User’s manual

VIVO BIPHASIC DEFIBRILLATOR MONITOR

MAN00005_03

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PREFACE

Congratulations on the acquisition of the VIVO Biphasic Defibrillator Monitor.

This product incorporates state-of-the-art technology aimed at helping patients in the midst of a medical emergency and at their resuscitation.

The complete reading of the operating instructions must precede the use of the equipment.

All the data necessary for the safe and correct use of the equipment are found in this manual, in addition to information on essential care for the conservation of the VIVO Biphasic Defibrillator Monitor and clarifications related to technical assistance and the Warranty Certificate.

A Quick Guide to emergency operations will be provided with the manual, which should be kept and kept on the equipment for future reference.

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2. INTRODUCTION

PRESENTATION

The VIVO Biphasic Defibrillator Monitor is a lightweight and portable electronic equipment, developed and designed for monitoring and resuscitation processes, where electrical stimuli will be applied to the heart, if cardioversion and/or defibrillation are indicated.

The equipment has the revolutionary biphasic technology, with which defibrillation requires less energy than that used in conventional monophasic Defibrillator Monitors, thus having a better performance. In addition, it has microprocessors for analyzing the activity of the heart, which takes approximately 10 seconds to do so.

One of its differentials is the color liquid crystal display (LCD), of high resolution and high contrast that allows perfect viewing from different angles through the exclusive Lap Top.

The VIVO Biphasic Defibrillator Monitor can be used in adult and child patients, and in any position in the hospital environment, on the ground, on the surgical bed and on benches in air and ground rescue units, etc., providing better management in advanced life support and increasing the human survival rate in a cardiorespiratory arrest.

DISCLAIMERS

The company will be exempt from any and all liability that may arise with respect to personal or material damage caused as a result of:

- Application other than the intended purpose.
- Improper use and repair in the equipment.
- Failure to comply with the instructions in this manual regarding the use, repair and maintenance of the equipment.
- Use of accessories and replacement parts manufactured by other companies (not authorized by Cmos Drake).
- Interventions, repairs or structural changes to the equipment are not permitted.

3. SAFETY INFORMATION

WARNINGS

⚠**The Vivo Biphasic Defibrillator Monitor was developed for applications in clinical monitoring with guarantee of functioning, when used correctly, in an appropriate medical place and by properly trained people.**

⚠**The operator must check the condition of the equipment and its accessories (regular tests), as well as their functioning before use.**

⚠**The operator must be aware and aware of all possible side effects caused during the use of the Vivo Biphasic Defibrillator Monitor.**

⚠**The use of the Vivo Biphasic Defibrillator Monitor is restricted to one patient at a time and of INFREQUENT USE.**

⚠ **Do not touch the patient, the bed (or stretcher), the equipment or any accessory connected to the patient during the electrical discharge (shock).**

⚠ **When installing the equipment, make sure that it is in a place with enough space for ventilation, away from heat radiation and that it is possible to easily disconnect the power cable from the equipment (10cm distance at the top, 20cm at the back and 15cm on the sides).**

⚠ **Risk of electric shock if the equipment cabinet is opened. Any type of service or future updates of this equipment can only be performed by personnel duly trained and authorized by CMOSDRAKE.**

⚠ **This equipment cannot be used in the presence of flammable agents, such as anesthetic gases, fuels, among others.**

⚠ **When the Vivo Biphasic Defibrillator Monitor is used together with an electric scalpel, the guidelines indicated in this manual on operating the equipment in the presence of high frequency devices must be observed.**

⚠ **The Vivo Biphasic Defibrillator Monitor equipment is intended for connection to the public electrical network, not suffering any interference or electromagnetic disturbances in its operation - in accordance with the recommendations of NBR IEC 60601-1-2 / CISPR 11 - Limits and measurement methods of electromagnetic disturbance in radio frequency of industrial, scientific and medical equipment (ISM).**

⚠ **To prevent fire or shock hazard, avoid operating or placing the Vivo Biphasic Defibrillator Monitor near a water source; avoid any liquid product on your cabinet.**

⚠ **Protection against the effects of cardiac defibrillation discharge is present in the modules inside the equipment. Sensors and cables do not provide additional protection against the effects of cardiac defibrillation discharge or when used in conjunction with equipment operating at high frequency.**

⚠ **Disposable materials must not be reused even after undergoing a cleaning and sterilization process. They must be disposed of in appropriate places according to the special procedures for hospital wastes.**

⚠ **In general, the equipment parts and accessories of the Vivo Biphasic Defibrillator Monitor intended to come into contact with biological tissues, cells or body fluids are tested and analyzed in accordance with the guidelines and principles of ISO 10993-1, which deals exclusively with testing of biocompatibility of the applied parts.**

⚠ **If there is a need to replace any part of the equipment, except for disposable materials, contact the manufacturer or the authorized network for the acquisition and replacement of parts.**

⚠ **There is a risk of polluting the environment associated with the use of accessories and consumables at the end of their useful life. Accessories and consumables must be disposed of in hospital wastes in accordance with environmental law. Internal batteries must be returned to the manufacturer after replacement due to a defect or end of life.**

⚠ **All material replacement must be made in accordance with the specifications included in this manual. CMOSDRAKE will only be able to guarantee the perfect functioning of the equipment if the guidelines are followed.**

⚠ **Never reuse disposable accessories. This practice can cause harm to the patient.**

⚠ **After using the equipment, discard the disposable accessories; clean the permanent accessories and store them together with the equipment.**

⚠ **Always use the equipment handle to transport it.**

⚠ **Proper grounding is mandatory for patient safety. We recommend, for the installation of the Vivo Biphasic Defibrillator Monitor, the observance of the requirements of the NBR 13534 Standard – Electrical Installations in Health Care Establishments – Safety requirements, published by ABNT in November 1995.**

⚠ **Avoid connecting the patient to multiple devices at once. Leakage current limits can be exceeded.**

⚠ **Conductive parts of accessories used in the equipment, including the Neutral Electrode, must not come into contact with other conductive parts, including earth.**

⚠ **Certain factors can cause ECG misinterpretation, such as: Misplaced electrodes; Patient movements; Pacemaker present (may decrease cardiac arrest detector accuracy); Radio frequency interference, including cell phones; Excessive hair or wet skin in the region where the electrodes are applied.**

⚠ **No modifications to this equipment are permitted.**

⚠ **The Vivo Biphasic Defibrillator Monitor is capable of operating for ECG monitoring with differential offset voltage not less than +/- 300mV. In case of overload, the ECG signal**

saturates on the equipment screen, making the monitoring parameter inoperative, until the equipment returns to the normal condition of use.

⚠**In special cases that are necessary, CMOSDRAKE makes available, by agreement, all technical material, such as: circuit diagrams, technical information, component lists, instructions for calibration and gauging or whatever is necessary for the personnel qualified technician can repair parts designated repairable by the manufacturer. The authorization for maintenance must be formally expressed by CMOSDRAKE.**

⚠**In case of maintenance of the Vivo Biphasic Defibrillator Monitor, disconnect the network cable from the equipment and wait 5 minutes before opening the equipment.**

⚠ **The Defibrillator Monitor must not be used too close to other equipment. Under no circumstances, any other equipment may be stacked or positioned on the Defibrillator Monitor. If these determinations are not complied with, the user must, obligatorily, test the features of the Defibrillator Monitor before its use.**

⚠ **The equipment has a Watch Dog circuit designed to activate the system reset if any unexpected error condition occurs, resetting the equipment. The watch dog circuit (hardware reset) is an additional security system that exists in any electronic device that uses embedded software.**

⚠ **The Watch dog circuit is used to reset the motherboard, without the need for operator intervention, in case the crash occurs due to external reasons.**

⚠ **The Watch Dog circuit during the normal operation of the equipment is in “stand by”. Therefore, it has no active function on the equipment. It only comes into operation if the lock occurs.**

⚠ **The Watch Dog circuit does not cause risk to the patient and the user, does not influence stability and does not affect the performance of the product.**

ACRONYMS AND ABBREVIATIONS


Dangerous Voltage.


General symbol for warning.


Class II Equipment


Defibrillator-proof BF type applied part.


Defibrillator-proof CF type applied part.


It refers to the instructions manual / booklet.


Do not trigger with the shock pads sort-circuited.


Prohibition.


Printing.


NIP.

Synchronism.


Freezes.


Inhibitts beep.


Activated alarm


Alarm inhibited by user configuration


It inhibits alarm for 2 minutes.


Alternating Current


Direct Current


This side up: indicates the correct position in which the box should be transported.


Fragile: indicates that the package must be transported and handled with care.

Keep dry: indicates that the package should be kept in a dry place

Number 5: indicates the maximum stacking of five overlapping units

It indicates that it is a medical equipment and, therefore, it deserves special handling

It indicates that it is composed of recyclable raw material

Symbol for marking electrical and electronic devices in accordance with Directive 2002/96/EC. The device, accessories and packaging must be disposed of correctly at the end of use. Please follow Local Ordinances or Regulations for disposal.

Manufacturer

Date of Manufacture

UNITS OF MEASUREMENT

Unit	Magnitude	Description
m, cm, mm	Length	Meter, centimeter, millimeter
h, m, s, ms	Time	Hour, minute, second, millisecond
Kg, g	Mass	Kilogram, gram
°F, °C	Temperature	Degree Fahrenheit, degree Celsius
mmHg, hPa	Pressure	Millimeters of mercury, hectopascal
hz, rpm, bpm, ppm	Frequency	Hertz, respirations per minute, beaets per minute, pulses per minute
V, mV	Voltage	Volts, millivolts
m/s, mm/s, bps, l/m	Speed	Meter per second, millimeter per second, beats per second, liters per minute
A, mA	Current	Amperes, Milliamperes
Ω	Impedance	Ohms
J	Energy	Joules
m^3, mm^3	Volume	Cubic meters, cubic millimeters

Table 1 - Units of measurement.

SYMBOLS USED IN THIS USER'S MANUAL

- ACLS: Advanced Cardiology Life Support;
- AHA: American Heart Association;
- BLS: Basic Life Support;
- ICD: Implantable Defibrillator Monitor-Defibrillator
- ECG: Electrocardiogram;
- VF: Ventricular Fibrillation;
- Hb: Hemoglobin; (cHb: Hemoglobin concentration);
- HbO2: Oxyhemoglobin (cHbO2: oxyhemoglobin concentration);
- PRT: Printer;
- INCOR: Instituto do Coração;
- LED: Light Emitting Diode;
- LCD: Liquid Crystal Display
- PM: Pacemaker;
- SAN: Sinoatrial Node;
- BP: Blood Pressure;
- CRA: Cardiorespiratory Arrest;
- NIP. Noninvasive Pressure;
- CPR: Cardiopulmonary Resuscitation;
- SBC: Brazilian Cardiology Society;
- SPO2: Oxygen Saturation;
- VT: Ventricular Tachycardia;
- ICU: Intensive Care Unit;
- VOO: Pacemaker Asynchronous Mode;
- VVI: Pacemaker Demand Mode.
- ETCO2: Capnography Module
- Watch Dog: Electronic device that triggers a "reset" to the system when an error condition is identified.

CONTRAINDICATIONS

- This equipment cannot be used in the presence of flammable agents, such as anesthetic gases, fuels, among others;
- This equipment should not be used by laypersons, only by properly trained and qualified professionals.
- Asynchronous defibrillation is contraindicated in patients who have one or any combination of the following conditions:

    - Consciousness;
    - Spontaneous breathing;
    - Palpable pulse;
    - Child under 8 years of age or weighing less than 25 kg

- This equipment must not be used in asystole. Defibrillation in case of asystole can inhibit the recovery of natural pacemakers in the heart and completely eliminate any chance of recovery. Therefore, shock should not be applied in asystole.

4. BASIC GUIDELINES OF THE VIVO BIPHASIC DEFIBRILLATOR MONITOR

PRESENTATION

Basic Guidelines for the Vivo Biphasic Defibrillator Monitor

The Vivo Biphasic Defibrillator Monitor's main function is to monitor vital signs, such as electrocardiogram, pulse oximetry, non-invasive pressure and capnography, so that the medical professional can interpret and diagnose the patient's data that will be presented on the display.

The equipment is intended to be used only by qualified physicians trained to operate it and in ACLS - Advanced Life Support, advanced cardiac support or defibrillation.

OPERATION

If, during the electrocardiogram monitoring process, the medical professional diagnoses any malignant arrhythmia that has an indication for treatment by electric shock, he must activate the charge key, where an electronic circuit will produce energies, which vary from 0 to 360 joules, to be discharged onto the patient. The doctor himself is the one who determines what energy is needed to shoot. During this procedure, the patient remains under monitoring for the physician to review the ECG results after the shock(s).

Patient cables, transthoracic electrodes and sensors are accessories used to capture the vital signs that will be monitored.

Dedicated electronic circuits and microprocessors capture, amplify the signals, process and send them to the liquid crystal display.

Numerical data such as heart rate, oxygen saturation value, among others, and the curves (waves) that represent the electrical activity of vital signs are displayed on the screen.

INTENT OF USE

Medical product whose main and first function is to capture the patient's cardiac signal and display the ECG tracing (electrocardiogram) on the equipment screen, in cases where a shockable cardiac arrhythmia is identified, it will be possible to apply a shock (electrical energy) to the patient's chest for arrhythmia reversal (secondary function of the equipment). Only a medical professional able to analyze arrhythmias can interpret and decide on shock delivery.

The equipment can be used in hospital environments, ambulances, places of emergency care and during patient transport. It can be used in pediatric and adult patients, where the energy adjustment and decision to use the shock pads (pediatric or adult) must be made by the medical professional. The equipment can also be used whenever it is necessary to monitor any of the functions that are included (as optional).

MANUAL DEFIBRILLATION

For Cardioversion/defibrillation, additional assessments of the patient's clinical condition are required to determine the need for shock delivery. The equipment can also be used for synchronized

cardioversion of certain atrial or ventricular arrhythmias. The suitably qualified medical professional must decide when synchronized cardioversion is appropriate.
The energy can be adjusted on the equipment (by the medical professional) according to the following scale:
Child mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50 Joules.
Adult Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200.

AED MODE (OPTIONAL)

In this mode, the equipment analyzes the patient's ECG signal and identifies, based on the analysis algorithm, whether or not shock is required. Shockable arrhythmias in AED mode are:

- Afib - Atrial Fibrillation
- VFIB - Ventricular Fibrillation
- VTACH - Ventricular Tachycardia
- CVF - Coarse Ventricular Fibrillation
- FVF - Fine Ventricular Fibrillation
- MVT_140
- MVT_160
- PVT_140
- PVT_160

AED mode should be used with professionals with BLS (Basic Life Support) training. In this mode, the equipment will issue voice and text commands that will guide the operator during the entire patient resuscitation procedure.

EXTERNAL PACEMAKER (OPTIONAL)

Module used to temporarily supply the heart's natural pacemaker, applying electrical stimuli with adjustable frequency, amplitude and pulse width. It can be used on conscious or unconscious patients.

CAPNOGRAPHY (OPTIONAL)

Module used to monitor, in a non-invasive way, the respiratory rhythm and the concentration of carbon dioxide during the patient's respiratory cycle (inspiration and expiration). It can be used in pediatric and adult patients (according to specific accessory for each type of patient).

PRINTER (OPTIONAL)

Record the current ECG signal permanently.

PULSE OXIMETRY (OPTIONAL)

Monitor the patient's blood oxygenation rate. Transmit the information to the qualified and trained medical professional who must interpret the condition of the patient's blood circulation.

NON-INVASIVE BLOOD PRESSURE (OPTIONAL)

Measure the patient's blood pressure using the oscillometric method. Measurements of systolic, diastolic and mean pressure are provided.

CHARACTERISTICS

The Vivo Biphasic Defibrillator Monitor integrates several functions and can be configured according to the specific needs of each customer.

Factory default setting:

- ECG and heart rate monitoring;
- Biphasic Defibrillator;
- Rechargable battery.

In addition to the factory default configuration, it is possible to include the following configurations:

- Non-Invasive Pressure (NIP)
- Monitoring of functional arterial oxygen saturation (SPO2) and Methemoglobin;
- Non-invasive transcutaneous external pacemaker (demand and asynchronous, with switch to emergency mode);
- Non-invasive pressure monitoring (NIP);
- Capnography (CO2);
- Thermal printer
- Drug software;
- Ventilation/intubation software;
- Automatic external defibrillator (AED) mode with voice and text command.

OBSERVATIONS

- With simple operation, the equipment, through its AED mode (optional), offers the possibility of being used by properly trained people and under medical supervision. It is highly safe and presents minimal risk of injury to the patient and operator. In AED mode (optional) it has voice and text commands to instruct the rescuer during the resuscitation sequence.
- Any of the parameters can be integrated into the equipment, without changing the product's purpose characteristics.

GENERAL CHARACTERISTICS

Defibrillation in truncated exponential biphasic waveform, with load from 1 to 200 Joules and options from 1 to 360 Joules, with operating instructions on the Vivo Biphasic Defibrillator Monitor panel:

❖ 200 Joules Version:
- Child Mode or for use with internal pads: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50 Joules.
- Adult mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200 Joules.

❖ 270 Joules Version:
- Child mode or for use with internal pads: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50 Joules.
- Adult Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200, 270 Joules.

❖ 360 Joules Version:
- Child mode or for use with internal pads: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50 Joules.
- Adult Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200, 240, 360 Joules.

❖ It has an intelligent safety system that limits the load to 50J for children's use, when unscrewing the adult plates from the pads..
❖ High-impact, electrically insulated ABS enclosure;
❖ Self test at startup;
❖ Low battery alarm – audible and visual;
❖ 10-Way ECG Cable – optional;
❖ It allows, through connection or other means, communication with a microcomputer, for visualization of memory data;
❖ Analysis of the patient's thoracic impedance, increasing defibrillation efficiency and reducing the risk of cardiac injuries;
❖ Automatic internal discharge after 30 seconds if there is no trigger, or manually through the key cancel the charge at the user's discretion at any time;
❖ Clock/date;
❖ Counter of Shocks performed;
❖ Permanent interchangeable adult/child pads;
❖ Visual indicator of contact on PADS (optional); It monitors the contact of the pads on the patient's chest via the bargraph on the display and optionally on the pads themselves via LED's;
❖ Internal rechargeable battery - sealed;
❖ Battery Status Indicator – Low, Charging and Charged;
❖ Color liquid crystal display for viewing ECG, SPO2, NIP, Pacemaker, AED Mode, Printer and Capnography parameters; visualization of battery status, alarms, pre- and post-shock programming parameters, indication of energy selected for triggering, impedance indicator and PAD contact;
❖ Internal event memory including 2GB curve, date and time – Via USB cable (optional);

- It has voice command with volume control (optional) and text to instruct the rescuer during the resuscitation sequence (When in AED Mode);
- When in “SYNCHRONIZED MODE”, it triggers synchronized with the QRS complex, with energy delivery time <40ms;
- It has a beep for CPR guidance (100 Comp/min) in AED MODE;
- Complete system of audible and visual alarms with the possibility of programming maximum and minimum values, including technical alarms for Loose Electrode and physiological alarms for Asystole, Tachycardia, Bradycardia and Fibrillation;
- When the Vivo Biphasic Defibrillator Monitor is configured in automatic mode, the load energy follows a firing sequence of 150J, 200J and 200J;
- Charge time of 4 seconds for 200J and 7 to 15 seconds for 360J;
- Pacemaker pulse detection;
- Impedance detection in the range from 25 Ohm to 500 Ohm, for triggers;
- Drug calculation software (Optional);
- Software for ventilation/intubation mode (Optional);
- Software for ST Segment Analysis and Arrhythmias (Optional);
- Software with impedance indicator and PAD contact (Optional);
- Selection of the load level by the “APEX” pad button and load by pressing the “STERNUM” pad button.

DAILY USE

The Vivo Biphasic Defibrillator Monitor has a basic Cardioversion/Defibrillation function for cardiac arrhythmias. The equipment has quick access keys (1 - Select Energy; 2 - Load; 3 - Trigger) so that the operator can perform the patient's resuscitation quickly.
In addition, it has an ECG cable for monitoring the heart signal. To do so, simply connect the cable to the equipment and attach the disposable electrodes to the patient's chest, and the equipment automatically starts reading the ECG signal, which will be displayed on the screen.

UNPACKING AND INSTALLING THE EQUIPMENT

- Remove the equipment from the packaging box as indicated below:

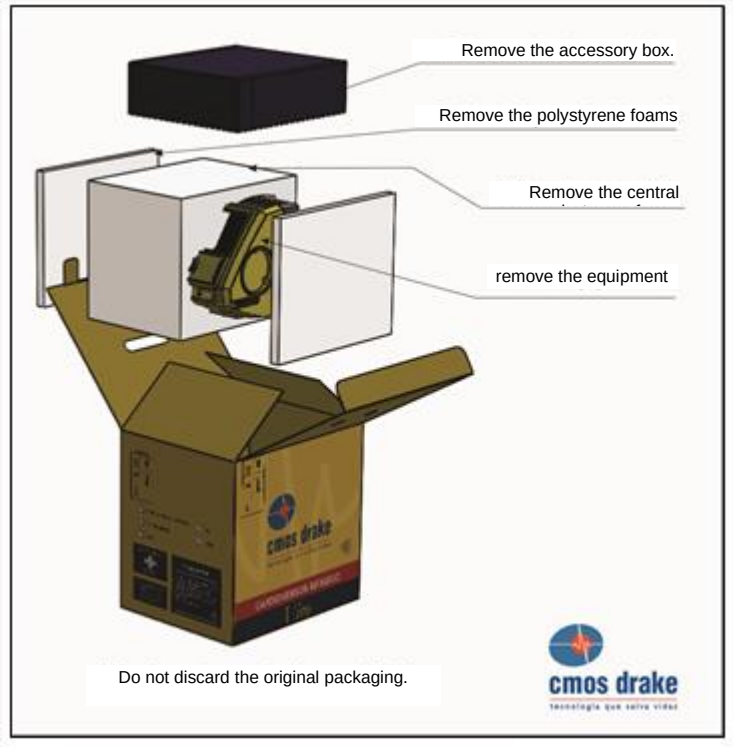


Figure 1 – Unpacking the equipment.

- Place it in a suitable and easily accessible place;
- Make sure that the installation location has adequate ventilation and is within the pressure and temperature ranges indicated in this manual;
- Remove all accessories from the packaging box;
- Connect the power cable to the equipment's network input;
- Connect the power cable to the mains;
- Check that the AC and battery charge indicator LEDs are lit;
- Keep the rear of the equipment a minimum distance of 20 cm from any other device or from the wall, so that there is no risk of the power cord being pinched or disconnected from the equipment, and that the power cord can be easily disconnected from the VIVO Defibrillator Monitor;
- Keep the equipment always connected to the electrical network to preserve battery charge;
- This equipment is designed to work in environments that do not contain flammable anesthetics and cleaning agents. Do not operate it in the presence of Flammable Gases in general.

⚠**Avoid turning the equipment on or off if it is connected to a patient; remove the electrode cable first.**

⚠**If the patient connected to the Vivo Biphasic Defibrillator Monitor, equipped with a floating insulation (not connected to the ground of the electrical network), is connected to any other device that does not have the same type of insulation, the patient may come into contact with conductive parts and cancel the protective effect of the equipment;**

⚠**The Vivo Biphasic Defibrillator Monitor should only be operated by properly trained personnel. It is the responsibility of the hospital administration to have adequate and accessible operating instructions.**

⚠The interconnection of the Vivo Biphasic Defibrillator Monitor with any other equipment is only allowed when it is not harmful to the patient, the operator, the environment and the equipment;

⚠Check the correct operation of the equipment before its clinical use;

⚠If the specifications of the additional part do not inform about the interconnection effects of the equipment, consult the manufacturer or an expert in the field;

⚠It is possible to quickly check the functionality of the alarms (visual and audible); when with the aid of a parameter simulator, it is possible to test a situation where the measured values exceed the minimum or maximum limits set by the operator in the equipment. The alarms (visual and audible) can also be checked by pressing the inhibit alarm key, silencing all the equipment's alarms for 2 min;

⚠The Vivo Biphasic Defibrillator Monitor must only be operated by properly trained personnel. It is the responsibility of the hospital administration to have adequate and accessible operating instructions.

OVERVIEW

Figure 2 – Overview.

REAR PANEL

The sensor inputs are located on the rear panel of the equipment. The following is an illustrative picture of the back panel when Masimo Oximetry is present as an option:

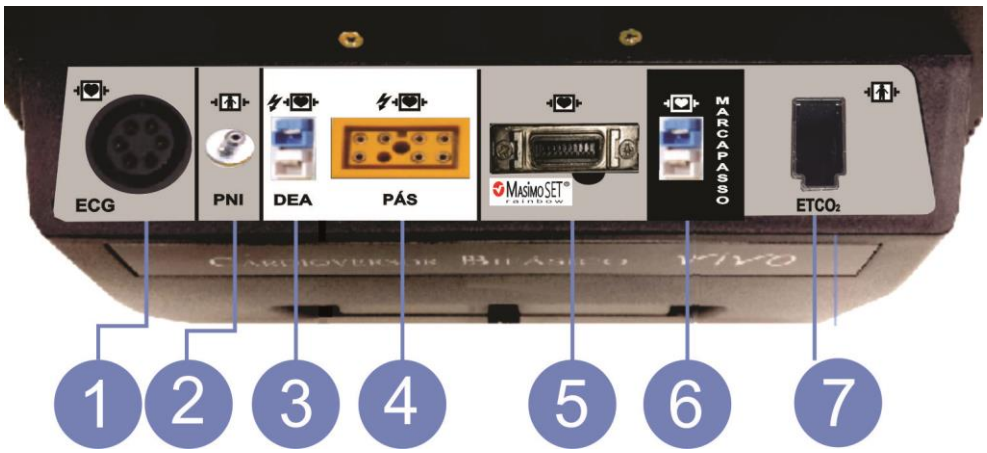


Figure 3 – Rear panel.

1. ECG connector
2. NIP connector
3. AED Mode Connector / Adhesive Shock Pads
4. Permanent Shock Pad Connector
5. Masimo SPO_2 Connector (Methemoglobin)

6. Pacemaker Adhesive Shock Pad Connector
7. Capnography Cannula Connector

If Biolight Oximetry is present as an option, the back panel will be presented as follows:

Figure 4 – Rear panel (Biolight Oximetry).

POWER AND COMMUNICATION INPUTS

Figure 5 – Power and communication inputs.

1. fuse holder
2. Electric mains input
3. USB connector
4. Ambulance input connector

IDENTIFICATION OF THE VIVO BIPHASIC DEFIBRILLATOR MONITOR PARTS AND COMMANDS

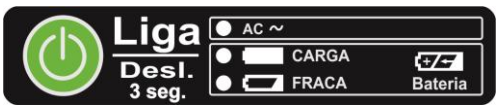
Figure 6 – Identification of equipment commands.

1. Permanent interchangeable adult/child shock pads
2. Quick access keys
3. Power on/off and network and battery charge indications
4. Power Navigation and Selection/Confirmation Button
5. Quick access keys Pacemaker;
6. Monitor
7. Carrying handle

2 Quick access keys

	Key to charge the shock capacitor.
	Key to cancel loading of the shock capacitor.
	Trigger button.
	Synchronism - Enables/disables sync with ECG signal.
	Key to enter the equipment's AED Mode.
	NIP – Start/suspend NIP measurement.
	Print key – press once to start printing. To suspend printing, press the key again.
	Freezes.
	It inhibits all alarms for 2 minutes.

3 Power on/off and battery charge network indications



1. On/Off Key

2. Indicator LEDs:

Electric mains;
Battery charging;
Low battery.

4 Navigation Button.

The Navigation Button has two functions, namely:

1 – Navigation/Selection in the Settings Menu:

To enter the configuration MENU, just press the browser for 3 seconds, and the settings screen will appear on the display.

When pressing the navigation button for three seconds, the display will show the Parameter Setup Menu. An arrow-shaped cursor (>) will appear to the left of one of the items in this menu indicating that this is the selected item. Turning the navigation knob clockwise or counterclockwise, the cursor will move pointing to a new menu item, according to the rotation direction. To configure the desired module, position the cursor pointing to this module and press the navigation key.

After choosing the module to be configured, a new menu will appear on the display with the configuration items for the selected module.

To exit the menu, position the cursor on the **Exit** item or press the **Exit** shortcut key located on the panel next to the navigation button.

OBSERVATIONS:

- In the Configuration Menu, only the parameters that are installed in the Defibrillator Monitor will appear (configuration options);

2 – Change/confirm the selected energy:

To change the selected energy, simply rotate the navigator (right – increase energy/Left decrease) and the value is indicated on the screen. To confirm the energy, just press the browser button and the value will be confirmed and displayed in white on the screen. If the power has not been confirmed, and the charge key is pressed, the message will appear: ***"Press the menu button to confirm power and charge."*** As long as the power is not confirmed, the equipment will not charge the capacitor.

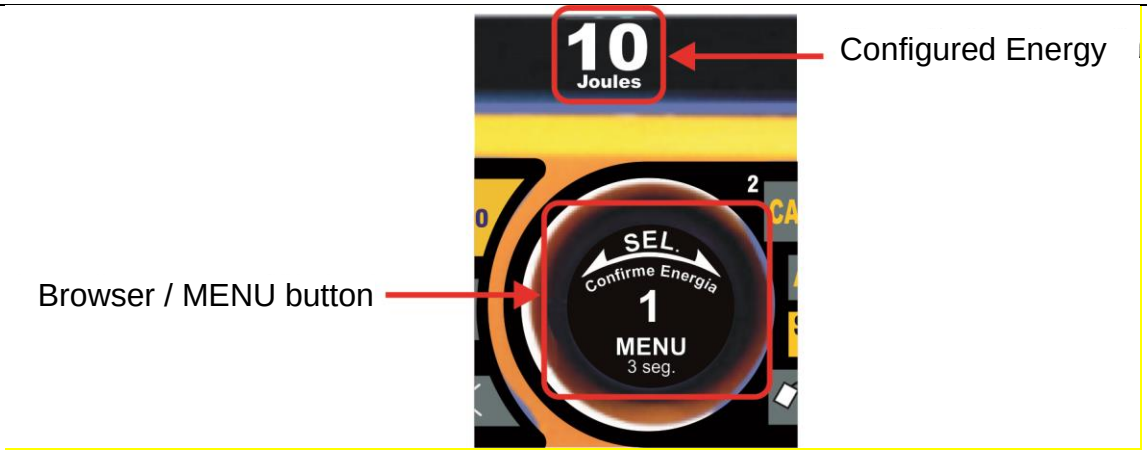


Figure 7 – Encoder identification.

- By turning the navigation knob without pressing it previously, it will be possible to select the energy in case of treatment (1 to 200 Joules, or up to 360joules - optional).

5 Quick access keys Pacemaker.

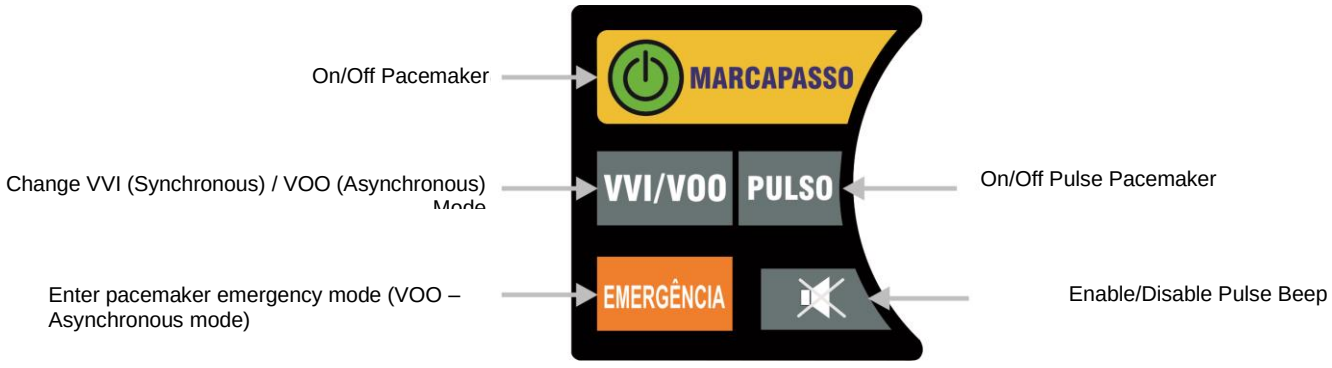


Figure 8 – Pacemaker Keys.

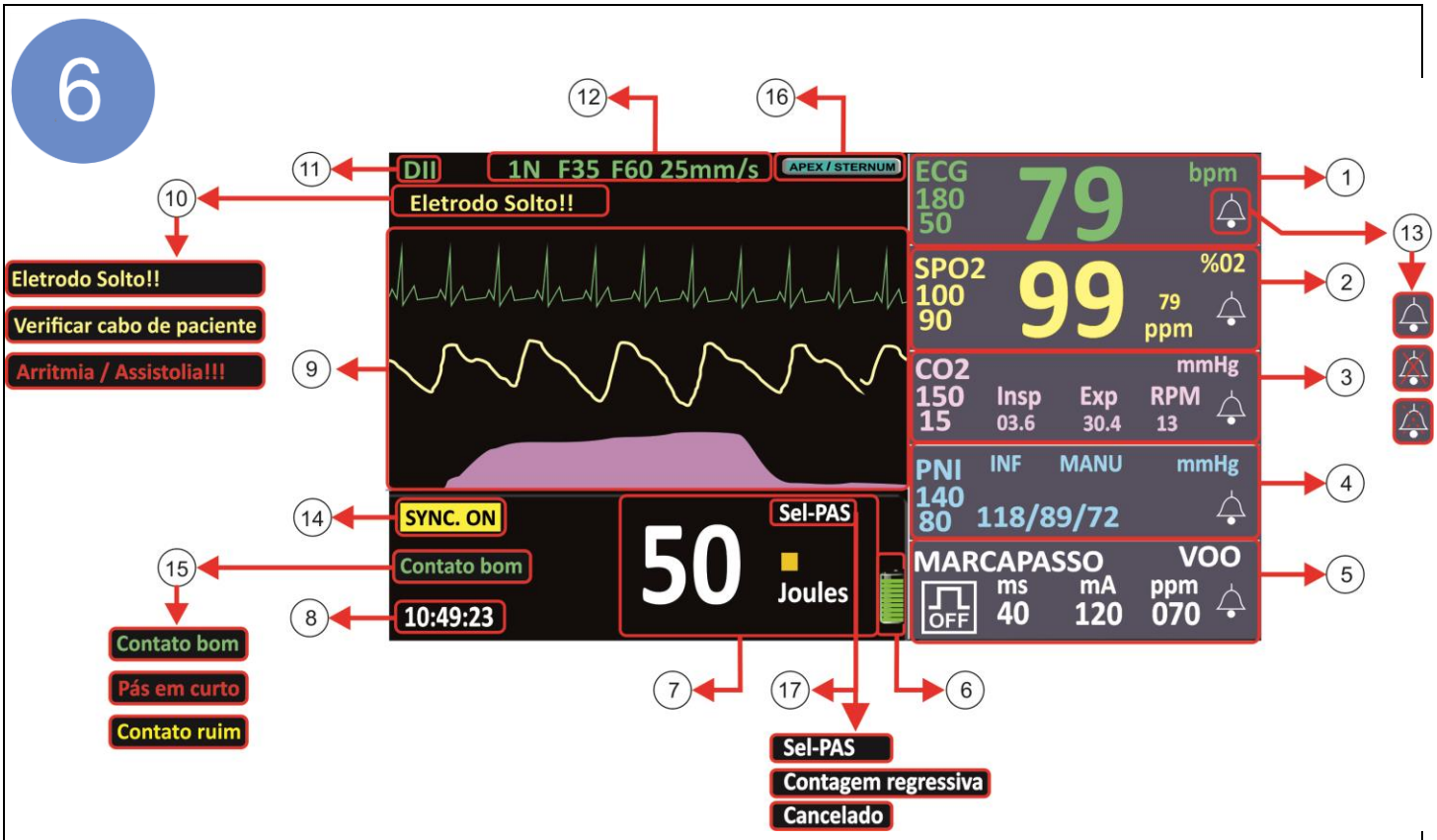


Figure 9 – Identification of display information

1- **ECG:** Beats per minute (bpm).
2- **SPO2** oximetry: Oxygen saturation (%) and pulse per minute (ppm).
3- CAPNOGRAPHY: Breaths per minute (rpm), measurement of expired carbon dioxide (EtCO) and inspired value (FiCO).
4- **NIP**: Numerical display of non-invasive pressure and provides systolic, mean and diastolic blood pressure.
5- **PACEMAKER** stimulus data: Setting display of Width (ms), Amplitude (mA) and frequency (ppm) of pulse, Operating mode (VOO/VVI). Indicates whether the pulse is Activated (ON) or deactivated (OFF).
6- Displays battery charge status.
7- **ENERGY** Display: Displays the energy configured for triggering.
8- time indicator
9- Graphic area: It has divisions where the curves of the physiological parameters being monitored are displayed.
10- Alarm reporting (Lead lead, Arrhythmia/Asystole, Check Patient Cable).
11- Indication of the **ECG LEAD**: Presentation of the electrocardiogram lead presented in the graphics area (CAL = calibration, D1, D2, D3, AVR, AVL, AVF, V).
12- Settings indication: FILTER 35 and 60 (Hz), Gain (1/2N; 1N; 2N) and Sweep speed (12.5mm/s; 25mm/s; 50mm/s) of the ECG trace on the display.
13- Alarm status (Alarm on, alarm off, alarm off for 2 minutes
14- Synchronism activated.
15- Pad contact indicator (good contact, shorted pads, bad contact).
16- Pad connection indicator (APEX/STERNUM is displayed once the permanent pads are connected to the equipment).

17- Displays the enable for selection and triggering through the pads, countdown to load cancellation, load canceled.

INITIALIZING THE EQUIPMENT

To start the device, press the power button for 1 second, located on the front panel of the device.

Figure 10 - On/Off key

The equipment will start and be ready for use, just connecting the accessories and adjusting the alarm levels (as per the instructions below).
During the entire procedure, keep the Defibrillator Monitor approximately 0.5 m from the patient and operator, as shown below.
The operator must remain next to the patient, close to the chest, to check vital signs.

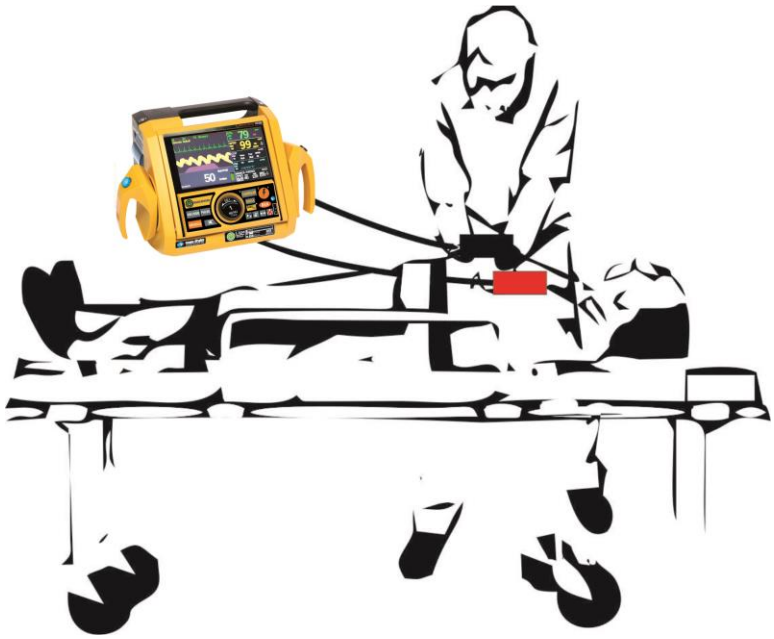


Figure 11 – Operator position.

TURNING OFF THE EQUIPMENT

After the procedure is completed:

1. Turn off the Defibrillator Monitor by pressing the on/off button for three seconds;
2. Disconnect all patient accessories;
3. Clean the Defibrillator Monitor and its accessories, according to the cleaning procedure described in this manual;
4. If the equipment has been used on battery power, reconnect the power cable to the equipment and keep it connected at all times. To connect/disconnect the power cord, turn the back of the equipment to fit the plug.

Figure 12 – Electric power supply mains connection.

5. MODE OF OPERATION OF THE ALARMS

ALARMS

The Vivo Biphasic Defibrillator Monitor has audible and visual indications of physiological alarm conditions (HIGH PRIORITY - !!!) and technical alarm conditions (MEDIUM PRIORITY - !!).
Alarms will sound according to their priority.

High Priority Alarm (Physiological Alarms): It indicates the patient's physiological changes and will be activated when the value measured by the equipment exceeds the minimum or maximum limits previously configured by the operator on the equipment.

Medium Priority Alarm (Technical Alarms): Indicates that the equipment is not able to monitor the patient's condition.

Informational messages: They are displayed on the machine's screen (in white or cyan). These messages are indications only and do not require immediate operator action.

AUDIBLE INDICATORS

If the equipment has alarms of different priorities occurring simultaneously, the high priority audible alarm overrides the medium priority one.

VISUAL INDICATORS (LEDS)

Two alarm indicator LEDs are located on the keyboard of the VIVO Defibrillator Monitor.

Figure 13 – Visual indicators.

VISUAL INDICATORS SYMBOLS AND TEXT MESSAGES.

In addition to the audible and visual alarms (LEDs), symbols and text messages will be displayed on the screen indicating the cause of the alarm.

ALARM SYMBOLS.

Alarm symbol	Cause
	Alarming parameter.
	Alarm silenced for 2 minutes.*1
	Alarm disabled by user configuration.*2

Table 2 – Alarm Symbols.

*1 All alarms, regardless of priority, will be inhibited for two minutes.

*2 User can disable the equipment's medium-priority alarms, just enter the parameter setting menu. High priority alarms cannot be disabled.

alarm messages

ECG

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
Loose Electrode!!	MEDIUM PRIORITY	Yellow	electrode is offline electrode is worn out lack of conductive gel Insufficient preparation of the patient's skin
Check Patient Cable!!	MEDIUM PRIORITY	Yellow	
Bradycardia!!!	HIGH PRIORITY	Red	When bpm is below the value set in alarm setup
Tachycardia!!!	HIGH PRIORITY	Red	When bpm is below the value set in alarm setting
Arrhythmia / Asystole!!!	HIGH PRIORITY	Red	Absence of bpm electrode is worn out lack of conductive gel Insufficient preparation of the patient's skin

Table 3 – ECG Alarm Text Messages.

Masimo SPO2

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
High SAT!!!	HIGH PRIORITY	Red	SpO2 saturation above the determined limits

Low SAT!!!	HIGH PRIORITY	Red	SpO2 saturation below the determined limits
High PPM!!!	HIGH PRIORITY	Red	PPM above the determined limits
Low PPM!!!	HIGH PRIORITY	Red	PPM below the determined limits
Low perfusion!!!	HIGH PRIORITY	Red	Low blood perfusion
Loss of pulse!!!	HIGH PRIORITY	Red	Pulse not found
No sensor!!!	MEDIUM PRIORITY	Yellow	Sensor not connected. Connect a compatible sensor
Defective Sensor!!	MEDIUM PRIORITY	Yellow	Defective sensor Replace sensor
Check connection of the sensor!!	MEDIUM PRIORITY	Yellow	Poor sensor connection. Disconnect and connect the sensor. If the message continues, replace the sensor
Too Much Light!!	MEDIUM PRIORITY	Yellow	Ambient light interfering with sensor operation
Improper sensor!!	MEDIUM PRIORITY	Yellow	Sensor not compatible. Replace the sensor with a compatible one
	MEDIUM PRIORITY	Yellow	MASIMO card not enabled*. Use the necessary update keys to enable the card*
Low SIQ!!	MEDIUM PRIORITY	Yellow	Low signal quality index. Check patient. May indicate motion and/or low perfusion
Error - Oximetry	MEDIUM PRIORITY	Yellow	The MASIMO plate was not initialized correctly. Restart the device. If the error persists, send the device to an authorized technical support center.

Table 4 – Masimo SPO2 Alarm Text Messages.

*Technical support

Informational messages:

- ❖ Sensor initializing (cyan color) - Initialization can take up to 20 seconds;
- ❖ Searching for pulse (cyan color) – Sensor searching for patient pulse;
- ❖ No patient (cyan color) - Sensor disconnected from the patient.

Perfusion alarm

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE

High PI!!!	HIGH PRIORITY	Red	PI above the determined limits
Low PI!!!	HIGH PRIORITY	Red	PI below the determined limits

Table 5 – Masimo SPO2 Perfusion Alarm Text Messages.

Methemoglobin Alarm

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
High Met-Hb!!!	HIGH PRIORITY	Red	Methemoglobin saturation above the determined limits
Low Met-Hb!!!	HIGH PRIORITY	Red	Methemoglobin saturation above the determined limits

Table 6 – Masimo SPO2 methemoglobin Alarm Text Messages.

Carbon Monoxide Alarm

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
High CO!!!	HIGH PRIORITY	Red	CO above the determined limits
Low CO!!!	HIGH PRIORITY	Red	CO below the determined limits

Table 7 – Masimo SPO2 carbon monoxide Alarm Text Messages.

NIP.

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
NIP Pressure Insufficient!!	MEDIUM PRIORITY	Yellow	Module filled for more than 30 seconds Pressure is not high enough to produce result
NIP DO NOT Repeat the Measurement!!	MEDIUM PRIORITY	Yellow	Measured for a time longer than 90 seconds (Adult) Measured for a time longer than 60 seconds (Neonatal)
NIP Repeat the Measurement!!	MEDIUM PRIORITY	Yellow	Weak pulse
NIP Excess Movement!!	MEDIUM PRIORITY	Yellow	Excess movement of the patient
NIP Irregular measurement!!	MEDIUM PRIORITY	Yellow	Incorrect cuff and connection

PNI Measurement exceeded 90s!!	MEDIUM PRIORITY	Yellow	Measured for a time longer than 90 seconds (60 seconds for Neonatal)
NIP +100 neutral pulses!!	MEDIUM PRIORITY	Yellow	More than 100 pulses were observed without any result
NIP wrong cuff!!	MEDIUM PRIORITY	Yellow	Inappropriate cuff Review the positioning of the cuff
NIP wrong measurement!!	MEDIUM PRIORITY	Yellow	Irregular measurement, check the waveform
Divergent NIP!!	MEDIUM PRIORITY	Yellow	Divergent measurement, check the waveform
NIP <10 mmHg or > 250 mmHg!!!	HIGH PRIORITY	Red	Wrist pressure is less than 10 mmHg (Adult mode)
NIP <5 mmHg or > 150 mmHg!!!	HIGH PRIORITY	Red	Wrist pressure is less than 5 mmHg (Neonatal mode)
NIP Out of rhythm pulse!!!	HIGH PRIORITY	Red	Failed to take pulse measurement
PNI High pressure!!!	HIGH PRIORITY	Red	Pressure value is above the value set in alarm setting
NIP Low pulse!!!	HIGH PRIORITY	Red	Weak pulse
PNI High Systolic!!!	HIGH PRIORITY	Red	Diastolic pressure value is above the value set in alarm setting
NIP Low Diastolic!!!	HIGH PRIORITY	Red	Diastolic pressure value is below the value set in alarm setting

Table 8 – PNI Alarm Text Messages.

Capnography

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
High RPM!!!	HIGH PRIORITY	Red	RPM is above the value set in alarm setting
Low RPM!!!	HIGH PRIORITY	Red	RPM is below the value set in alarm setting
High CO2 Exp!!!	HIGH PRIORITY	Red	CO2 EXP is above the value set in alarm setting
Low CO2 Exp!!!	HIGH PRIORITY	Red	RPM is below the value set in alarm setting
High CO2 Insp!!!	HIGH PRIORITY	Red	CO2 INSP is above the value set in alarm setting
Apnea	HIGH PRIORITY	Red	Absence of RPM for an established period in alarm setting
No Sensor!!	MEDIUM PRIORITY	Yellow	Cannula is disconnected

Table 9 – Capnography Alarm Text Messages.

Pacemaker

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
Electrode Loose pacemaker!!	MEDIUM PRIORITY	Yellow	electrode is offline electrode is worn out Insufficient preparation of the patient's skin

Table 10 – Pacemaker Alarm Text Messages.

Informational message:

Pulse PM off - The deflagration of the pacemaker pulses is disconnected

Printer

Informational messages:

- Door Open (white) - The printer's paper compartment door is open.
- Out of Paper (white color) - Printer is out of paper.
- Printing...Menu Lock (white color) – During printing, it is not possible to enter the equipment's MENU.

SILENCE ALARM

To silence the equipment's alarms, simply press the silence alarms key  and all audible alarms will be silenced for 120 seconds.
The “Silence alarm” icon will appear on the equipment screen indicating that the alarms are silenced.
If a physiological alarm is initiated, for safety reasons, it will not be possible to change the previously set levels so that the alarm stops. As long as the situation does not return to normal, the change menu will remain disabled.
In case of an NIBP alarm, just press the NIP button once and the alarm will be considered as displayed and the beep will be inhibited.

SETTING ALARM LIMITS

The alarm limit configuration must be done in the menu of each parameter separately. To change the alarm limits, just select the parameter, through the equipment's navigation button, where the operator must adjust the desired value, pressing the navigation button again.

The VIVO Defibrillator Monitor maintains the previous alarm settings, in case of shutdown for a period of 30 seconds or less, after this time, the equipment automatically returns to the factory default settings to ensure safety in case of patient exchange.
When simultaneous messages occur, they will be managed by priority. High priority alarms are always primary. In case of messages of the same priority, there will be an interleaving between these messages.

Example: When an asystole high priority alarm occurs, the numeric value and bell icon flash. A message will appear indicating this alarm situation which cancels any other message within this parameter.
The equipment has alarm indicator LEDs located on the equipment panel. Yellow LED indicates low and medium priority alarms; Red LED indicates high priority alarms. If medium and high-priority alarms occur simultaneously, the equipment prioritizes the audible alarm and on-screen messages from the high-priority alarms.

⚠ **It is important to point out that the Defibrillator Monitor has a default configuration of alarm limits, but the operator must parameterize the alarms according to the patient at each use of the equipment.**

⚠ **Before starting the NORMAL USE of the equipment, make sure that the alarm adjustment ranges are within the values consistent with the common behavior of the patient.**

PROCEDURE FOR ALARM TESTS

LOW PRIORITY - ! and MEDIUM PRIORITY - II

With the device on and the sensor disconnected, check the indication on the screen of sensor disconnected. Once the visual indication is confirmed, correctly connect the sensor and check again. If the indication disappears, the alarm is working correctly. If not, change the sensor and repeat the operation. If the result is the same, the alarm is probably faulty.
Repeat this procedure for the other modules, remembering to test with their respective sensors and parameters.

HIGH PRIORITY - !!!

With the device turned on and the electrode properly connected, check the BPM value of the ECG parameter shown on the screen. Once this is done, press the Navigation Button for 3 seconds, position the indicator (in red) on the ECG module and select it by pressing this Navigation Button again once. Turn to alarm option (high or low), press the Navigation button once, and then vary its value until the initially measured value is out of range. Confirm by pressing the Navigation Button and press the EXIT button to return to the home screen. Once this is done, the alarm should go off. If no triggering occurs, this alarm is probably faulty.
Repeat this procedure for the other modules, remembering to test them with their respective sensors and parameters.

We recommend that the frequency of checking the functionality of the VIVO DEFIBRILLATOR MONITOR VIVO alarm system is carried out according to the table below or at the customer's discretion:

Verification Frequency	Indication
Quarterly	Advisable
Semiannual	Recommendable

Annual	Mandatory

Table 11 – Frequency of checking the alarm system.

RESTORING FACTORY SETTINGS

The Vivo Biphasic Defibrillator Monitor function to restore all the equipment's factory settings.

To restore the settings just enter the MENU - SETTINGS - REST. *CONF. FACTORY.* A confirmation request will appear on the screen to restore the equipment settings.

Figure 14 – Restoring factory settings.

The factory default settings are:

- ECG – Tachycardia: 180
- ECG – Bradycardia: 50
- Oximetry - SpO2 Max: 100
- Oximetry - SpO2 Min: 90
- Oximetry - PPM Max: 160
- Oximetry - PPM Min: 50
- NIP - Systolic: 140
- NIP - Mean: 100
- NIP - Diastolic: 60
- Capnography – High RPM: 150
- Capnography – Low RPM: 8
- Capnography – CO2 Exp. High: 150
- Capnography – CO2 Exp. Low: 15
- Capnography – CO2 Insp. High: 30
- Alarm volume - 5
- Info. volume – 2
- Key volume - 1

⚠ The operator must check the cause of all alarms presented by the equipment (technical and physiological). If the cause of the alarm is not identified or the operator does not know what action to take, immediately call a qualified professional for advice.

⚠ It is possible to view (by the operator) the alarms at a distance of 0.5 m from the equipment.

⚠There can be danger if different alarm presets are used for the same or similar equipment in the same area, such as an intensive care unit or operating room.

⚠ When power is lost for 30 seconds or less, the pre-loss alarm settings will be automatically restored.

⚠ When pressing the equipment's alarm inhibit key, the option to change the alarm levels of all parameters will remain disabled while the alarm inhibit time has not expired (2 minutes). This interlock guarantees that the operator will not change the alarm levels already set so that the equipment stops alarming.

6. POWER SUPPLY

The VIVO Defibrillator Monitor works with mains power or its internal batteries.
In the event of a power outage, the batteries power the equipment automatically, with no need for user interference.

MAINS POWER SUPPLY

When connected to the mains, the AC LED will remain on. The batteries will be in constant monitoring of the charge level and, if necessary, the equipment will automatically start their charge cycle.

POWER SUPPLY / BATTERY

The Vivo Biphasic Defibrillator Monitor has an internal sealed Lithium Polymer battery, with a capacity of up to 220 shocks (trips) with a load of 200J; 50 shocks (triggers) with a load of 360J or up to 4 hours of monitoring. It has an internal battery charger that performs all battery charge control automatically with a charging time of approximately 4 hours.
Optionally, to increase the shock capacity and monitoring time, it is also possible to use additional batteries or external power, as follows:

a) The equipment has a connector for powering ambulances and aircraft. On occasions where there is no power supply for prolonged periods of use, it is enough to connect the equipment to external power, thus preserving the equipment's battery for situations in which it is necessary to move the equipment to the place where the patient is.
Do not use the mains cable when the ambulance power cable is being used (optional accessory);
b) Easy-to-replace external (backup) batteries and a maximum charging time of approximately 4 hours.

Battery Charge Digital Status

On the equipment panel there is an indicator in the form of an LED as shown below:

- Connected to the mains: 

;
- Battery status (status) 

Charging: 

;
- Battery status (status) 

Discharged:

Battery Charge Level

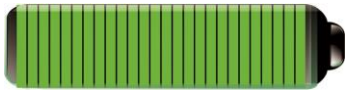
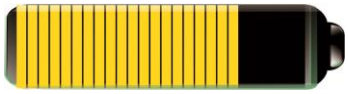
Battery indicator (display)	Battery level	Equipment Autonomy
	100% load	Approximately 4 hours of monitoring.
	80% load	Approximately 3 hours of monitoring.
	60% load	Approximately 2 hours of monitoring.
	40% load	Approximately 1 hour of monitoring.
	20% load	Approximately 20 Minute from monitoring.
	0% load	Equipment with 0 minutes monitoring.

Table 12 – Battery charge level.

⚠**Low battery: when reaching 20% of battery, the equipment will emit the following verbal alarm every 1 minute: *"Low Battery, recharge batteries".* After the low battery alarm has started, the equipment must be immediately connected to the mains or replaced by another with a charged battery.**
A high battery current is required to charge the capacitor, this can cause the battery to reach the equipment shutdown voltage level without low battery warning.

7. MONITORING

MONITORING SIGNAL THROUGH ECG CABLE

1. Connect the ECG cable to the Defibrillator Monitor;
2. Shave excess hair at the electrode application site. Avoid locating the electrodes over tendons and larger muscle masses;
3. Check the expiry date of the disposable ECG electrodes;

a. Apply the electrodes to the patient's chest;

b. Observing the correct position through the patient cable markings, position the electrodes on the chest as described below.

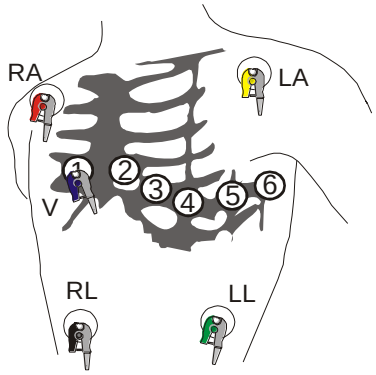


Figure 15 – Positioning of the ECG electrodes.

There are two color standards for ECG cables, the Vivo Biphasic Defibrillator Monitor uses the American standard. See 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
Chest	C - White	V - brown

Table 13 – Identification of the ECG electrodes.

ECG Menu Settings

In the ECG configuration menu, the user can configure the lead to be monitored, gain, velocity and alarms.

Figure 16 – ECG menu.

1. Lead – Defines the electrocardiogram lead to be shown on the display (CAL = calibration, D1, D2, D3, AVR, AVL, AVF, V);
2. 60Hz Filter - Enables (YES) or disables (NO) 60 Hz filter;
3. 35Hz Filter - Enables (YES) or disables (NO) 35 Hz filter;
4. Tachycardia – Defines the bpm value for triggering the tachycardia alarm (100 – 220);
5. Bradycardia – Defines the bpm value for triggering an alarm in bradycardia (25 – 60);
6. Speed – Selects the ECG sweep speed to 12.5, 25.0 or 50.0 mm/s;
7. Gain – Selects the ECG amplitude for N/2 (0.5cm), 1N (1.0cm) or 2N (2.0cm);
8. Beep - Enables (YES) or disables (NO) the synchronism beep with the QRS complex of the ECG signal;
9. Alarm - Enables (YES) or disables (NO) any ECG alarm;
10. Exit - Returns to the previous Menu;

SPO2 MONITORING

Operation

The operation of Masimo is based on the fact that the light absorption capacity, for different wavelengths, is different between oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin and blood plasma, and that the volume of arterial blood in the tissues is variable in relation to the pulse, also varying the absorption of light.
The Masimo Rainbow SET technology, through the optical sensor that uses 7+ different wavelengths, offers the measurement of both pulse oximetry parameters, such as oxygen saturation, pulse rate and perfusion index, as well as co-oximetry parameters, in this device there is saturation of methemoglobin. Its technology offers greater reliability in the measurement in cases of movement and low perfusion, in addition to enabling future updates, including new measurement parameters.

Information about the sensor

The Masimo sensor used must be compatible with the parameters found on the device. If the sensor only supports SpO2, dashes (- - -) will be displayed in the SpMet and SpCO parameter values. The sensor may take up to thirty seconds to display all values. Calibration of this device is neither necessary nor possible and a functional tester cannot be used to assess the accuracy of the meter or pulse oximeter system with a co-oximeter.

Using the Clip Sensor

To place the finger sensor on the patient, open the posterior fins of the sensor so that it does not rub the finger. If the indicator cannot be used for sensor connection, preferably use a small finger; do not use the thumb sensor. The sensor must be positioned so that its cable passes through the upper part of the hand (figure below). When selecting a sensor location, choose an end free from other devices such as: arterial catheter, blood pressure monitor, or intravascular infusion lines.

Figure 17 – Clip sensor.

When reading errors are found, the user must accommodate the patient in order to correct his posture and return blood circulation normally, thus being able to restore the quality of the signals.
In the presence of bright light sources such as direct sunlight, surgical lamps, infrared heating, cover the area where the sensor is placed with opaque material. This will minimize the possibility of ambient light interference, which can cause erroneous readings.
Avoid applying tape or tape over the reusable sensor. This reduces the risk of venous pulsation, erroneous saturation measurements and the possibility of pressure damage to the area. However, applying a tape over the cable can help prevent the sensor from slipping out of place.
Sensor expiry date: Indeterminate.

Use of the Y Type Sensor

The recommended sensor for infant/neonatal application is the Y-model. The fixation of this sensor is done by means of an adhesive tape around the foot; other sites may not provide acceptable results, due to incorrect perfusion or inadequate light. Make sure that the fixation tape is securely fastened, but not too tight, avoiding interference with blood flow, which can cause incorrect readings or skin damage. If the sensor is not positioned correctly (alignment between the emitter and the receiver), inaccuracies and instabilities in the reading and in the plethysmographic curve may occur. Prevent radiant light from radiotherapy equipment from reaching the tissue and interfering with the SpO2 measurement.
Patient foot movements can misalign the transceiver assembly (Y sensor) and result in inaccuracies in SpO2. Correct sensor placement is critical for good oximeter performance.

Important Features of the Y-Sensor:

The index finger is the ideal area for application, with the handle along the back of the hand. As alternative areas we recommend the thumb, or other finger, big toe, with the handle along the sole of the foot;
Change location between 2 to 4 hours;

Sensor expiry date: Indeterminate.

⚠ **When positioning the sensors, the physiological conditions of the patient must always be observed. Patients with burns that may exhibit greater sensitivity to heat and pressure should receive special care, such as changing the applied area of the sensor more frequently.**

⚠ **Do not use oximetry in continuous monitoring.**

Parameters

Four new parameters will be inserted: SIQ curve, perfusion index (PI), percentage of methemoglobin (SpMet), and percentage of carbon monoxide (SpCO). The SIQ curve will be below the plethysmographic curve. The PPM, PI, SpCO and SpMet values appear below the SpO2 value, on a smaller scale.

Signal IQ Curve (SIQ)

The SIQ curve is a visual indicator of the reliability of the plethysmographic curve data, and is directly related to the SpO2 and PPM data. The SIQ curve is located below the plethysmographic curve, and the quality of the signal is indicated as traces of variable height that coincide with the blood pulse, this variation being according to the quality of the signal. In situations of motion, low perfusion, or artifacts in the plethysmographic curve, the SIQ curve indicates to the clinician whether the oximeter data is reliable. Low SIQ value may indicate a problem with the patient or sensor situation.

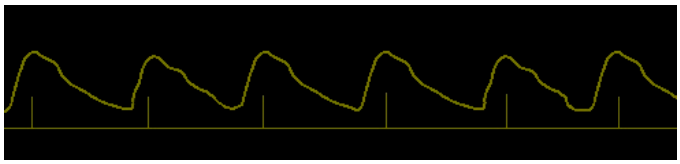


Figure 18 – IQ curve.

PI

The Perfusion Index (PI) is a value that indicates the signal strength of the arterial pulse through the percentage between the pulsating and non-pulsating signal. The PI assists the clinician in determining the optimal location for placement of the SpO2 sensor. This parameter is also useful as a troubleshooting tool helping a clinician to establish whether a questionable value is due to low perfusion and/or a low signal-to-noise condition.
High PI values reflect strong pulse signals, which facilitates more consistent measurements. Changes in perfusion can also be an indicator of important changes in the patient's physiological state.

SpMet

Methemoglobin is the oxidized form of hemoglobin, which in addition to not binding to oxygen, increases its affinity for the partially oxidized portion of hemoglobin. The increased concentration of methemoglobin in the blood is due to congenital alterations and exposure to various chemical agents, resulting in a picture with multiple differential diagnoses, which, if left untreated, can lead to death[1].
The SpMet module measures the percentage of methemoglobin saturation in the blood, assisting in

the clinical assessment of methemoglobinemia, facilitating early detection and prompt treatment and decreasing patient risks – especially in care areas where drugs likely to cause methemoglobinemia are more commonly used , such as procedure laboratories and operating rooms.

SpCO

Carbon monoxide poisoning is the most common form of poisoning in industrialized cities. This problem is sometimes misdiagnosed because its symptoms, when present, are common to flu symptoms.

SPO2 Masimo Setup Menu (optional)

The Oximetry menu consists of four other submenus, SpO2, PPM, PI, and SpMet, in addition to network frequency and alarm status settings. The mains frequency must be adjusted according to the frequency of the electrical network where the device will be used, and directly influences the efficiency of the sensor. The Alarm option enables or disables the audible alarm of the oximetry modules.

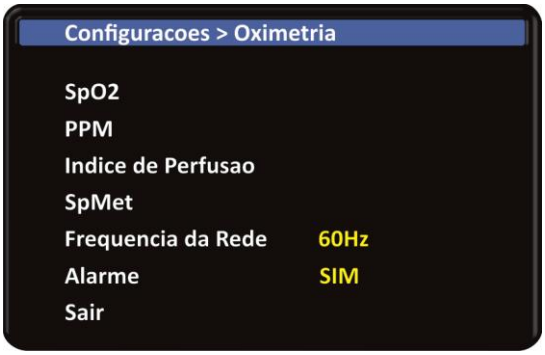


Figure 19 – Masimo SPO2 configuration menu.

Parameter	Value	Standard
Network frequency	50Hz - 60Hz	60 Hz
Alarm	YES - NO	YES

Table 14 - Basic Masimo SPO2 configuration.

Masimo SpO2 Menu

The SpO2 menu offers settings for maximum, minimum, sample averaging time, sensor algorithm sensitivity, plethysmographic curve gain, and audible alarm delay time.

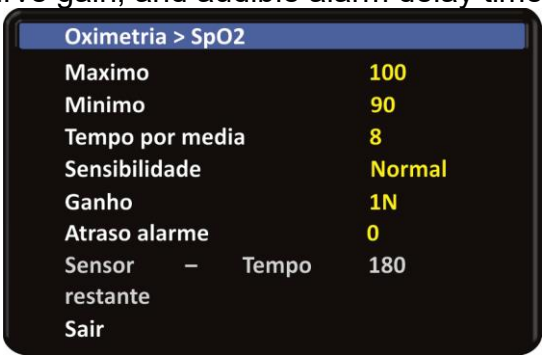


Figure 20 – Masimo SPO2 menu.

Parameter	Value	Standa	Step

		rd	
Maximum	40-100	100	1%
Minimum	40-100	90	
Time by average	2-4; 4-6; 8; 10; 12; 14; 16	8	
Sensitivity	Max-Normal-APOD	Normal	
Gain	N/4-N/2-1N-2N	1N	
Alarm delay	0-5-10-15	0	

Table 15 – Masimo SPO2 Alarm Settings Levels.

- Sample averaging time is the time used by the sensor to obtain information from the patient before averaging the values. The variation of this time influences the visibility of quick and sudden variations in the measured value. Depending on the patient's acuity and/or area of care, short times are preferred (sleep testing) over long times (neonates). The 8-second time is commonly used for most patients because it is short enough to detect sudden desaturations, and long enough to minimize changes in SpO2 due to rapid, transient desaturations.

- The sensitivity of the sensor algorithm allows adaptation of the measurement sensitivity to the patient's signal level and quality.

- NORMAL – Recommended for most patients, it has the best combination of measurement sensitivity and responsiveness in cases of unannounced sensor removal.

- MAXIMUM – Recommended for patients with weak signals (high interference from the environment or low perfusion) and for use during procedures or when contact between clinician and patient is continuous, such as in high acuity situations.

- APOD (Adaptive Probe Off Detection) – Less sensitive mode for patients with low perfusion, but greater responsiveness in cases of unannounced sensor removal. Prevents erroneous sensor readings when the sensor is disconnected from the patient. Recommended for cases where the patient is not accompanied by the clinician.

- The gain sets the magnification of the plethysmographic curve.

- The SpO2 audible alarm delay time sets the delay time of the audible alarm in relation to the indication of a new alarm. Many desaturations are real but transient, and therefore may not require clinician intervention. This option allows the clinician to minimize the audible alarm in cases where such desaturations exist.

- Sensor time remaining information is displayed when a compatible Masimo sensor is connected and its lifetime is 180 minutes or less. If it reaches the end of its useful life, the sensor will remain functional until it is disconnected from the patient for more than three minutes. If this happens, the information “Defective sensor” is displayed, and the sensor will no longer be accepted by the equipment.

Masimo PPM Menu

The PPM menu offers settings for maximum and minimum values and enable beep.(Only with Masimo Oximetry).

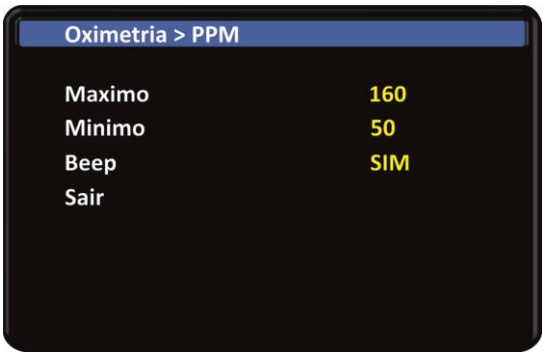


Figure 21 – Masimo PPM Menu.

Parameter	Value	Standard	Step
Maximum	40-240	160	1
Minimum	30-120	50	
Beep	Yes - No	Yes	

Table 16 – Masimo SPO2 PPM Alarm Setting Levels.

Masimo PI Menu

The Perfusion Index – PI – menu offers settings for maximum and minimum values. (Only with masimo oximetry).

Figure 22 – Masimo PI Menu.

Parameter	Value	Standard	Step
Maximum	0.04 – 20	19	Up to 0.1 – 0.01 0.1 to 1 – 0.1 After 1 – 1
Minimum	0.00 – 18	0.03	
Active	Yes - No	Yes	

Table 17 – Masimo SPO2 PI Alarm Setting Levels.

Masimo SpMet Menu

The Methemoglobin – SpMet – menu offers settings for maximum and minimum values. (Only with masimo oximetry).

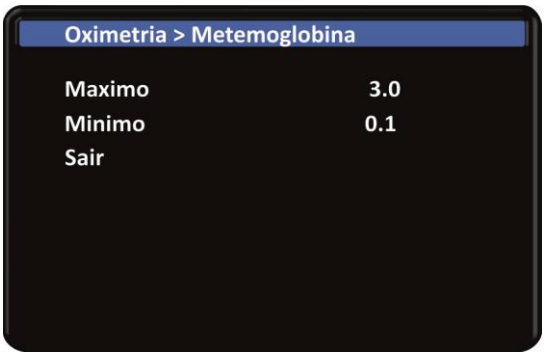


Figure 23 – Masimo SpMet Menu.

Parameter	Value	Standard	Step
Maximum	1.0 – 100	3.0	Up to 2.0 – 0.1 After 2.0 – 0.5
Minimum	0 – 99.0	0	
Active	Yes - No	Yes	

Table 18 – Masimo SPO2 SpMet Alarm Setting Levels.

Masimo SpCO Menu

The Carbon Monoxide – SpCO – menu offers settings for maximum and minimum values.

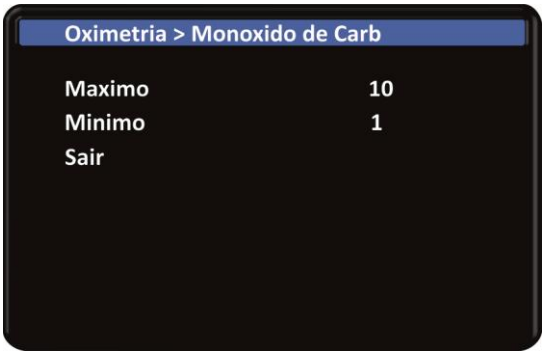


Figure 24 – Carbon Monoxide Menu

Parameter	Value	Standard	Step
Maximum	1 – 100	99	1
Minimum	0 – 98	0	
Active	Yes - No	Yes	

Table 19 – Masimo SPO2 SpCO Alarm Setting Levels.

Biolight Oximetry - Nellcor (optional)

If the model of the optional Oximetry parameter is Biolight (as illustrated in figure 4 – rear panel), the additional parameters described above will not be available (as they are exclusive to Masimo).

Biolight Oximetry provides plethysmographic curve and numerical oxygen saturation indication in percentage; plethysmographic waveform amplitude adjusted on the screen; it has a complete alarm system and auditory and visual indication of the SPO2 level, through the pulse signal tone; alarm and audible pulse indicator volumes are independently adjusted; adjustable audio-visual alarms: low and high SPO2 and low and high heart rate (bradycardia and tachycardia); pulse not detected alarms; sensor disconnected; looking for pulse; alarm silence key for 02 minutes; good response at low perfusions. The frequency measured by the equipment is approximately between 30 and 250 ppm, with a precision of 3%.

Pulse oximetry is used in situations where oxygen saturation (SPO2) is essential: in anesthesia, during surgery and postoperatively, patients in intensive care, in ambulances and even in homes. It features high efficiency with a sampling range of approximately 70 to 100% with a precision of 3%. The precision of the measured saturation is indeterminate when it is between 0% and 69%.

7.3 MONITORING NON-INVASIVE PRESSURE

1. Choose the appropriate cuff for the type of patient;
2. Connect the air hose to the cuff and equipment;
3. Place the cuff on the patient's arm as shown below;
4. Make sure the following ф mark on the cuff is positioned over the brachial artery;
5. The white line on the cuff must be within the range of "⇔", otherwise you will need to replace it with another suitable cuff (smaller or larger);
6. The cuff should be placed in the same plane as the heart, in order to avoid errors in readings caused by the hydrostatic effects of the column of blood between the heart and the cuff;

a. If the position of the cuff is higher than the plane of the heart, the measured BP reading tends to be lower; if the position of the cuff is lower than the plane of the heart, the measured BP reading tends to be higher.

When using the Automatic Mode function, for a time of less than 15 minutes between measurements, the equipment for safety measures automatically reconfigures itself to take measurements every 120 minutes, after the 15 minutes have elapsed.

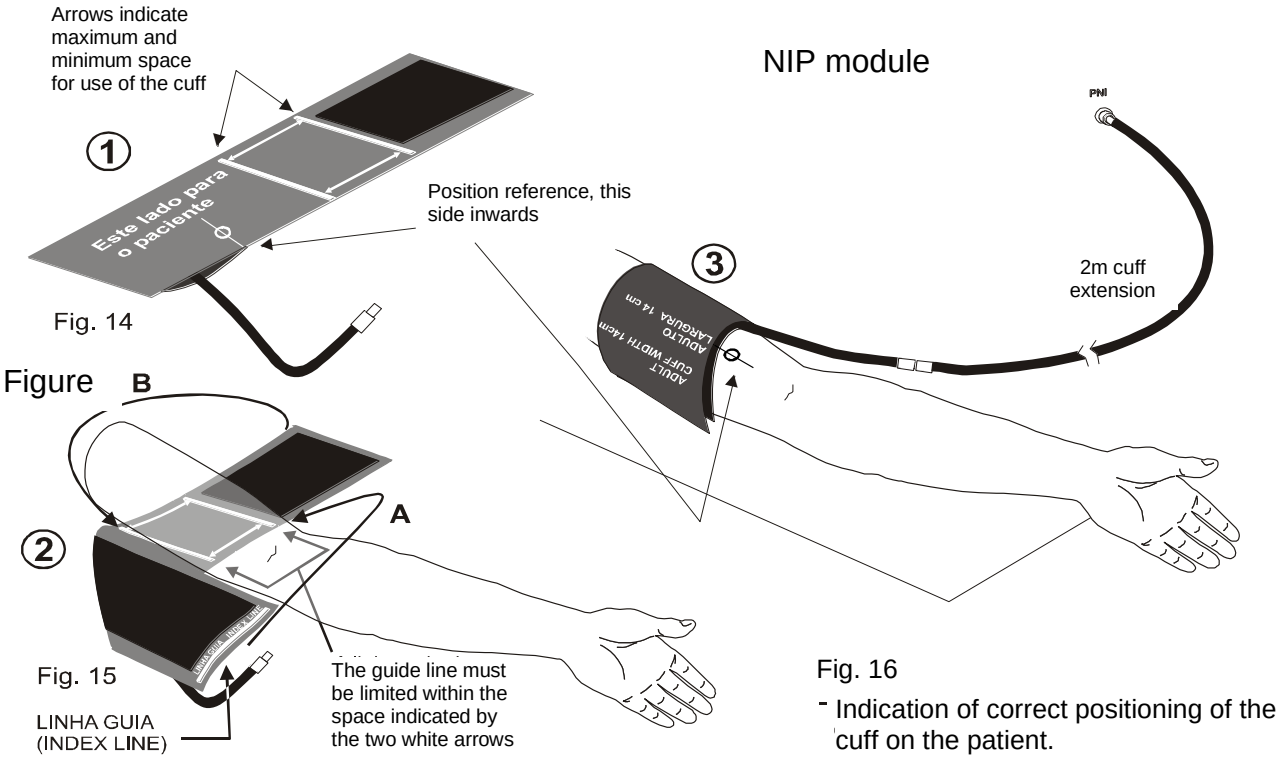


Figure 15 -Indication of correct positioning of the cuff on the patient

⚠ **The precision of the BP measurement depends on the suitability of the cuff. Select the cuff size according to the patient's arm size. The cuff width should be 40% of the arm circumference or 2/3 of the arm's length.**

⚠ **Do not perform NBP measurements on patients in any condition where skin is damaged or expected to be damaged.**

- ❖ **For a patient with thrombosis, it is important to determine whether the blood pressure measurement should be done automatically. The determination should be based on clinical evaluation;**
- ❖ **Prolonged non-invasive blood pressure measurements in automatic mode can be associated with blood pressure, ischemia and neuropathy in the limbs that are using the cuff. When Monitor a patient, examine limb extremities frequently, prepare for normal color and temperature and sensitivity. If any abnormality is observed, stop blood pressure measurements.**

⚠ **Do not use cuffs and/or hoses that have liquid inside, as there is a risk of damaging the equipment. If liquid infiltrates the equipment, immediately disconnect it from the electric mains, collect it and call a technician to check the equipment.**

⚠ **As a safety measure, the equipment has the default setting in child mode. If the patient is an adult, it is necessary to enter the NIP configuration menu and change to adult mode.**

⚠Do not compress or restrict the NIP cuff pressure tubes.

Features Non-Invasive Pressure (NIP)

Characteristics of Non-Invasive Pressure (NIP)

- Measured by oscillometric method in adult, pediatric, child and neonatal patients;
- Manual and automatic operating mode;
- Measurements of systolic, diastolic and mean blood pressure;
- Programmable interval to inflate the cuff;
- Automatic zero before each measurement;
- Alarm for minimum, average and maximum pressure;
- Validity of the NIP cuff: Indeterminate.

NIP configuration menu

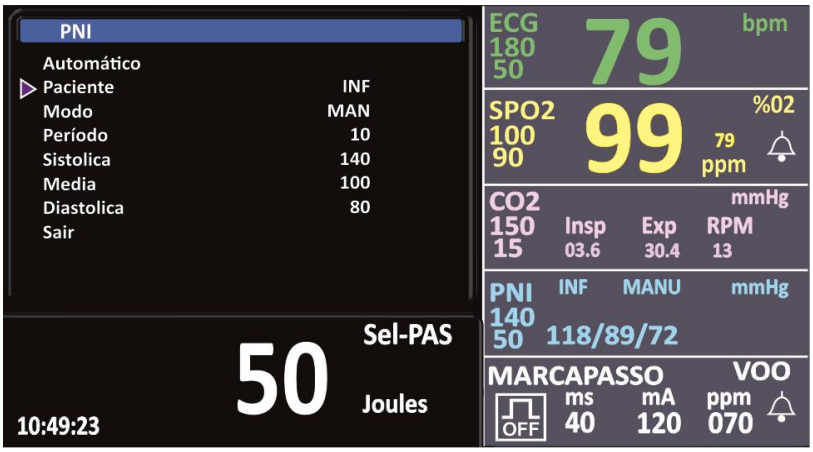


Figure 26 - NIP Menu

1. Automatic – Automatic measurement of pressure as determined by the period;
2. Patient – Select patient: Adult or Child;
3. Mode – Select measurement mode: Manual or Automatic;
4. Period – Defines the measurement time interval when automatic mode is selected;
5. Systolic – configures the systolic pressure for triggering the alarm (from 40 to 300 mmHg);
6. Mean – configures the mean pressure for triggering the alarm (from 40 to 300 mmHg);
7. Diastolic – configures the diastolic pressure for triggering the alarm (from 40 to 300 mmHg);
8. Returns to the previous Menu;

The Defibrillator Monitor has, on the front panel, a quick access key to start/suspend NIP measurements.

To start or suspend the measurement, just press the key  .

7.4 MONITORING CAPNOGRAPHY

The CO2 produced during cellular metabolism is transported by the venous system to the right atrium and ventricle, reaches the lungs and diffuses from the capillaries to the alveoli. From the alveoli, this gas is finally eliminated with the exhaled mixture. The amount of CO2 reaching the alveolar spaces is proportional to cardiac output and pulmonary blood flow. The elimination of this gas to the environment depends on the effectiveness of ventilation. Thus, the measurement of end-expiratory carbon dioxide (ETCO2) allows continuous and non-invasive monitoring of alveolar gas, indirectly reflecting its circulating levels.
Capnography is a non-invasive measurement, whose graphic presentation is performed as a function of the patient's respiratory rate (rpm) and involves the measurement of carbon dioxide exhaled at the end of expiration (EtCO) and the inspired value (FiCO).
CO2 detection can be done through two types of sensors Sidestream and Mainstream. Both sensors have a self-calibration system that eliminates the use of specific gases for periodic calibration.
Respironics Technology – MADE IN USA.

The capnography module uses miniaturized 'Sidestream' and 'Mainstream' sensors, with an optional self-calibration procedure that eliminates the use of specific gases for periodic calibration. Provides the user with the following parameters:

- Expired CO2 curve, shown continuously on the screen;
- Expired CO2 value;
- Inspired minimum of CO2;
- Respiratory rate value;

After connecting the sensor, it is necessary to wait a time of approximately 1 minute for the set to be ready for measurements. After this time, a light on the sensor should be observed, indicating its enable. Once connected to the respirator tube, we will have the patient information. The capnography sensor must be placed over the adapter to prevent condensation, if any, from interfering with the reading measurement.

Use of Capnography

The Vivo Biphasic Defibrillator Monitor can use both the nasal line and intubation for capnography. In case of using Capnography in intubated patients, one of the adapters as shown in the figures below should be used.
Capnography may be damaged due to reuse of the water filter. Follow the instructions for using the accessories supplied by the manufacturer. The water filter must be changed for each patient and/or according to the manufacturer's instructions for use.

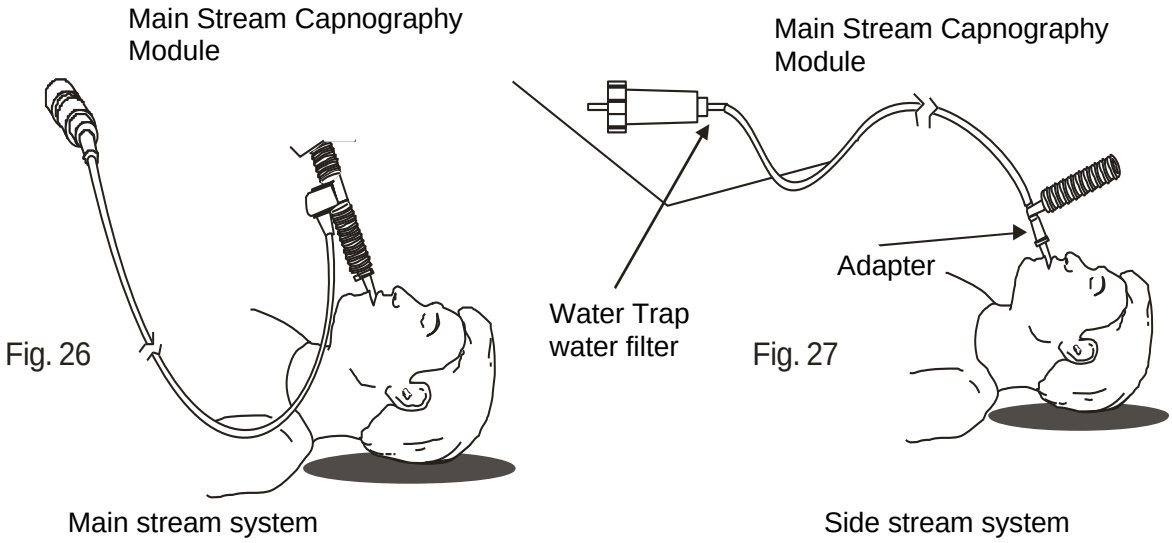


Figure 27 - Mainstream Assembly Layout

Features of the Capnography

- 'Sidestream' and 'Mainstream' sensors;
- Expired CO2 curve, shown continuously on the screen;
- Optional self-calibration procedure that eliminates the use of specific gases for periodic calibration;
- Exhaled C02 value, minimum inspired C02 value and respiratory rate value shown continuously on the screen;
- Miniaturized sensor with self calibration;
- Sidestream, Mainstream, or both option;
- Disposable water filter;
- Disposable nasal line;
- Disposable intubated line;
- Disposable tube adapter.

CAP (Capnography) configuration menu

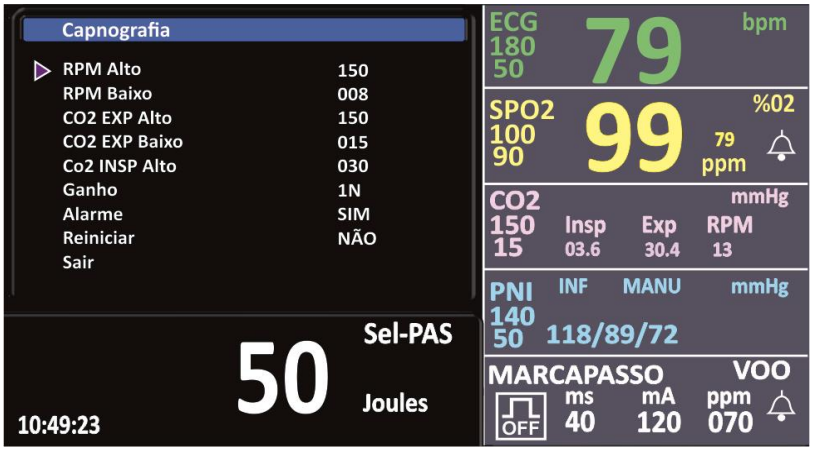


Figure 28 - Capnography Menu

1. High RMP – Respiration per minute alarm setting;
2. Low RMP – Respiration per minute alarm setting;
3. High CO2 Exp - Allows you to adjust the High Alarm range;
4. Low CO2 Exp - Allows you to adjust the Low Alarm range;
5. High CO2 Insp. - Allows you to adjust the High Alarm range;
6. Gain – The available gains are 0.5N to 2N;
7. Alarm – Enables (YES) or disables (NO) Capnography alarm;
8. Reset – Allows you to reset the capnography.
9. Exit - Returns to the previous Menu.

8. TREATMENTS

CARDIOVERSION

Cautions When Applying Defibrillation / Cardioversion

⚠**Before using the defibrillator, disconnect all patient equipment that does not have defibrillation protection.**

⚠**Do not place the pads directly on top of the ECG electrodes.**

⚠**Do not shock with short-circuited pads, as the triggering device may be damaged.**

In patients with a pacemaker, some care must be taken to avoid damage to the device and to the patient:

- **The energy applied must be as little as possible;**
- **Keep an external pacemaker close by;**
- **Check the pacemaker right after defibrillation;**
- **Maintain adequate distances between the patient's pacemaker generator and the shock pads;**
- **Protection against the effects of defibrillator discharge is present in the equipment's internal modules;**
- **Cables, electrodes, and accessories are not protected against burns caused by the use of high frequency equipment.**

Adapting Permanent Shock Pads

1. Check that the pads are connected to the Vivo Biphasic Defibrillator Monitor. If not, connect the cable to the input of the pads located on the back of the equipment;
2. Make sure the patient is not on a wet surface with conductive materials;
3. Remove hair from the places where the pads will be connected;
4. Put conductive gel on the shock pads;
5. Place the pads on the patient's chest as shown below.

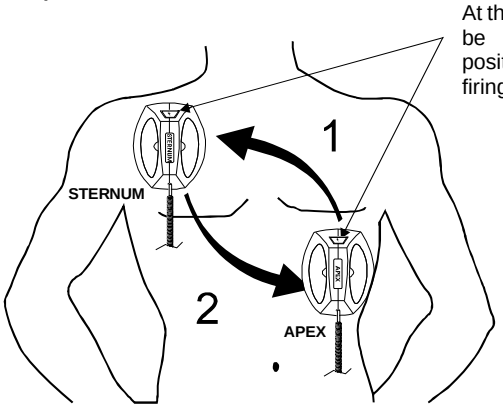


Figure 28 - Positioning of the shock pads at the time of the trigger.

6. Check the ECG signal on the equipment display;
7. Press the load button (Sternum), or the load key on the equipment panel; When charging is complete, the equipment will emit a beep indicating that the equipment is ready for triggering;

8. Move away from the patient and check that everyone has moved away;
9. To trigger, simultaneously press both buttons on the shock pads or the trigger key on the equipment panel. If the shot is not performed within 30 seconds, the charge will be automatically canceled;

If synchronized shock is required, simply press the Sync key. on the equipment's panel, the led above the key will light up, indicating that synchronism is enabled. Check that the led flashes at each detected QRS complex;

⚠To synchronize the discharge, the patient must be monitored only by the ECG cable or by the Defibrillator Monitor's shock pads. Never use other devices for synchronism.

Use of Child Pads

The Defibrillator Monitor has interchangeable shock pads. To use the child pads, just follow the instructions below.

1. Unscrew the base of the shock pads;

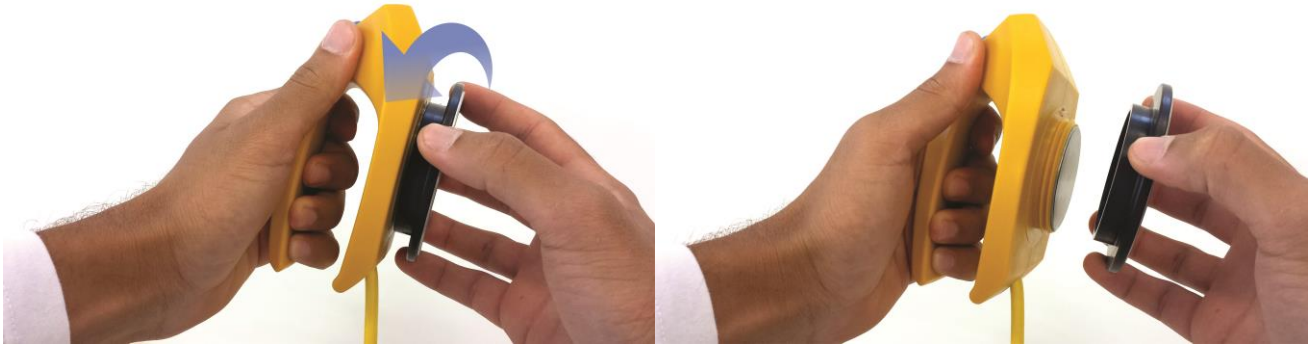


Figure 29 – Unscrewing the Shock Pad.

2. After removing the adult plate, the electrode with the smallest disc (infant) can be seen.

Figure 30 - Adult and Child Disc

The Defibrillator Monitor automatically identifies the child mode and limits the energy to up to 50 Joules.

Impedance Indicator

The equipment informs the quality of the contact of the pads with the patient's skin.
The contact indicator is used in the evaluation of:

- ❖ Proper placement of the shock pads on the patient;
- ❖ The quality and integrity of the shock PADS;
- ❖ The contact of the shock pads on the patient's skin;
- ❖ The correct connection of the shock PADS to the equipment;

⚠**The contact indicator is only shown on the display when using the ECG reading via the Shock PAD.**

The impedance indicator will indicate on the equipment screen:

- ❖ **Good Contact;**
- ❖ **Bad Contact;**
- ❖ **shorted pads**

In addition to the indicator on the equipment display, the STERNUM pad optionally has a bicolor patient contact indicator. This led assists in the orientation to position the pads at the moment of shock.

- ❖ Open pads off;
- ❖ Good contact green;
- ❖ Bad contact blinking red;

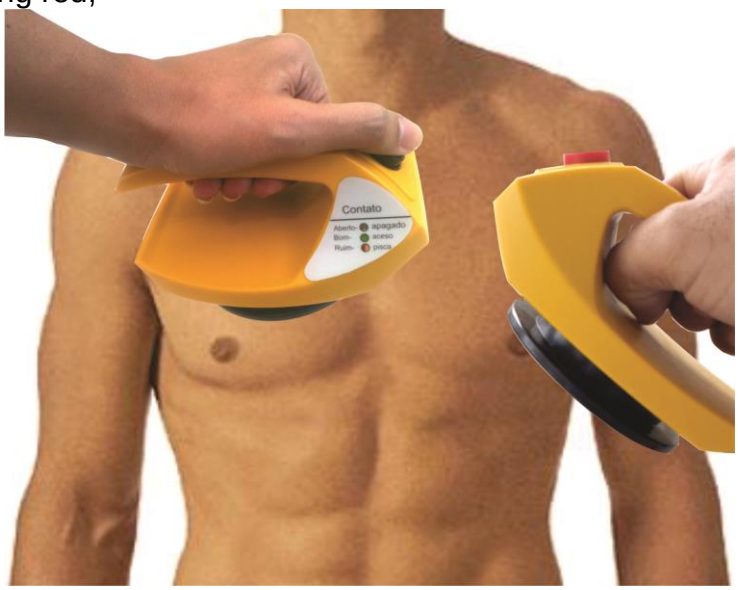


Figure 31 - Pad Contact Led

Delivered Energy Trigger Test

The VIVO Defibrillator Monitor is equipped with terminals for energy shooting tests, which are positioned close to the equipment's transport handle.

Figure 32 - Ttrigger Test Terminal

The User must select a load of 20 Joules. Key 1 - Selection, confirm the selection by pressing the Navigation Button (navigator); Press key 2 – Load, after emitting the sound signal that will identify that the load is ready for firing, execute the shock firing process with the pads placed over the terminals, applying a pressure of approximately 10 kg.
As soon as the trigger buttons are activated, the information that the shock was performed will appear on the screen (above the selected energy), confirming the good operation in the delivery of the load. This procedure can be performed daily as a form of preventive inspection.
This test is important as it guarantees that the selected energy will be delivered to the patient when used in real performance.

AED MODE

About Defibrillation

The heart has a system that produces and transmits impulses throughout the heart muscle, which in turn is responsible for contracting and pumping blood throughout the whole body. These impulses can be measured on the surface of the body, generating an electrocardiogram (ECG).
The analysis of an ECG signal allows the detection of electrical and mechanical problems in the heart. Cardiac arrhythmias can reflect disturbances in the initiation or conduction of impulses that, in the most severe cases, can manifest as Sudden Cardiac Arrest (SCA). During a PCS, there is a lack of adequate blood flow to the body and brain, which can quickly lead to death if not reversed. As a PCS rarely reverses spontaneously, the use of a defibrillator may be indicated to treat it. In this context, the application of a defibrillatory shock aims to restore the normal rhythm of the heart.
The most common arrhythmias that lead to Sudden Cardiac Arrest are Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). An Automated External Defibrillator (AED) is able to analyze a patient's ECG and recognize the presence or absence of VF and VT to indicate whether or not a shock should be delivered to the patient.
It is important to note that, according to the European Resuscitation Council (ERC), in its most recent Guide to Resuscitation [1], the use of an AED is only indicated in patients with Sudden Cardiac Arrest (SCA) who are unconscious and not breathe normally - therefore, the Vivo Biphasic Defibrillator Monitor in AED mode should only be used if the patient has such conditions.

Heart Rhythm Analyzer

The equipment in AED mode is capable of analyzing the patient's ECG and automatically identifying the presence or absence of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). According to the American Heart Association (AHA) [2] [3], VF and VT are the arrhythmias that should be treated with shock (shockable) by the AED. Thus, if the Rhythm Class, when evaluating the ECG of the patient in PCS, identifies the occurrence of a VF or a VT, the equipment will emit audible and visual signals of the indicated treatment, signaling that a shock must be administered to the patient.
During the analysis of the patient's ECG, the equipment will emit the audible and visual signal "Analyzing". During this period, for the analyzer to work correctly, the patient must not be touched, ensuring that the patient is still. At the end of the analysis, the Vivo Defibrillator Monitor in AED mode will indicate the treatment (shock) or not, by sound and visual messages on the display. If treatment is indicated, move away from the patient before pressing the treatment button. If AED mode does not indicate treatment, resume CPR.

Validation

The performance of the Rhythm Class algorithm was evaluated using defibrillator analyzers and ECG databases referenced worldwide, the MIT Arrhythmia Database [4, 5, 6] and the CU Arrhythmia Database [5, 7].
According to the American Heart Association [2] [3], the performance of the rhythm analyzer should be evaluated in terms of Sensitivity (Se) and Specificity (Sp):

$$Se = \frac{VP}{VP + FN}$$

$$Sp = \frac{VN}{VN + FP}$$

Where
FN: False Negative
FP: False Positive
VP: True Positive
VN: True Negative

The performance tests performed resulted in a sensitivity Se = 93.83% and specificity Sp = 95.01%, for the RO230704 evaluation group.
The patient's transthoracic impedance will be measured through the defibrillation electrodes. If the Baseline Impedance is greater than the maximum limiting value, the system will determine if the electrodes do not have adequate contact with the patient or have not been properly connected. As a result, ECG analysis and delivery of defibrillation shocks will be interrupted. The voice and text message on the display will instruct the user to place the electrodes on the patient's chest if electrode contact is not sufficient.

AED Mode Specifications

- ❖ Automatic ECG assessment system that detects QRS complexes and automatically identifies malignant arrhythmias (ventricular tachycardia and ventricular fibrillation) that require defibrillation;
- ❖ Impedance measurement to adjust phase 1 and 2 of the biphasic wave, not allowing tripping with open or short-circuited pads;
- ❖ It has voice and text command to instruct the rescuer during the resuscitation sequence;

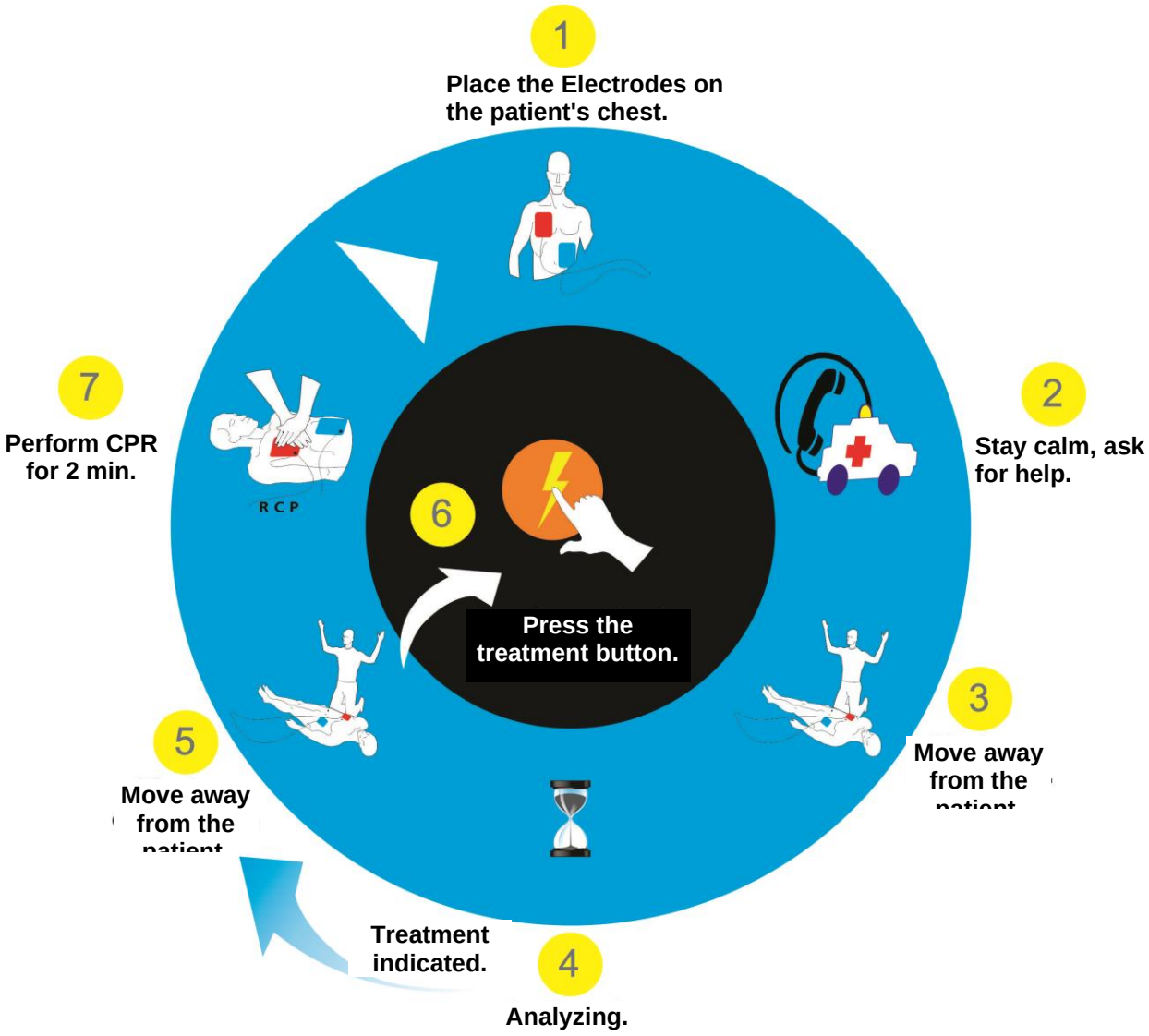
Using AED Mode

When the AED MODE is activated, the equipment performs the functions of an automatic external defibrillator with text and voice commands through the key DEA to instruct the rescuer during the resuscitation procedure.
To exit the AED MODE, simply press the AED key on the equipment panel again.

⚠While the device is in AED Mode, the other device parameters will not be displayed on the screen.

The VIVO Defibrillator Monitor has an AED mode operating sequence, as illustrated below.

Indicated treatment sequence



Sequence for non-indicated treatment

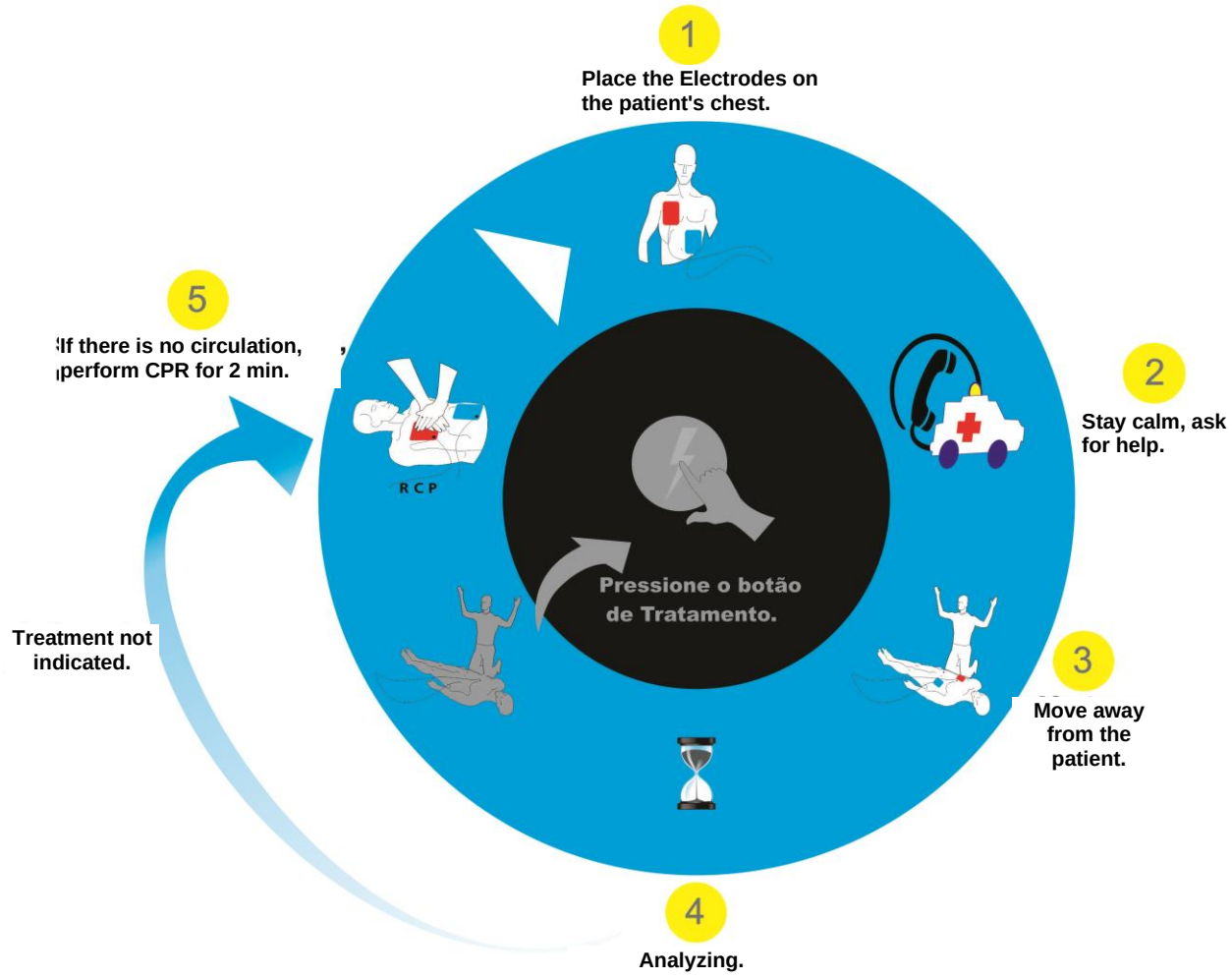


Figure 33 – Resuscitation procedure in cases of non-indicated treatment

---

Place the electrodes on the patient's chest.
Stay calm, ask for help.

The equipment automatically starts the sequence of commands and only proceeds to the next command when the user executes the procedure.
Before starting the procedure, call the emergency service.

To attach electrodes to the patient's chest, the rescuer must:

1. Check the expiry date of the pads;
2. Open the package and remove the electrodes;
3. Connect the electrodes to the equipment, as shown in the following figure;
4. Open the patient's shirt for quick access to the chest;
5. Check this if the skin is dry;

6. If there is a large amount of hair, perform shaving (shaving the hair) for better contact of the electrodes with the patient's chest;
7. Fix the electrodes on the patient's chest according to the indication of the pads (following figure);

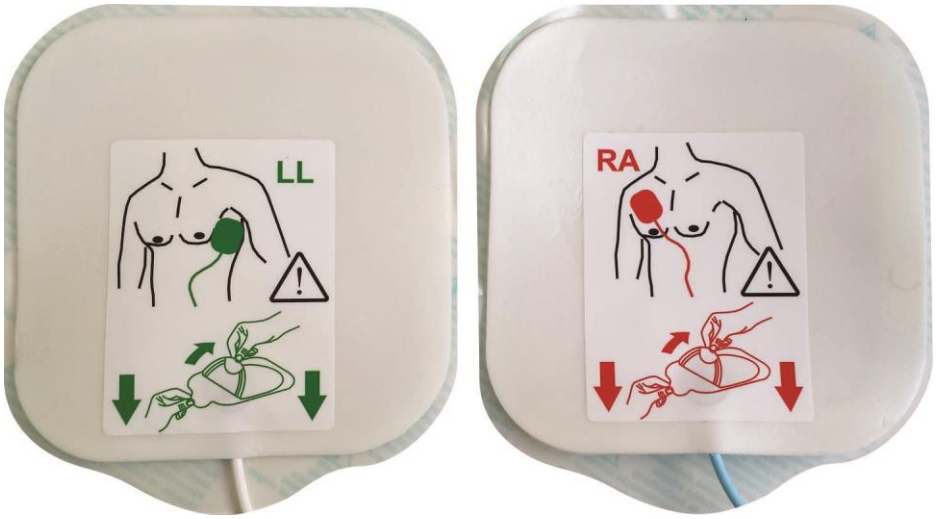


Figure 34 – Indication of the position of the electrodes on the paient's chest

As per the 2015 AHA Guidelines, the electrodes can be fixed in the anteroposterior, anteroleft infrascapular and anteroright infrascapular position with the same efficiency.

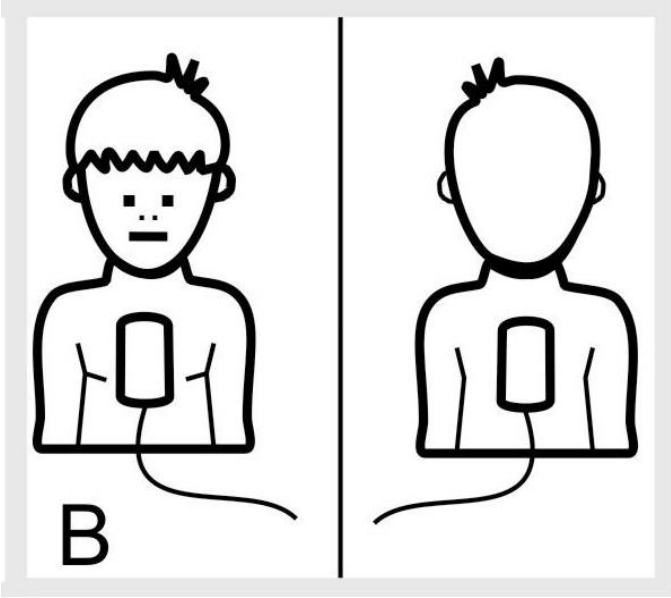


Figure 35 – Position of electrodes on children

⚠ The user must pay attention to replace a new pair of transthoracic adhesive electrodes after use, so that the equipment is always ready for another emergency;

⚠ The expiry date of the electrodes must be checked in order to ensure prompt and rapid service. If the electrodes are expired, replace them immediately.

⚠ **Disposable electrodes are Single Use, therefore they must not be resterilized;**

⚠ **Do not use disposable electrodes if their packaging is damaged.**

3 **Move away from the patient.**

Make sure the patient is still and everyone should move away from the patient to avoid reading errors.

4 **Analyzing.**

The equipment will analyze the ECG signal according to the pre-programmed algorithms and will determine whether the treatment is indicated (TV/FV) or not.

For indicated treatment:

5 **Move away from the patient.**

Everyone should move away from the patient for shock delivery.
At this time the shock capacitor will be charged. There is no risk of electric shock, as the equipment has protection relays that only enable energy delivery when the rescuer presses the treatment button.

6 **Press the treatment button.**

By pressing the treatment button, energy will be delivered to the patient.

⚠ **Do not touch the patient or any accessory connected to the patient during defibrillation.**

⚠ **Keep the patient away from conductive and/or wet surfaces and dry the patient's chest if necessary, before using the equipment.**

⚠ **If there is no triggering (Treatment button) within 30 seconds, the shock capacitor will automatically discharge and the equipment will restart the analysis of the ECG signal.**

⚠ **Risk of burning the patient's skin when applying defibrillation.**

After the trigger, the icon ⚡1 with the amount of shocks delivered to the patient will be indicated on the display during the treatment.

7 **Perform CPR for 2 minutes.**

The equipment has a metronome with the CPR beep to guide compressions (100 compressions per minute).

After 2 minutes, the AED automatically restarts ECG rhythm analysis.

For non-indicated treatment:

5 **If there is no circulation, perform CPR for 2 minutes.**

In cases of non-indicated treatment, it is necessary for the rescuer to check again for circulation and, only if there is no circulation, CPR should be performed for 2 minutes.

PACEMAKER

The external pacemaker is composed of a control unit based on a microcontroller capable of detecting the QRS and generating electrical pulses with sufficient amplitude, frequency and width to stimulate the heart.

As these are pulses for non-invasive transthoracic stimulation, the Pacemaker of Vivo Biphasic Defibrillator Monitor delivers stimuli to the patient ranging from 30 to 200 pulses per minute, in asynchronous mode. The frequency, amplitude and width of the pulses can be programmed in order to obtain reliable stimulation with minimal energy delivered, in order to minimize patient discomfort.

Applications

The non-invasive pacemaker is appropriate in both pre-hospital and hospital settings. Some transthoracic applications where continuity is indicated are:

- Treatment of symptomatic bradycardia during an emergency.
- During and after heart surgery.
- To facilitate implantation of an intravenous stimulator electrode.

The procedure described is recommended for supportive pacing in a patient with bradysystole (absence of intrinsic rhythm). In case of bradycardia support, care must be taken to ensure that the stimulation frequency is higher than the patient's own rhythm and that the patient's QRS capture is reliable. There is a risk of inducing ventricular fibrillation if the pacing pulse happens during the T wave ascension period.

In order to obtain a reliable QRS capture, the operator will have to modify the amplitude and width of the pulses to smaller levels, in order to:

- ❖ Reduce the energy delivered to the patient, prolonging the battery life of the equipment;
- ❖ Look for parameter values that cause less discomfort to the patient, in case he is conscious.

Operating Modes

The Pacemaker has three modes of operation:

1. VOO;
2. VVI;
3. Emergency.

- ❖ In VOO mode the pacemaker continuously stimulates the patient.
- ❖ In VVI mode, stimulation will only occur when the patient's natural rate is below that selected by the operator.
- ❖ Emergency - Regardless of the operating mode in which the pacemaker is, when pressing the EMERGENCY key the pacemaker switches to VOO mode, and assumes the following parameters: 70 ppm, 150 mA, 40 ms.

⚠ **When pressing the emergency key, the following message will appear on the screen: *"This operation will start the VOO mode of the pacemaker. Press the MENU button to confirm or any other key to cancel."***

Adjusting Pacemaker Pads

1. Inspect the shock pads cable and check for loosening of connections and other wear and tear;
2. Check the expiry date of the shock pads;
3. Connect the cable of the adhesive shock pads to the equipment's Pacemaker input;

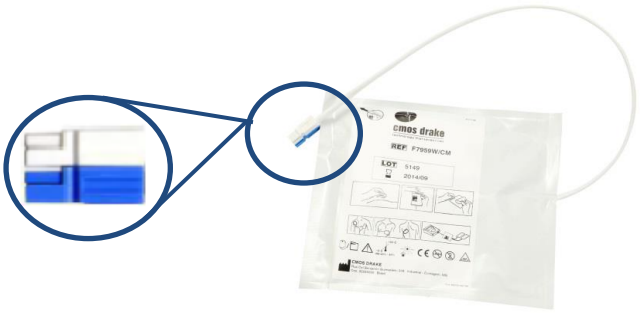


Figure 34 - Pacemaker Connector

4. Place the shock pads on the patient;

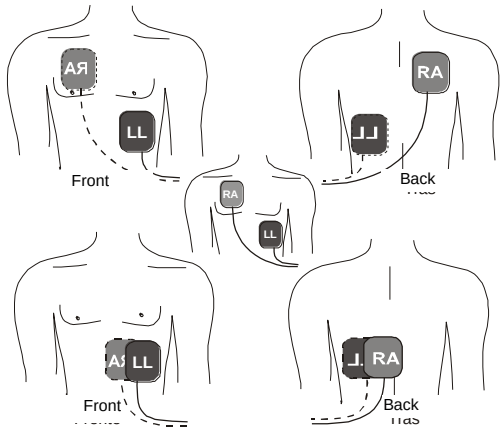


Figure 35 - Variations in the positioning of the PAD's of the pacemaker on the patient

Stimulation electrodes must be positioned so as not to interfere with possible defibrillation. Typically, non-invasive pacing is performed in either the Apex/Anterior or the Anterior/Posterior configuration. However, the Anterior/Posterior configuration is recommended to facilitate a possible defibrillation procedure.

Pacemaker Features

- Stimulation current: No load connected: 200 mA; Off: 0 mA;
- Power supply: 12V;
- ECG capture by the adhesive pads themselves;
- Stimulation output through the adhesive pads;
- Stimulation frequency: 30 ppm to 200 ppm for every 1 ppm;
- Pulse Amplitude: 05 mA to 200 mA of 1 in 1 mA;
- Pulse width: 05ms to 50ms of every 1ms;
- Emergency: 70 ppm, 150 mA, 40 ms.
- Other specifications can be configured at the user's discretion.

⚠**In case of bradycardia support, it must be ensured that the pacing rate is higher than the patient's own rhythm, and that the detection is reliable;**

⚠**In VVI mode, the region where the pacemaker electrodes are fixed must be checked, since, as it is external and has negative voltage, the stimulation can produce polarizations that change the voltage in the common mode, compromising the normal detection of heartbeats;**

⚠**This equipment must only be operated by qualified technical personnel;**

Sources of electrical interference can affect pacemaker operation. In the presence of excessive levels of interference, the EQUIPMENT may:

- **Fail to stimulate;**
- **Revert to asynchronous simulation, or inappropriately interpret interference as cardiac activity;**

⚠**Prolonged use of the pacemaker can cause the patient's skin to burn.**

⚠**In cases of doubts a supplementary monitoring of the patient should be considered.**

⚠**After using the pads, dispose of them following the procedure for disposing of medical waste and contact CMOSDRAKE or authorized personnel for the purchase of new shock pads.**

⚠**Reuse of disposable pads can cause patient burns and incorrect reading of the ECG signal.**

⚠**CMOSDRAKE is not responsible for the reuse of disposable accessories;**

⚠**In case of cable or conductor breakage, avoid using them, under penalty of risk to the operator.**

Pacemaker configuration menu

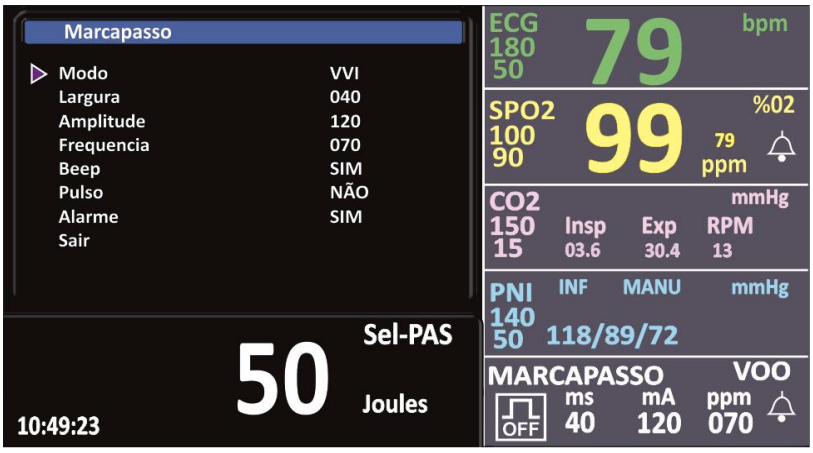


Figure 36 - Pacemaker Menu

1. Mode – Selects the Pacemaker (MP) operating mode for the following modes:

- ❖ VOO: The PM sends pulses according to the configured parameters regardless of any ECG signal detected in the patient;
- ❖ VVI: The PM sends pulses according to the configured parameters only if the signal detected in the patient is outside the range of these parameters.

2. Width – Sets the pulse width from 5 to 50 ms;
3. Amplitude - Sets the pulse amplitude from 5 to 200 ms;
4. Frequency - Sets the pulse rate from 30 to 200 ppm (pulses per minute);
5. Beep - Enables (YES) or disables (NO) the pulse beep;
6. Pulse - Enables (YES) or disables (NO) the sending of pulse from the PM;
7. Exit - Returns to the previous Menu;
8. Alarm – Enables (YES) or disables (NO) the pacemaker alarm;
9. Exit - Returns to the previous Menu.

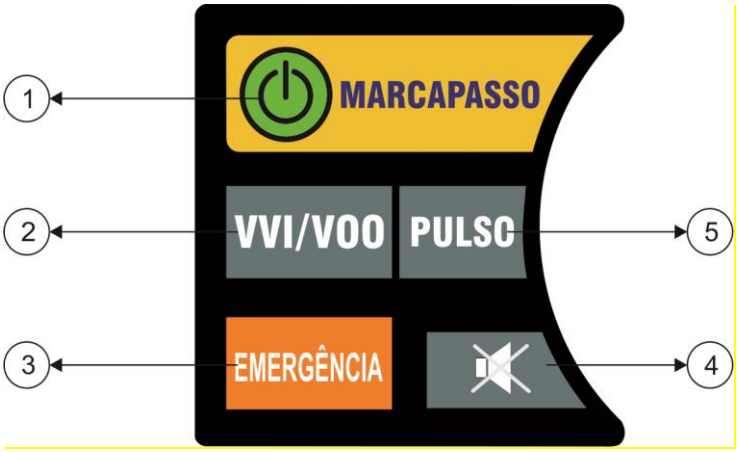


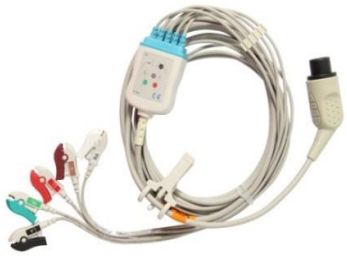
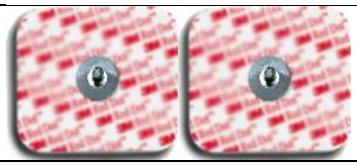
Figure 37 - Pacemaker Command Panel

The Pacemaker is a separate parameter from the others used in the Defibrillator Monitor. To use it, just press the on/off button located on the front panel of the equipment or press the emergency button. In addition to the configuration through the menu, the pacemaker has some quick access keys for configuration:

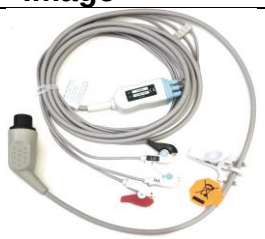
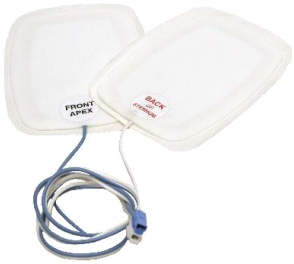
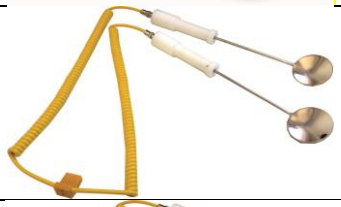
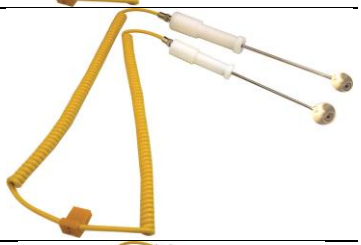
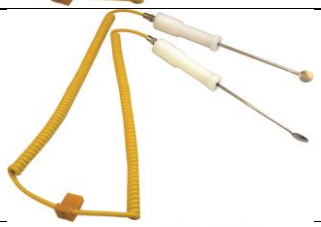
1. On–Off – Enables or disables the Pacemaker function;
2. MODE (Sync or Asynch) – Switches between VOO and VVI modes;
3. EMERGENCY – Changes the Pacemaker setting to Emergency Mode (VOO, 70 ppm, 150 mA, 40 ms);
4. Inhibit Beep – Enables or disables the Beep synchronized with the Pacemaker pulses;
5. Inhibit Pulse – Enables or disables the triggering of Pacemaker pulses.

9. DESCRIPTION OF ACCESSORIES

Basic Accessories

Description	Code / Ref	Supplier	Image
TRIPOLAR POWER CABLE	LT7031 / 021	ITALCABOS ITALFLEX ECA ELCOA	
ADULT / CHILD PERMANEN SHOCK PADS	LT27275	CMOSDRAKE exclusively	
5-WAY ECG CABLE	LT649 / 2540 RP	CMOSDRAKE/ Unimed Medical Suplies	
DISPOSABLE ELECTRODES	661/ SF10	CMOSDRAKE Kendall Medi Trace 200 Harbo Medical	
CONDUCTIVE GEL	4861 / GEL FOR ECG	CMOSDRAKE Suprimed Gel In Shape Carbogel	

Accessories Parameters (Optional)

Parameter	Description	Code / Ref	Manufacturer	Image
ECG	3-WAY ECG CABLE	LT650 / 2541 RP	CMOSDRAKE exclusively	
AED MODE PACEMAKER	DISPOSABLE ADHESIVE SHOCK PADS - **ADULT**	8289/ F7959W/CM	CMOSDRAKE/ FIAB	
		LT72471/ OBS-DE/M	CMOSDRAKE/ OBS	
	DISPOSABLE ADHESIVE SHOCK PADS - **CHILD**	8295/ F7959P/CM	CMOSDRAKE/ FIAB	
		LT72488/ OBS	CMOSDRAKE/ OBS	
INTERNAL PERMANENT SHOCK PADS.	INTERNAL PERMANENT SHOCK PADS - ADULT	P320	CMOSDRAKE exclusively	
	INTERNAL PERMANENT SHOCK PADS - CHILD	P336	CMOSDRAKE exclusively	
	INTERNAL PERMANENT SHOCK PADS - NEONATAL	P342	CMOSDRAKE exclusively	
NIP.	NIP CUFF -SIZES NEONATAL, CHILD, ADULT AND OBESE.	1005 / 1882 SSNL 4305 / 1881 SSNL 12671 / 1880 SSNL	BAUMANOMETER/MEDIKALL/ PAR MEDIZINTEC	

CAPNOGRAPHY	ADULT / CHILD NASAL CANNULA	26873 26867 / 3468ADU-00	Distribuidores RESPIRONICS	
	CAPNOGRAPHY TUBE ADAPTER	34371	Distribuidores RESPIRONICS	
MASIMO RAINBOW SET	ADULT SENSOR - CLIP TYPE: SpO2, SpCO, SpMet Weight > 30Kg.	LT32922/ DCI-DC3 2407	CMOSDRAKE/ Masimo	
		LT70437/ DCI-DC12, 2054 – SS-009RB-AF30	CMOSDRAKE/ Orantech INC	
	CHILD SENSOR - CLIP TYPE: SpO2, SpCO, SpMet Weight 10kg - 50kg	LT36015/ DCIP-DC12 2070	CMOSDRAKE/ Masimo	
		LT70443/ DCIP-DC12, 2257 – SS-009RB-PF30	CMOSDRAKE/ Orantech INC	
	ADULT DISPOSABLE SENSOR: SpO2, SpCO, SpMet. Weight > 30Kg.	LT36021/ R25 2221	CMOSDRAKE/ Masimo	
	CHILD DISPOSABLE SENSOR: SpO2, SpCO, SpMet Weight 3kg - 30kg	LT36051/ R20L2220	CMOSDRAKE/ Masimo	
		LT70450/ SS-009RB-MY30	CMOSDRAKE/ Orantech INC	

	ADULT / NEONATAL DISPOSABLE SENSOR: SpO2, SpCO, SpMet Weight < 3kg OR > 30kg	LT36038/ R25L 2219	CMOSDRAKE/ Masimo	
	EXTENSOR CABLE FOR MASIMO DISPOSABLE SENSORS.	LT36044/ RC-12 2404	CMOSDRAKE/ Masimo	
BIOLIGHT-NELLCOR OXIMETRY	CLIP TYPE OXIMETRY SENSOR (ADULT)	LT218/ U410-62D A0212-SA125PU XY-5	CMOSDRAKE/ Biolight - Nellcor	
		LT72460/ SS-067D-AF30	CMOSDRAKE/ Orantech INC	
	SOFT TYPE (CHILD) OXIMETRY SENSOR	LT247/ U210-62D A0212-SP125PU XY-4	CMOSDRAKE/ Biolight - Nellcor	
	Y TYPE OXIMETRY SENSOR	LT231/ U810-62D A0212-SW125PU XY-7	CMOSDRAKE/ Biolight - Nellcor	
		LT72465/ SS-067D-MY30	CMOSDRAKE/ Orantech INC	
BAG	TRANSPORT BAG	1838	CMOSDRAKE exclusively	

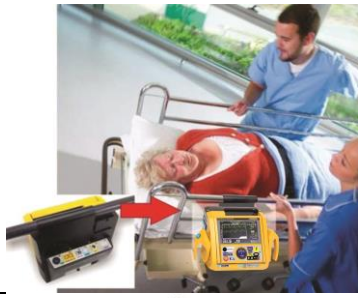
SUPPORT	SUPPORT FOR STRETCHER	33927	CMOSDRAKE exclusively	
SUPPORT	MOBILE ICU SUPPORT	31756	CMOSDRAKE exclusively	
PRINTER	PRINTING BOBBIN	490	CMOSDRAKE/ Daru	
POWER SUPPLY CABLE	EXTERNAL POWER SUPPLY CABLE	33324	CMOSDRAKE exclusively	
USB CABLE	EXTENSOR CABLE USB A/B - SHIELDED FOR DATA TRANSFER.	35375	Cmos Drake / Computer Store	
PHOENIX SOFTWARE	PHOENIX SOFTWARE IN CD.	35369	Cmos Drake exclusively	

Table 20 – List of accessories.

⚠ **All accessories must be stored in a ventilated place, free from moisture and dust;**

⚠ **Before putting the equipment in contact with the patient, the operator must regularly check that it is in working;**

⚠ **Use only the accessories, consumables and others listed in this manual. CMOS DRAKE does not guarantee the proper functioning of the equipment with the use of unknown accessories, in addition to not being responsible for failures in the operation of the equipment or possible damages caused by them;**

⚠ **In general, parts of equipment and accessories intended to come into contact with biological tissues are tested and analyzed in accordance with the guidelines of ISO 10993-1, which deals with biocompatibility assays;**

⚠ **Cmos Drake guarantees that all permanent and disposable materials in contact with the patient do not cause any type of damage or harmful physiological effect, provided that: the procedures described in this manual are followed; that they are installed in an appropriate medical place; that it is used with the correct accessories; be operated by trained personnel and that all precautions described in this User's Manual are followed.**

10. CLEANING

Carry out the cleaning of the Defibrillator Monitor after each use. If it has not been used, it is recommended that cleaning be carried out quarterly. Follow the instructions below:

- Disconnect the appliance from the mains supply before cleaning.
- Cleaning and disinfection of the cabinet should be done with a cloth slightly moistened with alcohol. Do not use cleaning agents with organic solvents, chlorine, alcohol or hydrocarbon solvents. To prevent scratching the display, carefully wipe with a dry flannel or, in case of dirt, a cloth slightly dampened with water, and remove dust or particles of dirt.
- The labels present on the equipment and its accessories are important, and therefore must not be removed or damaged.
- Cleaning and disinfection of permanent cables must be carried out after each use of the equipment. This cleaning is done with a cloth slightly dampened in demineralized water and neutral liquid soap and another cloth slightly soft and dampened in demineralized water. Once dry, disinfect them using a gauze moistened with 70% ethyl alcohol.
- After using disposable electrodes and accessories, discard them in appropriate places according to special procedures for hospital waste.
- To clean the capnography sensor after use, use a tissue moistened with demineralized water with a small amount of neutral liquid soap and for disinfection, use a gauze moistened with isopropyl alcohol.
- The tubing, water filter (Side-etream water-trap), Main-stream sensor adapter and micelles are considered disposable, must not be reused and must be disposed of in hospital waste according to each hospital's procedure.
- The cleaning and disinfection of the NIBP cuff must be done with each use of the equipment. This cleaning is done with a cloth slightly dampened in demineralized water and neutral liquid soap and another cloth slightly soft and dampened in demineralized water. Once dry, disinfect it using a gauze moistened with 70% ethyl alcohol.
- After using the permanent shock pads, remove the conductive gel from the surface of the pads with a paper towel; clean the shock pads with a clean cloth dampened with 70% ethyl alcohol. If infant mode pads were used, perform the same procedure and then re-attach the adult pads to the shock pads.

- For cleaning of the internal pads using an autoclave:

    1. Remove the handle cables of the shock pads; Wipe them with a clean cloth dampened with 70% ethyl alcohol;

    2. Do not use a brush on the internal pads;

    3. Individually protect the internal pads before and after sterilizing them, to avoid any damage to their surface;

    4. Examine pads, cables, and connector for damage or signs of wear (loose cable connections, exposed wires, and cable connection corrosion);

5. Examine the electrodes for scratches, holes, or cracks, or if the electrode surfaces are blistered. If any of these situations occur, immediately remove the affected component from use;

6. Place the pads (without the cables) in the autoclave with pressure (1.1 Kgf) and temperature (121° C) for 30 minutes.

❖ For cleaning of the internal pads using Ethylene Oxide:

1. Remove the handle cables of the shock pads; Wipe them with a clean cloth dampened with 70% ethyl alcohol;

2. Do not use a brush on the internal pads;

3. Individually protect the internal pads before and after sterilizing them, to avoid any damage to their surface;

4. Examine pads, cables, and connector for damage or signs of wear (loose cable connections, exposed wires, and cable connection corrosion);

5. Examine the electrodes for scratches, holes, or cracks, or if the electrode surfaces are blistered. If any of these situations occur, immediately remove the affected component from use;

Sterilization method	**Adult Internal shock pads (code P320)**	**Child Internal shock pads (code P336)**	**Neonatal Internal shock pads (code P342)**
Ethylene Oxide	25 cycles	25 cycles	25 cycles

Cmos Drake has approved the cold sterilization method using the following specifications:

Ethylene Oxide Concentration: 30%
Temperature: 50°C ± 10°C
Humidity: 30% to 90%
Exposure time: 180 min

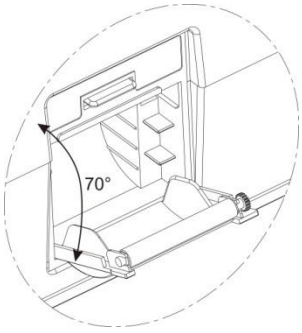
⚠ **The instructions provided above have been validated by the accessory manufacturer as being able to prepare the medical equipment for reuse. It remains the processor's responsibility to ensure that the processing, regardless of the equipment, material and personnel used to carry it out in the processing facilities, achieves the expected result. This requires routine process validation and monitoring. Likewise, any deviation by the processor from the instructions provided must be properly evaluated for effectiveness and potential adverse consequences.**

11. SETTINGS OPTIONS

INSERTING THERMAL PAPER INTO THE PRINTER

Use appropriate heat-sensitive paper that is readily available at medical, hospital and surgical supply stores or directly from CMOS DRAKE. In this way, a clear impression is guaranteed by the equipment.
It should be noted that thermal papers have great variation in sensitivity and abrasiveness, therefore, it is possible that there is a difference in the shades of the tracing during printing, according to the different manufacturer or batch.

Instructions for Loading Thermal Paper in the TR-50 or SP-48 Printer



1 - Press the cover latch;
2 - Move the cover until it is positioned at 70º;
3 - Insert the paper roll into the clip with the print side facing up;
4 - Drag the paper out centering it in the direction of the figure;
5 - Lift the printer cover in the opposite direction to the one in the figure without locking it;

6 - Adjust the printing paper again so that it is centered with the printer as shown in figure 39;
7 - After the paper is correctly positioned, press the printer cover until it is locked. After locking the cover, the equipment is ready for use. If the paper does not move correctly during printing, repeat the procedure;

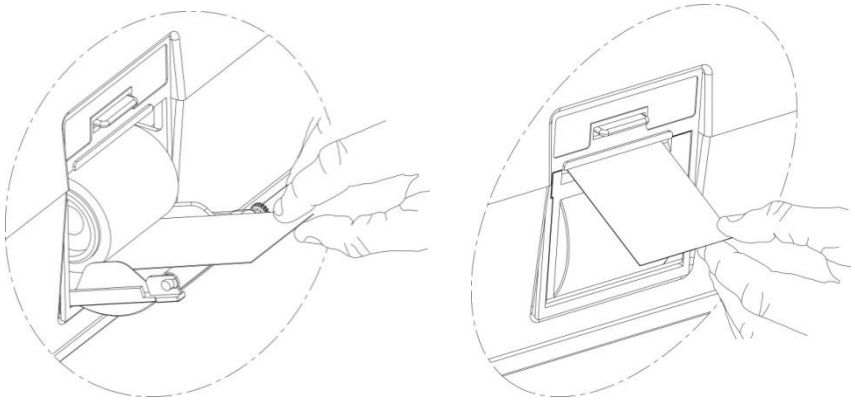


Figure 38 - Loading Paper into the Printer

The printer has two LEDs with the following indications:

LED Error (yellow): Indication of open door or lack of paper;
LED Power (green): Indicates that the printer is on.

FEATURES OF THE THERMAL PRINTER

- High resolution thermal printer, with automatic and manual recording of one channel, with optional two and three channels, with the possibility of recording the ECG with quality for diagnosis with manual or automatic activation after defibrillation with annotation of date and time, heart rate, lead, ECG amplitude, etc.
- Allows independent manual recording of cardioversion by pads.
- This registration is made on thermosensitive paper measuring 48 mm (width) x 20 m (length) or 50 mm (width) x 20 m (length) for the TR-50 or SP-48 printers;
- Printing speed of 12.5-25-50 mm/sec.

Printer configuration menu

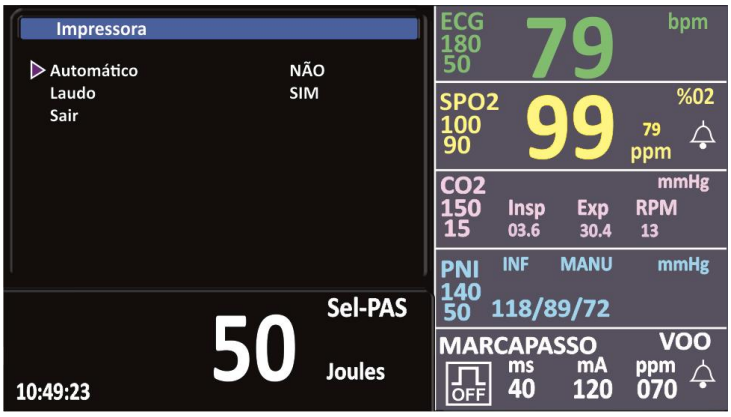


Figure 39 - Printer Menu

1. Automatic – Enables (YES) or disables (NO) Automatic Printing when the use of shock pads is detected;
2. Report – Enables (YES) or disables (NO) Printing of the Report;
3. Returns to the previous Menu.

Data that will be printed when enabling the report:

- Signature field;
- Field for writing the patient's name;
- Field for writing the patient's age and weight;
- Date and time;
- Start and end time of printing;
- Number of shocks applied;
- Synchronism Status Indication (enabled or disabled);
- NIP - Mean/Diastolic/Systolic;
- SPO2 blood saturation (%);
- ECG: Curve amplitude/Lead/speed/heart rate;
- Other data can be implemented if requested by the customer.

The Defibrillator Monitor has, on the front panel, a quick access key to start/finish printing.

Pressing this key  for the first time starts printing; pressing it again stops the process.

⚠If the equipment configuration menu is open and the print key is pressed, the MENU screen will automatically close.

⚠During printing, it is not possible to enter the equipment's MENU. The informational message will appear on the screen: "Printing... MENU Blocked." To re-enter the MENU, simply stop printing.

MAIN SCREEN

To enter the main screen press the navigation button and select the desired menu.

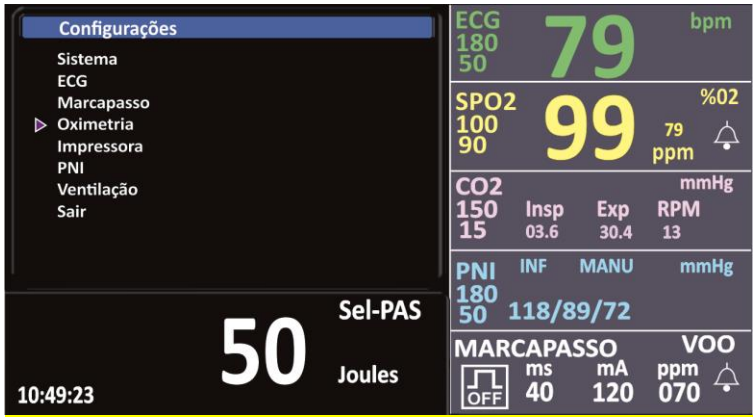


Figure 40 - Main Screen

GENERAL SETTINGS SCREEN

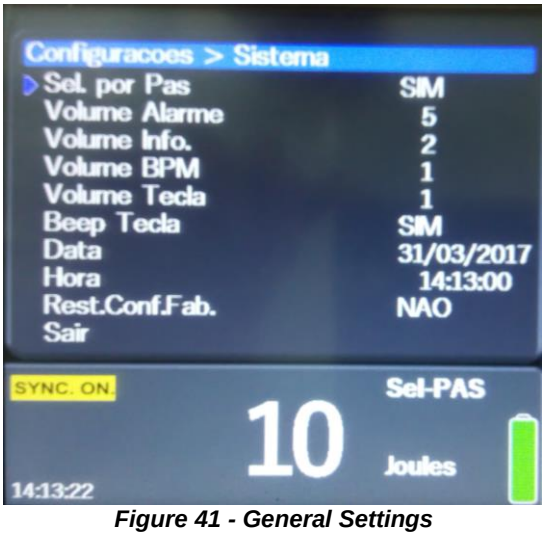


Figure 41 - General Settings

1. Sel. by Pads – Enables (YES) or disables (NO) command by the Pad buttons;
2. Volume. Alarm – Configure Alarm volume, 001 = minimum, 009 = max;
3. Info Volume – Low and medium priority information volume.
4. BPM Volume – Volume of beats per minute.

5. vol. key – Sets keypad beep volume, 001 = minimum, 004 = max;Alarm – Configure Alarm volume, 001 = minimum, 004 = max;
6. Key Beep – Enables (YES) or disables (NO) the keyboard beep sound;
7. Date – Sets the day/month/year.
8. Rest. Conf. Manuf. – Restores all equipment settings;
9. Exit - Returns to the previous Menu;

VENTILATION CONFIGURATION MENU

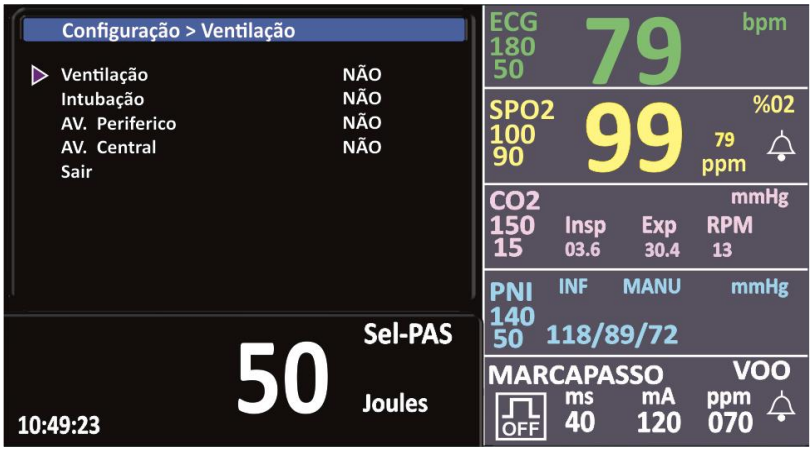


Figure 42 - Ventilation Menu

1. Ventilation - It allows the ventilation mode to be defined. Spontaneous, Assisted, Controlled;
2. Intubation - Allows you to define between YES or NO and the intubation mode: Oral, Nasal, Tracheostomy;
3. VA Peripheral – Allows you to set YES or NO;
4. Central VA – Allows VJI, VSC, OUT, NO;
5. Exit - Returns to the previous Menu;

DRUG CONFIGURATION MENU

The Vivo Biphasic Defibrillator Monitor has, optionally, drug software for recording drug levels used during patient treatment.

1. Procainamide – Selects the injected Drug level;
2. Lidocaine – Selects the injected Drug level;
3. Amiodarone – Selects the injected Drug level;
4. Dolfetilide – Selects the injected Drug level;
5. Sotalol – Selects the injected Drug level;
6. Verapamil – Selects the injected Drug level;
7. Drug 8 - and others used in CPR;
8. Drug 9 - and others used in CPR.

12. DATA MANAGEMENT

It is possible to record the data of the events that occurred while using the Cardiovesor through the internal memory:

- For recording via internal memory, no previous equipment configuration is required.

To view the data recorded in the device's internal memory:

- Turn on the equipment;
- Using the USB A/B extender cable - connect side B to the Defibrillator Monitor and side A to the computer;
- Open the Phoenix software for download of the data.

PHOENIX SOFTWARE

With the Phoenix software it is possible to visualize all the events that occurred while using CMOSDRAKE products.
Through the Memory card or USB cable, data transfer to the Phoenix software and detailed analysis of the events recorded during the use of the AED will be possible.

- Insert the program CD into the CD/DVD ROM drive;
- The installation will start automatically;
- Follow the instructions that appear on the screen;
- At the end of the Fênix software installation, a Java virtual machine installation window will appear, which must also be installed;
- After the installation is complete, a shortcut will be created on the user's desktop, just click on the shortcut to open the program.

VISUALIZATION OF STORED DATA

To view the stored data, simply enter the “File” menu, click “Open”, or directly click the “Open” icon on the toolbar, and select the desired file.

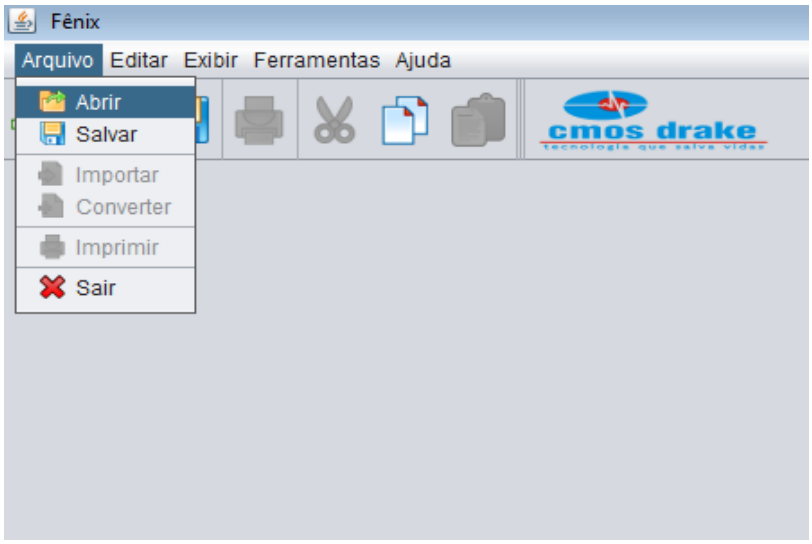


Figure 43 – Opening Data File.

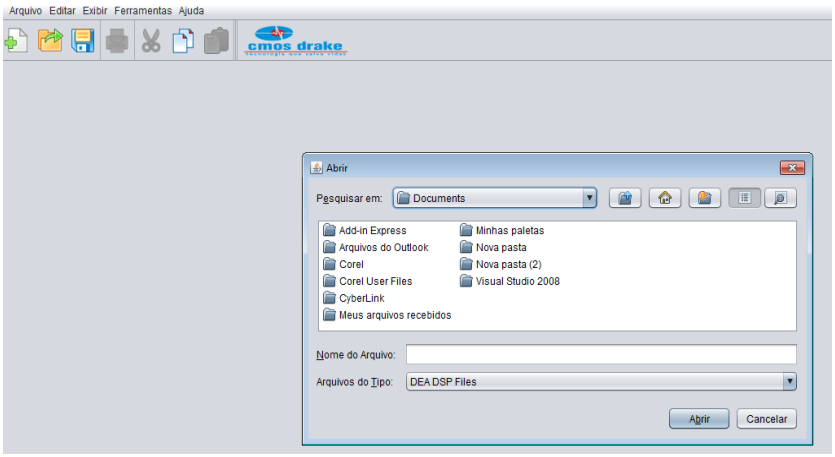


Figure 44 – When clicking on “Open”, a window for selecting the file will open.

3 tabs will be displayed on the screen: curves, events, general information. To change the tabs, just click directly on the tab, or through the “View” menu and choose one of the tabs.

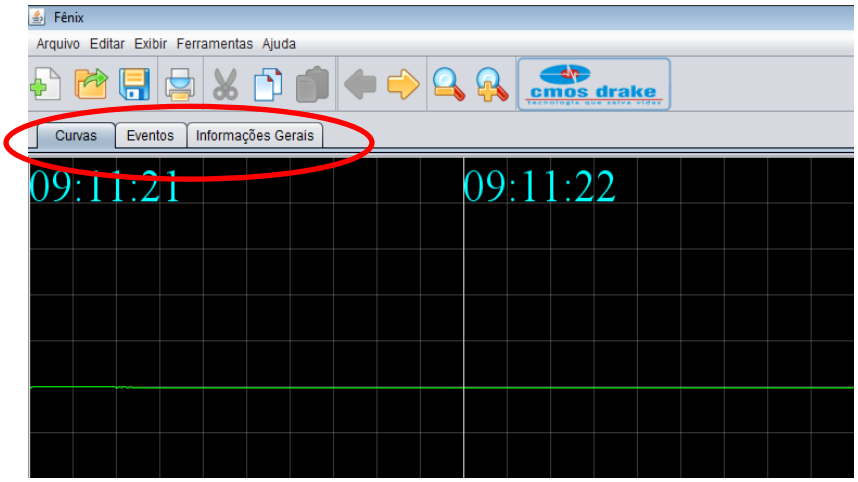


Figure 45 – Data display tabs.

SAVE ECG IMAGE

To save the image, click on the “Save” icon, or go to the “File” menu and click on “Save”.

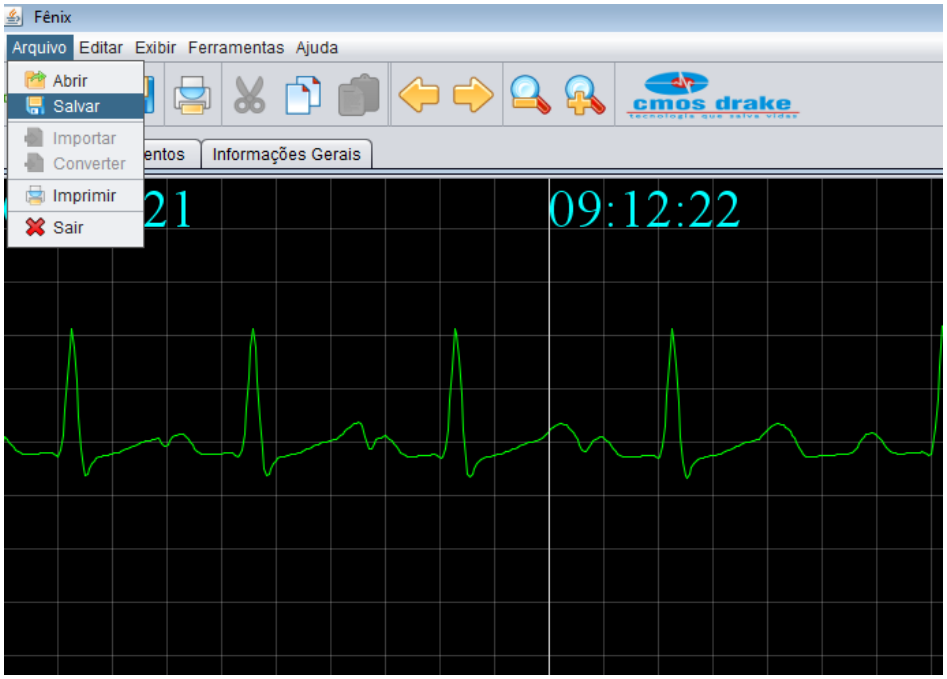


Figure 46 – Saving file.

A screen will appear to choose the folder and file name. After selecting the folder and file name, the user must click on “Save”.

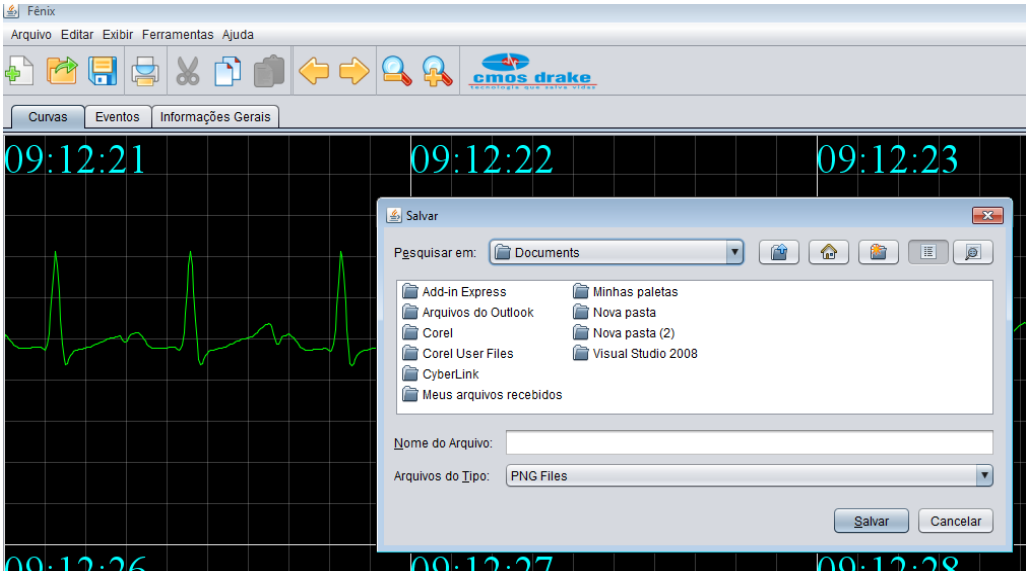


Figure 47 – Window for selecting the file to be saved.

PRINT FILE

To print the data, just click on the “Print” icon, or through the menu “File” - “Print”.

Figure 48 – Printing file through the menu “File” - “Print”.

A window for selecting the document to be printed will appear.
Although it is possible to select more than one document to print, the prints will be individual.

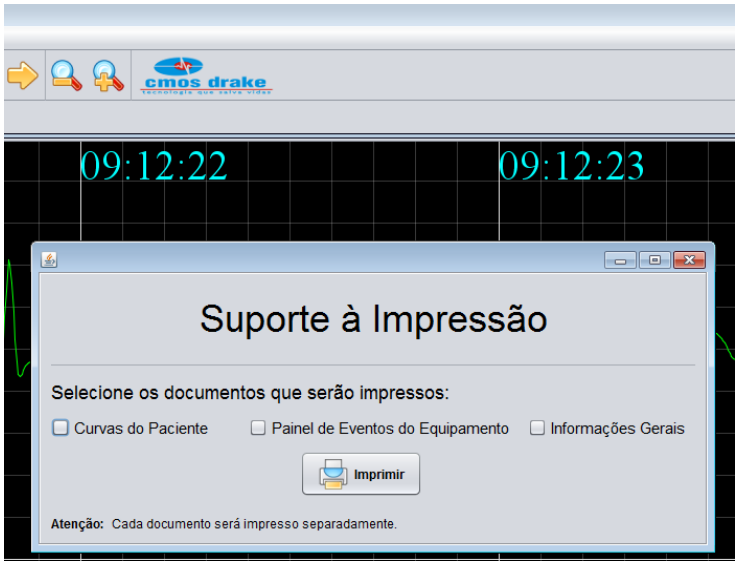


Figure 49 – Window for selecting the file to be printed.

COPY PROGRAM CONTENT

The “Copy” function will make a copy of the tab displayed on the screen, as follows:

- ECG Tab – It will copy an image to the transfer area (clipboard).
- Events tab – It will copy text contained in the selected table cell.
- General Information tab – It will copy the text contained in the selected area.

To use this function, click on the “Copy” icon, or go to the “Edit” menu and click on “Copy”.

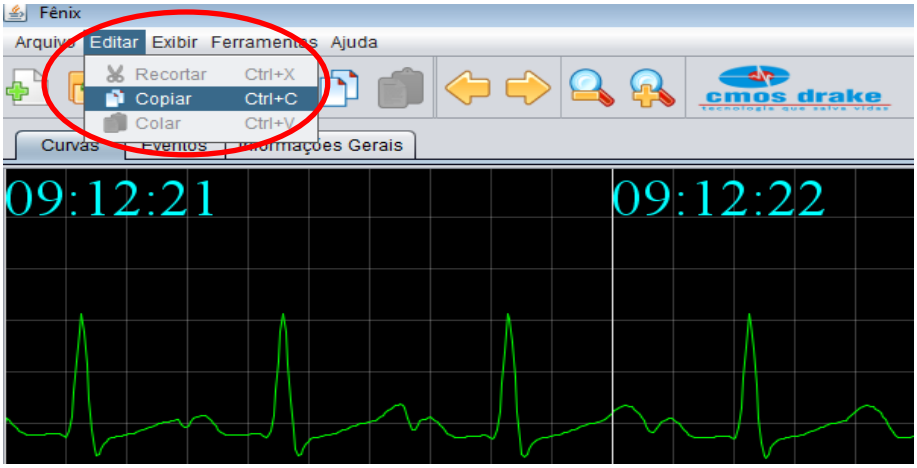


Figure 50 – Copying screen content.

CHANGE THE LANGUAGE

To change the language, go to “Tools” – “Language” and select the desired language. Phoenix software is available in English, Spanish and Portuguese.

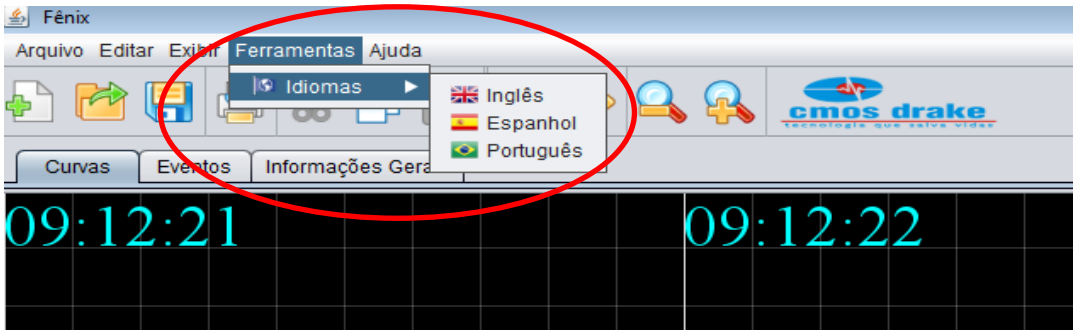


Figure 51 – Language selection.

CHANGE PAGE

On the toolbar, click on the yellow arrow to the right. Pages will change in the chronological sequence in which they were recorded.

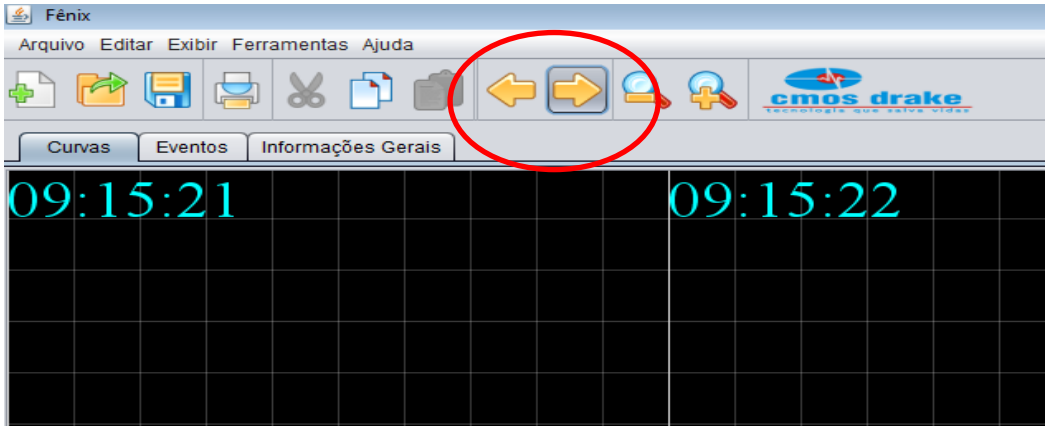


Figure 52 – Next page (right arrow).

To return to the previous page, just click on the left arrow.

VIEW EVENTS

Right click on the curves canvas and select events.

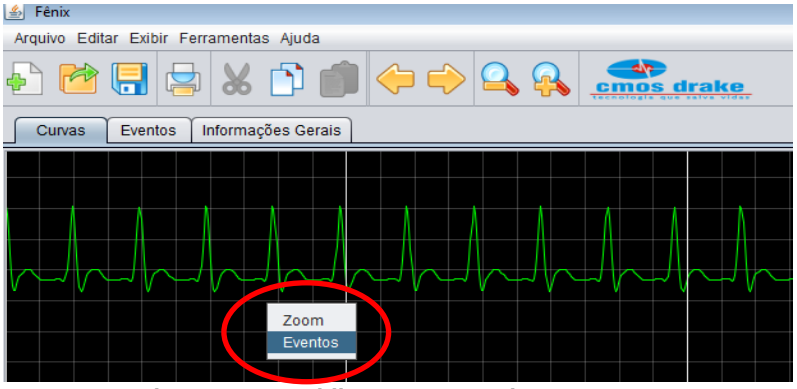


Figure 53 – Enabling Events on the Curve.

Event messages must appear flagged at the time of the event.

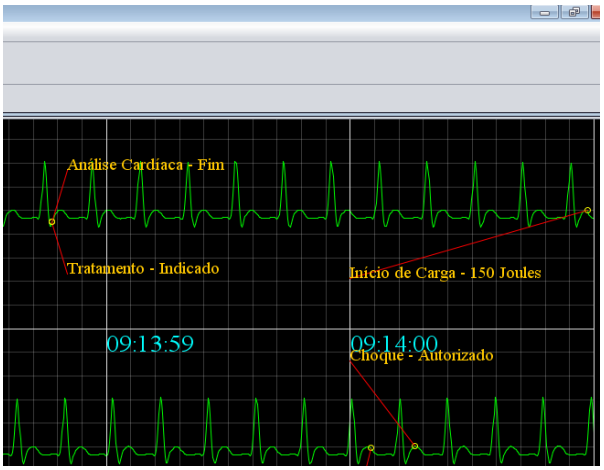
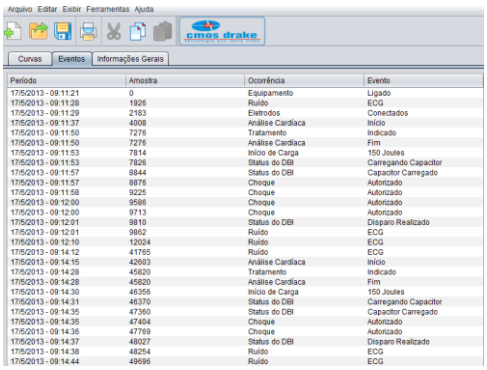


Figure 54 – Description of the events that occurred.

In the Events tab it is possible to view all the events with date and time, description of occurrence and event.



Período	Amostra	Ocorrência	Evento
17/5/2013 - 09:11:21	0	Equipamento	Ligado
17/5/2013 - 09:11:28	1926	Ruído	ECG
17/5/2013 - 09:11:29	2183	Eletrodos	Conectados
17/5/2013 - 09:11:37	4008	Análise Cardíaca	Início
17/5/2013 - 09:11:50	7276	Tratamento	Indicado
17/5/2013 - 09:11:50	7276	Análise Cardíaca	Fim
17/5/2013 - 09:11:53	7814	Início de Carga	150 Joules
17/5/2013 - 09:11:53	7826	Status do DBI	Carregando Capacitor
17/5/2013 - 09:11:57	8844	Status do DBI	Capacitor Carregado
17/5/2013 - 09:11:57	8876	Choque	Autorizado
17/5/2013 - 09:11:58	9225	Choque	Autorizado
17/5/2013 - 09:12:00	9586	Choque	Autorizado
17/5/2013 - 09:12:00	9713	Choque	Autorizado
17/5/2013 - 09:12:01	9810	Status do DBI	Disparo Realizado
17/5/2013 - 09:12:01	9862	Ruído	ECG
17/5/2013 - 09:12:10	12024	Ruído	ECG
17/5/2013 - 09:14:12	41765	Ruído	ECG
17/5/2013 - 09:14:15	42603	Análise Cardíaca	Início
17/5/2013 - 09:14:28	45820	Tratamento	Indicado
17/5/2013 - 09:14:28	45820	Análise Cardíaca	Fim
17/5/2013 - 09:14:30	46356	Início de Carga	150 Joules
17/5/2013 - 09:14:31	46370	Status do DBI	Carregando Capacitor
17/5/2013 - 09:14:35	47360	Status do DBI	Capacitor Carregado
17/5/2013 - 09:14:35	47404	Choque	Autorizado
17/5/2013 - 09:14:36	47769	Choque	Autorizado
17/5/2013 - 09:14:37	48027	Status do DBI	Disparo Realizado
17/5/2013 - 09:14:38	48254	Ruído	ECG
17/5/2013 - 09:14:44	49696	Ruído	ECG

Figure 55 - Events tab

ZOOM

ZOOM OUT OF THE SCREEN

Click the icon magnifying glass  , or right click on the screen, select Zoom and slide the slider to the left, this will zoom out the screen.

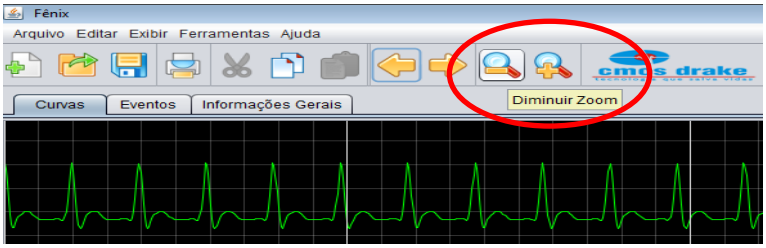


Figure 56 – Zoom out of the screen.

ZOOM IN OF THE SCREEN

Click the icon magnifying glass  , or right click on the screen, select Zoom and slide the slider to the left, this will zoom out the screen.

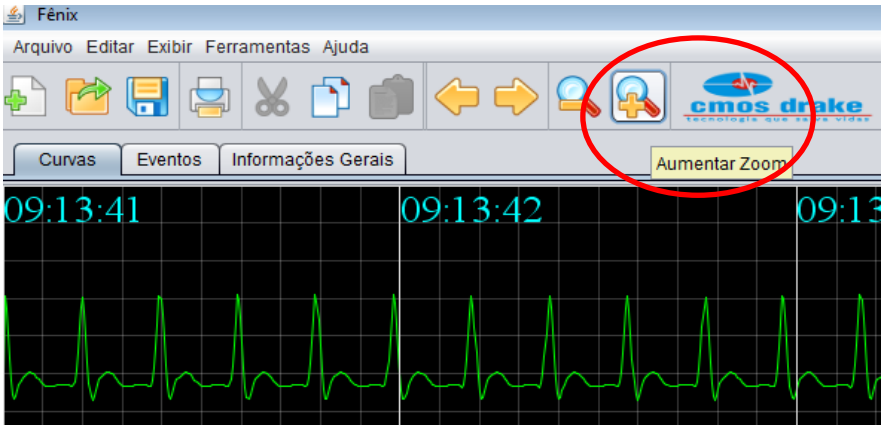


Figure 57 – Zoom in of the screen.

GENERAL INFORMATION

On the General Information tab, the user can fill in patient and operator data. There is also a comment field that can be used to include additional information.

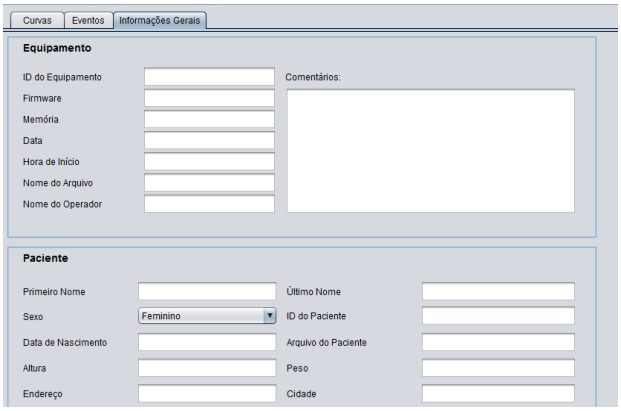


Figure 58 - General Information Tab

HELP

Click on “help” - “About”.

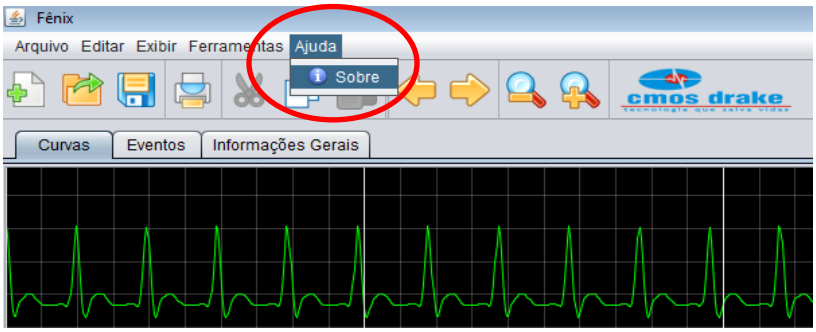


Figure 59 – Help Menu.

A window will open with information about the software version and contact for support in case of doubts.

Figure 60 – Help window.

EXIT THE PROGRAM

Click on the menu "File" - "Exit". Execution of the software should be ended.

Figure 61 – Exit the Phoenix Software.

14. MAINTENANCE

CORRECTIVE AND PREVENTIVE MAINTENANCE

PRECAUTIONS AND SPECIAL CARES

- Do not lean any type of material against the equipment;
- Keep the Vivo Biphasic Defibrillator Monitor in a dry environment, avoiding places that allow liquids to be spilled on the equipment. Do not use the equipment if it is wet or excessively humid;
- The Vivo Biphasic Defibrillator Monitor must not be serviced or maintained during use on a patient;
- Do not reuse disposable materials, after use they must be discarded in appropriate places according to special procedures for hospital waste;
- We recommend keeping some auxiliary materials such as surgical scissors, a disposable razor blade for chest hair removal and disposable gloves, if necessary.

Preventive Inspections and Cleaning

For greater durability of the Vivo Biphasic Defibrillator Monitor and its accessories, we recommend that Preventive Inspections and Cleaning be carried out periodically following the table below.

Applied Verification	Frequency
Preventive Inspections	Biannual
Cleaning	Weekly

Table 21 – Preventive inspections and cleaning.

For each process, make sure that the equipment is turned off and its electrodes disconnected, thus avoiding the risk of shocks.
This process must be done following the criteria below:

Preventive Inspections

We recommend that the Vivo Biphasic Defibrillator Monitor and its accessories be inspected every six months, regardless of whether the equipment has been used or not, following the instructions below:

- Check the validity/expiration of the (disposable shock pads) and the functional status of the accessories. If some of these accessories are close to expiry or are already expired or in bad condition, we request that a new material be purchased only by the manufacturer CMOSDRAKE or in any representative;
- Check the conservation of the equipment and its accessories, if there is any irregularity in the equipment, it must be sent to the manufacturer for maintenance, and in the case of accessories, a new material must be purchased only by the manufacturer;
- Carry out the tripping test on the equipment terminals, following the instructions described in the manual, if there is any irregularity, send it to the manufacturer or any authorized technical assistance.

Preventive Maintenances

Maintenance and periodic testing of the VIVO Defibrillator Monitor and its accessories are preventive measures that help to prevent and detect possible electrical and mechanical failures. During the maintenance schedule recommended by CMOS DRAKE, if the test reveals a possible discrepancy with the Defibrillator Monitor, accessories and sensors, remove it from use immediately and contact the qualified technical area.

PROGRAMMING OF TESTS AND MAINTENANCE

The tables below should be used in conjunction with the hospital's internal quality control program or any location where the Defibrillator Monitor is used. The following list, called **Checklist**, will help the operator to verify the recommended corrective action after the problem.
Electrical safety, Defibrillator Monitor analyzer, performance and calibration tests must be performed by qualified technical assistance authorized by CMOS DRAKE.
These tables must remain with the equipment for the team's verification regarding the equipment.

Programming	Before use	After USE	If necessary	Daily	Weekly	3 months	6 months	12 months
Check the quality of th ECG electrodes, Pacemaker and AED	X							
Inspect the Defibrillator Monitor (visual and mechanical)	X	X						
Clean the Defibrillator Monitor		X	X					
Clean the accessories		X	X					
Check if all necessary materials and accessories are complete				X				
Daily self test				X				
Internal discharge test in 20 Joules					X			
Verifications of the Functions:								
AED Mode (Check message on the screen and voice command)						X		
Monitoring of adult / child permanent pads							X	
Monitoring by the patient’s cable					X		X	
Verification of synchronized cardioversion through permanent pads							X	
Electrical safety test								X
Electrical safety test after technical intervention	X							
Test with Defibrillator Analyzer on the first and second year								X
Test with Defibrillator Analyzer on the third year onwards							X	
Check the battery charge level		X	X					

VIVO Biphasic Defibrillator Monitor

Unit Serial no. _____
Location _____

Objective:

We recommend that this appliance be inspected and tested daily.
We authorize the reproduction of this Check List form.

Instruction	Recommended Corrective Action	Date / Initials						
		ENTER A V IN THE BOX AFTER EXECUTING EACH COMPLETED STATEMENT						
1- Inspect the physical conditions to look for:								
foreign substances	clean the device							
damages or cracks	Contact the qualified technical department							
2- Inspect the power supply to look for:								
Power cable connected to the unit and the mains; the LED is not lit	Check the connections on the device and on the socket, if the LED remains off, replace the power cord. If it is still off, check the fuses and finally contact qualified and authorized technical assistance.							
Broken power cable. loose or worn>	Replace damaged or broken parts							
3- Check ECG electrodes and pacemaker electrodes and AED mode								
Expiration date	Replace if expired							
Spare electrodes available	Replace the electrodes							
4- Examine the cables for cracks. damage, broken or bent parts or pins, and surfaces of the pads for damage.	Replace damaged or broken parts							
5- Disconnect the device from the mains, press the ON key and check for								
Battery charge level	If it is low, connect the power cord until the charge is full. Repeat the procedure, if the charge is still low, contact qualified and authorized service.							
Run the discharge test at 20 Joules	If the test fails, repeat;, if it fails twice, contact qualified and authorized service.							
6-Check the ECG printer by looking for:								
Adequate paper supply	replace if necessary							
Printing capacity	If it is not working, contact technical support.							

Observation:
Test on a routine basis if the Defibrillator Monitor consumes energy, for this run the discharge trigger test with the device connected to the electric mains.

CAREFUL!
Possibility of damages to the equipment.
Do not clean any part of this device or its accessories with bleach, bleach dilution or phenol-based chemical compounds. Do not use abrasive or flammable cleaning agents. Do not try to sterilize this device or any of its accessories.

WARNING!
Possibility of damages to the pad and burns on the patient.
When carrying out discharge tests, firmly press the pads onto the test terminals to prevent sparks and the formation of holes on the surfaces of the pads. Pierced or damaged pads can cause skin burns during defibrillation.
During the discharge test the discharged energy passes through the connector and cables. Connect the connectors securely and ensure the contact is perfect.

Every 12 months the equipment must be sent to the authorized technical assistance for preventive maintenance. This procedure ensures that all equipment functionalities are in full working condition.
It is not necessary to perform the periodic calibration of the Vivo Biphasic Defibrillator Monitor, as it is calibrated at the factory according to technical specifications, not requiring new calibrations.
The oximetry parameter is calibrated after the manufacturing process is completed. Therefore, there is no need to recalibrate the equipment during its lifetime. It was calibrated between 70 and 100%, and at lower values it is not possible to guarantee the accuracy of the calibration. In the range of 70-100% there is an error of ±2%.

SOFTWARE VERSION

To check the software version of the equipment, just press the Cancel key for 30 seconds. After this time, the equipment will display the installed software version on the screen.

UNLOCK AND UPDATE BY UPDATE KEYS FOR MASIMO.

To unlock or update MASIMO board parameters, a programming key must be connected to the device, in the sensor connector. This procedure must be done AFTER the device is started.
After connecting the upgrade key, an instruction screen will be displayed on the device.

MASIMO
An upgrade key has been entered. The process takes up to 1 minute. Press MENU to continue or another key to cancel.

To continue with the update, the MENU key must be pressed. If another key is pressed, the procedure will be cancelled. A screen asking you to remove the upgrade key will appear. If the user does not disconnect the upgrade key before proceeding, a new upgrade process will start.

MASIMO
Remove the update key and press any key to continue

If the MENU key is pressed, the device will enter update mode. Any parameter referring to oximetry will be disabled. The process can take up to ten seconds. At the end of the process, a message is displayed informing you if the update was completed successfully. If so, the message will inform you of the success of the update and will ask you to remove the programming key, before continuing the procedure. After the withdrawal, the user must press any key on the device. The device will then restart with the new parameters enabled.

MASIMO
The update completed successfully. The device

MASIMO
will restart. Remove the update key and press any key to continue

If the update fails, the device will report the failure and error code (N). You will be asked to remove the upgrade key before proceeding with the procedure. After the withdrawal, the user must press any key on the device. The device will then restart without the updates.

MASIMO
Update failed (N). The device will be restarted. Remove the update key and press any key to continue

BATTERY REPLACEMENT

At the end of the battery life, the battery must be replaced following the procedures below:

The battery compartment is located at the bottom of the equipment, to access it lay the equipment down.

1. Using a Phillips screwdriver, remove the 4 screws on the battery compartment cover;
2. Pull out the battery compartment.
3. Disconnect the battery from the equipment.

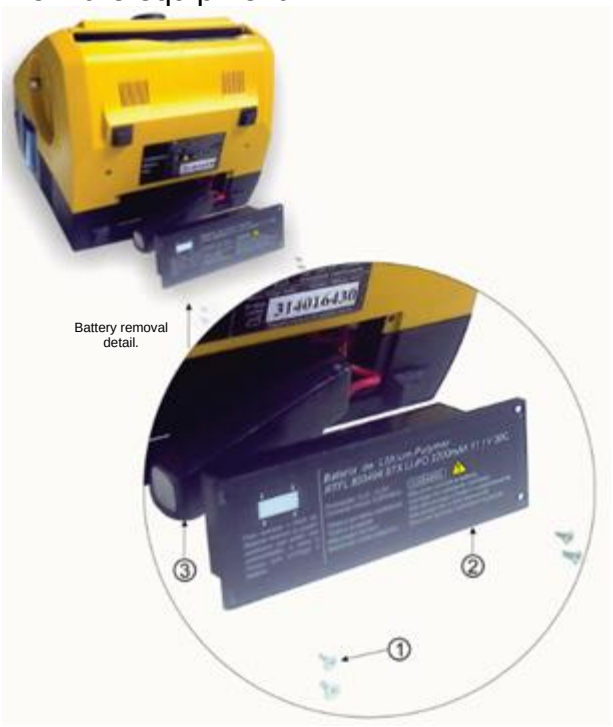


Figure 62 – Replacing the Battery Pack

⚠ **Do not remove the battery while the equipment is operating on battery before turning it off.**

⚠**The user must request from CMOSDRAKE the supply of a new battery for proper replacement at the end of their useful life or failure.**

If the equipment shows a loss of performance, with low battery life, ask CMOSDRAKE technical assistance or an authorized representative for verification.

⚠ **Battery life is at least 600 cycles (full charge and discharge).**

If the Vivo Biphasic Defibrillator Monitor is not used for a long period of time, the battery will need to be recharged. To recharge the battery, connect the equipment to the mains through the power cable.
It is recommended to replace the battery every 2 years, or when the autonomy time is less than 1 hour.

⚠
In case of spare batteries, do not use any other battery charger than the one supplied by CMOSDRAKE;
Do not short-circuit the battery;
Charge in a ventilated environment;
Do not discharge the battery completely;

- **Do not compress or disassemble;**
- **Risk of burning, fire and explosion, if the above recommendations are not followed;**
- **Keep the equipment always connected to the mains to preserve the battery. If the equipment is stored for a period longer than 60 days without it being possible to connect it to the electrical network, it is recommended that the battery be removed from the equipment so that there is no risk of leakage and possible damage to the equipment.**
- **If it is necessary to dispose of the battery, contact the manufacturer for more information.**

⚠**The Vivo Biphasic Defibrillator Monitor has an automatic battery charging system and can remain connected to the electrical grid continuously.**

REPLACEMENT OF FUSES

To replace the fuses, proceed as follows:

1 - Check if the equipment is turned on. If so, turn it off by pressing the ON/OFF button on the front panel for 3 seconds;
2 - Remove the power cord from the socket and the equipment;
3 – On the back of the equipment, press the tab to unlock the fuse holder compartment as shown in the image below:

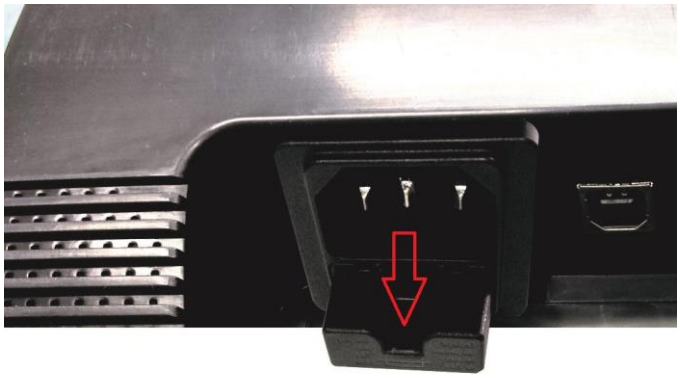


Figure 63 – Replacement of fuses.

4 - Replace and fit the compartment in its place until you hear a “click”.

HANDLING OF CABLES AND ACCESSORIES

- Before placing the equipment in contact with the patient, the operator must verify that it is in operating conditions. Observe the expiration date and integrity of transthoracic electrode packaging regularly.
- Use only the accessories, consumables and others listed in this manual. CMOSDRAKE does not guarantee the proper functioning of the equipment with the use of unknown accessories, in addition to not being responsible for failures in the operation of the equipment or possible damages caused by them.
- The Capnography module may be damaged due to reuse of the water filter. Follow the instructions for using the accessories supplied by the manufacturer. The water filter must be changed for each patient and/or according to the manufacturer's instructions for use.
- In general, parts of the EQUIPMENT and ACCESSORIES of the Vivo Biphasic Defibrillator Monitor, intended to come into contact with biological tissues, cells or body fluids, are tested and analyzed in accordance with the guidelines and principles of ISO 10993-1, which deals exclusively with testing of biocompatibility of the applied parts.
- CMOSDRAKE guarantees that all permanent and disposable materials in contact with the patient do not cause any type of damage or harmful physiological effect, provided that: the procedures described in this manual are followed; that they are installed in an appropriate medical place; that it is used with the correct accessories; be operated by trained personnel and that all precautions described in this User’s Manual are followed.
- Disposable electrodes are for Single Use and therefore should not be resterilized.
- Do not use disposable electrodes if its packaging is damaged;
- Risk of burn on the patient's skin when applying defibrillation;
- Consult the Operating Mode instructions and other information in this manual.

POWER AND GROUNDING

When connecting any medical equipment to the electric mains, the possibility of current leakage from some point of its structure to the patient must be observed. When this occurs, a current can flow between the equipment and the patient's body eventually connected to it.
In the absence of a proper mains ground, dangerous currents can flow from the cabinet in the event of an internal electrical fault. Grounding must be carried out following the standards for electrical installations. In addition to the mains cable with plug and 3-pin connector. The third conductor (connected to the protective grounding contact of the MAINS PLUG) is used only as a functional ground, as the equipment is CLASS II.
In the absence of mains power, the VIVO DEFIBRILLATOR MONITOR starts to work through its Internal Battery. When the electricity supply returns to normal, the equipment itself will automatically switch to the mains power option and the battery will automatically recharge.

15. DISPOSAL PROCEDURE OF THE VIVO BIPHASIC DEFIBRILLATOR MONITOR AFTER THE END OF ITS USEFUL LIFE

At the end of the equipment's useful life (period greater than 5 years), the customer must contact the manufacturer (CMOSDRAKE) to receive instructions on how to dispose of the product.
After receiving the equipment, CMOSDRAKE will disassemble it, separating recyclable and non-recyclable parts. The recyclable parts will be sent to companies duly accredited and qualified to recycle materials. The non-recyclable parts will be sent to accredited companies that follow the resolutions of CONAMA and the presidency of the republic for the disposal of non-recyclable materials

DISPOSING OF EQUIPMENT ACCESSORIES

To dispose of parts and accessories, follow your local regulations related to hospital waste.

 Wastes from electrical and electronic equipment. Dispose of separately from other objects in the establishment. Consult local waste regulations (see European Directive 2002/96/EC).

16. TROUBLESHOOTING

The User must always be checking the condition of his equipment. This section aims to solve functionality problems of the Vivo Biphasic Defibrillator Monitor. The solutions suggested here involve common procedures that are the user's own responsibility to solve. These procedures do not at any time involve opening the main cabinet, modules or permanent accessories. If the procedures described here do not solve the problems, the user must collect the equipment and call CMOSDRAKE's technical assistance.

Among the items that should be observed are:

- The condition of the cabinet (whether it is intact or has cracks, dirt);
- The battery condition (whether it is charged or not);
- Does it have all the necessary accessories for its use? (Adult and/or pediatric electrodes, patient cables, oximetry sensor, among others);
- Are these accessories in good condition?

PROBLEM	RECOMMENDED ACTION
The Vivo Biphasic Defibrillator Monitor does not turn on.	Check the three-pole power cord, making sure that it is well connected to the equipment and the electrical outlet.
The power cable is in perfect condition, but the equipment still does not turn on.	Check the safety fuses (located on the back): After disconnecting the equipment from the mains, open the fuse holders and remove the fuse that is housed inside. Check to see if the internal wire is broken. If so, replace the component with another of the same model. If you cannot see this wire, install another good fuse to eliminate this possibility. (Fuse replacement model (quick type): F L5A 20AG).
Battery does not hold charge	Check if the low battery LED located on the equipment panel is blinking. If so, contact authorized technical assistance or CMOSDRAKE.
Instability of Parameter Curves	The main causes of trace instability are: poor connection of sensors and electrodes on the patient and lack of grounding. Therefore, if this occurs, verify that the connections of the sensors on the patients are perfect, and that the equipment is properly grounded. Also check the existence of a leak in the NIBP cuff and the condition of the cables and connectors of the other sensors.
ECG Trace Instability and Noises**	The vast majority of cases of signal instability and excess noise in the ECG trace are caused by the following factors: Use of inappropriate or damaged electrodes; Inadequate fixation of electrodes to the patient; Insufficient functional grounding of the equipment; Absence of conductive gel.
Selected energy does not exceed 50 Joules	Check that the adult electrode (disc) on the side (right or left) is well connected to the infant electrode (disc) attached to the base of the pad. There is a small black colored switch/sensor attached to the base of the infant electrode. When the adult disc is threaded, this

	switch/sensor when closed allows user power selection up to full load. For children's use, the load is automatically limited up to 50 joules, as the switch/sensor will be in the open position.
It does not show the SPO2 Value	Check that the sensor is correctly positioned to the patient; Check if the patient's finger is not cold – If it is, change the finger sensor; Check that there is no light source shining on the sensor, this could interfere with the reading. Continuous and prolonged monitoring can increase the risk of unwanted changes in skin characteristics, such as irritation, redness, blisters or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonate patients with poor peripheral blood circulation or sensitive skin, inspect the sensor application site more frequently.
In AED Mode the equipment does not identify the shock pads.	Check the validity of the shock pads, if they are expired, replace the pads. The equipment will not identify the pads, because the contact through the gel of the pads was not carried out. Before connecting the shock pads, it is necessary to shave the hair on the chest and remove the fat from the skin.
Equipment does not charge capacitor through the charge button of the shock pads.	Check the equipment screen for the indication Sel. Pads. If not, press the equipment's encoder, go to Settings – Sel. by the pads - Yes.
Equipment does not measure NIP in adult patients.	Safety measuring equipment is always configured for NIP measurements in neonatal patients. To carry out measurement in adult patients, press the equipment dial, go to NIP - patient - Adult.
Equipment locks out for some unknown reason.	Wait for the device to automatically restart. If it does not occur within 3 seconds, press the on and off key on the equipment and check if it returns to normal operation. Check if any adverse external events occurred in the environment where the equipment is being used.

Table 22 - Troubleshooting.

 If the recommended actions are not enough to correct the problem, contact CMOSDRAKE Authorized Technical Assistance.

NIBP MODULE ERROR CODES

When the equipment detects an error related to the NIP module, it will show a message on the display that must be observed. It could be one of the following:

MESSAGE SHOWED ON DISPLAY	ERROR DESCRIPTION	RECOMMENDED ACTION
Pressure Insufficient	Module filled for more than 30 seconds.	Do not repeat measurement, check cuff and connecting tube.
	Pressure is not high enough to produce results.	Check cuff placement.
< 10 mmHg or > 250 mmHg	Wrist pressure is less than 10 mmHg (Adult mode).	Check cuff placement.
05 mmHg or > 150 mmHg	Wrist pressure is less than 5 mmHg (Neonatal mode).	Check cuff placement.
Excess movement	Excess movement.	Try to calm down the patient.
Irregular Measurement	Irregular Measurement	Check Waveform
Pulse without Rhythm	Failed to take pulse measurement.	Check cuff placement.
Measure exceeded 90s	Measured for a time longer than 90 seconds (60 seconds for Neonatal). Measured for a time longer than 90 seconds (60 seconds for neonatal).	Only if the patient is an adult, repeat the measurement; do not remeasure in the Neonatal case
+100 neutral pulses	More than 100 pulses were observed without any results.	Check the equipment configuration.
High pressure	High pressure.	Keep the patient under observation.
Weak pulse	Weak pulse	Check cuff placement and Repeat the measurement.
Wrong cuff	Incorrect cuff.	Review the cuff connection.

Table 23 - NIP Messages.

CAPNOGRAPHY MESSAGES

MESSAGE SHOWED ON DISPLAY	MESSAGE DESCRIPTION	RECOMMENDED ACTION
Initializing...	Time used by the capnography module to start taking the measurement	None.
Calibrating...	While the sensor is calibrating	Wait approximately 1 min. for the end of the calibration.

Check Line Input Flow !, or Check Line Output Flow ! (Occlusion) Click Reset Option	These last messages appear when any existing dirt or bends in the hose that prevent the passage of air	Check the condition of the hose and, if necessary, replace the filter. Finally reset the capnography

Table 24 - Capnography Messages.

17. APPLIED PARTS OF THE VIVO BIPHASIC DEFIBRILLATOR MONITOR

Applied part - part that comes into physical contact with the patient so that the equipment performs its function.

The applied Parts of the Vivo Biphasic Defibrillator Monitor are:

Applied Part	Ingress protection
❖ ECG Cable	Defibrillation-proof CF
❖ Oximetry Sensor	Defibrillation-proof BF
❖ NIP Cuff	Defibrillation-proof BF
❖ Capnography Cannula	Defibrillation-proof BF
❖ Permanent Shock Pads	Defibrillation-proof CF
❖ Internal Permanent Shock Pads	Defibrillation-proof CF
❖ AED Mode Disposable Shock Pads	Defibrillation-proof CF
❖ Pacemaker Disposable Shock Pads	Defibrillation-proof CF

Table 25 - Ingress protection of applied parts.

Despite having different functions, the Permanent Shock Pads, AED Mode Shock Pads and ECG Cable are the same applied part.

⚠ Do not use the permanent shock pads, ECG electrodes and Disposable Shock Pads at the same time, to avoid damage in case of discharge.

18. TECHNICAL SPECIFICATIONS

Defibrillator Monitor, portable, transportable, carrying handle, microprocessor, used for cardiac monitoring of vital signs, has support for fixing the pads on the equipment itself. Equipment works in simplified steps 1-2-3.
Through access to the equipment's menu using the rotating button (NAVIGATOR), all parameters are configured and adjusted. Used in adult, child and neonatal patients.

According to technical standards	EN 980, EN 1041, EN ISO 10993-1, EN ISO 13485, EN ISO 14155-1, EN ISO 14971, EN ISO 15255, EN 60601-2-4, ABNT NBR IEC 60601-1, ABNT NBR IEC 60601-2 -27, ABNT NBR IEC 60601-2-49, ABNT NBR IEC 60601-1-2, ABNT NBR IEC 80601-2-30, ABNT NBR ISO 80601-2-61, ABNT NBR IEC 60601-1-6, ABNT NBR IEC 60601-1-8, EN 62304 and others.
Relevant Certifications	Product Certification - INMETRO Registration with the Ministry of Health: 80058130015
Type of protection against electric shock	Class II
Degree of protection against electric shock	Applicable to each module. ECG/ Defibrillator/ AED Mode/ Pacemaker – Defibrillation-proof type CF applied part. SPO2/ PNI/ EtCO2 – Defibrillation-proof type BF applied part.
Protection against harmful penetration of water and particulate matter	IP44
Operation Mode	Applicable to each module
Degree of safety degree of use in the presence of flammable anesthetic mixture	Equipment not adequate for use in the presence of flammable mixture with air, O_2 and N_2O.
Print format	1 channel Automatic and Manual
Input impedance	< 10 MΩ
Impedance detection range	25 Ohm – 500 Ohm
Frequency response	w/ filter: 0.5 – 35 Hz w/o filter: 0.5 – 100 Hz
Filters	AC: 50/60 Hz – Muscular: 35 Hz
Gain	5 – 10 – 20 mm/mV
Detections	Detects and rejects pacemaker pulse
Monitor	Color liquid crystal of approximately 7”, high resolution. Optional: Touch Screen of approximately 8.2¨ Optional: Contrast adjustment.
Display indicators for visualization	Clear indication of phases, charging, ready, discharging and disassembly. Indicates the mode and load value on the screen. Automatic load adjustment. Programming beep indicator, battery status and others.
Pad contact indicator	It has a contact indicator of the pads on the patient's chest, visualized on the liquid crystal display in the form of a bar

	graph and/or on the shock pads themselves through indicative LEDs.
Data viewed on the display	ECG trace, SPO2 trace, ETCO2 trace, NIBP data, leads, heart rate, beep indicator, pulse oximetry range with saturation values, pulse, battery status, maximum and minimum alarms of all parameters, pulse pacemaker, energy selected, energy delivered, filter, trace speed, amplifier, battery charge indicator, LED indicating whether it is charged or charging. OBS: to view the parameters on the display, the equipment must include them. Every CMOSDRAKE brand Defibrillator Monitor has a basic ECG/DEFRIBRILLATOR factory configuration.
Audible and visual alarms	Loose electrode, asystole, bradycardia, tachycardia, low and high SPO2 alarms, sensor disconnected, loose cuff, low and high NIBP alarms, ETCO2, low battery. It has an alarm silence key for 2 minutes. All alarm systems strictly adhere to the standardized standards of IEC 60601-1-8 General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidelines for alarm systems in electromedical equipment and electromedical systems.
Timer	Clock counter in seconds, date and shock counter.
Test on equipment	Performs daily self-test when powered on
Memory	It has internal memory, including curve, date and time with a capacity of 256 MB that corresponds to more than 100 hours of continuous recording, allows recording in memory of continuous ECG, critical events and procedures performed.
External memory card – OPTIONAL	It enables communication with a microcomputer through a connection for viewing memory data with later reading of the ECG trace, of events through dedicated software (optional).
USB connection	USB port for shipping and firmware upgrade only
Software - Optional	Software for drug calculations and intubation/ventilation procedures.
ST segment	Optional
ECG signal capture	By the permanent defibrillator pads, by the adhesive pads of the pacemaker and by the patient cable.
Energization	100 – 240 VAC – Automatic – 50/60 Hz Internally Powered – Internal battery. External DC: 10 - 16 VDC
Means used to separate equipment from the electric mains	Network plug
Consumption (maximum)	Electric mains: 100V – 5A 240V – 2.5A Battery: 10A
Internal DC power (internal battery)	Type: Lithium-Polymer (LI-PO) rechargeable, 11.1 VDC, 2200mAh – Sealed.

	Battery full charge time (completely discharged): 4 hours Temperature +10ºC to +60ºC
External DC power (backup)	10 hours to 15 hours of monitoring or 100 shocks to 150 consecutive shocks respectively.
AC Current	100 VAC - 5A / 240V - 2.5A maximum
Pad output voltage	256 - 1570 VDC
Pad output current at 50 ohms	50 A maximum
maximum charging time	According to configuration
Fast Type Fuse	20AG F L5A, 250V 20AG F L5A, 250V
Defibrillation scale	According to configuration
Cabinet	High impact with electrical and thermal insulation (flameproof – Rohs Directive)
Discharge time	< 240 ms
Discharge time with synchronism	< 40 ms
Operating Temperature	10ºC to 50ºC
Operating Humidity	10% to 95%
Storage Temperature	0 to 60°C.
Storage Humidity	10 to 95%, no condensation
Transport Conditions	Ambient temperature range from 15º to 30º C; Relative humidity range from 10% to 95%; Atmospheric pressure range from 700 hPa to 1060 hPa (525 mmHg to 795 mmHg). Maximum stacking of 5 boxes. Transport in original box of the equipment. CMOSDRAKE does not guarantee and is not responsible for any damage that occurs to equipment that is transported or stored in other packaging.
Dimension	Approximately H-125 x D-355 x W-280 mm
Weight	Approximately 4.3 kg including all accessories.
Operating Atmospheric Pressure	700 to 1060 Pa (525 mmHg to 795 mmHg)
Equipment Software Version	CBI400_DSP_01_00_CVV
Available languages	Portuguese, Spanish and English
Operation in conjunction with frequency inverter	Output waveform: Pure sinusoidal. Output frequency: 60 Hz ± 3Hz. Suggested in/out ratio: 12Vdc/ 127Vac. Maximum in/out ratio: 12Vdc/ 220Vac. Suggested output power: 1000 W

Table 26 - General technical specifications.

DEFIBRILLATOR TECHNICAL SPECIFICATIONS

Wave type	Truncated exponential biphasic
Multifunctional, adult and child,	Interchangeable permanent pads.
	From 1 to 200 biphasic joules

Energy	Optional up to 360 joules biphasic
	Optional from 1 to 270 joules biphasic
	Limited to 50 Joules for Child mode – interchangeable shock pads;
Maximum voltage applied to the patient	1450 V (200 J)/ 1850 V (360 J)
Manual Power Selection	200 Joule Versions: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50 joules for child defibrillation (external pad) and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180 and 200 joules for adult defibrillation (external pad).
	270 Joule Versions: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50 joules for child defibrillation (external pad) and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200 and 270 joules for adult defibrillation (external pad).
	360 Joule Versions: 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50 joules for child defibrillation (external pad) and 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200, 240, 270 and 360 joules for adult defibrillation (external pad).
	Child load: Automatically caps at 50 joules when disconnecting the adult pad in any version above.
Pre-configured loads	The equipment, when in automatic mode, obeys the scale of 150-200 and 200 joules.
Precision of Delivered Energy	1 to 10 Joules - +/- 2 J 11 at 360 Joules - +/- 15%
Load activation method	The load (joules) can be selected by the pads, by the panel and by the navigator button, when selected by the pads, the APEX pad is used to select the energy, the STERNUM pad to load and simultaneously pressing the two buttons, one on each pad to fire, thus minimizing the risk of accidental shock. Through the panel the 1-2-3 system is used, 1 to select energy, 2 to charge and 3 to trigger (treatment).
Test on the pads	Performs pad operation test with light indication.
Thoracic impedance	Automatically analyzes the patient's thoracic impedance, increasing defibrillation efficiency and reducing the risk of cardiac injuries. Impedance detection in the range of 25 Ohm to 50 Ohm for triggers.
Cancels load	The equipment cancels the load manually using the cancel key with information on the display or internally discharges within 30 seconds if there is no trigger. Cancellation time can be configurable as per request – Optional.
Synchronization	It triggers synchronized with the QRS complex, with energy delivery time less than 40ms. Maximum delay time for signal

	stabilization in 5 seconds after optimal connection of the sensor to the patient.
Operation Mode	Non-continuous operation

Table 27 - Technical specifications of the Defibrillator.

TECHNICAL SPECIFICATIONS AED MODE

It has a voice and text command presented on a display, which instructs the rescuer/professional during the resuscitation sequence according to the 2015/American Heart Association Guideline, has an automatic ECG evaluation system that detects QRS complexes and identifies malignant arrhythmias (tachycardia ventricular fibrillation) that require defibrillation, informing whether or not triggering is necessary.
Impedance measurement for adjusting phase 1 and 2 of the biphasic wave, not allowing triggering with open or short-circuited pads.

Wave type	Truncated exponential biphasic
Disposable pads.	Disposable pads for use of pacemaker and AED mode.
Maximum Energy	200 J
Maximum voltage applied to the patient	1450 V
Signal Analysis	Automatic analysis of the patient's ECG signal and decision on the need for shock treatment.
Power delivered in AED mode	Standard Setting: 1st shock 150, 2nd shock 150 3rd shock 200 J.
Precision of Delivered Energy	+/- 15%
Cancels load	The equipment cancels the load manually using the cancel key with information on the display or internally discharges within 30 seconds if there is no trigger.
Operation Mode	Non-continuous operation

Table 28 - Technical specifications of the AED Mode.

TECHNICAL SPECIFICATIONS OF THE PACEMAKER (PM)

Operation	Asynchronous, demand (fixed) and emergency/VOO. VVI and emergency.
Disposable pads.	Disposable pads for use of pacemaker and AED mode.
stimulation output	Through adhesive electrodes
Protection against defibrillation	Internal suppression diode, 400 joules
HF filter	Filter against high frequency interferences
output pulse current	0 mA to 200 mA Stable in steps of 1mA - 10% precision
Output pulse frequency	30ppm to 200ppm, adjustable in steps of 1ppm - with precision of ± 10%
Pulse width	5ms to 50ms adjustable in steps of 1ms
Frequency	30 ppm to 200 ppm precision ±1.5%

Escape Interval	Time between a detected beat or pulse and the posterior unsynchronized pulse of the Pacemaker - Precision ± 10%
refractory period	340 ms (from 30 to 80 ppm); 240 ms (from 90 to 200 ppm).
Power supply	12 V
Operation Mode	Continuous Operation
Degree of protection against electric shock	Defibrillator-proof CF type applied part
ALARMS	
Limits	30 to 200 BPM
Adjustment	Manual; maximum and minimum limits
Silent Alarm	Sonorous bip deactivated for 120 s
Delayed	0 to 7 s

Table 29 - Technical specifications of the Pacemaker.

TECHNICAL SPECIFICATIONS OF THE CAPNOGRAPHY (ETCO2)

Parameter reading method	*Sidestream and Mainstream*
Parameters	EtCO2, CO2 inspiration, Respiratory rate
Curve	Expired Co2 curve shown continuously on screen
Procedures	Self-calibration option that eliminates the use of specific gases for periodic calibration.
CO_2 Concentration Reading Range	0 - 150 mmHg Accuracy: 0 - 40 mmHg ± 2 mmHg 41 - 70 mmHg ± 5% 71 - 100 mmHg ± 8% 101 - 150 mmHg ± 10%
Respiratory rate reading range	2 - 150 respirations per minute (rpm) Accuracy: +/- 1 rpm
Response time	< 3 Seconds
Compensation	N_2O, O_2 and Desflurane
Degree of protection against electric shock	Defibrillator-proof BF type applied part
Operation Mode	Continuous operation
ALARMS	
Type	Manual for max limits. In. of respiratory rate, EtCO2, steady state and CO2 inspiration
Silent alarm	Sonorous alarm deactivated for 2 min
Characteristics	Disable audio, adjust tone and volume, alarm delay
Limits	CO2 inspiration: 0 to 10 mmHg Respiratory rate: 0 to 35 RPM EtCO2: 0 a 50 mmHg

Table 30 - Technical specifications of the Capnography.

ECG TECHNICAL SPECIFICATIONS

Leads	DI, DII, DIII, aVL, aVR, AVF, V1 TO V6
ECG Cables	5 ways
Input impedance	> 10 Mohms
Frequency response	Monitor: 0.5 to 25 Hz Diagnosis: 0.05 to 100 Hz
Rejection	In common mode greater than 90 dB
Sensitivity	ECG amplification step, 5, 10, 15, 20, 30 and 40 mm/mV
Filters	*Notch:* 60 - 50 Hz Muscular: pass - below 35 Hz
Gains	5 - 10 - 20 mm/mV
Beat reading range	0 a 300 BPM - accuracy of 01 BPM with numeric presentation
Tolerance	± 3%
Output	Analog ECG signal 1V/mV_{PP}
Offset (potential)	± 300 Mv
Leak current	< 10 uA
Defibrillation protection	Maximum of 360 J
Baseline recovery	Less than or equal to 4 s after defibrillation
Systolic indicator (QRS)	Audible beep
Calibration signal	1 mVpp ± 3 %
Degree of protection against electric shock	Defibrillator-proof CF type applied part
Operation Mode	Continuous operation
ALARMS	
Limits	25 to 220 BPM
Adjustment	Manual; maximum and minimum limits
Silent Alarm	Sonorous bip deactivated for 120 s
Delayed	0 to 7 s

Table 31 - Technical specifications of the ECG.

TECHNICAL SPECIFICATIONS OF THE NON-INVASIVE PRESSURE (NIP)

Measurement technique	Oscilometric
Operation mode	Manual / automatic Non-continuous operation
Automatic mode time programming	1 to 480 minutes
Degree of protection against electric shock	Defibrillator-proof BF type applied part
Reading ranges:	
Adult systolic	25 to 300 mmHg
Adult Systolic	10 a 220 mmHg
Adult Mean	15 a 260 mmHg

Child Systolic	20 a 260 mmHg
Child diastolic	10 a 220 mmHg
Child Mean	10 a 230 mmHg
Neonatal Systolic	20 a 150 mmHg
Neonatal Diastolic	5 a 110 mmHg
Neonatal Mean	10 a 130 mmHg
Maximum pressure:	
Adult	300 mmHg
Neonatal	150 mmHg
Resolution	1mmHg
Reading Precision	Mean deviation of ± 5 mmHg Standard deviation within 8 mmHg
Time for reading	Normal 20s Adult: 90s max. Neonatal: 60s max.
Accessories	Adult cuff / complete clamp, Child cuff / complete clamp, Neonatal cuff / complete clamp
ALARMS	
Type	Manual; maximum and minimum limits
Delayed	0 to 7 s

Table 32 - Technical specifications of the NIP.

TECHNICAL SPECIFICATIONS OXIMETRY MASIMO RAINBOW SET (SPO2)

Curve	Plestimographic, with adjustable amplitude; signal quality
Presentation on display	Arterial oxygen saturation, arterial carboxyhemoglobin saturation and arterial methemoglobin saturation values in percentage; heart rate numerically.
Pulse Reading Range	25 to 240 BPM Tolerance: ± 3 digits without movement ± 5 digits under movement Resolution: 1 BPM
Oximetry Reading Range (SPO_2)	00 to 100% Accuracy: 60 – 80 +/- 3% (adult, child and neonatal) – no movement. 70 - 100%: +/- 2% (adult, child) +/- 3% - neonatal – no movement. 70 - 100%: +/- 3% (adult, child and neonatal) – with movement. 70 - 100%: +/- 2% (adult, child and neonatal) – low perfusion.

PI Reading Range	0.02 to 20% Resolution: 00 to 1 – 0.01% 1 to 10 – 0.1% 10 to 20 – 1%	
Carboxyhemoglobin Reading Range (SpCO)	00 to 99% Accuracy: 1 – 40 +/- 3%	
Methemoglobin Reading Range (SpMet)	0 to 99.9% Resolution: 2.1 at 2 - 0.1%: 2 to 100 – 0.5% Tolerance: ± 1 digit	
Total Hemoglobin reading range (SpHb)	0 – 25 g/dL	
Degree of protection against electric shock	BF	
Operation mode	Continuous operation	
ALARMS		
Type	Manual; maximum and minimum limits	
Limits	SpO_2	Min: 40 – 100%
		Max: 40 – 100%
	PPM	Min: 30 – 120
		Max: 40 – 240
	PI	Min: 0.03 – 18%
		Max: 0.04 – 20%
	SpCO	Min: 0 – 98%
		Max: 1 – 100%
	SpMet	Min: 0 – 99%
		Max: 1 – 100%
Silenced Alarm	Auditive alarm deactivated for 120 s	
Delayed	0 to 7s Configurable sonorous SpO_2 alarm 0 - 15 s	

Table 33 - Technical specifications of the Masimo SPO2.

PRINTER

Channels	Of 1 or 3 channels
Resolution	High
Activation	Automatic or manual after each shot, it allows independent manual recording of cardioversion by the pads.

Record	On thermosensitive paper from: 48 mm (width) x 20 m (length) or; 50 mm (width) x 20 m (length) or; 75 mm (width) x 20 m (length)
Record type	Recording of the diagnosis with manual or automatic activation after defibrillation or any other alarm activating event with annotation of date and time, heart rate, selected defibrillation energy level during defibrillation, impedance, heart rate, synchronized defibrillation, alarm activation, lead, ECG amplitude, number of shocks administered.
Speed	12.5, 25, 50 mm-sec.
Accessories	Roll of paper
Operation mode	Continuous operation
Delayed	0 to 7 s

Table 34 - Technical specifications of the Printer.

⚠ The equipment must be used in the working ranges specified above (for each module). **Using the product outside of these specifications may give inaccurate results.**

19. FUNDAMENTALS CARDIOVERSION/DEFIBRILLATION

DEFIBRILLATION CONCEPT

Defibrillation is the emergency procedure that consists of the application of a non-synchronized shock of electric current in the patient's chest (external defibrillation) or directly on the heart muscle (internal defibrillation) with the objective of reversing Ventricular Fibrillation or Ventricular Tachycardia without pulse. It must be distinguished from Cardioversion, which consists of an elective or emergency procedure that requires synchronization and is classically indicated in cases of unstable tachycardias or at medical discretion.

IMPORTANCE OF DEFIBRILLATION

Early Defibrillation is one of the links of the Survival Chain. It allows complete depolarization of the myocardium, thus enabling the heart rate regulatory centers to re-assume control of cardiac electrical activity. Defibrillation is the only effective treatment against Ventricular Fibrillation (VF) – the most serious arrhythmia – which is characterized by the presence of irregular waves, in amplitude and frequency, defining a chaotic heart rhythm.
In cases of VF, it is necessary to perform defibrillation early, as the chance of a successful treatment for these cases decreases rapidly over time - about 7 (seven) to 10 (ten) percent every minute.

CARDIOVERSION

Cardioversion is another modality of electrical therapy aimed at treating certain cardiac arrhythmias. Unlike defibrillation, Cardioversion is performed by applying an electrical discharge synchronized with ventricular depolarization. Synchronization is achieved by detecting the QRS complex.
When opting for synchronized shock (SYNC) every time the QRS complex is detected by the Defibrillator Monitor, it will be responsible for providing an audible and visual signal.
It is worth remembering that there is a mechanism to inhibit energy output in certain situations, the QRS signals captured by the ECG are difficult to detect, for example, when there is a wide and short R wave. When the Defibrillator Monitor is loaded in synchronized mode, its discharge will only occur if an R wave is present, the patient impedance is within the range of 25Ω to 500Ω and the buttons of the pads are simultaneously activated.
Care must be taken not to apply the load asynchronously during the vulnerable period, as in this case ventricular fibrillation (VF) can be induced.

20. APPLIED TECHNOLOGY

RECORDING METHODS (FOR AED MODE)

Arrhythmias susceptible to VT and VF defibrillation are pre-programmed in the equipment, eliminating the need for operator configuration, resulting in a significant gain in treatment time.

SOURCE OF RHYTHM (FOR AED MODE)

Through the equipment, Defibrillator Analyzer, model QA-40M, from the company METRON, the cardiac rhythms subject to defibrillation, such as VT and VF, the natural rhythms, in different amplitudes and frequencies are simulated.

RHYTHM SELECTION CRITERION (FOR AED MODE)

The selected rhythms are those famously known as the classic indication for defibrillation, which are: Ventricular Fibrillation and Ventricular Tachycardia.

ANNOTATION METHODS

The Vivo Biphasic Defibrillator Monitor is equipped with an electroluminescent liquid crystal display, where emergency care procedures and ECG tracings are plotted, allowing the graphic recording of heart rhythms.

DETECTOR PERFORMANCE RESULTS

Rhythm	Classification
Ventricular Tachycardia	A/(A+B)
Ventricular fibrillation	A/(A+B)

True Positive (A): Correct classification of rhythm susceptible of being defibrillated.
True Negative (B): Organized or perfused rhythm or asystole that has been incorrectly classified as a rhythm susceptible of being defibrillated.
False positive (C): It is a VT or VF associated to a cardiac arrest that was incorrectly classified as not susceptible of being defibrillated.
False negative (D): Correct classification of all rhythms in which a shoc is not indicated.

TRUNCATED EXPONENTIAL BIPHASIC WAVEFORM

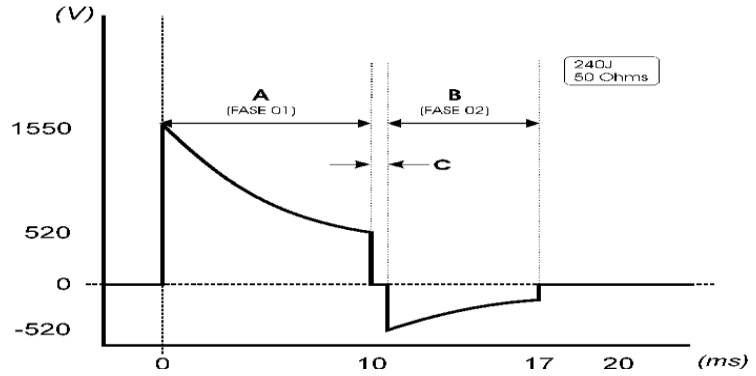


Figure 64 - Truncated Biphasic Waveform

VARIATIONS ACCORDING TO THE PATIENT'S THORACIC IMPEDANCE

IMPEDANCE	A (PHASE 01)	B (PHASE 02)
= 25 Ohms	5 ms	3.3 ms
= 30 Ohms	6 ms	4 ms
= 40 Ohms	8 ms	5.3 ms
= 50 Ohms	10 ms	6.7 ms
≥ 60 Ohms	12 ms	8 ms

Table 35 - Wave time variation in accordance with the patient's impedance.

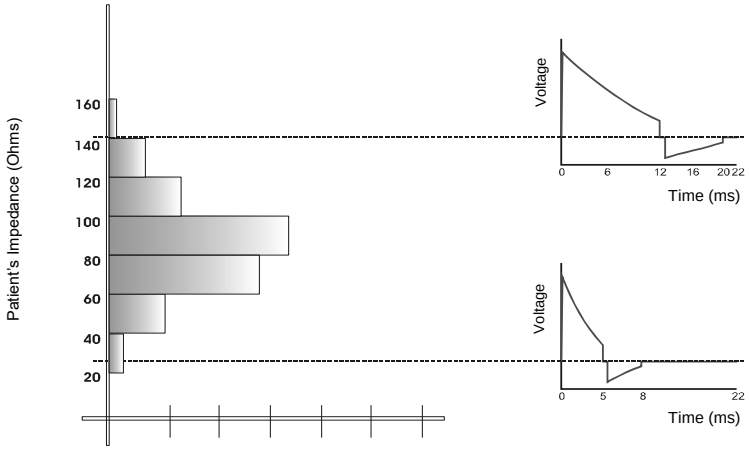


Figure 65 - Waveform variation in accordance with the patient's impedance

Tthe phase B corresponds to 2/3 of phase A
Maximum width (A+B): 20 ms

Dead-time (C): 0.5 ms**Figure**

VARIATION OF ENERGY DELIVERED X DURATION OF PHASES WITH TRUNCATED BIPHASIC WAVE

Capacitor Load 1237 Volts (150 Joules)					
Impedance Ω	**Phase 1 – A ms**	**Phase 2 – B ms**	**A + B ms**	**%A – %B**	**Energy delivered in Joules**
25	5.0	3.3	8.3	60% – 40%	130.16
50	10.0	6.7	16.7	60% – 40%	137.46
75	12.0	8.0	20.0	60% – 40%	155.32
100	12.0	8.0	20.0	60% – 40%	148.28
125	12.0	8.0	20.0	60% – 40%	165.23
150	12.0	8.0	20.0	60% – 40%	154.07
175	12.0	8.0	20.0	60% – 40%	143.89

Table 36 - Variation of energy delivered (150 J) in function of impedance.

Capacitor Load 1428 Volts (200 Joules)					
Impedance Ω	**Phase 1 – A ms**	**Phase 2 – B ms**	**A + B ms**	**%A – %B**	**Energy delivered in Joules**
25	5.0	3.3	8.3	60% – 40%	172.25
50	10.0	6.7	16.7	60% – 40%	177.84
75	12.0	8.0	20.0	60% – 40%	209.14
100	12.0	8.0	20.0	60% – 40%	198.80
125	12.0	8.0	20.0	60% – 40%	219.35
150	12.0	8.0	20.0	60% – 40%	204.44
175	12.0	8.0	20.0	60% – 40%	191.20

Table 37 - Variation of energy delivered (200 J) in function of the impedance.

OBS: All delivered energy values will be subject to a tolerance of +/-15% or +/-3 J, whichever is greater.

RECOMMENDATIONS ON ENERGY LEVELS NEEDED FOR THE TREATMENT OF ARRHYTHMIAS

According to the 2015 AHA Guideline for Truncated Biphasic Technology)

Transthoracic (Indirect) Cardioversion/External Defibrillation in adults:
❖ Atrial Fibrillation - 100 J to 120 J;
❖ Atrial flutter - 50 J;
❖ Paroxysmal supraventricular tachycardia - 100 J;
❖ Monomorphic ventricular tachycardia - 100 J
Transthoracic (Indirect) External Defibrillation in adults:
❖ First Defibrillation: 150 J;
❖ Second Defibrillatiton: 150 to 200 J;

- Third and subsequqent Defibrillations: 200 J.

Transthoracic (Indirect) External Defibrillation in children:

- First Defibrillation: 2 J/Kg;
- Subsequent defibrillations: 2 to 4 J/Kg;

Internal (Direct) Defibrillation in children:

- First defibrillation: use the lowest energy level possible, with the unit around 2 J;
- Subsequent defibrillations: 3 to 10 J;

ST SEGMENT ANALYSIS CHARACTERISTICS

The first step in performing ST segment analysis is to digitize the signal for 10 seconds at a rate of 500 samples per second. Eight of the leads are of direct acquisition (I, II and V1 to V6). The remaining four leads (III, aVR, aVL and aVF) are derived via Einthoven's law as follows:

$$III = II - I$$

$$aVR = -\frac{(I + II)}{2}$$

$$aVL = I - \frac{(II)}{2}$$

$$aVF = II - \frac{(I)}{2}$$

We strongly recommend filtering the signal in order to reject noise and achieve better results. The result of these steps is the digital ECG.

Following acquisition, the program measures the ECG as the second phase of the interpretation process. Measurements can be detailed in five steps:

1. QRS detection: This step is very important, because if it is performed incorrectly, the next steps will be wrong. An auxiliary function for QRS detection is computed, based on 8 independent leads. Complexes are classified into normal and abnormal in order to achieve a normal QRS pattern from lead to lead. Also, the RR interval is measured and the heartbeat is computed.
2. Identification of the T wave end: This point is very important because it identifies the end of the cardiac cycle and is used to measure the QT interval.
3. P wave study: The program looks for P waves in all T-Q segments (from the end of the T wave to the beginning of the next QRS complex) in order to determine if the PR interval duration is varying.
4. Starts and ends: These points are identified for each wave in order to measure its duration and find its peaks.
5. Measurement: For each wave, the amplitude and duration are measured, lead by lead. Also, ST segment deviation is measured as well as other parameters.

The result of the measurement process is as follows:

- Normal QRS complex duration;
- PR interval duration;

- QT interval duration;
- Heartbeat (beats per minute);
- PR interval duration;
- P, Q, R, and R' wave duration;
- Amplitude of P, P', Q, S, R' and T waves;
- Amplitude at the start, middle and end of the ST segment;
- Intrinsic Deflection (time from the beginning of the QRS complex to the peak of the R wave);
- Projection of electrical axes in the frontal plane (P wave, RS complex and T wave vectors). The ventricular gradient
- is also measured.

The median cardiac cycle lead is also stored as it is useful for printed reports.

The last step is the evaluation of medical reports from the ECG measurements taken. The ST Segment analysis brings a series of advantages, among which the following can be mentioned:

- Considerable time savings for cardiology professionals devoted to ECG interpretation in hospitals that offer a large number of these tests.
- Stability and homogeneity in ECG interpretation and homogeneity in ECG interpretation. Human fatigue or work pressure can cause specialists not to interpret ECGs while maintaining the same necessary homogeneity. The EQUIPMENT always applies the same algorithm and the same rules for ECG interpretation, thus providing more stable conclusions in a timely manner.
- The ability to store all information related to a patient allows you to get the same exam report over and over again without any need to repeat the ECG. This information is a valuable component of an ECG database in research applications.

All medical criteria used in this ST segment analysis range from a simple recommendation or warning about ECG results to a complete diagnosis of a specific abnormality. That is why these criteria have different degrees of specificity and can include phrases such as: **“NOT NECESSARILY PATHOLOGICAL”, “CONSISTENT WITH”, PROBABLE...”, CONSIDERING...”** when there is no absolute certainty of the specific pathology. In these cases, the physician must determine whether the measures given and other complementary factors are conclusive or not.

The EQUIPMENT evaluates all medical criteria taking into account all measurements made previously and determines in its conclusions which criteria are exclusive and which ones exclude others due to their greater diagnostic precision.
These criteria were grouped as follows:

- Changes in heart rhythm
- Changes in electric axes
- Left or right ventricular hypertrophy
- Intraventricular block
- Left bundle branch block
- ST segment changes
- T wave modifications
- Infarctions
- Other cases

In no way should this type of diagnosis be considered a substitute for the diagnosis of cardiologists, simply because they are not. They should be seen as an efficient tool that assists the specialized physician in his diagnosis because they are highly efficient in the classification of normality, as well as having high sensitivity for the detection of pathological cases. This relieves the physician from reviewing normal cases and serves as a guide for classifying pathological cases. When electrocardiographic indications are ambiguous or extremely complex, the final diagnosis is left to the physician. The following is a list of medical criteria:

The interpretive ST segment analysis report using the VIVO BIPHASIC CARDIVERTER is one of the valuable tools that help the clinician to interpret ECG efficiently, but only when combined with a detailed patient history and medical examinations. Every computerized ECG system is incapable of analyzing the ECG wave like the human eye-brain system. The clinician should reread and correct the automatic ECG interpretive report.

The ACC/AHA has recommended interpretation of computerized ECGs to physicians.

"Several studies have examined the accuracy of computerized ECG interpretation programs and have suggested that computer analysis cannot replace the physician's interpretation of ECGs. A systematic study of computerized ECG interpretation done in 1991 showed that computer programs were on average 6.6% less accurate than the cardiologist in identifying ventricular hypertrophy in myocardial infarction (MI). Rhythm disturbances were not evaluated in that investigation, and informal experience suggests that computerized interpretation has a higher error rate in rhythm analysis than in the diagnosis of MI and hypertrophy. A more recent Japanese study reported that the false-positive and false-negative rate was 18 times higher for computerized interpretation than for trainee physicians on major ECG diagnoses. However, computerized interpretation of ECGs can be useful in accurately calculating heart rate, conductive intervals, and axes, provided there is manual review. Thus, while computerized interpretations of ECGs may have useful adjunctive value, they cannot replace the interpretations of experienced electrocardiographers and should not be used to make clinical decisions."[1)]

CHARACTERISTICS OF SOME TYPES OF CARDIAC ARRHYTHMIAS

The symptoms of arrhythmias are quite variable, and may be silent (no symptoms).
They can be diagnosed by the doctor during a cardiological examination (examination of the pulse and auscultation of the heart with a specific device).
The most common symptom is palpitation. Fainting may also occur (rapid, spontaneous recovery and without motor changes), dizziness, shortness of breath, malaise, feeling of heaviness in the chest, weakness, fatigue, chest pain, among others.
Symptoms that indicate severity are mental confusion, low blood pressure, chest pain, and fainting. If any of these symptoms occur, it is necessary to perform urgent medical care to avoid death of the patient.
Cardiac arrhythmias can be classified in different ways, depending on the frequency, formation mechanism, place of origin, etc. We will present some more general terms, common in people's daily lives.
In terms of frequency, arrhythmias can be classified into:

[1)] A report of the ACC/AHA/ACP-ASIM Task Force on Clinical Competence (ACC/AHA Committee to Develop a Clinical Competence Statement on Electrocardiography and Ambulatory Electrocardiography), ACC/AHA Competence Statement, 2001;104:3169-3178.

- Bradycardia: Occurs when the heart beats less than 60 times per minute. In some people, it may be a normal finding, as in athletes. Several types of bradycardia are known, each with its own peculiar characteristics. Cardiac pacemakers are used to treat this type of arrhythmia.

TYPES OF BRADYCARDIAS

There are 3 basic types of bradycardias, depending on where the heart's electrical system is blocked. When blockage occurs in the sinus node, which is the heart's natural pacemaker, it is called sinus node dysfunction. In addition, electrical impulse blockage can occur in the atrioventricular node or in the right or left branches of the heart's electrical system.
The important thing is that all these types of blockages can lead to a decrease in the number of heartbeats and cause symptoms such as dizziness and fainting. Depending on the type of block, and the symptoms it is causing, an artificial pacemaker may need to be implanted.

- Tachycardia: Occurs when the heart beats more than 100 times per minute. It usually occurs during physical activity, emotional stress, in the presence of anemia and other diseases. There are several types, some extremely serious.

TYPES OF TACHYCARDIAS

- Atrial Tachycardia: It is a rapid heart rhythm that originates in the atria.
- Atrial Flutter: It is an arrhythmia caused by slow-conducting electrical circuits that originate in the atria and promote a rapid and regular rhythm of the heart.
- Nodal reentry tachycardia (NRT): an extra electrical pathway near the atrioventricular node that causes the electrical impulse to move in a circle and pass through areas it has previously passed, causing the heart to beat at a rate well above the normal.
- Accessory tachycardia or Wolff-Parkinson-White syndrome: extra electrical pathway that exists from birth and connects the atria to the ventricles, causing the electrical impulse to reach the ventricle faster.
- Atrial fibrillation: extra electrical impulses originating in the atria that trigger rapid, disorganized, and irregular beats.
- Ventricular extrasystole: extra electrical impulse originated in the ventricle that promotes beats ahead of time.
- Ventricular Tachycardia: An electrical impulse originating in the ventricles that promotes a rapid and potentially life-threatening rhythm. It is usually a medical emergency.
- Ventricular Fibrillation: It is a rapid, disorganized and erratic rhythm that does not produce ventricular contraction that causes sudden death and requires immediate cardiopulmonary resuscitation and defibrillation (electric shock).

Regarding the place of origin, arrhythmias are classified into:

- Atrial: As we know, the heart is made up of four chambers (or divisions), two atria and two ventricles. The normal stimulus for the heartbeat is generated in the right atrium. In some arrhythmias, these stimuli are generated in excess or in fewer numbers, by the very structure that normally generates them; in others, the stimulus arises elsewhere in the atria, leading to atrial arrhythmias.

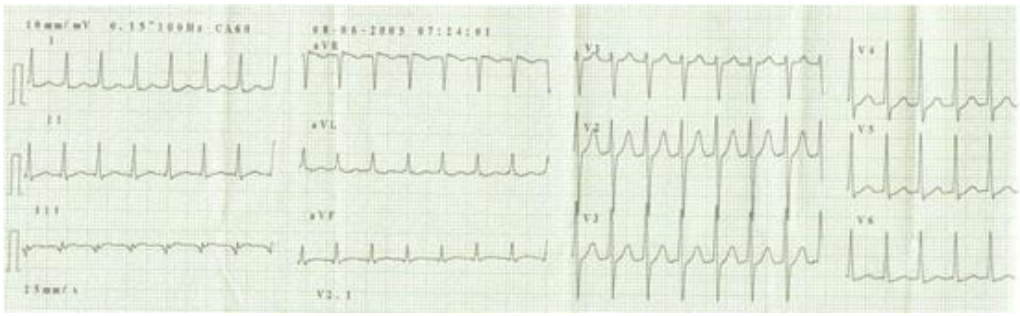


Figure 66 – Atrial arrhythmia electrocardiogram

- Junctional: These arrhythmias arise at the junction between the atria and ventricles.
- Ventricular: arise within the ventricles, some with great potential to lead to death.

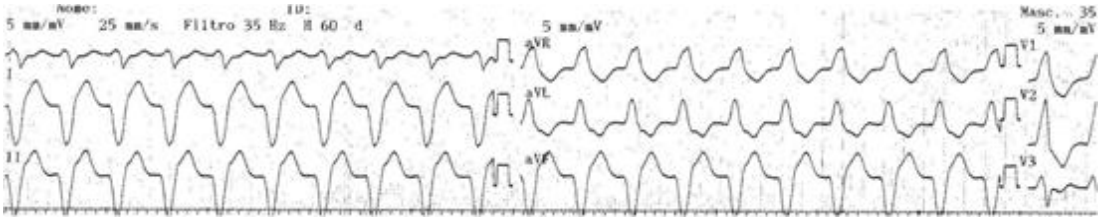


Figure 67 – Ventricular arrhythmia electrocardiogram

21. APPENDIX A - ECG TRACE INSTABILITY AND NOISES

When noticing degradation in the output signal, such as frequent saturations (signal loss), presence of noise superimposed on the ECG (even with the activation of the filters) and deformations in the wave morphology, carefully check the following items:

- Status of the connection cable of the electrodes. Note the existence of cracks or breaks along the cable, which must be homogeneous throughout its length.
- Integrity of cable ends and junctions, close to connector, junction box and electrodes. These points are more susceptible to handling and therefore more prone to breakages.
- If possible damage to the connecting cable is found, it must be tested by specialized personnel and, if necessary, replaced.
- Status of clip-type and precordial electrodes, especially observing the metallic part in contact with the patient's skin. There should be no sign of oxidation or dirt.
- Status of disposable electrodes, which must be of good quality and used only once.
- Type of conductive gel used in the electrodes, which must be suitable for ECG. Other types of gel, such as gel for ultrasound and/or other purposes, are contraindicated, as they may not only introduce noise and make the examination unfeasible, but also cause premature wear of the electrodes themselves.
- Preparation of the patient's skin before attaching the electrodes. Excess skin oils, together with the layer of dead epithelial cells that naturally accumulate in the epidermis, increase the impedance of the electrode-patient interface, degrading the cardiac signal and introducing noise from different sources into the ECG. Prepare the electrode attachment sites according to usual clinical practice (hair cleaning and shaving, if necessary).
- Grounding of the power outlet where the Vivo Biphasic Defibrillator Monitor is installed. Observe the power and grounding recommendations described in this manual.
- Proximity to sources of external interference (radio frequency generators and power lines), if this occurs, keep them away.
- Adjustment of equipment filters.
- For additional support, please do not hesitate to contact CMOSDRAKE.

MOST COMMON TYPES OF INTERFERENCES ON THE ECG

The ECG signal recorded under normal conditions, without noise contamination, is shown in figure B1. If the ECG acquisition conditions are not suitable, four main types of interference can occur: **(1)** Power supply (AC) interference; **(2)** muscle artifacts (“muscle tremors”); **(3)** baseline shift (“drift”); and **(4)** motion artifacts.

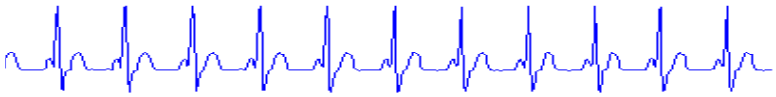


Figure 68 – Noise-free electrocardiogram.

AC POWER MAINS INTERFERENCE

The power supply induces interference of a specific frequency (50 or 60 Hz), which is superimposed on the ECG signal, as shown in figure B2. The main causes of contamination by the AC mains can be listed as follows:

- Presence of electromagnetic fields near the equipment and electrode cables, such as X-rays, electrical transmission lines, fluorescent lamp ballasts, etc.;
- Insufficient connection to ground;
- Patient electrode cable and power cable crisscrossing;
- Breakage or breakage of the electrode cable. In this case, the interference is of high amplitude and appears exclusively in the branch related to the damaged cable;
- Loose or worn electrode, lack of conductive gel, or insufficient preparation of the patient's skin. These conditions raise the impedance of the electrode-skin interface and deregulate the signal impedance seen by the equipment, compromising the common-mode rejection effect of the input amplifiers. In these cases, the tracing normally appears saturated.

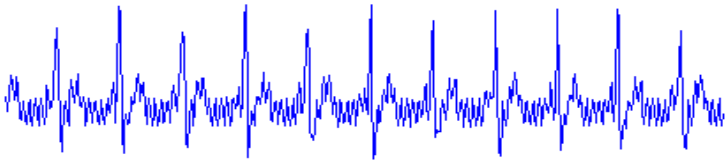


Figure 69 - ECG with 60 Hz interference from the AC power supply.

MUSCLE ARTIFACTS

Muscle activity appears superimposed on the ECG as irregular and inconstant waves, as shown in Figure B3. The main causes are listed below:

- Restless patient, due to cold or discomfort during the examination;
- Specific pathologies (e.g. Parkinson's disease).

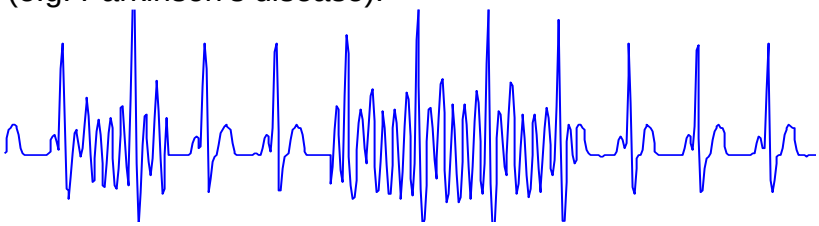


Figure 70 – ECG contaminated with muscle artifacts (“muscle tremor”).

BASELINE SHIFT

This tracing disturbance causes a displacement of the ECG baseline in relation to the central zero of the graph (center of the printing paper), taking some time to return to the normal condition (depending on the order of the equipment's internal filters). The tracing may momentarily saturate, making the examination difficult (figure B4). The main causes are listed below:

- Improper connection of the electrode to the patient, with little gel or using worn electrodes;

- Badly positioned or non-adhering electrode fixation tapes;
- Presence of foreign particles (dirt, for example) between the electrode and the patient's skin;
- Rupture at the junction between the patient cable and the electrode. In this case, abrupt oscillations usually appear between the extremes of the graph, with a delay in returning to the baseline.

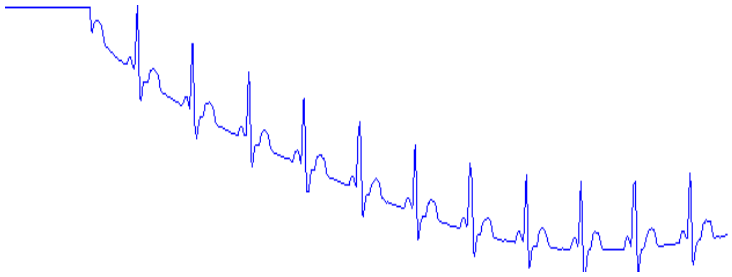


Figure 71 – ECG with baseline oscillation ("drift").

MOVEMENT ARTTIFACTS

Motion artifacts have their origin at the contact interface between the electrode, the conductive gel, and the patient's skin. In fact, the electrode works not only as an electrical sensor, but performs a more complex electrochemical transduction, the frequency measured by the equipment is between 0 and 300 ppm with an accuracy of 3%; transforming the ionic activity of the skin surface – which reflects the internal electrical generators, including cardiac activity – into electrical current.

When attached to the patient's body, through a layer of conductive gel, the electrode establishes chemical equilibrium conditions at this interface, generating a double layer of potential called the half-cell potential. The input amplifier perceives this potential as a constant voltage level, not interfering with the ECG measurement. However, when moving the electrode, the interface balance is momentarily altered, making it necessary to reach a new equilibrium condition. This transient disturbance produces an electrical motion artifact (figure 40), which can be on the order of several times the biomedical signal to be measured. Furthermore, this type of noise is predominantly of low frequency, spectrally superimposing on the ECG and making it impossible to eliminate it by means of simple filtering.

The correct application of conductive gel between the electrode and the patient's skin and the use of Ag-AgCl electrodes substantially reduce the generation of movement artifacts, stabilizing the electrode-gel-skin interface.

Proper preparation of the skin contact site with the electrode also contributes to obtaining a more defined ECG signal. The superficial layer of the skin (extract corneum) is composed of dead epithelial cells, in addition to having a fat film, presenting characteristics of high impedance. After cleaning and abrading the site - for example, using gauze soaked in alcohol - the skin contact impedance can be reduced from 200 kOhms to something around 5 kOhms in 90% of patients.
Some practices can help minimize motion artifacts on the ECG:

1. Always use electrodes in perfect condition, preferably Ag-AgCl.
2. The electrodes of all leads must be of the same material, in order to decrease the resulting DC potential and prevent saturation of the amplifier.
3. Clean the skin with alcohol to remove the oil and the layer of dead cells.

4. Use Cl-based conductive gel or paste, specific for ECG exams; never use other types of gel (eg gel for ultrasound examination).
5. Apply the gel only under the electrode contact area.
6. Never apply abrasive or conductive paste to injured skin.
7. If it is necessary to remove excess hair from the area, cut them and not shave the area.
8. Glue the proper adhesive tape (micropore or tape) on the back of the electrode and fix it to the contact site on the skin, making sure that there is a slight pressure of the electrode against the skin.
9. When the connection is well made, when moving the electrodes, a small momentary artifact should be observed, with rapid restoration of the normal tracing.
10. In prolonged recordings, the conductive gel tends to dry, modifying the characteristics of the interface; in these cases (for example, bedside recordings) periodically replace the electrodes on the patient, preferably in a slightly displaced place from the previous one.
11. Clean the skin after the examination, applying damp gauze with mild soap to completely remove the conductive gel.
12. Clean the electrodes with running water. If necessary, use pressurized water (waterpick). Dry them completely before storing them.

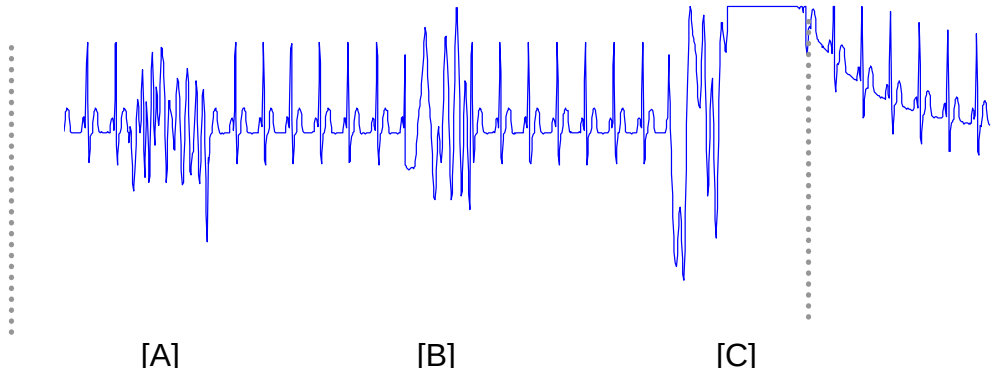


Figure 72 – ECG with contamination by motion artifacts.

In [A] and [B] the detection of the cardiac signal is impossible and in [C] the amplifier saturates, taking some time to return to the baseline.

22. APPENDIX B - PERFORMANCE CHARACTERISTICS

USE OF THE VIVO BIPHASIC DEFIBRILLATOR MONITOR IN INTENSE ELECTROMAGNETIC FIELDS

Subways, helicopters and train stations can interfere with the Defibrillator Monitors when in external automatic mode, as they are composed of intense electromagnetic fields in which high changes in sensitivity and specificity were observed. Do not operate the equipment near cell phones, wet surfaces, high voltage lines, or in locations near strong electromagnetic fields.

DEFIBRILLATOR MONITOR OPERATION IN HIGH FREQUENCY ENVIRONMENTS

- Extreme care must be taken when performing surgeries that use equipment operating at high frequency, especially in patients with pacemakers. In addition to the risk of damage to the pacemaker, electrocautery currents can cause patient fibrillations. Always keep a Defibrillator Monitor close by.
- Respect the minimum distance of 15 cm between the ECG electrodes and the electric scalpel or defibrillator, if they are used at the same time. If in doubt, disconnect the ECG cable.
- This equipment may cause radio interference or may interrupt the operation of nearby equipment. It may be necessary to take mitigating measures, such as reorienting or relocating the CARDIOVERSOR or shielding the site.

SAFETY AND PROTECTION

Patient

- The capacitor is charged just before the trigger and the charging voltage is connected to the electrodes only at the time of shock.
- The trip command is only enabled to trip if the capacitor is charged with the selected voltage and within the trip time (30 s). Outside this period, or when the capacitor is charging and/or when detecting any anomaly in the operation, the relay that controls the discharge of the capacitor is turned off, causing the internal discharge of the capacitor.

Operator

- Internal battery to isolate the equipment from the external power supply.
- Internal manageable battery charger with external source and isolation between mains, patient and operator.
- Do not shock with short-circuited pads, as the triggering device may be damaged.

Aircrafts

- Low level of radiation from electromagnetic fields.
- High immunity to transients and external electromagnetic fields.
- High mechanical resistance to vibration.

PHYSIOLOGICAL EFFECTS

In general, the Vivo Biphasic Defibrillator Monitor does not cause any damage or cause any physiological effect, provided that it is installed for operation in an appropriate medical location, that it is used with the correct accessories, is operated by trained personnel and all the precautions described in the user's manual are followed.
We highlight some basic special care procedures:

ECG MODULE

- The appropriate gel, as indicated in this manual, should be placed on the electrodes only at the time of use on the patient;
- If the electrode is pre-gel, do not forget to check the expiration date;
- Use good quality permanent or disposable electrodes;
- All these procedures must be followed regardless of the patient (Adult or Pediatric / Neonatal);
- Other standard procedures must also be followed, already mentioned in the Description of the Vivo Biphasic Defibrillator Monitor and its Components, item "Presentation" of this manual.

NON-INVASIVE PRESSURE MODULE (NIBP)

- Use the appropriate cuff for each type of patient (adult, adolescent, pediatric, neonatal) and install it correctly. Make sure the equipment is correctly configured so that its use is in accordance with the patient, so that the pressure is compatible with the same and thus avoiding interruption of circulation.
- When using the Automatic Mode function, at intervals of less than 15 minutes between measurements, the equipment, as a safety measure, after the first 15 minutes have elapsed, automatically resets itself to perform measurements every 120 minutes. This reconfiguration prevents harm to the patient in cases of long monitoring periods. Timer uncertainty (intervals between measurements): 10 ms/min.

OXIMETRY MODULE

- A sensor composed of LEDs and light sensors is used, placed on the patient's finger (adult or pediatric). The sensor must be changed position every 4 hours to avoid possible skin burns, bruises or skin injuries;
- Pediatric and neonatal patients deserve special care, using another type of Y-model sensor; this should be changed position every 2 hours, avoiding possible skin burns, bruises or skin injuries. This application in a neonatal patient is done by attaching adhesive tape, which cannot be done too much, to avoid skin lesions or incorrect readings;

Prolonged sensor use

Oximetry sensors (adult, child or universal) are not indicated for prolonged use, due to the heat emitted by the sensor and the continuous pressure exerted on the patient. In monitoring for a longer period, it is recommended to reposition them in another location on the patient every 02 (two) hours or 4 hours according to the type of sensor.

DEFIBRILLATION MODULE

- Care must be taken not to discharge the defibrillator during a vulnerable period, as in this case ventricular fibrillation may be induced;
- Special care must be taken regarding the different conditions of use of the equipment: Defibrillation or Cardioversion.

For the use of the equipment as a defibrillator, if it has the synchronism function turned on, the shock will not be given in cases of Ventricular Fibrillation – “VF” – or Asystole (even activating the pad contacts), as the applied part of load is waiting for the information of the presence of the R wave, which is not identifiable (either because the ECG is not turned on or because the R wave does not exist).
In this situation, the operator activates the pad switches, but the equipment does not fire. This may make the user think that the equipment is defective, but in fact, the equipment will only trigger when there is no R wave signal or when the sync is turned off by pressing the sync key on the Defibrillator Monitor control panel.
In the opposite situation, if the objective is cardioversion (discharge synchronized with the R wave) and the equipment is configured for defibrillation, when the trigger buttons of the pads are activated, the discharge will occur immediately, regardless of the presence of the R wave. As consequence, in trigger randomness, shock can occur during a vulnerable period and cause ventricular fibrillation.

CAPNOGRAPHY MODULE

It must be verified that the adapters in both the Sidestream System and the Mainstream System are clean, sterilized, in perfect condition, to avoid possible contamination with bacteria.

ADVERSE EFFECTS

CMOSDRAKE, as a manufacturer of medical-hospital equipment, requests users to report possible defects or the occurrence of any undesirable event, in order to guarantee the quality of the equipment. Therefore, in case of any failure or malfunction, contact the nearest Authorized Technical Assistance or directly with the sales consultant through the website: www.cmosdrake.com.br

23. APPENDIX C - GUIDELINES AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

The Vivo Biphasic Defibrillator Monitor is designed for operation in any environment shown below.
The customer or user of the Vivo Biphasic Defibrillator Monitor must ensure its operation in one of these environments.

MEASUREMENTS OF RF EMISSIONS	COMPLIANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RF emissions according to ABNT NBR IEC CISPR 11	**Group 1**	The Vivo Biphasic Defibrillator Monitor uses RF energy exclusively for its internal functions. Thus, the RF emission of the same is very low and is not likely to cause any interference in nearby electronic equipment.
RF emissions according to ABNT NBR IEC CISPR 11	**Class B**	The Vivo Biphasic Defibrillator Monitor is suitable for use in all residential establishments and those directly connected to the public low-voltage electricity distribution network that supplies buildings for domestic use.
Harmonics Emissions IEC 61000-3-2	**Class A**	
Emissions due to voltage fluctuation / scintillation IEC 61000-3-3	**Conform**	

The Vivo Biphasic Defibrillator Monitor is designed for operation in any environment shown below.
The customer or user of the Vivo Biphasic Defibrillator Monitor must ensure its operation in one of these environments.

Interference Resistance test	ABNT NBR IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) in accordance with IEC 61000-4-2	±6kV per contact ± 8 kV by air	**Conform**	Floors must be made of wood or cement, and must have ceramic tiles. If the floor is made of synthetic material, the relative humidity must be at least 30%
Fast transient electrical disturbances / discharges in accordance with IEC 61000-4-4	±2 kV on power supply lines ±1 kV on input/output lines	**Conform**	Power supply quality should match the voltage supplied in a typical commercial or hospital environment
About voltages in accordance with IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	**Conform**	

Voltage dips, brief interruptions and voltage fluctuations Supplied in accordance with IEC 61000-4-11	< 5% Ut (>95% voltage drop in Ut) for 0.5 cycle. 40% Ut (60% voltage drop in Ut) for 5 cycles. 70% Ut (30% voltage drop in Ut) for 25 cycles. < 5% Ut (> 95% voltage drop in Ut) for 5 seconds.	**Conform**	The quality of the supplied voltage must correspond to the voltage provided in a typical commercial or hospital environment. If the Vivo Biphasic Defibrillator Monitor user requires continuous operation even when there are interruptions in the power supply, the Vivo Biphasic Defibrillator Monitor must receive power without interruptions or with a battery
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	**Conform**	Magnetic fields at the power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note *Ut is the AC supply voltage before the test level is applied.*

Table C2

The Vivo Biphasic Defibrillator Monitor was designed for operation in any environment shown below.
The customer or user of the Vivo Biphasic Defibrillator Monitor must ensure its operation in one of these environments.

Interference Resistance test	**ABNT NBR IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
RF Conducted IEC 61000-4-6 **RF Radiated IEC 61000-4-3**	3 Vrms	[V1]V Conform	Portable and mobile RF communication equipment should only be used near any part of the Vivo Biphasic Defibrillator Monitor, including cables, with a separation distance less than what is recommended. This safe distance will be calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: d = [3.5 / V1] √P d = [3.5 / E1] √P 80 MHz up to 800Mhz d = [7 / E1] √P 800 MHz up to 2.5 Ghz P is the rated maximum output power of the transmitter in watts (w), according to the

	150 kHz up to 80 Mhz 20 V/m 80 Mhz up to 2.5 Ghz	[E1] V/m Conform	transmitter manufacturer, and d is the recommended separation distance in meters (m) It is recommended that the field strength established by the RF transmitter, as determined through an electromagnetic on-site inspection a, be less than the compliance level in each frequency range. Interference may occur around equipment marked with the following symbol: 

Note 1 *At 80 MHz and 800 MHz, the higher frequency range is applied.*
Note 2 *These guidelines may not be applied in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people*.

[a] *Field intensities established by fixed transmitters, such as base stations, wireless (cellular) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with precision. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the field strength measurement at the location where the* ***Vivo Biphasic Defibrillator Monitor*** *is used exceeds the compliance level used above, the* ***Vivo Biphasic Defibrillator Monitor*** *should be observed to verify that the operation is normal. If abnormal performance is observed, additional procedures may be necessary, such as reorienting or relocating the* ***Vivo Biphasic Defibrillator Monitor.***

[b] *Over the frequency range 150 kHz to 80 MHz, the field intensity should be less than [V1] V/m.*

Recommended separation distances between portable and mobile RF communications equipment and the Vivo Biphasic Defibrillator Monitor.

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

Immunity test	**ABNT NBR IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Rated maximum transmitter output power (W)	Separation distance according to the transmitter frequency (meters)		
	50 kHz up to 80 MHz $d=1.2\sqrt{P}$	80 MHz up to 800 MHz $d=1.2\sqrt{P}$	800 MHz up to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.1 m	0.1 m	0.2 m
0.1	0.4 m	0.4 m	0.7 m
1	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

For transmitters with a maximum output power rating not listed above, the recommended separation distance “d” in meters (m) can be determined from the applicable equation for the transmitter frequency, where “P” is the maximum output power rating. of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80MHz and 800MHz, the separation distance for the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

24. TECHNICAL ASSISTANCE

Permanent Technical Assistance

Mr./Mrs. Proprietor,

CMOS DRAKE has a large list of representatives and technical assistance throughout the Brazilian territory.

So that we can provide you with a personalized service, we ask that you send us the registration form. This aims to update our database for the best targeting of authorized technical assistance services for each region of Brazil, training and others.

For complaints, doubts, suggestions, and technical assistance, please contact our **CAS** (Customer Assistance Service) below:

CMOSDRAKE
Av. Regent, 600 – Alphaville Lagoa dos Ingleses Nova Lima/ MG
CEP: 34.018-000
www.CMOSDRAKE.com

25. FORM FOR CUSTOMER REGISTRATION

EQUIPMENT DESCRIPTION	SERIAL NUMBER
Vivo Biphasic Defibrillator Monitor	

CUSTOMER NAME:	
ADDRESS:	
CITY:	**STATE:**
TELEPHONE:	**FAX:**

MANUFACTURER'S NAME:
TECHNICAL ASSISTANCE:

ATTENTION:

Mr./Mrs. PROPRIETOR,

Please fill in the fields below with your data and send to us by fax for registration in our system.

It is very important that you send us your data, so future contacts referring to inquiries and technical assistance.

26. CERTIFICATE OF WARRANTY

Cmos Drake do Nordeste Ltda

CERTIFICATE OF WARRANTY

CMOS DRAKE DO NORDESTE LTDA guarantees Legal Warranty against any manufacturing defect applicable under the following conditions:

1- The warranty period starts from the date of issuance of the sales invoice referring to the equipment purchased by the consumer with mandatory identification of the model, serial number and equipment characteristics.

2- The warranty period is 12 (twelve) months from the corresponding date in the form of the item above

3 - CMOS DRAKE do NORDESTE LTDA does not grant any form or type of warranty for equipment unaccompanied by the sales invoice to the consumer.

Prescribed conditions of this guarantee

- Any defect diagnosed during the installation and (or) use of the product, the consumer must immediately contact CMOS DRAKE DO NORDESTE LTDA. The same will activate the accredited representatives listed at the end of this manual, who will only be able to intervene with FORMAL AUTHORIZATION, complying with the validity periods of this authorization.

- It will be the responsibility of the manufacturer to replace parts and products that present anomalies verified as a manufacturing defect, in addition to the labor involved in this process.

- Sensors, cables in general and accessories necessary for the perfect functioning of the product are guaranteed against manufacturing defects for a legal period of 90 (ninety) days, starting from the date of purchase of the product prescribed in the invoice.

- Accessories marked as disposable and consumable (non-durable) will have their warranty in accordance with art.26, item I, Consumer Defense Code.

The warranty will be canceled when:

1 - There is removal or alteration of the serial number of the equipment purchased by the consumer.

2 - The equipment is installed or used in a manner different from that provided for in the USERS MANUAL.

3- The equipment is used with cables, sensors, accessories or consumables not recognized by CMOS DRAKE or outside the normal conditions of use, such as expiration date or period or use.

4- The consumer will lose the warranty right for a period of 12 (twelve) months in the event that the equipment:

a) It has been serviced or repaired by a professional not accredited by the manufacturer
b) It is used in a manner different from that described in the manual of use
c) It suffers damage caused by accidents or natural phenomena.

5- The manufacturer is not responsible for expenses with installations, products or accessories damaged due to transport accidents, handling, scratches, dents, non-functioning or failures resulting from problems in the electricity supply. In locations where there is no authorized technical assistance from CMOS DRAKE, the costs of transporting the device or the authorized technician to the place where the equipment is located will be borne by the Consumer requesting the service.

Serial number