used very near to or stacked on top of other equipment.

When in a surgical procedure it is used simultaneously with an electrobisturí, there is a risk of burnouts if a defect in the connection of the neutral electrode of the high frequency appliance matches a defect in the ECG input of the Cardiomax. This type of accident will only occur when the defects occur simultaneously, as the ECG input of the Cardiomax is electrically protected against risks of burnouts, being totally insulated.

3 - Defibrillation

Excessive charge in Joules can cause burns on the skin or later discomfort. It is the responsibility of the specialized doctor to select the charge correctly according to the patient.

The metallic contacts of the intracavitary blades, made of stainless steel, which come into contact with the patient, are autoclavable in oxyacetylene and can be reused approximately 100 times.


Electromagnetic emissions

Directives and declaration of the manufacturer – electromagnetic emissions		
<p>The CardioMax is intended for use in the specific electromagnetic environment below. The customer or user of the CardioMax is advised to ensure that it is used in such an environment.</p>		
Tests	Compliance	Electromagnetic environment - directives
Emissions of RF ABNT NBR IEC CISPR11	Group1	<p>The CardioMax only uses RF power for its internal functions. Nevertheless, its RF emissions are very low and they are not likely to cause any interference with nearby electronic equipment.</p> <p>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 supplying buildings for domestic use.</p>
Emissions of RF ABNT NBR IEC CISPR11	Class B	
Emissions of harmonics IEC 61000-3-2	Class A	
Emission due to the fluctuation of voltage /sparking IEC 61000-3-3	Complies	
<p>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 place are checked to ensure that they meet or exceed the minimum values specified.</p>		

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 customer or user of the CardioMax should ensure that it is used in such an environment.			
Immunity Test	Test Level of ABNT NBR IEC 60601	Level of Compliance	Electromagnetic Environment – Directives
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by the air	± 6 kV by contact ± 8 kV by the air	Floors should be made of wood, concrete or tiles. If the floors are covered with synthetic material, the relative humidity should be at least 30%.
Quick electric transient/Train of pulses ("Burst") IEC61000-4-4	± 2 kV in the power supply lines ± 1 kV in the input/output lines	± 2 kV in the power supply lines ± 1 kV in the input/output lines	The quality of the power supply should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV line(s) by line(s) ± 2 kV line(s) to ground	± 1 kV line(s) by line(s) ± 2 kV line(s) to ground	The quality of the power supply should be that of a typical commercial or hospital environment.
Drops of voltage, short interruptions and variances of voltage in the power supply input lines IEC 61000-4-11	< 5% U_T (drop of > 95% in U_T) for 0.5 cycle 40% U_T (drop of 60% in U_T) for 5 cycles 70% U_T (drop of 30% in U_T) for 25 cycles < 5% U_T (drop of > 95% in U_T) for cycle of 5 seconds	< 5% U_T (drop of > 95% in U_T) for 0.5 cycle 40% U_T (drop of 60% in U_T) for 5 cycles 70% U_T (drop of 30% in U_T) for 25 cycles < 5% U_T (drop of > 95% in U_T) for cycle of 5 seconds	The quality of the power supply should be that of a typical commercial or hospital environment. If the user of the CardioMax requires continued operation during interruption of power, it is advisable that the CardioMax is supplied by an uninterrupted power supply source or a battery.

Electromagnetic immunity – Equipment with life support functions

Distances of separation advisable between the mobile and portable RF communication equipment and the CardioMax			
The CardioMax is intended to be used in the electromagnetic environment specified below. The customer or user of the CardioMax should ensure that it is used in such an environment.			
Immunity Test	Test Level of ABNT NBR IEC 60601	Level of Compliance	Electromagnetic Environment - Directive
Conducted RF IEC 61000-4-6	3 Vrms	[V ₁]V	<p>Portable and mobile RF communication equipment should not be used near any part of the CardioMax, including cables, with a distance of separation less than the one advised, calculated using the equation applicable to the frequency of the transmitter.</p> <p>Advisable Distance of Separation</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
	150 kHz up to 80 MHz outside bands ^a ISM		
Conducted RF IEC 61000-4-6	10Vrms	[V ₂]V	$d = \left[\frac{12}{V_2} \right] \sqrt{P}$
	150 kHz up to 80 MHz outside bands ^a ISM		
Conducted RF IEC 61000-4-6	10V/m	[E ₁]V/m	$d = \left[\frac{12}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz até } 800 \text{ MHz}$ $d = \left[\frac{23}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz até } 2,5 \text{ GHz}$
	80MHz up to 2.5GHz		
<p>Where P is the nominal maximum output power of the transmitter in watts (W), according to the manufacturer of the transmitter, and d is the advisable distance of separation in meters (m)^b.</p> <p>The field intensity established by the RF transmitter, as determined through an electromagnetic inspection on site, ^c should be less than the compliance level in each frequency range.^d</p> <p>Interference can occur around the equipment marked with the following symbol:</p> 			
NOTE 1 : At 80MHz and 800MHz, the highest frequency range is applied.			
NOTE 2: These directives may not be applicable in every situation. Electromagnetic transmission is affected by the absorption and reflection of structures, objects and people.			
^a The bands of ISM (industrial, medical and scientific) between 150kHz and 80MHz are 6,765MHz thru 6.795MHz; 13.553MHz thru 13.567MHz; 26.957MHz thru 27.283MHz; and 40.66MHz thru 40.70MHz.			
^b The levels of compliance in the ISM frequency bands between 150kHz and 80MHz and in the frequency range between 80MHz and 2.5GHz intend to reduce the likelihood of mobile and portable communication equipment causing interference if they are brought inadvertently to the patient's environment. Therefore, an additional factor of 10/3 is used to calculate the advisable distance of separation for transmitters in these frequency ranges.			
^c The field intensities established by the fixed transmitters, such as base radio stations, telephones (cell phone/wireless) mobile land radio transmitters, amateur radio transmitters, AM and FM radio and TV transmission cannot be forecast theoretically with any accuracy. In order to evaluate the electromagnetic environment due to fixed RF transmitters, it is advisable to execute an electromagnetic inspection of the site. If the measure of the field intensity on the site where the CardioMax is used exceeds the level of RF compliance used above, the CardioMax should be observed to check if the operation is normal. If abnormal performance is observed, additional procedures may be required, such as reorienting or repositioning the CardioMax.			
^d Above the range 150kHz thru 80MHz, the field intensity should be less than [V ₁]V/m.			

Electromagnetic immunity – Equipment with life support functions

Distances of separation advisable between the mobile and portable RF communication equipment and the CardioMax

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

Nominal maximum output power of the transmitter W	Distance of separation according to the frequency of the transmitter m			
	150 kHz thru 80 MHz outside the ISM bands	150 kHz thru 80 MHz outside the ISM bands	80 MHz thru 800 MHz	800 MHz thru 2.5 GHz
	$d = \left[\frac{3.5}{V_i} \right] \sqrt{P}$	$d = \left[\frac{12}{V_i} \right] \sqrt{P}$	$d = \left[\frac{12}{E_i} \right] \sqrt{P}$	$d = \left[\frac{23}{E_i} \right] \sqrt{P}$
0.01	0.35	1.2	0.12	0.23
0.1	1.1	3.8	0.38	0.73
1	3.5	12	1.2	2.3
10	11	38	3.8	7.3
100	35	120	12	23

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

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

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

NOTE 3: An additional factor of 10/3 is used to calculate the advisable distance of separation for transmitters in the ISM frequency bands between 150kHz and 80MHz and in the frequency range 80MHz thru 2.5GHz to reduce the likelihood of interference that the mobile/portable communication equipment could cause if taken inadvertently to areas of patients.

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

Symptom	Probable Cause	Probable Solution
CardioMax does not turn on	There is no electricity	- check connections CardioMax/Power cable/Plug.
Does not select energy > 50J	Identification of adult paddles	- Check if adult paddles are connected to CardioMax and if adult electrodes are well connected.
Does not deliver shock	Impedance measuring	- Check the graphic bar of patient impedance indication.
Does not capture ECG through the electrodes	Lead selection	- Select one lead other than the "paddle" lead.
No tracing	Instable from the last time it was turned off	- Restore initial configuration.
Low battery	Defective battery	- Replace battery.
No QRS audio indication	BIP volume	- Turn BIP volume on through the configuration menu.
No audio indication on Alarm	Monitor mode	- Alarm indications are activated only in the monitor mode.
Pacemaker does not turn on	Adhesive paddles	- Check that the adhesive paddles are connected; - Check to see if there is a "Bad Contact" message.
Does not print	No printer paper	- Check if there is paper in the printer.
Printer makes noise and does not print	Too much paper on the roll	- Take some of the paper off of the roll.

Accessories

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Accessories accompanying equipment:

Basic

Quantity	Description	Code
01	Power Cable (3 Pins)	555-0
01	Auxiliary cable for grounding and potential equalization	549-5
01	Removable battery	79008
01	User's Guide	22619

Defibrillation

Quantity	Description	Code
01	Adult and Children's external defibrillation paddle set	79001

ECG

Quantity	Description	Code
01	5 lead-ECG cable	18376

Pacemaker

Quantity	Description	Code
01	Trunk cable	19528
01	Multifunctional Paddles	19461

List of optional accessories:

Description	Code
Adult external defibrillation electrode	79013
Children's external defibrillation electrode	79013
Cable for adult and children intracavitary electrodes	79013
Y 3043 Type Oximetry Sensor Holder	12475
Cable for connecting to external DC	70319
Paper for thermal printer	10766

Specifications and Safety

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General specifications

Dimensions with paddles:	30 cm (11.81 in) (L) 21 cm (8.27 in) (W) 23 cm (9.05 in) (H)
Weight:	Equipment - 4.8 kg (10.58 lbs) Battery - 1.1 kg (2.42 lbs) External paddles - 0.8 kg (1.76 lbs) Complete Equipment - 6.7 kg (14.77 lbs)
Power:	AC: 100 a 265 VAC, 50/60 HZ External DC: 11 to 16 VDC
Removable Battery	Type: NiMH, 14.4V DC 4.5 A/h Life: 3.5 hours (full charged battery) Without printer or minimum of 140 in 360 joules shock or minimum of 200 in 200 joule shocks. Fully charged battery (completely discharged) 8 hours.
Maximum Consumption	AC 400W Battery 15A
Fusible:	AC Mains 5A
Battery storage:	Battery storage: Storing the battery for a long period of time in temperatures higher than 40° C (104° F) will reduce its capacity and life cycle.
Memory:	Type: Flash Nand. Capacity: 2 Mbytes Patients stored: > 150 patients ECG: 2.5 hours continuous hours of recording of ECG curve. Storage: 15 seconds of ECG when in shock, physiological alarm and panel events.

Protection Index	IPX0.
Classification:	- Class I. - CF Type.
Mode of functioning:	Continuous Operation.
Window:	- Size: 99.36 mm x 132.48 mm. - Diagonal: 6.5 inches. - Type: color LCD TFT. - Resolution: 640 x 480 pixels (VGA).
Speed of raster:	12.5, 25 and 50 mm/s

Environmental specifications

Temperature:	Operational: 0 to 50°C (32 to 122 °F). Storage: 0 to 70 °C (32 to 158°F).
Humidity:	Operational: 10 to 95% RH, without condensation. Storage: 10 to 100% RH, without condensation.

WARNING: If the CardioMax is used outside these conditions, 15 thru 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 patient's impedance.
Shock application:	By means of multifunctional paddles (adhesive) or paddles.

Scales for adult/external defibrillation:	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 40 and 50, 80, 100, 150, 200, 250, 300 and 360 Joules. Maximum energy limited to 50 J with internal or children's paddles.
Commands:	On/off, charging, shock, sync key.
Energy selection:	Button on front panel.
Charge command:	Button on front panel, buttons on external paddles.
Shock command:	Button on front panel, buttons on external paddles.
Synchronized command:	Sync key on front panel.
Charge Indicators:	Audio signal of equipment being charged, audio signal of charge completed, LED on external paddles and charge indicated on display.
Maximum charge time from energy source or battery:	< 6s com 90% a 100% da mínima tensão de rede especificada. < 6s com bateria a plena carga. < 13s apartir inicialização do equipamento.
External paddles size:	Adult: 10.3 cm x 8.5 cm (4.05 in x 3.34 in). Contact Area – 81.9 cm ² (12.69 in ²). Children: 4.5 cm x 4 cm (1.77 in x 1.57 in). Contact Area – 18 cm ² (2.79 in ²).
Cardioversion:	55 ms after QRS's peak. O equipamento não possui sinal de saída externo de Sincronismo para outro desfibrilador.
Tensão de saída máxima:	2000V.
Corrente de saída máxima:	70A(25 Ω).

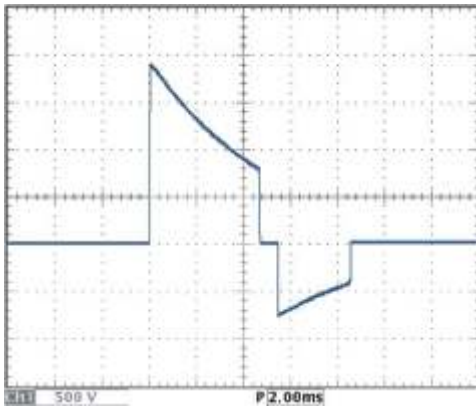
User's Manual | Specifications and safety

Energy Selected	Impedance							Accuracy
	25	50	75	100	125	150	175	
1	1.2	1.1	1.3	1.2	1.2	1.2	1.0	±2J
2	2.2	2	2.2	2.3	2.2	2.1	2.1	±2J
3	3.2	3	3.3	3.6	3.5	3.6	3.5	±2J
4	4.3	4	4.2	4.2	4.2	4.2	4.2	±2J
5	5.5	5	5.2	5.4	5.5	5.4	5.2	±2J
6	6.5	6	6.2	6.6	6.5	6.6	6.3	±2J
7	7.5	7	7.4	7.6	7.7	7.8	7.3	±2J
8	8.5	8	8.5	8.8	8.5	8.7	8.4	±2J
9	9.5	9	9.2	9.6	9.7	9.6	9.4	±2J
10	10.3	10	10.1	10.6	10.7	10.8	10.5	±2J
20	22.3	20	21.4	21.4	21.6	21.9	21.3	±15%
30	32.0	30	31.3	31.5	31.4	31.4	30.4	±15%
50	52.3	50	51.5	52.5	52.3	52.7	52.4	±15%
80	81.5	80	80.5	80.8	81.6	81.7	81.8	±15%
100	102.0	100	99.6	101.6	100.8	101.5	101.7	±15%
150	149.2	150	149.2	148.3	149.5	150.6	149.9	±15%
200	198.1	200	196.5	198.4	196.8	199.4	199.6	±15%
250	247.6	250	264.8	248.7	248.1	246.4	248.8	±15%
300	297.7	300	292.5	294.6	295.9	295.2	296.7	±15%
360	354.5	360	349.6	353.9	352.6	357.2	357.9	±15%

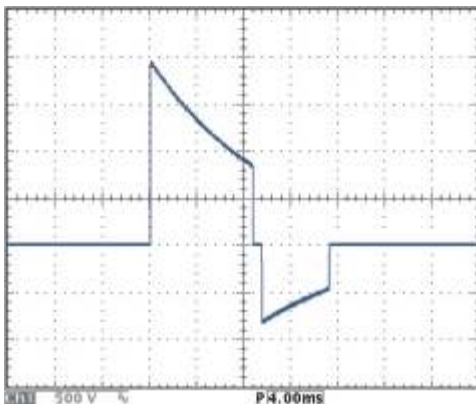
Patient's impedance response table:

Patient Impedance	Shock
Short-circuit	Shock inhibited
< 25 Ohms	Shock inhibited
> 25 Ohms and < 300 Ohms	Shock delivered and the waveform is adjusted according to the patient's impedance
> 300 Ohms	Shock inhibited
Open Circuit	Shock inhibited

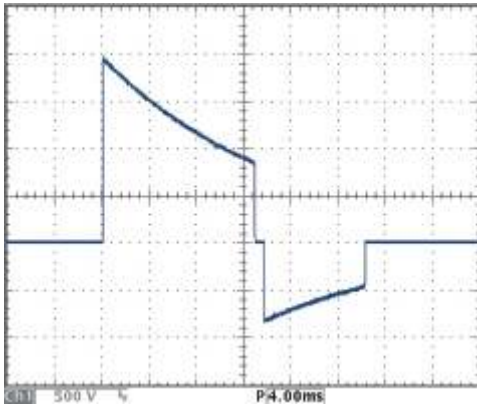
The values on the Y axis refer to voltage (volts) and the values on the X axis refer to time (milliseconds).



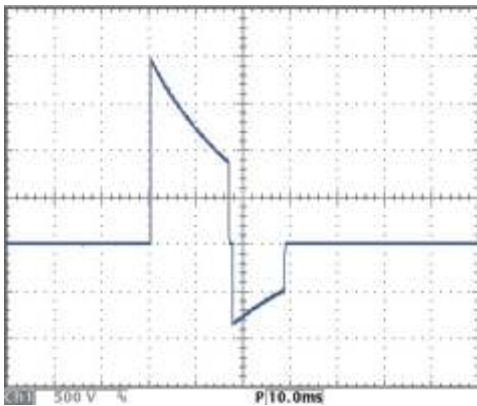
360J of energy over 25R impedance



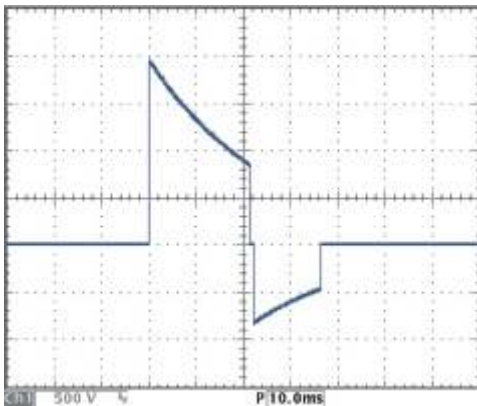
360J of energy over 50R impedance



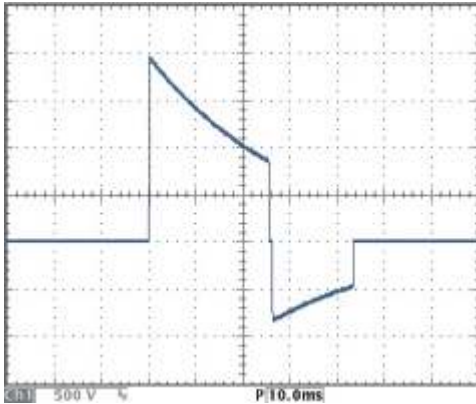
360J of energy over 75R impedance



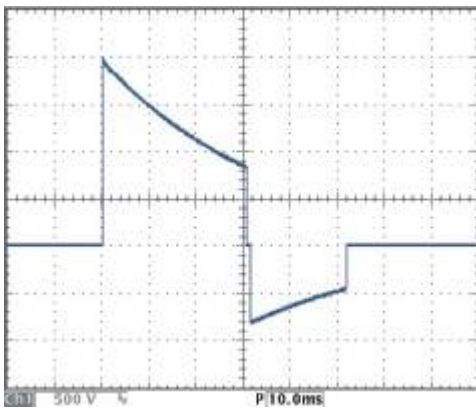
360J of energy over 100R impedance



360J of energy over 125R impedance



360J of energy over 150R impedance



360J of energy over 175R impedance

Pacemaker

Wave form: Truncated exponential monophasic.

Modes: Demand or Fixed.

Amplitude: From 5 mA to 200 mA (resolution of 5 mA), precision 10%.

Pulse Width: 20 ms (+/- 1ms)

Frequency: From 30 ppm to 180 ppm (increments of 5 ppm), precision $\pm 2\%$.

Refractory period: 340 ms (from 30 to 80 ppm); 240 ms (from 90 to 180 ppm).

Maximum output voltage 350 V

ECG

Input:	3 or 5 lead ECG cable, external paddles and multifunctional paddles
Electrode Error:	NO ELECTRODES and a trace line will appear on the display if there is a disconnected cable or electrode.
Low amplitude ECG: d	The ECG SIGNAL TRYING message appears on the display or printer (electrocardiograph mode) when the amplitude of ECG in 10mm/mV is less than 2.4mm peak to peak (or proportional sensitivity)
Adhesive paddle error:	If an adhesive paddle is disconnected, a trace line will appear on the display.
Range:	15 to 300 BPM
Precision:	+/- 1 BPM from 30 to 250 BPM
Rejection on common mode:	Higher than 90 dB, measure according to AAMI for heart monitors (EC 13)
Sensibility:	5, 10, 20 and 40 mm/mV
CA line filter:	60 Hz or 50 Hz
ECG response frequency:	Diagnostic mode (0.05 100 Hz) Monitor mode (1 40 Hz)

Isolation of the patient (defibrillation proof):	ECG: CF type..
Physiological Alarm:	<ul style="list-style-type: none">- Alarm not locked.- Minimum level (30-100).- Maximum level (100-250).- Visual indication.- Sound indication.- Function: suspend sound indication.- Function: silence sound indication.
Technical Alarm:	<ul style="list-style-type: none">- Alarm not locked.- Visual indication.- Sound indication.- Function: suspend sound indication.- Function: silence sound indication.
Discharge of defibrillator:	< 5 seconds.
Input impedance of the ECG amplifiers:	4.7 Mohms (Mega ohms).
Rejection of stimulus of pacemaker:	Stimuli of pacemaker with widths between 0.1ms and 2ms and amplitude between +/- 2mV and +/- 700mV are rejected in the counting of heartbeats. Concerning the overshoot, it complies with method A of standard AAMI EC13:2002. In the range 30BPM thru 300BPM the pacemaker pulses are rejected.
Maximum amplitude of the T wave:	It complies with the minimum recommended value of the rejection of the amplitude of the T wave of 1.2mV.
Standard 50.102.15 of IEC 60601-2-27, Cardiac Frequency Range, Accuracy and Range of Detection of QRS:	In order to maintain accuracy in low and high cardiac frequencies, the equipment must be in diagnosis mode.

Accuracy of the cardiac frequency in irregular rhythms:	It complies with the AAMI standard of ventricular bigeminy (FC = 40 bpm), slow alternating ventricular bigeminy (FC = 30 bpm); fast alternating ventricular bigeminy (FC = 120 bpm); bidirectional systoles (FC = 45 bpm).
Dynamic Input Range and Differential Voltage of Offset:	The equipment complies with standard 50.102.2 of IEC 60601-2-27.
Response time of cardiac frequency:	- 80 thru 120 bpm: maximum of 7 seconds. - 80 thru 40 bpm: maximum of 11 seconds.
Alarm time of tachycardia:	- 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.

PRINTER

Type:	Thermal
Weight:	0.4 kg (.88 lbs).
Speed:	12.5, 25 or 50 mm/s 5% accurate
Paper size:	50 mm (W) x 30 mm (L) (1.96 in (W) x 1.81 in (L))

Warranty Certificate

INSTRAMED Indústria Médico Hospitalar Ltda., guarantees the equipment described in this Certificate for 12 (twelve) months, starting from the delivery date. This warranty covers manufacturing or material defects that impede 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 damage occurs due to accident, natural disaster, improper connection to power source, use distinct from that described in the User's 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 the case of alterations made to this contract, the fiscal receipt, or to the equipment's series 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: _____

SERIES NUMBER: _____

PURCHASE DATE: _____

FISCAL RECEIPT NUMBER: _____

CARDIO**MAX**

Biphasic Monitor Defibrillator

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