User Manual

DEFIBRILLATOR E-HEART

Version 02 rev. 00

US DEFIB
MEDICAL TECHNOLOGIES

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PREFACE

Congratulations for purchasing the Biphasic Defibrillator Monitor E-HEART.

This product incorporates the latest technology designed to aid patients through a medical emergency and resuscitation procedures.

Full reading of the operating instructions should precede the use of the equipment.

All data necessary for the safe and correct use of the equipment, as well as information on the essential care for the conservation of the Biphasic Defibrillator Monitor E-HEART and clarifications related to technical assistance and the Warranty Certificate are detailed in this manual.

A Quick Guide for emergency operations, which must be kept and maintained close to the equipment for future reference, will accompany this manual.

Summary

1. PICTURES

2. INTRODUCTION

PRESENTATION

The E-HEART Biphasic Defibrillator Monitor is a light and portable electronic device, developed and designed for resuscitation and monitoring processes, where electrical stimuli are applied to the heart, if cardioversion or defibrillation are recommended.

The device has the revolutionary biphasic technology that requires less energy for the defibrillation than the conventional monophasic devices, enhancing its performance. In addition to that, it also has microprocessors for the heart activity analysis, which takes around 10 seconds to run.

One of its main features is its colored high resolution and contrast Liquid Cristal Display, which makes it possible the visualization of the information displayed from different angles because of the flip down system.

The E-HEART Defibrillator Monitor can be used in adult and pediatric patients and in different locations in the hospitalar area: on shelves, beside surgic beds, in rescue vehicles and aircrafts. It provides the best solution in the advanced life support and increases the rate of human survival in cases of cardiac arrest.

LIABILITY DISCLAIMERS

US DEFIB will be free from any and all liability that may arise related to personal or material injury caused as a result of:

- Applications that differ from its intended purposes;
- Improper use and repair of the device;
- Failure to comply with the device's use, repair and maintenance instructions expressed on this manual;
- Use of accessories and materials manufactured by other companies (not authorized by US DEFIB);
- Unauthorized interventions, repairs or structural modifications to the device.

3. SAFETY INFORMATION

WARNINGS

⚠**The Biphasic Defibrillator Monitor E-Heart was developed for warranted clinical monitoring applications, if properly operated by trained individuals and if used in an appropriate medical facility.**

⚠**The operator must proceed with the device and accessories condition checking's (regular drills) and make sure all the accessories are functioning properly before actually using the device.**

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

⚠**The use of the Biphasic Defibrillator Monitor E-Heart is restricted to one single patient per time and it is a non-continuous use device.**

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

⚠ **While installing the device, make sure that it is done in a room with enough space and ventilation, away from heat radiation, and in such a position that the power cord will not get easily disconnected from the device (10cm on the upper side, 20cm on the back side and 15cm on both sides).**

⚠**Risk of electrical shock if the plastic case is open. All types of service or future updating of this device, can only be carried out by trained personnel and after authorized by US DEFIB.**

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

⚠**When the Biphasic Defibrillator Monitor is used along with a Harmonic scalpel, the guidelines indicated in this manual on the operation of the device in the presence of high frequency equipment must be noted.**

⚠**The Biphasic Defibrillator Monitor E-Heart is intended to be connected to the public power grid, without any electromagnetic interference – in compliance with the recommendations of NBR IEC 60601-1-2 / CISPR 11 – Limits and methods of measurements of electromagnetic interference characteristics in industrial, scientific and medical radiofrequency devices(ISM).**

⚠**To prevent from fire and shock risk avoid operate or place the device close to any type of water source and avoid liquids over its plastic case.**

⚠**The protection against the effects of cardiac defibrillation discharge is present in the modules inside the device. The sensors and cables do not have additional protection against the effects of the cardiac defibrillation discharge or when the device is used with other**

devices that operate in high frequency.

⚠**The disposable items must not be reused even after undergoing cleaning and/or sterilization processes. These items must be discarded in appropriate areas in compliance with the procedures adopted with hospital waste.**

⚠**In general, the parts and accessories of the Biphasic Defibrillator Monitor E-Heart that come in contact with biological tissues, cells or body fluids are tested according to the guidelines and rules of the ISO 10993-1, which deals exclusively with the biocompatibility applied to such parts.**

⚠**In case any part of the device, except for the disposable items, need to be replaced, one must contact the manufacturer or authorized technical representatives for the acquisition and replacement of those parts.**

⚠**There is a risk of environment pollution at the end of the disposable items and accessories at the end of their life spam. The accessories and disposable items must be accordingly discarded following the environmental rules and hospitalar regulations. The internal batteries must be returned to the manufacturer after replaced or when they reach the end of their lifespan.**

⚠**Every item used in the device must be carried out as per this manual. US DEFIB can only guarantee the perfect functioning of the device, in case all instructions are followed.**

⚠**Never reuse disposable materials.This practice may cause harm to the patient.**

⚠ **After using the device, discard the disposable items, sanitize the permanent ones and put them keep them with the device.**

⚠**Always use the device's handle to transport it.**

⚠**Proper grounding is required for safety to the patient. We recommend you to install the Biphasic Defibrillator Monitor E-Heart in compliance with the requirements of NBR 13534 - Electrical Installations in Health Care Facilities - Requirements for safety, published by ABNT in November 1995.**

⚠**Avoid connecting the patient to several devices at the same time. The vite conectar o paciente a diversos equipamentos de uma só vez. The limits of leakage current may be exceeded.**

⚠**Conductive parts of the used accessories, including the Neutral Electrode, must not come in contact withother conductive parts, including the grounding.**

⚠**A number of things may cause a misinterpretation of the ECG readings, such as: Electrodes poorly attached; patient movements, the presence of pacemaker (it can reduce the precision of the cardiac arrest detector); radio frequency interference, including cellphones; too much hair or wet areas on the patient's skin where the electrodes are attached.**

⚠ **No modifications to this device are allowed.**

⚠**The Biphasic Defibrillator Monitor E-Heart can run ECG monitoring at differential offset**

voltage not under +/- 300mV. In case of overload, a saturation of the ECG signal occurs, which makes the monitoring parameter inactive until the device returns to its normal conditions.

⚠**In special occasions, if necessary, US DEFIB will provide, under agreement, all technical information such as: circuit diagrams, technical files, list of components, calibration and testing instructions, so that the trained and qualified technical personnel may proceed with repairs of designated parts. The maintenance authorization must be formally expressed by US DEFIB.**

⚠**In case of maintenance of the Biphasic Defibrillator Monitor E-HEART, disconnect the power cable from the grid and wait for 5 minutes before opening the device.**

⚠**The Biphasic Defibrillator Monitor E-Heart must not be used at a very close range from other devices. Under no circumstances, should other devices be stacked or pilled over the Defibrillator Monitor E-Heart. In case these warnings are not followed through, the user must test the functionalities of the Defibrillator Monitor before its use.**

SYMBOLS AND ABBREVIATIONS


Dangerous Voltage.


General symbol for warning.


Class II Device


Defibrillation proof BF type applied part.


Defibrillation proof CF type applied part.


Refer to manual/Instructions booklet.


Do not discharge with the shocking paddles facing one another.


Do not sit.


Do not step on this surface.


Prohibition.


Exit.


Print.

NIBP.

Synchronize.

Freeze.

Inhibit pacemaker pulse beep.

Inhibit alarm for 2 minutes.

Alternating Current.

Continuous Current.

This side up: shows the Correct position for the transportation and storage of the box.

Fragile: shows that the box must be handled with care.

Keep dry: shows that the box must be kept in a dry area.

Number5: shows that the maximum stacking of boxes on top of others.

Indicates a medical device, and as such, requires special handling.

Indicates that the material used is recyclable.

Symbol for electrical and electronic devices according to EC 2002/96/EC Guidelines. The device and its accessories must be properly discarded at the end of their use or lifespam.Please follow the local regulations for disposal.

Manufacturer

Manufacturing date

MEASUREMENT UNITS

Symbols	Unit	Description
m, cm, mm	Length	Meter, centimeter, milimeter.
h, m, s, msec	Time	Hour, minute, second, millisecond
Kg, g	Mass	Kilogram, gram
°F, °C	Temperature	Fahrenheit degrees, Centigrate degrees
mmHg, hPa	Pressure	Milemeters of mercury, hectopascal
hz, bpm, bpm, ppm	Frequency	Hertz, breaths per minute, beats per minute, pulses per minute
V, mV	Voltage	Volts, milivolts
m/s, mm/s, bps, l/m	Speed	Meter per second, milemeter per second, beats per second, liters per minute
A, mA	Current	Ampere, Miliampere
Ω	Impedance	Ohms
J	Energy	Joules
m^3, mm^3	Volume	Cubic meter, cubic milimeter

Table 2

ACRONYMS USED IN THE USER MANUAL

- ACLS: Advanced Cardiac Life Support;
- AHA: American Heart Association;
- BLS: Basic Life Support;
- ICD: Implantable Cardioverter-Defibrillator Implantável
- ECG: Electrocardiogram;
- VF: Ventricular Fibrillation;
- Hb: Hemoglobin (cHb: Hemoglobin Concentration);
- HbO2: Oxihemoglobin (cHbO2: oxihemoglobin Concentration);
- PRINT: Printer;
- LED: Light-Emitting Diode;
- LCD: Liquid Crystal Display;
- PM: Pacemaker;
- SAN: Sinoatrial node;
- BP: Blood Pressure;
- CA: Cardiac Arrest;
- NIBP: Non-Invasive Blood Pressure;
- IBP: Invasive Blood Pressure;
- DBI: Desfibrilador;
- CPR: Cardiopulmonary Resuscitation
- SBC: Sociedade Brasileira de Cardiologia (reads Brazilian Cardiology Society in English);
- SPO2: Oxigen Saturation;
- VT: Ventricular Tachycardia;
- ICU: Intensive Care Unit;
- VOO: Pacemaker Asynchronuous Mode;
- VVI: Pacemaker Demand Mode;
- ETCO2: Capnography.

CONTRAINDICATIONS

- This device can not be used in the presence of flammable agents such as anesthetic gases, fuels, among others;
- This device should not be used by lay people, only by properly trained and qualified professionals.
- Asynchronous defibrillation is contraindicated in patients who have one or any combination of the following conditions:
- Awareness;
- Spontaneous breathing;
- Palpable pulse;
- Children under 8 years of age or weighing less than 25 kg (acCOLORding to AHA 2000 Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, I-64, 2000).

This equipment should 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, shocks should not beapplied in asystole.

4. BASIC ORIENTATION FOR THE BIPHASIC DEFIBRILLATOR MONITOR E-HEART

PRESENTATION

The Biphasic Defibrillator Monitor E-Heart's main function is to monitor the vital signs such as ECG, pulse oximetry, noninvasive blood pressure and capnography, so that the medical professional can diagnose and interpret patient data that will be presented on the device's display.

The device is intended to be used only by qualified doctors and professionalstrainedin ACLS-Advanced Life Support, Advanced Cardiac Support or defibrillation.

FUNCTIONING

If during ECG monitoring process, the medical professional diagnoses some malignant arrhythmia which has the electric shock treatment indication, it should trigger the load key, where an electronic circuit will produce energy, ranging from 0 to 360 joules, to discharge into the patient. The doctor is the one who determines what the energy needed is. During this procedure, the patient keeps on monitoring for the physician to analyze the results after the ECG (s) shock (s).

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

Dedicated electronic circuits and microprocessors enable this capture, amplify the signals, process them 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.

USE INDICATIONS

MANUAL DEFIBRILLATION

The asynchronous defibrillation is the initial treatment of cardiac arrhythmias in pulseless and unresponsive patients. The synchronized defibrillation is recommended for converting atrial fibrillation.

ELECTROCARDIOGRAM

Indicated to assess cardiac electrical activity and check the state of the muscles and nerves of the heart.

AED MODE (optional)

It is only indicated in cases of patients with sudden cardiac arrest (SCA) that are unconscious and do not breathe normally.

Pulse oximetry (optional)

The oximetry sensor should be used to help in the reading of oxygen saturation in the patient's blood.

Capnography (optional)
Used to verify the inspired volume of carbon dioxide exhaled by the patient, and display the respiratory rate.

NON-INVASIVE BLOOD PRESSURE (optional)
Used for non-invasive measurement of patient's blood pressure through a cuff.

Pacemaker
The non-invase pacemaker is adequate for pre-hospitalar and hospitalar facilities. Some of the transthoracic uses of the pacemaker are: Bradycardia treatment during an emergency; During and after a cardiac surgery; To facilitate the implantation of an intravenous electrode stimulator.

CHARACTERISTICS

The Biphasic Defibrillator Monitor E-HEART integrates several functions and can be configured acCOLORding to the specific needs of each patient
.
Factory Default Settings:

- ECG Monitoring and heart rate;
- Biphasic Defibrillator
- Rechargeable battery.

In addition to the factory default settingsit is possible to include the following settings:

- Non-Invasive Pressure (NIBP)
- Monitoring of functional arterial oxygen saturation (SPO2) and methemoglobin;
- Non-invasive transcutaneous external pacemaker (demand and asynchronous, switched to emergency mode);
- Non-invasive blood pressure monitoring (NIBP);
- Capnography (CO2);
- Thermal printer;
- Drugs software;
- Ventilation / intubation Software;
- ST segment analysis software;
- Automated External Defibrillator Mode (AED) with voice and text command.

NOTES

- With simple operation, through its AED (optional) mode, the device offers the possibility to be used by trained people under medical supervision. It is highly safe and has minimal risk

of injury to the patient and the operator. In AED mode (optional) it offers voice and text command to instruct the rescuer during resuscitation sequence.

- Any of the parameters can be integrated to the device, without altering the product characteristics purpose.

GENERAL CHARACTERISTICS

Defibrillation in the form of truncated exponential biphasic waveform, 1-200 Joules charge and optional of 1-360 Joules charge, with operating instructions on thedevice's panel itself;

❖ 200Joules Version:
- Pediatric 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 Joules.

❖ 270Joules Version:
- Pediatric 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, 270 Joules.

❖ 360Joules Version:
- Pediatric 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, 240, 360 Joules.

❖ It has smart safety system that limits the shocking charge to 50J for pediatric use, once the adult paddle blades are unscrewed and the pediatric blades are exposed.
❖ External case in high impact ABS, electrically insulated;
❖ Self Test to initialize;
❖ Low battery alarm - audible and visual;
❖ Heart Rate: Any reading frequency of 10 to 300 bpm with numerical display;
❖ ECG cable 10 leads - optional;
❖ Enablescommunication with microcomputer for memory data visualization through connection or other means;
❖ Tolerance defibrillation scale: (± 3 J or ± 15%, whichever is greater).
❖ Smart safety system that limits the shocking charge for pediatric / neonate use;
❖ Analysis of the thoracic impedance of the patient for increased defibrillation efficacy and reduced risk of cardiac injuries;
❖ Internal automatic discharge after 30 seconds if no shock, or manually through the key "cancel charge" at any time;
❖ Clock / date;
❖ Performed shocks counter;
❖ Permanent interchangeable adult / pediatric paddles;
❖ Paddles contact indicator (optional); Monitors the contact of the paddle bladesto the patient's chest through a barragraph on thedisplay and optionally on thepaddlesthrough LEDs;

- Performs Autotest once devices is connected;
- Internal rechargeable battery;
- External spare battery fully charged (optional);
- Battery status indicator - Low, charging and charged;
- Ability to perform up to 220 shocks (200J) on a full charge (new battery fully charged);
- Colored liquid crystal display for viewing the ECG, SPO2, NIBP, pacemaker, AED mode and capnography parameters and printer; battery status display, alarms, pre programming parameters and post-shock, selected energy indication for shocking, and contact and impedance indicators on the paddles;
- Event memory throughmemory stick, including information such as waveform, date and time of approximately 256MB, which is more than 100 hours of continuous recording - optional;
- Internal event memory including waveform, date and time of 2GB - through USB cable (optional);
- Available in the following languages: English, Spanish, German and others (Possibility of language change through software);
- Voice command features with volume control (optional) and text to instruct the rescuer during resuscitation sequence;
- When in "SYNCHRONIZED MODE", it performs synchronized shocks with the QRS complex, with the power delivery time below20ms;
- Maximum time of about 6 seconds forideal signal stabilization after connecting cable to the patient;
- Has a beep to guide CPR (100 Comp / min) in the AED MODE;
- Full system of audible and visual alarms with the possibility to program maximum and minimum values, including the technical alarm, loose electrode and physiological alarms for Asystole, tachycardia, bradycardia and fibrillation;
- When the Biphasic Defibrillator Monitor E-HEART is in the automatic mode, the discharging sequence of 150J, 200J and 200J is followed;
- Charging time of 5 seconds to 200J and 7 seconds to 360J;
- Pacemaker pulse detection;
- Impedance detection in the range of 25 Ohms to 500 Ohms for the shocking procedures;
- Drug calculation Software (Optional);
- Ventilation / intubation Software (Optional);
- Software for Analysis of ST Segment and arrhythmias (Optional);
- Software with impedance and contact indicators on the paddles (Optional);
- Selection of the charging level by paddle button "APEX" and charging through the "button STERNUM".

DAILY USE

The Biphasic Defibrillator Monitor E-HEART has basic function of cardioversion / defibrillation of cardiac arrhythmias. The device has hot keys (1 - Select Energy; 2 - Load, 3 - shooting) so that the operator can make the patient's resuscitation easily and promptly.
It also has the ECG cable for monitoring the cardiac signal. To do so, simply connect the cable to the product and attach the disposable electrodes to the patient's chest, and the devicewill automatically read the ECG signal and shows it on its display.

UNPACKING AND INSTALLING THE DEVICE

- Remove the device from its box;
- Place it in an appropriate and easily accessible location;
- 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 theirpacking box;
- Connect the power cord to the input of the device;
- Connect the power cord to the power grid;
- Check whether the AC and battery power LED indicators are lit;
- Keep the backside of the unit case at a minimum distance of 20 cm from any other device or wall, so that there is no risk that the power cord is pressed in or off the device, causing it to disconnect from the Defibrillator Monitor E-HEART;
- Keep the device connected to the power grid to make sure the battery is always charged ;
- This device is designed to work in environments not constituents offlammable anesthetic and cleaning agents. Do not operate it in the presence of flammable gases in general.

⚠Avoid turning the device on or off if it is connected to a patient; before doing it remove the electrode cables.

⚠If the patient is connected to the Defibrillator Monitor E-HEART, and has a floating insulation (not connected to electrical ground), or is connected to any other device that does not have the same type of insulation, the patient can come in contact with conductive parts and cancel the protective effect of the device;

⚠The Biphasic Defibrillator Monitor E-HEART should only be operated by properly trained people. It is the responsibility of the hospital administration to have adequate and accessible operating instructions.

⚠The interconnection of Biphasic Defibrillator Monitor E-HEARTwith any other device is only allowed when it is not harmful to the patient, the operator, the environment and the device itself;

⚠Check the COLORrect operation of the device before clinical use;

⚠ If the specification of the additional part do not inform about the device interconnection effects, look for the manufacturer or an expert on the subject;

⚠You can quickly check the alarm function (visual and audible) with the aid of a parameter simulator. One can test situations where the measured values exceed the maximum or minimum limits set by the operator of the device. The alarms (visual and audible) can also be checked by touching the key that inhibits the alarms, silencing all the device's alarms for 2 min;

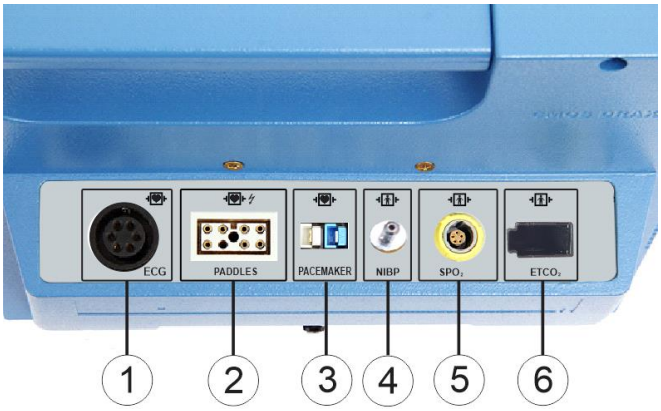
⚠The Biphasic Defibrillator Monitor E-HEART should only be operated by properly trained people. It is the responsibility of the hospital administration to have adequate and accessible operating instructions.

GENERAL VIEW

Picture 1 - General View

BACK PANNEL

The sensors inputs are located on the device's back pannel.

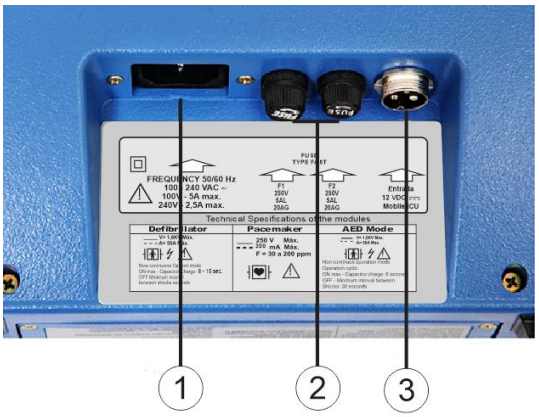


Picture 2– Identification of modules

1- ECG Connector.
2- Permanent shock paddles connector/Adhesive AED mode shock paddles.
3- Pacemaker adhesive shock paddles connector.
4- NIBP connector
5- SPO2 connector
6- ETCO² cannula connector.

The Biphasic Defibrillator Monitor E-HEART has only one input to the permanent shock paddles and adhesive shock paddles of the AED MODE. To use the pads of AED MODE, simply unplug the permanent paddles and connect the extender cable of theAED MODE.

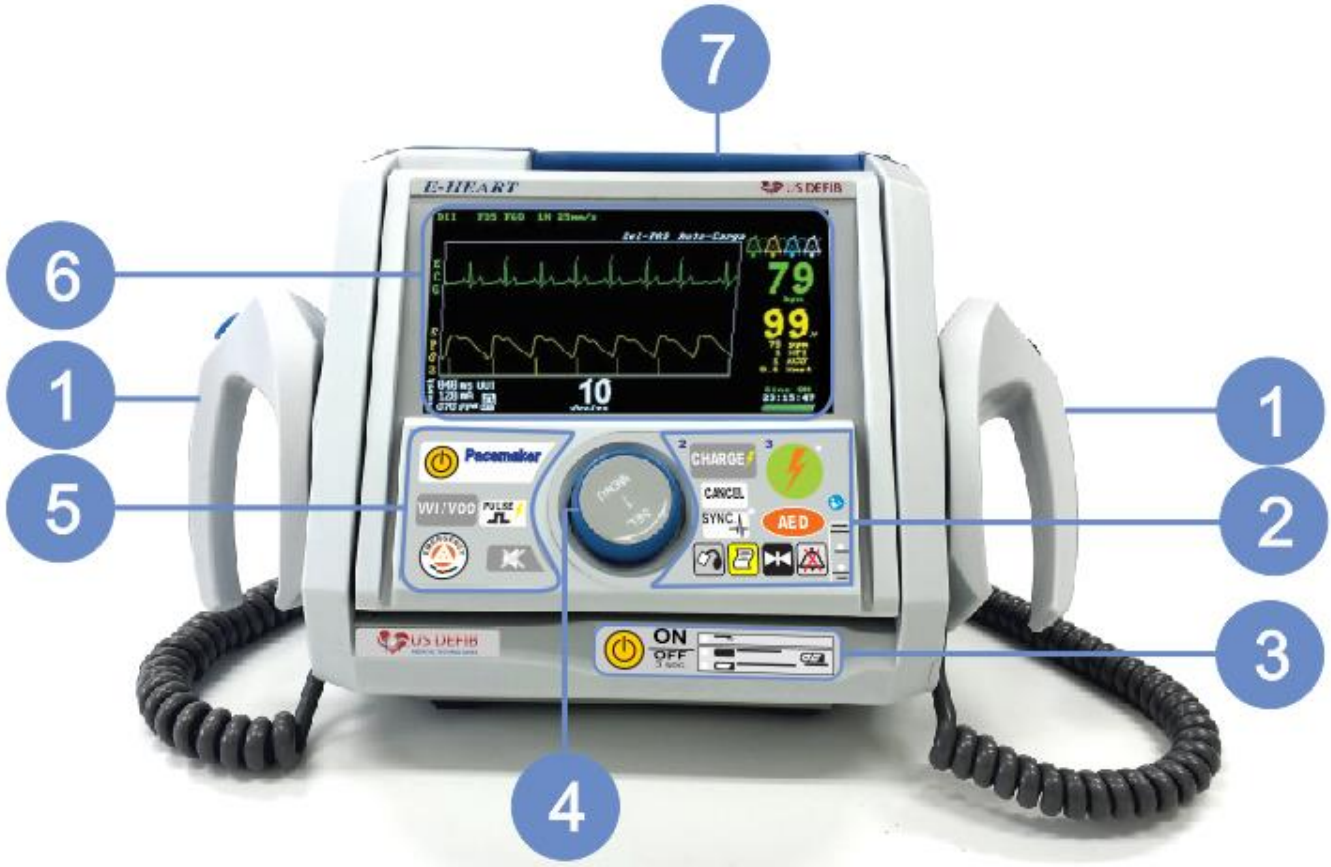
INPUTS



PICTURE3 - Identificação painel traseiro

1- Powergrid input
2- Fuses
3- Mobile care units input

IDENTIFICATIONOF PARTS AND COMMANDS OF THE BIPHASIC DEFIBRILLATOR MONITOR E-HEART



PICTURE4–Partsand commandsof the Biphasic Defibrillator Monitor E-HEART

1. Interchangeable permanent adult/pediatric shocking paddles;
2. Shortcutkeys;
3. On/off, power and charging indicators;
4. Menu/selection key;
5. Shortcut Keys of the pacemaking menu;
6. Display;
7. Transport handle;

2 Shortcut keys

Charges the shocking capacitor.

Cancels the charging and shocking process.

Shock button.

Sync - Enables/disables synchronized shocks with the ECG signal.

Accesses the AED MODE.

NIBP– Starts/stopsmeasuring the NIBP.

Print – Press it to start printing and press it again to stop printing.

Freeze.

Inhibits all alarms for 2 minutes.

3 On/Off and indicationsof power grid and battery status.

1. On/Off button.

2. Indicating LED's:

Power grid;
Bateria charging;
Low Battery.

4 Menu/Selecting Key

The Menu key has two functions, namely:

1 - Navigation / selection through the Settings menu:

To enter the Setup Menu, simply press the Menu/selection key and the settings screen appears in the display.

2 - Change / confirm the selected energy:

To change the selected energy simply turn the key (right - increases energy / Left decreases) and the value is displayed on the screen. To confirm the energy just press the Menu/selection key and the value will be confirmed and displayed in white on the screen. If the power has not been confirmed and the charge button is pressed, the message: "Press the menu button to confirm the energy and charge." As the energy is not confirmed the device will not trigger the charge on the capacitor.

By pressing the Menu/Selection key, the display shows the parameters of the Menu Settings. An arrow-shaped cursor (>) appears on the left of one of the items on this menu indicating that this is the selected item. By turning the navigation knob clockwise or anti-clockwise will move the cursor pointing to a new menu item, depending on the direction of rotation. To set the desired module, set the cursor pointing this module and press the Menu/Selection key.

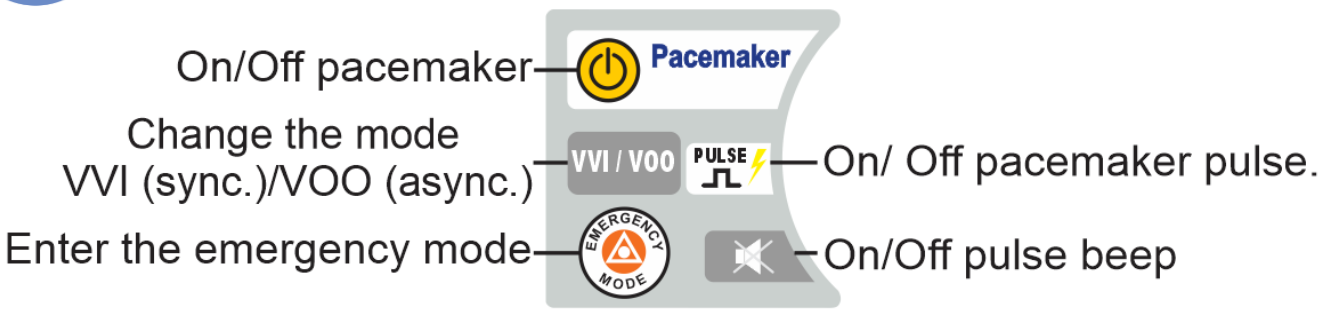
After choosing the module to be set, a new menu will appear on the display with the configuration items for the selected module.

To exit the menu, set the cursor on the item Exit or press the shortcut key Exit located on the panel beside the navigation button .

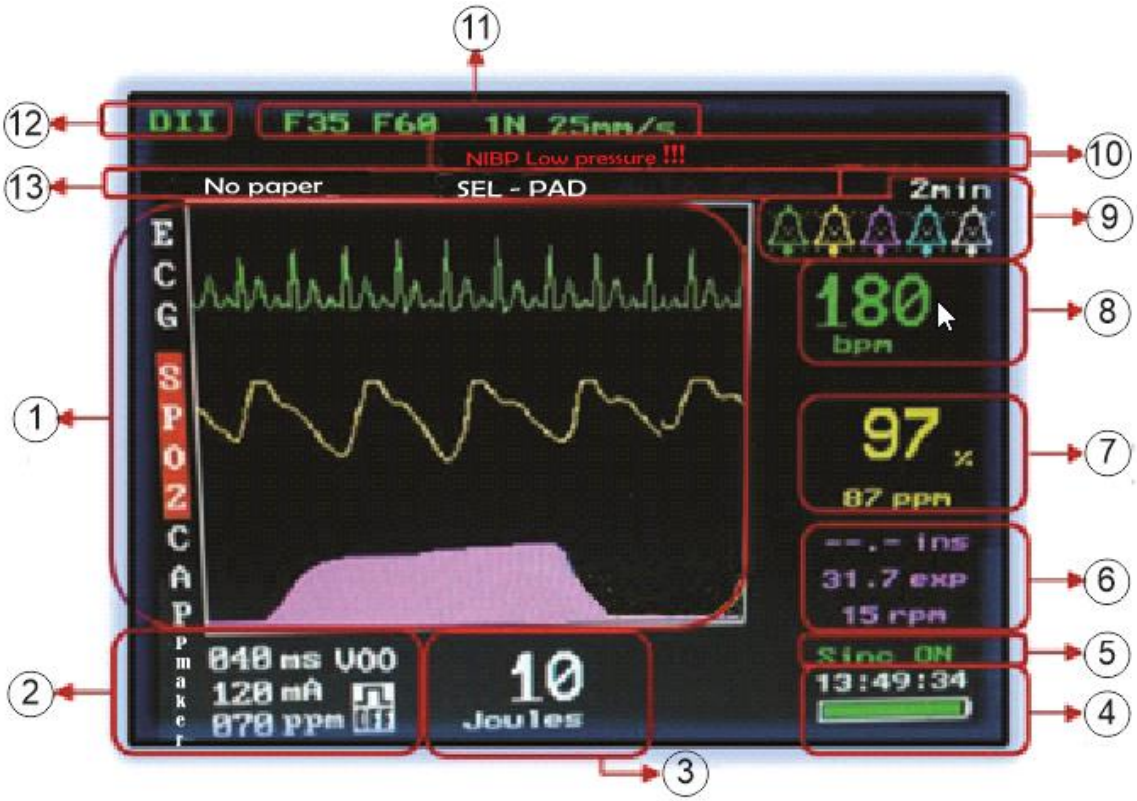
NOTES:

- In the Settings Menu only the parameters that are installed in the device will be displayed (Settings options);
- By turning the navigation button without pressing it before you can select the power in case of treatment recommendation (1 to 200 Joules, or even 360joules - optional).

5 Shortcut keys of the Pacemaking Menu.



6 Display



PICTURE 5–Defibrillator Monitor E-HEART table

1- Graphic area: It has divisions where the monitoring psysiological parameter curves are presented.	8- **ECG**: Beats per minute (bpm).
2- Pacemaker stimuli data: Shows the width (ms), Amplitude (mA) and pulse frequency (ppm), operation mode (VOO/VVI). Indicates whether the pulse is active (ON) orinactive (OFF).	9- **ALARM indications**: shows the alarming parameters. When the measured values exceed the minimum and maximum limits set by the operator, or when the key Inhibit alarm is pressed, silencing all alarms for 2 minutes.
3-**ENERGYvalues**: Shows the selected shocking energy.	10- **NIBP**: Numerical Presentation of non-invasive blood pressure and provides the systolic blood pressure, mean and diastolic.
4- Time and battery status indicator.	11- Indication of filter settings **35 and60** (Hz), **Gain** (1/2N; 1N; 2N) and**ECG trace scanning speed** (12,5mm/s; 25mm/s; 50mm/s).
5- Sync on indication(QRS)**.**	12- Indication of the **ECG derivation**: Shows the electrocardiogram derivatin displayed on the graphic area (CAL = calibration, D1, D2, D3, AVR, AVL, AVF, V).
6- **CAPNOGRAPHY**: Breathes per minute (bpm), measures the exhaled carbon dioxide (EtCO) and the inhaled value (FiCO).	13- PRINTER message,**Sel-PAD** indicates whether the command through the paddle buttons is activated or not and auto charge function, which indicates if the automatic defibrillation sequence is activated or not.
7- Pulse oximetry**SPO2**: Oxigen saturatin (%) and pulse per minute (ppm).	

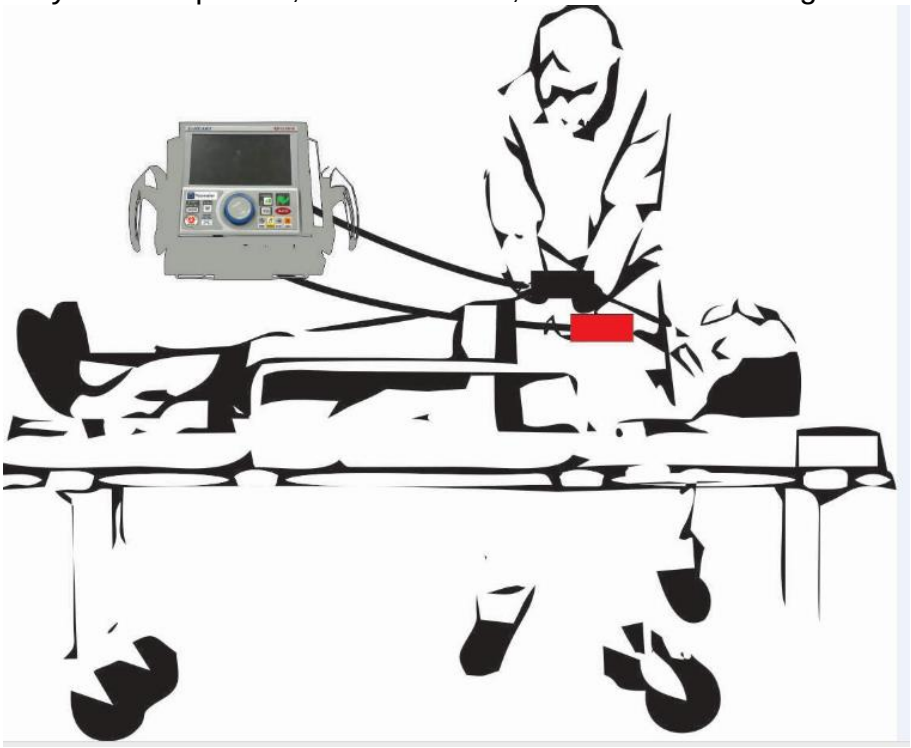
INITIALIZING THE DEVICE

In order to initialize the device, press the ON/OFF button located on the front pannel of the device.

PICTURE 6 - *On/Off button*

The device starts and is ready to use. Just connect the accessories and adjust the levels of alarms (as guidelines to follow) in order to start using the device.

Throughout the procedure, keep the device approximately 0.5m from the patient and the operator, as shown in the picture below.
The operator must stay with the patient, near the chest, to check the vital signs.



PICTURE7 - Operator's position

TURNING OFF THE DEVICE

After completion of the procedure:

1. Turn off the device by pressing the on / off button for three seconds;
2. Disconnect all patient accessories;
3. Clean the device and accessories, as in the cleaning procedures described in this manual;
4. If the device's battery has been used, reconnect the power cable to the device and always keep it connected. To connect / disconnect the power cord, turn the back of the defibrillator monitor to plug and unplug.

5. ALARMS OPERATION MODE

ALARMS

The Biphasic Defibrillator Monitor E-HEART has audible and visual indications of physiological alarm conditions (HIGH PRIORITY - !!!) and technical alarm (MEDIUM PRIORITY - !!).
Alarms will be triggered acCOLORding to their priority.

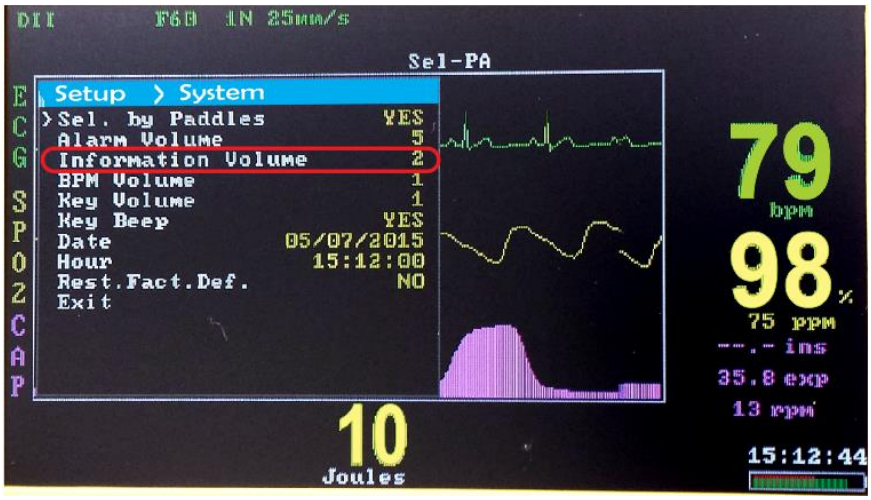
High Priority Alarm (Physiological Alarms): Indicates the patient's physiological alterationsand will be triggered when the value measured by the equipment exceeds the minimum or maximum limits set previously by the operator on the device's menu.

Medium PriorityAlarm (Technical Alarms): Indicates that the device is not able to monitor the patient's condition.

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

AUDIBLE INDICATORS

If the device has different priorityalarms occurring simultaneously, the high priority alarms overrides the medium priority alarms.
Audible information alarms can be adjusted through the device's settings menu SYSTEM as shown below.



PICTURE 8 – Information messages volume adjustment

It is possible to set the volume of the VIVO Cardioverter alarms from 1 to7, in which 1 is the lowest and 7 is the highest level. The alarm tones can vary from 45 to 85 dB.

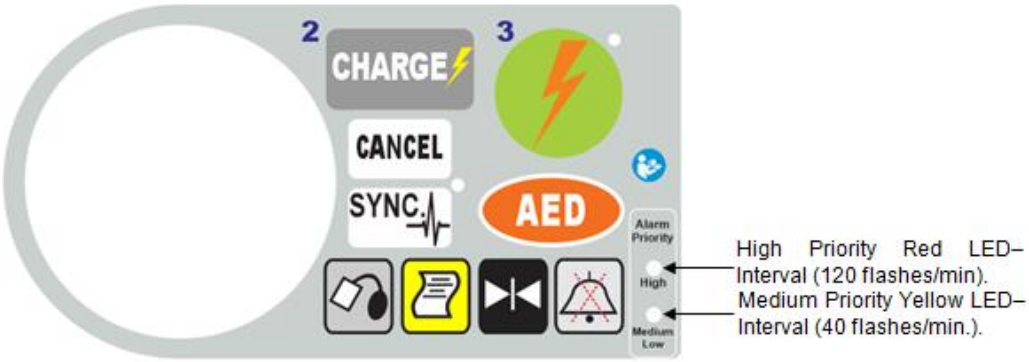
⚠ **The alarm volume setting should be performed by the user according to the noise at the place where the equipment is going to be used.**

⚠ Do not rely exclusively on the audible alarm system. Setting the alarm volume to a low level can result in risks to the patient. Always keep the patient under supervision.

⚠ Sound pressure levels of audible alarms that are lower than ambient levels may prevent the recognition of the alarm conditions.

VISUAL INDICATORS (LEDS)

Two alarm indicator LED's are located on the Biphasic Defibrillator Monitor E-HEART keyboard.



Picture 9 - Visual indicators (LEDs)

Visual indicators, symbols and text messages.

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

Alarm symbols.

Each parameter has a color for easy identification, as follows:

- ECG – Green;
- SPO2 – Yellow;
- NIBP – Blue;
- Pacemaker – White;
- Capnografia – Pink.

Alarm Symbol	Cause
	Alarmed ECG.
	AlarmedSPO2.

	AlarmedNIBP.
	AlarmedPacemaker.
	AlarmedCapnography.
	ECG alarm disabledby user.*[1]
	SPO2 alarm disabled by user. *[1]
	NIBPalarm disabled by user. *[1]
	Pacemakeralarm disabled by user. *[1]
	Capnographyalarm disabled by user. *[1]
	All alarms inhibitedfor two minutes.*[2]

*[1] The user can disable the medium priority alarms, simply by entering the parameters settings menu. You can not disable high priority alarms.

*[2]All alarms, regardless of priority, are inhibited for two minutes.

Alarm messages

ECG

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
Electrode disconnected!!	MEDIUMPRIORITY	YELLOW	Electrode is disconnected
Check ECG cable	MEDIUMPRIORITY	YELLOW	Electrode is worn out Not enough conductive gel Insuficient preparation of the patient's skin
Bradycardia!!!	HIGHPRIORITY	RED	When the bpm is above the determined limit set in the alarm settings menu
Tachycardia!!!	HIGHPRIORITY	RED	When the bpm is below the defined limit set in the alarm settings menu
Arrhythmia/asystole!!!	HIGHPRIORITY	RED	No bpm. Electrode is worn out

			Not enough conductive gel Not enough conductive gel

SPO2

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
No Sensor!!	MEDIUMPRIORITY	YELLOW	Disconnected sensor Defective sensor or cable Sensor is not correctly positioned Inadequate sensor
Defective Sensor!!	MEDIUMPRIORITY	YELLOW	
Excessive Light!!	MEDIUMPRIORITY	YELLOW	Sensor is not correctly positioned
Inadequate Sensor!!	MEDIUMPRIORITY	YELLOW	Inadequate sensor
Low Perfusion!!!	HIGHPRIORITY	RED	The Perfusionvalue is below the one defined in the alarm settings menu
Undetected Pulse!!!	HIGHPRIORITY	RED	No PPM
High Saturation!!!	HIGHPRIORITY	RED	Saturation is above the determined limit set in the alarm settings menu
Low Saturation!!!	HIGHPRIORITY	RED	Saturation is below the one determined in the alarm settings menu
High PPM!!!	HIGHPRIORITY	RED	PPM is above the determined limit set in the alarm settings menu
Low PPM!!!	HIGHPRIORITY	RED	PPM is below the one determined in the alarm settings menu

Information messages:

- Searching for pulse (COLOR cyan blue) – Sensor searching for patient's pulse;

SPO2 MASIMO

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
High SAT!!!	HIGHPRIORITY	Red	SpO2 saturation above the determined limits.
Low SAT!!!	HIGHPRIORITY	Red	SpO2 saturation below the determined limits.

High PPM!!!	HIGHPRIORITY	Red	PPM above the determined limits.
Low PPM!!!	HIGHPRIORITY	Red	PPM below the determined limits.
Lowperfusion!!!	HIGHPRIORITY	Red	Low blood perfusion.
No pulse!!!	HIGHPRIORITY	Red	Pulse not detected
No sensor!!	MEDIUM PRIORITY	Yellow	Sensor not connected. Connect a compatible sensor.
Defective Sensor!!	MEDIUM PRIORITY	Yellow	Defective sensor. Replace it.
Check sensor connection!!	MEDIUM PRIORITY	Yellow	Poor sensor connection. Disconnect and reconnect sensor. If alrm continues, replace sensor.
Excessive light!!	MEDIUM PRIORITY	Yellow	Room lighting is causing sensor malfunction.
Improper Sensor!!	MEDIUM PRIORITY	Yellow	Sensor not compatible. Replace sensor for a compativle one.
MASIMO board activated	MEDIUM PRIORITY	Yellow	MASIMO board activated*. Use the necessary update keys to activate the board.*
Low SIQ!!	MEDIUM PRIORITY	Yellow	Low signal quality index. Check patient. It may indicate movement and/or low perfusion.
Error – Oximetry	MEDIUM PRIORITY	Yellow	The MASIMO board was not initialized. Reset the device. In case the error continues, the device must be shipped to na authorized technical center.

*Technical Support

Information Messages:

- Sensor initializing (cyan blue) - The initialization process may take up to 20 seconds;
- Searching for pulse (cyan blue) – Sensor is searching for patient's pulse;
- No patient (cyan blue) - Sensor is disconnected from patient.

Perfusion Alarm

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
High PI!!!	HIGH PRIORITY	Red	PI over the determined limits.
Low PI!!!	HIGH PRIORITY	Red	PI belowthe determined limits.

Methemoglobin Alarm

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
Met-Hb Alto!!!	HIGHPRIORITY	Red	Methemoglobin saturationover the determined limits.
Met-Hb LOW!!!	HIGH PRIORITY	Red	Methemoglobin saturation below the determined limits.

CarbonMonoxideAlarm

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

NIBP

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
NIBP Insuficient!!	MEDIUMPRIORITY	YELLOW	Module inflated for more than 30 seconds. Pressure is not high enough to produce results.
NIBP Do not measure again!!	MEDIUMPRIORITY	YELLOW	Measured for longer than 90 seconds (Adult) Measured for longer than 60 seconds (Neonates)
NIBP Measure again!!	MEDIUMPRIORITY	YELLOW	Weak pulse signal
NIBP Excessive movement!!	MEDIUMPRIORITY	YELLOW	Excessive patient movement
NIBP Irregular measurement!!	MEDIUMPRIORITY	YELLOW	Inaquate cuff/hose and/or connectors
NIBP measurement exceeded 90s!!	MEDIUMPRIORITY	YELLOW	Measured for longer than 60 seconds (60 seconds for Neonates)
NIBP +100 neutral pulses!!	MEDIUMPRIORITY	YELLOW	More than 100 pulses without any results were identified.
NIBP inadequate cuff!!	MEDIUMPRIORITY	YELLOW	Inaquate Cuff/Hose Check the position of the cuff/hose
NIBP wrong	MEDIUMPRIORITY	YELLOW	Irregular measurment,

measurement!!			check wave form
NIBP Divergent!!	MEDIUMPRIORITY	YELLOW	Divergent measurement, check wave form
NIBP<10mmHg or >250mmHg!!!	HIGHPRIORITY	RED	Pulse pressure below 10mmHg (Adult mode)
NIBP<05mmHg or >150mmHg!!!	HIGHPRIORITY	RED	Pulse pressure below 5mmHg (Neonate mode)
NIBP Pulse off rhythm!!!	HIGHPRIORITY	RED	Could not measure pulse
NIBP High Pressure!!!	HIGHPRIORITY	RED	Pressure value is above the determined limit set in the alarm settings menu
NIBP Weak pulse signal!!!	HIGHPRIORITY	RED	Weak pulse signal
NIBP High Systolic!!	HIGHPRIORITY	RED	Systolic pressure value is above the determined limit set in the alarm settings menu
NIBP Low diastolic!!	HIGHPRIORITY	RED	Diastolic pressure value is below the determined limit set in the alarm settings menu

Capnography

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
High RPM!!!	HIGHPRIORITY	RED	RPM is above the determined limit set in the alarm settings menu
Low RPM!!!	HIGHPRIORITY	RED	RPM is below the determined limit set in the alarm settings menu
High CO2 EXP!!!	HIGHPRIORITY	RED	CO2 EXP is above the determined limit set in the alarm settings menu
Low CO2 EXP!!!	HIGHPRIORITY	RED	RPM is below the determined limit set in the alarm settings menu
High CO2 INSP!!!	HIGHPRIORITY	RED	CO2 INSP is above the determined limit set in the alarm settings menu
Apnea	HIGHPRIORITY	RED	No RPM for a period determined in the alarm settings menu.
No Sensor!!	MEDIUMPRIORITY	YELLOW	Cannula is disconnected

Pacemaker

ALARM	PRIORITY	COLOR	POSSIBLE CAUSE
Pacemaker electrode is disconnected!!	MEDIUM PRIORITY	YELLOW	Electrode is disconnected Electrode is worn out Insuficient preparation of the patient's skin.

Information Message:

PM pulse off. - Pacemaker pulse measurements is off.

Printer

Information Messages:

- Open latch (White color) - Paper roll compartment latch is open.
- No paper (White color) - No printing paper.
- Printing...Menu locked (White color) – It is not possible to access the device's menu while printing.

Silence alarm

In order to silence the device's alarms, the user just needs to press the mute alarm key and all audible alarms will be silenced for 120 seconds.
The Mute Alarm icon will be displayed on the device's screen indicating that all alarms have been silenced.
In case a physiological alarm is initiated, for safety reasons, it will not be possible to change the alarm levels set previously so that the alarm stops. The changing menu will remain inactive until a normal scenario is reached.
In the event of a NIBP alarm, just press the NIBP key once and the alarm will be considered visualized and the beep will be inhibited.

CONFIGURATION OF THE ALARM LIMITS

The alarm limit settings must be accessed separately for each parameter menu. To change the alarm limits, just select the parameter, through the equipment navigation button (select/menu key), where the operator must set the desired value by pressing the navigation button again.

The E-HEART Defibrillator Monitor keeps the previous alarm settings in case of shutdown for a period of 30 seconds or less. After this time, the device returns automatically to the factory default settings to ensure safety in the event of patient change.

When there are simultaneous messages, they will be managed by priority. High priority alarms will always receive primary attention . In case of messages with the same priority, there will be a merge between these messages.

Example: When there is a high priority asystole alarm, the numerical value and the bell icon will flash. A message indicating that alarm condition that cancels any other message within that parameter will be displayed.

The device has indicating LED alarms located on the pannel of the device. Yellow Led alarms indicate medium priority and red LED alarms indicate high priority alarms. In case there are medium and high priority alarms at the same time, the device prioritizes the high priority audible alarms and their information on the screen.

⚠ **It is important to point out that the device has is factory default settings for the alarm limits. However, the user must set the alarms according to each patient condition.**

⚠ **Before a standard initialization of the device, make sure that the alarm settings range match the values of the patient's normal behavior and response.**

ALARM TEST PROCEDURES

MEDIUM PRIORITY- !!

With the device running and sensor disconnected, check the indication of disconnected sensor of the screen. After the visual indication is confirmed, properly connect the sensor and check for the visual confirmation again. If the indication disapears, the alarm is working accordingly. Otherwise, replace the sensor and repeat the operation. If the result is the same, the alarm is probably defective.
Repeat this procedure for the other modules but make sure the proper sensors and parameters are used.

HIGH PRIORITY- !!!

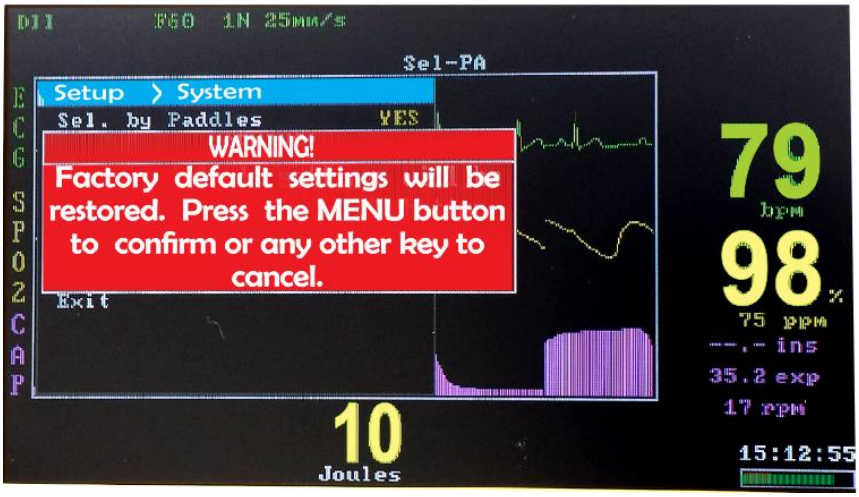
With the device running and electrode properly connected, check the ECG BPM value displayed on the screen. After that, press the Select/Menu key for 3 seconds, set the indicator (red color) on the ECG module ans select it by pressing once again the Select/Menu key. Turn it to the alarm option (high or low), press the Selec/Menu key again and then change its value so that the initially measured value is out of range. Confirm by pressing the Select/Menu button e push the Exit key to return to the initial screen. Once that is done the alarm should be triggered. If not it is not triggered this alarm is probably defective.
Repeat these procedures for the other modules but do it with each corresponding sensor and parameters.

We recommend that the functioning of the alarm system be checked as per the table below or criteria established the the user:

Verification frequency	Indication
Quarterly	Advisable
Semiannually	Recommendable
Annually	Mandatory

Reestablishing the default settings

It is possible to reestablish the defautl setting of the Biphasic Defibrillator Monitor E-HEART. In order to do that just access MENU - SETTINGS - REESTABLISH DEFAULT SETTINGS. Then a confirmation screen will pop up so that the default settings can be reestablished.



PICTURE10 - ***Confirmation screen for default settings reestablishment.***

The 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
- NIBP – Systolic: 140
- NIBP – Medium: 100
- NIBP – Diastolic: 60
- Capnography – RPM High: 150
- Capnography – RPM Low: 8
- Capnography – CO2 Exhaled. High: 150
- Capnography – CO2 Exhaled. Low: 15
- Capnography – CO2 Inhaled. High: 30
- Alarm Volume – 5
- Info Volume – 2
- Key Volume – 1
- Speed - 25 mm/s
- Gain - 1N
- Filter 60 Hz – enabled
- Filter 35 Hz - disabled

⚠ **The operator must check the cause of all alarms displayed by the equipment (technical and physiological). If not identified the alarm cause or if the action to be taken is unknown, the operator must call a qualified professional for guidance immediately.**

⚠ **It is possible (for the operator) to visualize the alarms on the device'a display from a distance of 0,5m.**

⚠ **There might be risks involved in using different alarm pre-settings for the same device or for similar devices in the same area, such as ICU's or surgery ward.**

⚠ **When there is an electrical power failure or blackout that is 30 seconds or shorter, the alarm setting defined before the failure will be reestablished automatically.**

⚠ **When the Silence alarm key is pressed the option of changing the alarm levels will be disabled until the silenced alarm time is over (2 minutes). This locking function ensures that the user can not change the pre-defined alarm levels in order to silence the equipment alarms.**

6. POWER SUPPLY

The Biphasic Defibrillator Monitor E-HEART works with main power supply or its internal batteries. In case of power failure, the batteries supply the power to the device automatically with no need for any user interference.

POWER GRID SUPPLY

When connected to power grid the AC LED stays on. The batteries will be constantly monitoring the charge level and if necessary the device automatically starts the batteries charging cycle.

BATTERY POWER SUPPLY

The Defibrillator Monitor E-HEART also runs on an internal lithium polymer battery, with which the is able to discharge up to 220 shocks at 200J; 50 shock at 360J or monitor a patient for up to 4 hours. As an option to increase the shocking and monitoring capacity, one may use additional batteries or other external power supplies, such as:

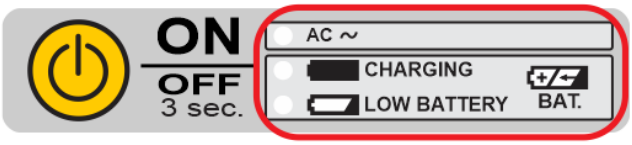
a) The device features a power connection to mobile care units and aircrafts. In situations where there is not external power grid, one may take advantage of this connection in order to save battery power for situations where the device will need to carried to same location as the patient.
Do not use the main power cord when the mobile care unit cable is being used (optional accessory);
b) External (spare) batteries that are easy to replace and have their own charger and with maximum monitoring time of about 4 hours.

External batteries can be delivered in different capacity versions, that range from 2 to 15 hours of monitoring time or 50 to 220 consecutive shocks with their own charger.

DIGITAL STATUS OF THE BATTERY CHARGE

On the device's pannel there is a LED indicator as shown below:

- Connected to the power grid supply;
- Battery status Charging;
- Battery status Discharged;



Picture 11: Battery Status

Battery Charge Level

Battery indicator (display)	Battery level	Device autonomy
	100% charge	Aproximately 4 hours of monitoring time.
	80% charge	Aproximately 3 hours of monitoring time.
	60% charge	Aproximately 2 hours of monitoring time.
	40% charge	Aproximately 1 hour of monitoring time.
	20% charge	Aproximately 20 minutes of monitoring time.

⚠**Low battery: once the battery charge level reaches 20%, a verbal low battery alarm will be heard: *"Low battery, recharge battery".* Once this alarm goes off, the user must immediately connect the device to a power grid, or replace the discharged battery with a new and fully charged one.**
In order to charge the capacitor a high battery voltage is required. That may cause the battery to reach the device's shutdown voltage level and not trigger the low battery alarm.

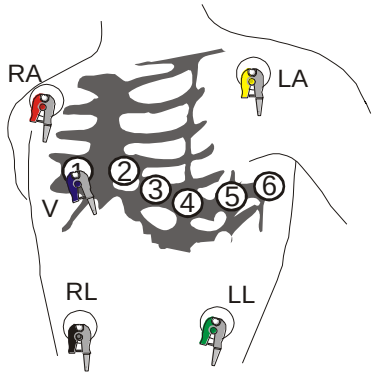
7. MONITORING

MONITORING SIGNAL THROUGH THE ECG CABLE

1. Connect the ECG cable to the device;
2. Shave the areas with excessive hair in order to apply the electrodes. Avoid placing the electrodes over tendons and areas of thick muscular tissue;
3. Check the expiry date of the disposable electrodes;

a. Place the electrodes on the patient's chest;

b. Note the correct position according to the markings on the ECG cable and place the electrodes on the patients chest as shown below:



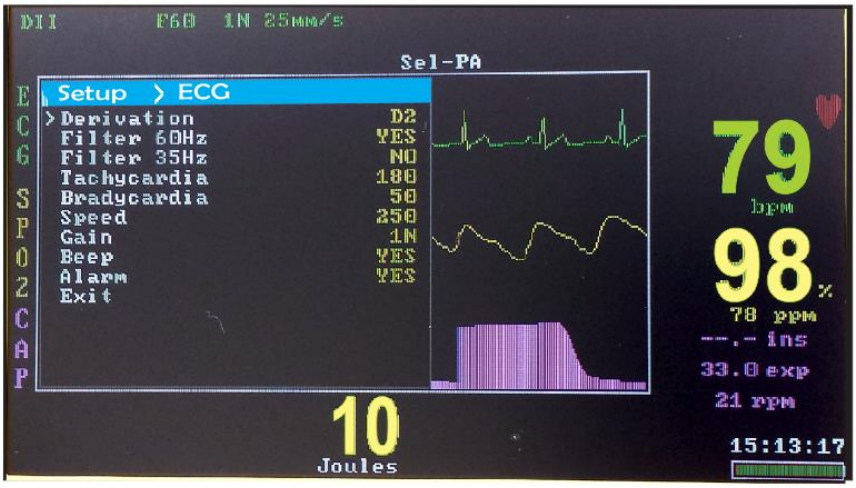
PICTURE 12 - Placing the ECG electrodes on the patient

There are two color standards for ECG cables. The E-HEART Defibrillator Monitor uses the Amarican 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
Tórax	C - White	V - Brown

ECG SETTINGS MENU

On the ECG Settings Menu the user can define the monitored derivation, gain, speed and alarms.



PICTURE 13 - ***ECG Menu***

1. Exit – Returns to previous Menu;
2. Derivation – Defines the ECG derivation to be shown on the display (CAL = calibração, D1, D2, D3, AVR, AVL, AVF, V);
3. Filter 60Hz - Activates (YES) or disables (NO) 60 Hz filter;
4. Filter 35Hz - Activates (YES) or disables (NO) 35 Hz filter;
5. Tachycardia – Defines the bpm value to trigger the alarm when in tachycardia (100 – 220);
6. Bradycardia – Defines the bpm value to trigger the alarm when in bradycardia (25 – 60);
7. Speed – Selects the ECG scanning speed to 12.5, 25.0 or 50.0 mm/s;
8. Gain – Selects the ECG amplitudeCG to N/2 (0,5cm), 1N (1,0cm) or 2N (2,0cm);
9. Beep - Activates (YES) or disables (NO) the QRS complex sync beep of the ECG signal - audible signal that varies according to the patient's beats per minute.
10. Alarm - Activates (YES) or disables (NO) any ECG alarm;

⚠ **Frequency meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely on the heart rate meter alarm signals. Keep patients with pacemakers under close surveillance.**

⚠ **It may be difficult to reject some stimulated pulses. The pulses may be counted as a QRS complex and may result in an incorrect heart rate, preventing the detection of cardiac arrests or some arrhythmias.**

MONITORING SPO2

Non-invasive method used to measure the oxygen saturation in arterial blood (SpO2) and thus monitor and evaluate the functioning of the respiratory and cardiac systems in patients.

Pulse oximetry is based on two basic principles: spectrophotometry and plethysmography. The spectrophotometer measures the amount of light transmitted (or reflected) by the capillaries of the patient, synchronized with the heart pulse, and plethysmography records the volume of arterial blood in the tissue (and consequently the absorption of light by this blood) that changes during the pulse.

Thus, the functional saturation is calculated, where the oxygenated hemoglobin is expressed as a percentage of hemoglobin that can transport oxygen.

The result is given immediately, where a saturation above 90% is satisfactory in the delivery of oxygen to tissues perspective, if the cardiac output and hemoglobin are adequate.

SpO2 is defined by:

$$SpO2 = \frac{HbO2}{100 - (CoHb + MetHb)}$$

Where:
HbO2 = Fractional hemoglobina
CoHb = Carboxihemoglobin
MetHb = Methemoglobin

SpO2 FUNCTIONING

The oximetry sensor flashes light beams produced by two LED's (light emitting diode), which pass through the patient's body and are captured by a photosensor positioned on the other side of the sensor. The diodes emit different wavelengths (red and infra red light) via peripheral regions of the body such as the fingertips.
The amount of infra-red and red light absorbed by hemoglobin saturated of oxygen (oxyhemoglobin) differs from the amount of light absorbed by hemoglobin unsaturated of oxygen. This difference in absorption of these wavelengths is measured by the photosensor, thereby calculating the percentage of oxyhemoglobin by comparing the light absorbed during the pulse. This way an oxygen saturation reading is possible.

FACTORS THAT COMPROMISE THE SpO2 READING

Technical factors:

- Adaptation, application or inadequate use of the sensor;
- The light emitter and photosensor must be directly opposite from one another;
- Excessive movement / vibrations;
- intense light in the environment (exposure to surgical lamps, infrared heating lamps, fluorescent or direct sunlight);

Patient-related factors:

- Hemoglobinopathies (carboxyhemoglobin or methemoglobin);
- Hypothermia: reading can be compromised by vasoconstriction;
- Anemia: There may be an underestimated reading when the hemoglobin concentration is below 5 g / dl;
- Venous congestion: due to the presence of venous pulse, the reading may be underestimated;

- Nail polish: It may impair reading, especially in black, blue and green colors;
- Intravenous injections: some substances such as methylene blue, indocyanine green and indigo carmine, have spectral activity in the wavelengths used for pulse oximetry. They may interfere in the accuracy of the readings;

CHARACTERISTICS

- Pulse oximetry with plethysmographic curve and indication of the number of oxygen saturation in percent; plethysmographic waveform amplitude adjusted on the screen;
- The frequency measured by the device is approximately 10 to 300 bpm, with an accuracy of 2%;
- Pulse oximetry is used in situations where oxygen saturation (SpO2) is essential: in anesthesia during surgery, post-operative, in patients in intensive care, in ambulances and even in homes. It has been efficient with a sampling range of approximately 70 to 100%, with an accuracy of +/- 2 digits for the finger clip, and sampling range of approximately 70 to 95% with an accuracy of +/- 3 digits for neonate patients. The accuracy of the measured saturation is unknown when it is between 0% and 69%.

NOTE: It is not recommended the use of oximetry sensors during magnetic resonance, because the sensors can affect the image or the accuracy of oximetry.

Each oximetry sensor is applied to specific parts of the patient. To choose the best place the following criteria should be considered:

- Patient weight;
- Perfusion in the extremities of the patient;
- Patient's activity level;
- Planned duration of the monitoring.

Clip Sensor Use

To perform the placement of the finger sensor on the patient, the sensor's posterior fins should be open so that it does not cause friction on the finger. If the indicator cannot be used for the sensor connection, use preferably a little finger; do not use the finger sensor on the thumb. The sensor should be positioned so that its cable goes through the top of the hand (picture below). When selecting a location for the sensor, choose a finger that is free from other devices such as: arterial catheter, blood pressure meter or lines of intravascular infusion

PICTURE 14 - ***Placing the finger clip oximetry sensor (adult).***

When reading failures occur, the user must place the patient in a more adequate position to correct the posture so that the the normal blood circulation can be reestablished and thus restore the quality of signals.
In the presence of bright light sources such as direct sunlight, surgical lamps, infrared heating, cover the area in which the sensor is placed with an opaque material. This way you will minimize the possibility of ambient light interference, which can cause erroneous readings.
Avoid applying tape, or tape on the reusable sensor. This reduces the risk of venous pulsation, wrong measurements of saturation and the possibility of harm caused by pressure over that area. However, applying a tape onto the cable can help prevent the sensor to dislocate and cause misreadings.
Life spam of sensor: Undetermined.

"Y" Type Sensor Use

The recommended sensor for children and neonate patients is the "Y" type one. This sensor is attached to the patient with the aid of an adhesive tape around the foot. Other parts may not offer acceptable results, because of inadequate perfusion and lighting. Make sure that the tape is well-attached, but do not apply too much of it, avoiding interference if the blood flow that may result in incorrect readings or skin lesions. In case the sensor is not properly attached (aligned between the emitter and the light receptor), inaccuracies and instabilities in the reading and plestymographic curve may result. Prevent the radiant light of radiotherapy equipment to exceed the tissue and interfere in the measurement of SPO2.
Patient foot movements can misalign the emitter-receiver assembly (Y sensor) and result in inaccuracies in the SPO2. The correct sensor placement is critical for good performance of the oximeter.

"Y" sensor important feature:

Pediatric Weight: 15-40 kg;
The index finger is ideal for the application, with the cable sticking out along the back of the hand. As alternative areas we recommend the thumb or another big toe, with the cable sticking out along the sole of the foot;
For patients of over 30 kg, another alternative would be: the earlobe and the flag of the ear;
Change location between 02-04 hours;
Expiry date: Undetermined.

⚠**When positioning the sensors, one should always observe the patient's physiological conditions. Patients with burns that may show more sensitivity to heat and pressure, should receive special attention, as changing the applied area of the sensor more often.**

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

MASIMO Rainbow SET characteristcs

Operation

The operation of the Masimo technology is based on the fact that the ability of light absorption for different wavelengths is different between oxyhemoglobin, deoxyhemoglobin, carboxyhemoglobin, methemoglobin and blood plasma, and the volume of arterial blood in the tissue varies according to the pulse, and do does the absorption of light.
The Rainbow Masimo SET technology, through an optical sensor that uses 7+ different wavelengths, provides the measurement of parameters such as pulse oximetry and oxygen saturation, but also pulse rate, perfusion index, co-oximetry parameters, and this devicealso features methemoglobin saturation. Its technology offers greater reliability in measurements in cases of movement and low perfusion and enables future updates as well as the inclusion of new measurement parameters.

Information on the sensor

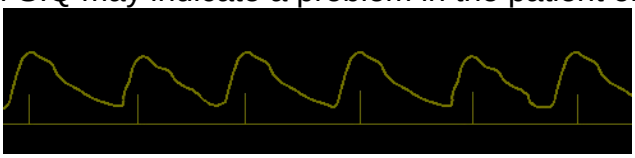
The Masimo sensor used should match the parameters featured by the device. In case the sensor allows only measures SPO², a dashed line (- - -) will be shown on the display for the values of SpMet and SpCo. It may take up to 30 seconds for the sensor to indicate all values on the display. It is not necessary or even possible to calibrate this device and a functional tester cannot be used to evaluate the precision of the pulse oxymetry system with a co-oxymeter.

Parameters

Four new parameters will be added: SIQ curve, perfusion index (PI), methemoglobin percentage (SpMet), and carbon monoxide percentage (SpCO). The SIQ curve will be shown below the plethysmographic curve. The PPM, PI, SpMet and SpCO will be shown below the SPO² value but in a smaller size.

IQ Signal Curve(SIQ)

The SIQ curve is a visual indicator of the reliability of the plethysmographic curve data, and is directly related to SpO2 and PPM data. The SIQ curve is located below the plethysmographic curve, and the signal quality is indicated as lines of different sizes in length that match the blood pulse, and this variation occurs acCOLORding to the signal quality. In situatios of movement, low perfusion or artifacts in the plethysmographic curve, the SIQ curve indicates the practitioner if the oximeter data are reliable. The low value of SIQ may indicate a problem in the patient or sensor situation.



Picture15 – SIQ curve

PI

The Perfusio Index is a value that indicates the signal strength of the arterial pulse through the percentage of the pulsed and non-pulsed signal. The PI assists the clinician to determine the ideal location for placing the SpO2 sensor. This parameter is also useful as a troubleshooting tool helping

a clinician establish a questionable value due to low perfusion and/or a low signal condition caused by noise.
High PI values reflect strong pulse signals, which facilitate more consistent measurements. Changes in perfusion can be also an important indicator of changes in the physiological state of the patient.

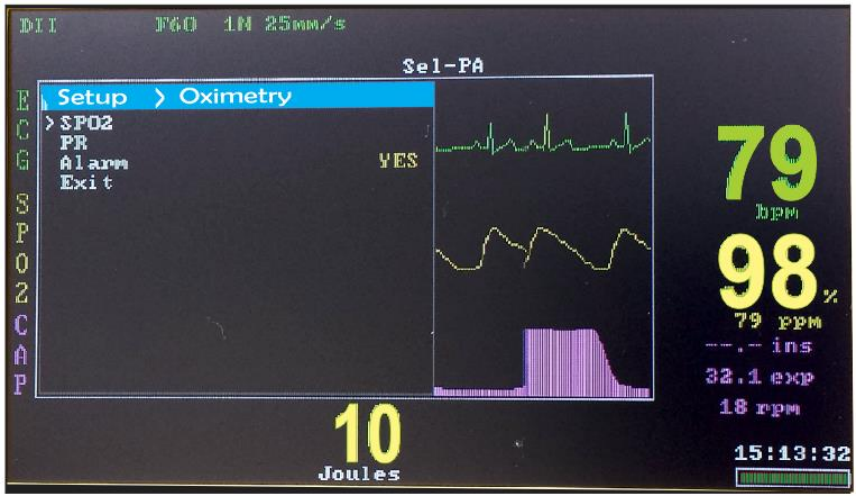
SpMet

Methemoglobin is the oxidized form of hemoglobin, which in addition to not bonding to oxygen, also increases the affinity of the latter for the partially oxidized portion of hemoglobin. Increased levels of methemoglobin in the blood are secondary to congenital changes and exposure to several chemical agents, resulting in a disorder with several differential diagnoses, which if not treated can lead to death [1].
The SpMet module measures the percentage of methemoglobin saturation in the blood, collaborating on the clinical assessment of methemoglobinemia, facilitating early detection and prompt treatment and reducing the risks to the patient - especially in areas of care where drugs likely to cause methemoglobinemia are most commonly used, such as laboratory procedures and operating rooms.

SpCO

The carbon monoxide poisoning is the most common form of poisoning in industrialized cities. This problem is sometimes misdiagnosed due to symptoms similarities with the influenza.

SPO2Settings Menu



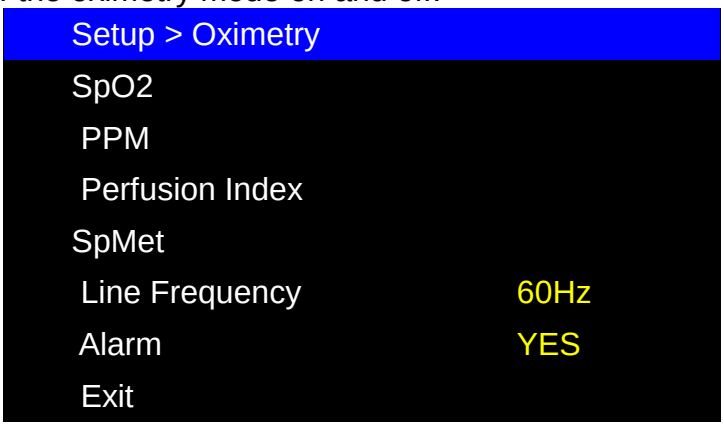
Picture16 - *SPO2 Menu*

1. Exit – Return to previous menu;
2. Max sat – Determines the maximum saturation to trigger the alarm (from 40 to 100%);
3. Min Sat – Determines the minimum saturation to trigger the alarm (from 40 to 100%);
4. Max PPM – Determines the maximum pulse frequency to trigger the alarm (from 30 to 240ppm);
5. Min PPM – Determines the minimum pulse frequency to trigger the alarm (from 30 to 240ppm);
6. Gain – Alloes the selection of the amplitude of SPO2 to N/2, 1N ou 2N;

7. Beep – Turns the pulse beep on (YES) or off (NO) – audible signal that varies acCOLORding to patient's pulse per minute;
8. Alarm – Activates (YES) or disables (NO) the SPO² alarm.

SPO2 MASIMO Settings Menu (optional)

The Oximetry Menu consists of four submenus, SpO2, PPM, PI and SpMet, besides the power grid frequency and alarm status settings. The power grid frequency must be adjusted acCOLORding to the area of installation of the device and has a direct influence on the sensor's efficiency. The Alarm option turns the alarm of the oximetry mode on and off.

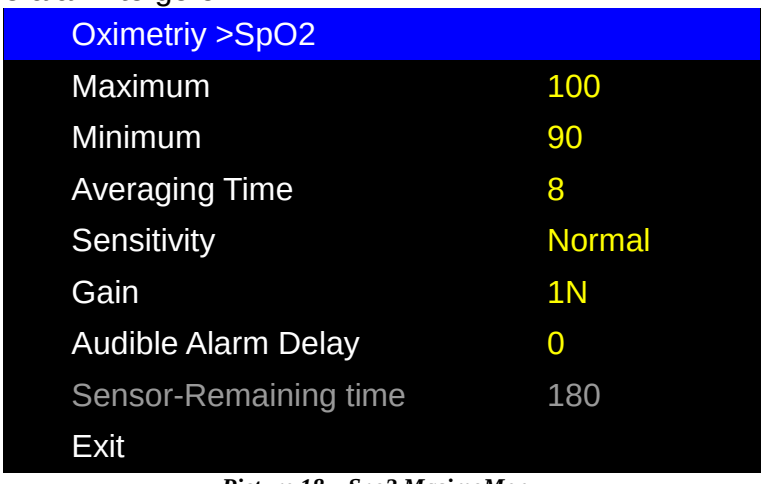


Picture17 – Defibrillator Monitor E-Heart with MasimoOximetryMenu

Parameter	Value	Default
Power Grid Frequency	50Hz - 60Hz	60Hz
Alarm	YES - NO	YES

MasimoSpO2Menu

The Masimo SPO² menu allows users to change settings for the following: maximum and minimum SPO2 limits, averaging time, sensor algorithm sensitivity, gain of the plethysmographic curve and delay time for the audible alarm to go off.



Picture 18 – Spo2 MasimoMenu

Parameter	Value	Default	Step
Maximum	40-100	100	1%
Minimum	40-100	90	
Averaging time	2-4; 4-6; 8; 10; 12; 14; 16	8	
Sensitivity	Max-Normal-APOD	Normal	
Gain	N/4-N/2-1N-2N	1N	
Audible Alarm Delay	0-5-10-15	0	

Picture19 – Levels of SPO² Alarm Settings

- The avaraging time is the time used by the sensor while gathering information from the patient before calculating the average values. The variation of this time impacts on the visibility of quick and sudden variations of the measured value. Depending on the condition of the patient and/or area of treatment, short times ar preferable (test while sleeping) to long times (neonates).The time of 8 seconds is commonly used for most patients because it is short enough to detect sudden desaturation, and long enough to minimize changes in SpO2 because of rapid and transient desaturation.

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

- NORMAL – Recommended to most patients, it features the best combination between measure sensitivity and response, in cases where the sensor is removed without warning.

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

- APOD – Less sensitive mode for patients with low perfusion, but higher responsiveness in cases of unwarned disconnection of the sensor. Prevents sensor's misreadings when disconnected from the patient. Recommended incases in which the patient is not being continually assisted by the doctor.

- Gain sets up the amplification of the plethysmographic curve.

- The time delay of the audible SPO² alarm controls the elapsed time of the SPO² alarm before the next alarm goes off. Many desaturations are real, but transient, and for that reason may not require clinical intervention. This option allows the doctor to turn down the audible alarm in case where the desaturations are present.

- The information "Sensor - Remaining time" is shown when a connected compatible Masimo sensor's lifespam is shorter than 180 minutes. In case the sensor lifespam expires, the sensor will continue functioning until it gets disconnected from the patient for 3 minutes or longer. If that

happens, the information “Defective Sensor” will be displayed and the sensor will no longer be accepted by the device. PPM

The PPM menu displays different setting for the maximum and minimum limit values and activate beep.

Picture20–PPM Level

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

Picture21–PPM Alarm setting levels

PI

The Perfusion Index menu – PI – displays different settings for maximum and minimum values.

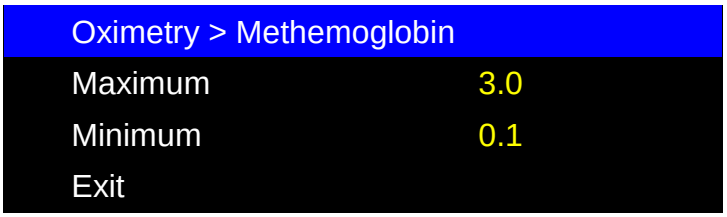
Picture22 – Perfusion Index Menu

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

Picture23–PPM Alarm setting levels

SpMet

The Methemoglobin menu – SpMet – displays different settings for maximum and minimum values.



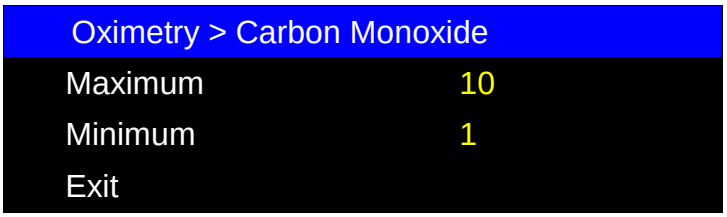
Picture24–Methemoglobin Menu

Parameter	Value	Default	Step
Maximum	1.0 – 100	3.0	Up to 2.0 – 0.1 Over 2.0 – 0.5
Minimum	0 – 99.0	0	
Active	Yes – No	Yes	

Picture25– Methemoglobin Alarms setting levels

SpCO

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



Picture26 – Carbon Monoxide Menu

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

Picture27–Carbon Monoxide Alarms setting levels

NIBP MONITORING

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 should be within the range of "□", otherwise it will be necessary to replace it with another appropriate cuff (smaller or larger);
6. The cuff should be placed in the same plane as the heart, so as to avoid errors in the readings caused by the effects of the hydrostatic column of blood between the heart and the cuff;

a. If the cuff position is higher than heart level, the reading of the BP measured and tends to be smaller; the position of the cuff is lower than heart level, reading the blood pressure measured tends to be higher.Escolha o manguito adequado para o tipo de paciente;

7. The user must enter the menu to configure the type of patient (child / adult) - for security the equipment initializes in the child mode.

When using the AUTO MODE for a period shorter than 15 minutes between measurements, for safety reasons, the device automatically sets itself for 120 minute interval measurements after the 15 minutes elapse.

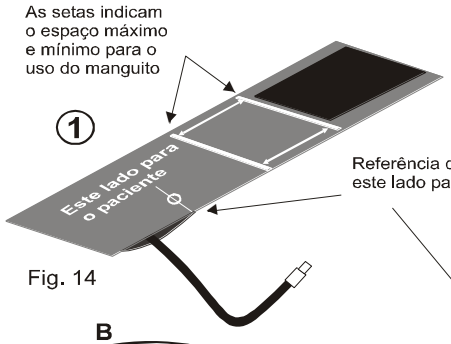


Fig. 14

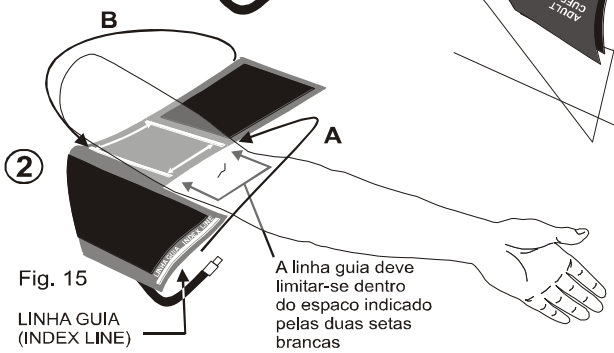


Fig. 15

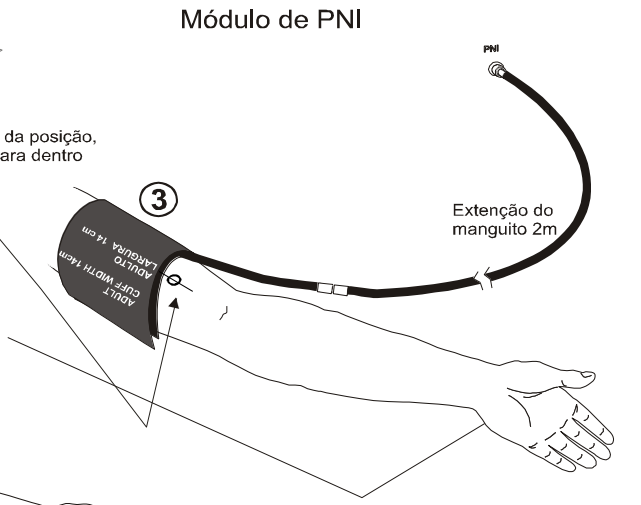


Fig. 16
- Indicação do posicionamento correto do manguito no paciente.

The measurement procedure should be done with the patient lying down, with his/her arm supported and his/her legs uncrossed.
It is recommended that the patient gets as relaxed as possible and do not talk during measurement.

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

⚠ Do not perform NIBP measurement in patients under any condition in which his/her skin is damaged or if the skin is getting damaged.

⚠For a patient with thrombosis, it is important to determine whether the blood pressure measurement should be made automatically. The determination must be based on clinical assessments;

⚠Prolonged measurements of non-invasive blood pressure in automatic mode may be associated with content, ischemia and neuropathy in the limbs that are using the cuff. To monitor a patient, examine the extremities of the member often and pay attention to normal

color, warmth and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

⚠ **Do not use cuffs and / or hoses that have liquid inside, as there is a risk of damaging the equipment. In case of liquid infiltration into the machine, unplug it immediately from the power grid, collect it and call a technician for the equipment conference**

⚠**For safety reasons the equipment is configured with its default settings in child mode. If the patient is an adult, go into the NIBP Setup menu and change to adult mode.**

⚠**Do not compress or restrict the pressure tubes of the NIBP cuff.**

⚠**Do not apply the cuff on a limb that has already been used for intravenous infusion and other access and intravascular therapies or an arteriovenous shunt (AV). The inflation of the cuff can temporarily block the blood from flowing and it may cause harm to the patient.**

⚠ **The cuff should not be applied to the arm if a mastectomy has been performed on the same side.**

⚠ **The cuff pressurization can temporary stop equipments that are simultaneously used to monitor.**

⚠ **A blood pressure reading may be affected by the place of measurement; the patient's position (standing, sitting, lying down); exercises or the physiological condition of the patient.**

⚠ **Some patient's conditions may affect the reading of the blood pressure, such as: common arrhythmias, such as atrial or ventricular premature beats or atrial fibrillation, artrioesclerose, low perfusion, diabetes, age, pregnancy, pre-eclampsia, kidney diseases, patient movement, tremors.**

⚠ **Use only cuffs that are provided by CMOS Drake. Other brands may compromise the accuracy of the equipment.**

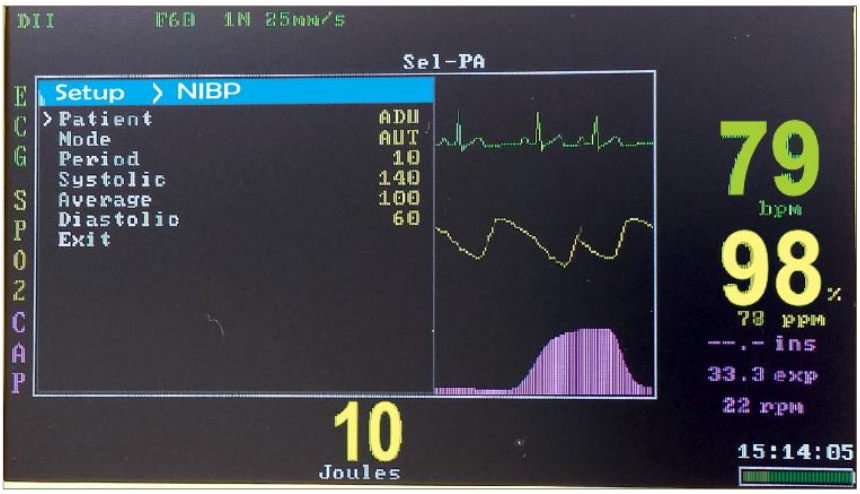
⚠ **The cuff should not be applied on the same limb or extremity in which the SPO2 sensor is. At the inflation of the cuff, the SPO2 monitoring may be affected.**

⚠ **Do not place the cuff on a limb or extremity that is being used for intravenous infusion or any area where circulation is compromised.**

Non-Invasive Blood Pressure (NIBP) features

- Measurements by oscillometric method in adult, pediatric, infant and neonatal patients;
- Manual and automatic operation mode;
- Systolic blood pressure measurements, diastolic and mean;
- Programmable interval to inflate the cuff;
- Auto zero before each measurement;
- Alarm for minimum, average and maximum pressure;
- Expiry date: Undetermined

NIBP Setup Menu



PICTURE 28 - NIBP Menu

1. Exit – Retorns to previous Menu;
2. Patient – Selects patient: Adult or Pediatric;
3. Mode – Selects the measurement mode: Manual or Automatic;
4. Automatic: defines the measurement time lapse when the automatic mode is activated;
5. Systolic – Defines the value of the systolic pressure for triggering the alarm (de 40 a 300 mmHg);
6. Mean – Defines the value of the mean pressure for triggering the alarm (de 40 a 300 mmHg);
7. Diastolic – Defines the value of the diastolic pressure for triggering the alarm (de 40 a 300 mmHg);

The Defibrillator Monitor features, on its front pannel, a shortcut key to start/stop the NIBP measurements.

In order to start or stop the NIBP measurements simply press the shortcut key  .

CAPNOGRAPHY MONITORING

The CO2 produced during cellular metabolism is carried by the venous system to the atrium and the ventricle, reaches the lungs of the capillaries and diffuses into the alveoli. Fron the alveoli, this gas is finally eliminated with exhaled mixture. The amount of CO2 that reaches the alveolar spaces is proportional to the cardiac output and pulmonary blood flow. The elimination of this gas into the atmosphere depends on the effectiveness of the ventilation. Therefore, measurement of exhaled carbon dioxide at the end of expiration (ETCO2) allows continuous and non-invasive monitoring of alveolar gas, indirectly reflecting in the circulating levels.
The capnography is a non-invasive measurement, which graphic display is carried out depending on the patient's respiratory rate (rpm) and involves the measurement of carbon dioxide exhaled at the end of expiration (EtCO) and the inhaled value (FiCO).
The detection of CO2 may be performed by two types of sensors: Sidestream and Mainstream. Both sensors have self-calibration system that avoid the use of specific gases to calibrate.
Respironics Technology - MADE IN USA.

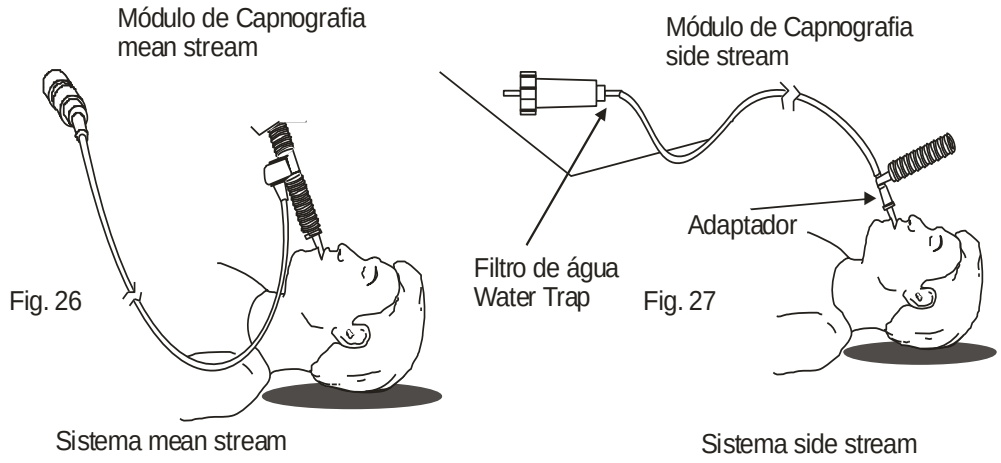
The capnography module uses the sensors 'sidestream' and miniaturized 'Mainstream' type, with optional of self-calibration procedures that eliminates the need for specific gases to calibrate. It features the following parameters:

- Exhaled C02 curve, continually displayed on the screen;
- Exhaled C02 value;
- Minimum C02 inhaled;
- Respiratory rate value;

After the sensor connection, the user must wait for about 1 minute for the measurements. After this time, a light shall be seen lit in the sensor indicating that it is ready. Once connected to the respirator tube, patient information can be observed. The capnography sensor must be on the adapter to prevent that the condensation, if any, interferes on the measurement reading.

Using the Capnography

The capnography parameter of the Biphasic Defibrillator Monitor E-HEART can be used with either the nasal or the intubated set. In case of use of the capnography in intubated patients one of the adapters should be used as shown in the pictures below.
The Capnography may be damaged due to the reuse of the water filter. Follow the instructions for using the accessories supplied by the manufacturer. The water filter must be changed for every patient, or according to the manufacturer's instructions.



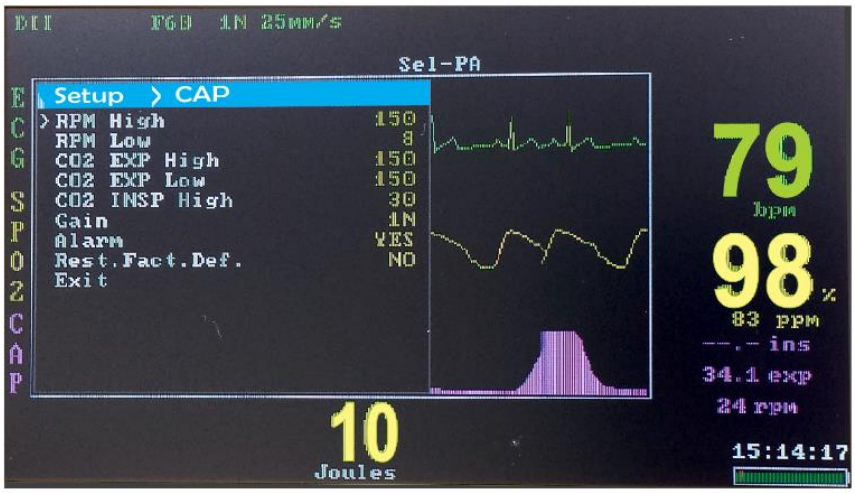
PICTURE29 – The Mainstream sensor

Capnography Features

- ‘Sidestream’ and ‘Mainstream’ sensors;
- Exhaled C02 curve shown continually on the screen;
- Optional procedure of auto calibration, which does not require the use of especific gases for periodic calibration;
- Exhaled C02, minimum inhaled C02 and respiratory frequency values shown continually on the screen;
- Miniature sensor with auto calibration miniaturizado com auto calibração;

- ❖ Sidestream-Mainstream option, or both;
- ❖ Disposable water filter;
- ❖ Disposable nasal set;
- ❖ Disposable intubation set;
- ❖ Disposable tube adapter;

Capnography Setting Menu ($ETCO^2$)



PICTURE 30 - ***Capnography Menu***

1. Exit - Retorns to previous Menu;
2. High RMP – Respirations per minute alarm settings;
3. Low RMP - Respiratios per minute alarm settings;
4. High Exhaled CO2 - Allows the adjustment of the high alarm range;
5. Low Exhaled CO2 - Allows the adjustment of the low alarm range;
6. High Inhaled CO2 - Allows the adjustment of the high alarm range;
7. Gain – The available gains are 0,5N up to 2N;
8. Alarm – Activates (YES) or disables (NO) the Capnography alarm;
9. Reset – Allows user to reset the capnography.

8. TREATMENTS

CARDIOVERSION

Precautions while Defibrillating / Cardioverting

⚠Before using the defibrillator, disconnect all devices that are not defibrillation proof from the patient.

⚠Do not place the paddles over the ECG electrodes.

⚠Do not apply the shock discharge with the paddles facing one another. There a risk of short circuit.

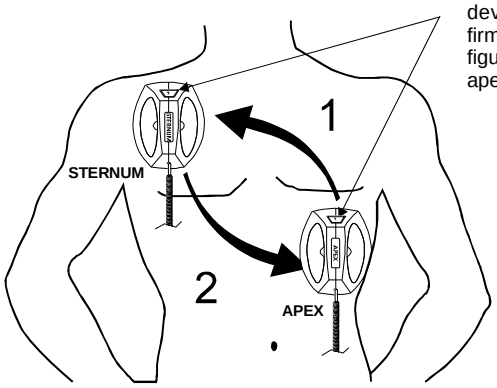
⚠In patients with pacemakers, some precautions must be taken in order to avoid damages to the implanted device and to the patient:

- **The energy discharged must be as low as possible;**
- **Keep an external pacemaker nearby;**
- **Check the pacemaker right after the the defibrillation procedure;**
- **Keep a safe distance between the patient's pacemaker generator and the shocking paddles;**
- **The pacemaker internal modules are protected against the defibrillator discharge effects;**
- **The cables, electrodes and accessories do not have protection against burns caused by the use of high frequency devices.**

Using the permanent shock paddles

1. Make sure the paddles are connected the the Biphasic Defibrillator Monitro E-Heart. In case they are not, connect the cable to the paddle input on the back of the device;
2. Make sure the patient is not ove a wet surface or close to conductive material;
3. Remove hair from the areas where the paddles will be placed;
4. Apply the conductive gel to the paddle blades;
5. Place the paddles on the patient's chest as shown in the picture below.

No momento do disparo as pás devem estar com gel condutor, firmemente posicionadas (conforme figura) e as teclas de disparo das pás apertadas simultaneamente.



PICTURE 31 - Placing the shock paddles at the moment of treatment.

6. Check the ECG signal on the device's display;
7. Press the charge button (Sternum), or the charge key on the device's pannel. Once the capacitor is charged, the device beep indicating that it is ready for treatment;
8. Move away from the patient and make sure everybody else is away too;
9. To apply the shock, press both paddles' buttons simultaneously or press the shock key on the device'ws pannel. In case the shock is not applied in up to 30 seconds the charge will be automatically canceled;

In case the synchronized shock is required, press the sync. Key on the device's pannel. A led above the key will light up to indicate that the Sync. is in use. Make sure the led will flash at every detected QRS complex.

⚠ **In order to synchronize the shock the patient must be monitored only bby the ECG cable or by the shocking paddles of the device. Never use other devices to synchronize the shocks.**

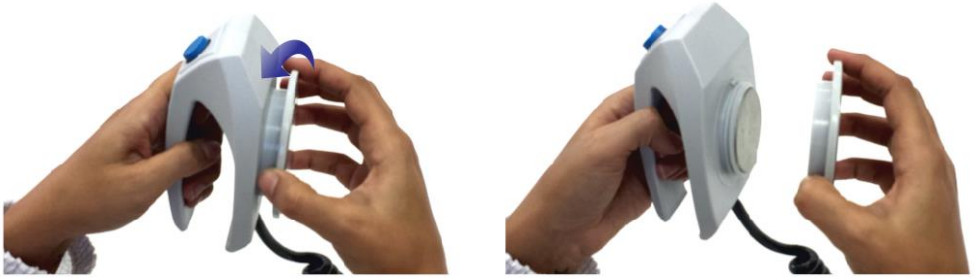
⚠ **Use only the conductive gel approved by CMOS Drake.**

⚠ **The use of a non-approved conductive gel may result in burns to the patient's skin during the shock and/or allergic reactions.**

Using the Pediatric Paddles

The Defibrillator Monitor E-HEART has interchangeables shocking paddles. To use the pediatric paddles just follow the instructions below:

1. Detach the adult shocking blades by turning them anti-clockwise;



2. After the removal of the adult blades the smaller ones will be exposed (pediatric).

PICTURE 32 – Adult and Pediatric blades

The device automatically identifies the pediatric mode and limits the energy to 50 Joules.

Impedance Indicador

The device shows the quality of the contact between the paddles and the patient.
The contact indicator is used the evaluate the following:

- Correct positioning of the shocking paddles to the patient chest;
- The quality and integrity of the shocking paddles;
- The contact of the paddles to the patient's skin;
- The correct connection of the paddles' cable to the device;

Warning:

The contact indicator is only shown on the display when the ECG reading is carried out with the paddles.
The impedance indicator will be displayed on the screen of the device:

- **Good contact;**
- **Poor contact;**
- **Short circuited paddles.**

In addition o the indicator on the device's display, the STERNUM paddles has a bicolor contact indicator led. This led help the user in the correct positioning of the shocking paddles.

- Off: No contact to patient;
- Green: Good contact to patient
- Flashing red: Poor contact to patient;

Delivered energy shocking test

The Defibrillator Monitor E-HEART had shocking test pins that are located close the the device's handle.

PICTURE 33 - Shocking test pins

The user must select an energy of 20 Joules. Key 1 - Select, confirm the energy by pressing the Menu/Select button; Push key 2 – Charge, after the beeping sound, which will inform that the device is ready to shock, carry out the shocking process by placing the paddles on top of the shocking test pins and apply a force of approximately 10Kg.
As soon as the shocking buttons are pressed, the information that the shock was applied will show up on the screen (above the selected energy) indicating the proper functioning of the device. This procedure should be carried out daily as part of the preventive inspection.
This test is important because it ensures that the selected energy will be delivered to the patient in the event of a real situation.

AED MODE

About the defibrillation

The heart has a system that produces and emits impulses throughout the entire cardiac muscles, whcih is responsible for contracting and pump the blood to all parts of the body. These impulses can be measured on the surface of the body through an electrocargiogram (ECG).
The analisys of an ECG signal allows the identification of electrical and mechanical heart problems. The cardiac arrhythmias can reflect disorders in the generation or conduction of the impulses which, in more severe cases, may manifest themselves as sedden cardiac arrests (SCA). During a SCA there is not enough blood flow on the body and brain, condition that may rapidly lead to death if not reverted. Since a SCA rarely revertes itself sponteneously, the use of a defibrillator to treat it is indicated. In this context the application of a defibrillation shock aims to reestablish the normal heart rhythm.
The most common arrhythmias that lead to SCA are: the Ventricular Fibrillation (VF) and the Ventricular Tachycardia (VT). And Automated External Defibrillator (AED) can analyse the ECG of the patient and identify the presence or absence of VF and VT and indicate if a shock must be applied to the patient or not.
It is important to point out that, according to the European Resuscitation Council (ERC), in its most recent Ressuscitation Guidelines [1], the use of a AED is only indicated in cases of unconscious and breathless patients with SCA - therefore, the Defibrillator Monitor E-HEART must only be use under such conditions.

Cardiac Rhythm Analizer

When in AED mode the device is able to analyze the patient's ECG and automatically identify if there are signs of ventricular fibrillation (VF) or ventricular tachycardia. According to the American Heart Association (AHA) [2] [3], the VF and the VT are arrhythmias that must be treated with shock by the AED. So, in case the Rhythm Class identifies either a VF or a VT while analyzing a patient, the device will emit audible and visual signals to inform that the treatment is indicated and that a shock must be applied to the patient.
During the ECG analysis the device will emit an audible and visual signal (Analyzing). At this time, in order to avoid any misreadings it is imperative that nobody touches the patient and that the patient remains still. By the end of the analysis, the Defibrillator Monitor E-Heart will advise if the treatment must be carried out or not through audible and visual messages on the display. Should the treatment be advised, keep away from the patient. Should the device not recommend the treatment, proceed with the CPR.

Validation

The performance of the Rhythm Class algorhythm, was evaluated with the use of defibrillator analyzers and ECG database glabally referred, 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 must be evaluated in terms of Sensitivity (Se) and Specificity (Sp):

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

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

where:
FN: False Negative
FP: False Positive
TP: True Positive
TN: True Negative

The performance tests resulted in a Sensitivity Se = 93,83% and Specificity Sp = 95,01%, to the evaluation group RO230704.
The algorhythm analysis time is of about 14 seconds.

The transthoracic impedance will be measured through the defibrillations electrodes. If the impedance of the baseline is higher than the maximum limit value, the system will determine aif the electrodes are not properly attached or were properly connected. As a consequence the ECG analysis and the defibrillation sequence will be interrupted. The voice message and text message will inform the user the place the electrodes on the patient's chest in case the contact with the skin is poor or if it is disconnected from the device.
Optionally, when in pediatric mode, the energy is limited to ¼ of the maximum adult energy automatically. As soon as the pediatric Pads are inserted, the system will automatically limit the energy at the mentioned proportion of the 1st, 2nd and subsequent shocks.

REFERENCES

[1] Nolan, Jerry P., et al. "ERC Guidelines Writing Group. European Resuscitation Council Guidelines for Resuscitation 2010 Section 1. Executive summary". Resuscitation 81.10 (2010): 1219-76.
[2] Link, Mark S., et al. "Part 6: Electrical Therapies Automated External Defibrillators, Defibrillation, Cardioversion, and Pacing2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care". Circulation 122.18 suppl 3 (2010): S706-S719.
[3] Kerber, Richard E., et al. "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, InCOLORporating New Waveforms, and Enhancing Safety A Statement for Health Professionals From the American Heart Association Task Force on Automatic External Defibrillation, Subcommittee on AED Safety and Efficacy". Circulation 95.6 (1997): 1677-1682.
[4] Moody GB, Mark RG. The impact of the MIT-BIH Arrhythmia Database.*IEEE Eng in Med and Biol*20(3):45-50 (May-June 2001). (PMID: 11446209)

[5] Goldberger AL, Amaral LAN, Glass L, Hausdorff JM, Ivanov PCh, Mark RG, Mietus JE, Moody GB, Peng C-K, Stanley HE. PhysioBank, PhysioToolkit, and PhysioNet: Components of a New Research Resource for Complex Physiologic Signals. Circulation 101(23):e215-e220 [Circulation Electronic Pages; http://circ.ahajournals.org/cgi/content/full/101/23/e215]; 2000 (June 13).
[6] MIT Arrhythmia Database. http://physionet.inCOLOR.usp.br/physiobank/database/mitdb/. Acessado em novembro de 2014.
[7] Nolle FM, Badura FK, Catlett JM, Bowser RW, Sketch MH. CREI-GARD, a new concept in computerized arrhythmia monitoring systems.Computers in Cardiology 13:515-518 (1986).

AED mode Features

- Automatic ECG evaluation systems that detects QRS complexes and automatically identifies malignant arrhythmias (ventricular tachycardia and ventricular defibrillation) that require defibrillation;
- Pacemaker detection;
- Adjustment of the impedance measurement for the phases 1 and 2 of the biphasic waveform. Does not allow the user to shock with the short circuited pads or not attached to patient.
- It has a voice and text messages to instruct the rescuer during ressuscitation sequence;

Using the AED Mode

When the AED mode is activated through the key 

, the device performs the functions of an automated external defibrillator with voice and text messages to help the rescuer during the ressuscitation procedure.
To exit the AED MODE just press the AED key again on the front pannel of the device.

⚠As long as the device is in AED MODE, the other parameters cannot be displayed on the screen.

1. Ensure that the disposable adhesive shock pads are connected to the device;
2. Check the expiration date of the pads;
3. Verify that the patient is not on a wet surface and/or over conductive materials;
4. Remove hair from places where the pads are connected;
5. Open the package of disposable adhesive shock pads;
6. Connect the adhesive shock pads on the patient's chest according to the pictures on the pads packages;

PICTURE 34 - Disposable adhesive shock pads

After the shock pads are attached the device starts running the ECG analysis sequence and the voice messages. The user must follow all commands.

PACEMAKER

The external pacemaker is made of a control unit based on a microcontroler with the ability to detect the QRS and generate electrical pulse with enough amplitude, frequency and width to stimulate the heart.
Because it has to stimulate the heart, the pacemaker pulses of the Biphasic Defibrillator Monitor E-HEART range from 30 to 200 pulses per minute on the non-synchronous mode. It is possible to program the amplitude and width of the pulses in order to obtain a reliable stimulation with minimum energy and cause less discomfort to the patient.

Use

The non-invase pacemaker is adequate for pre-hospitalar and hospitalar facilities. Some of the transthoracic uses of the pacemaker are:

- Bradycardia treatment during an emergency.
- During and after a cardiac surgery.
- To facilitate the implantation of an intravenous electrode stimulator.

The discribed procedure is recommended for the support stimulation in patients with bradyassistole (no intrinsic rhythm). In the case of bradycardia support, care should be taken so that the pacing rate is higher than the patient's own pace, and that the capture of the patient's QRS is reliable. There is a risk of inducing ventricular fibrillation if the stimulation pulse happen during the ascension period of the T wave.

To achieve reliable reception of the QRS complex, the operator will have to modify the amplitude and pulse width of the lower levels, with the following purpose:

- Reduce the delivered energy to the patient, prolonging the device's battery time;
- Search for parameters' values that cause less discomfort to the patient, in case the patient is unconscious.

Operating modes

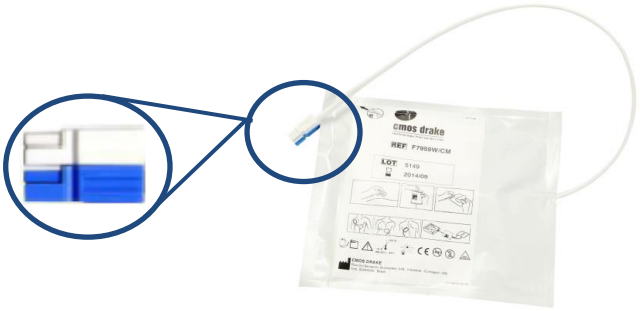
The pacemaker has three operating modes:

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

- ❖ In the VOO mode the pacemaker stimulates the patient cintinually.
- ❖ In the VVI mode the stimulation will occur when the natural frequency of the patient is below the one established by the operator.
- ❖ Emergency - No matter what the operating mode is, when the EMERGENCY key is pressed, the pacemaker will change to the VOO mode and it will operate on the following parameters: 70 ppm, 150 mA, 40 ms.

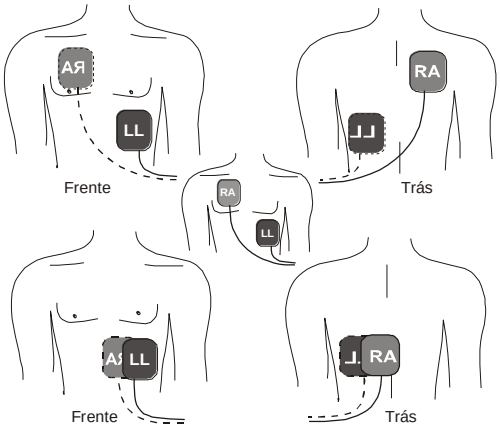
Positioning the pacemaker pads

1. Inspect the pads cable for any damages;
2. Check the expiration date on the pads package;
3. Connect the adhesive pads' cable to the pad's input to the back of the device;



PICTURE 35 – Pacemaker connector

4. Place the electrodes on the patient's chest;



PICTURE 36 - Variations of the positioning of the pacemaker pads to the patient

Stimulation electrodes should be positioned so as not to interfere with a possible defibrillation. Typically, non-invasive stimulation is done either in Apex / Front configuration or in the Front / Back. Nevertheless, it is recommended the Front / Back configuration to facilitate a possible defibrillation.

Pacemaker Features

- Stimulation current: Not connected to power supply: 200 mA; Off: 0 mA;
- Power supply: 12V;
- ECG reading through adhesive pads;
- Stimulation output through adhesive pads;
- Stimulation frequency: 30 ppm to 200 ppm - 1 by 1 ppm;
- Pulse amplitude: 05 mA to 200mA - 1 by 1mA;
- Pulse width: 05 ms to 50ms - 1 by 1ms;
- Emergência: 70 ppm, 150 mA, 40 ms
- Other settings may be defined by the user.

⚠ **In the case of bradycardia support, care should be taken so that the pacing rate is higher than the patient's own pace, and that the capture of the patient's QRS is reliable;**

⚠ **In the VVI mode, the area to attach the pacemaker electrodes must be verified. Since it can be external and the voltage negative, the stimulation may produce polarizations that change the voltage of the normal mode and compromize the detection of the regular cardiac beats;**

⚠ **This device ca only be operated by trained and qualified personnel;**

Electrical interference power supplies may affect the operation of the pacemaker. In the presence of excessive interference levels the device may:

- **Fail to stimulate;**
- **Revert to non-synchronous or interpret incorrectly as cardiac activity;**

⚠ **The long-term use of the pacemaker may burn the patient's skin tissue.**

⚠ **In case of doubts a complementary monitoring of the patient should be considered.**

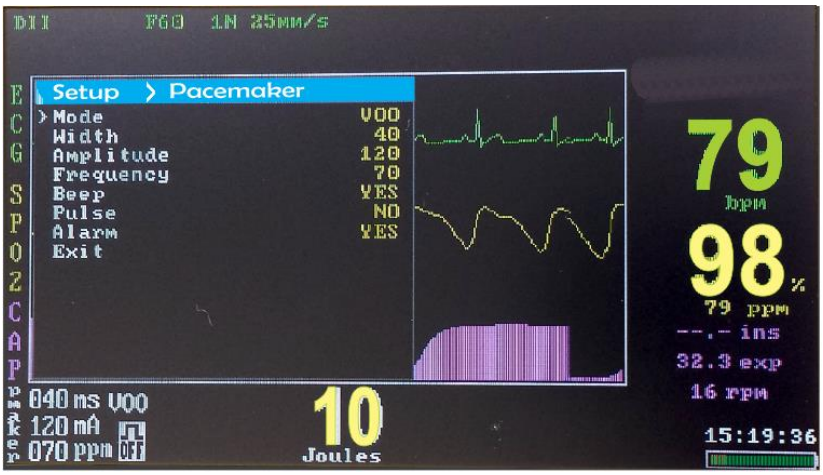
⚠ **After the use of the pads, follow the procedures of hospital waste disposal e contact US DEFIB or authorized distributors to purchase new shock pads.**

⚠ **The reuse of the disposable pads may cause burns and ECG misreadings to the patient.**

⚠ **US DEFIB cannot be held liable for the reuse of disposable accessories;**

⚠ **If you suspect that the ECG cable and connector is broken, avoid the use of the pads, under the risk of harm to the operator.**

Pacemaker Setup Menu

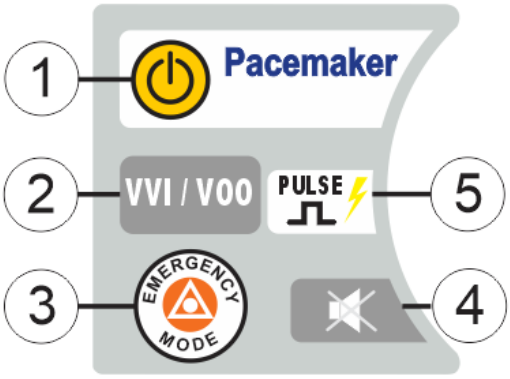


PICTURE 37 - *Pacemaker Setup Menu*

1. Exit – Returns to previous Menu;
2. Mode – Selects the operation modes of the pacemaker (PM) to one of the following options:

- ❖ VOO: The PM transmits pulses according to the parameters defined in the menu, regardless of the detected ECG signal;
- ❖ VVI: The PM transmits pulses according to the parameters defined in the menu only if the detected ECG signals exceed the limits of the defined parameters.

3. Width – Defines the pulse width - from 5 to 50 ms;
4. Amplitude - Defines the pulse amplitude - from 5 to 200 ms;
5. Frequency - Defines the pulse frequency - from 30 to 200 ppm (pulses per minute);
6. Beep - Activates (YES) or disables (NO) the pulse beeping;
7. Pulse - Activates (YES) or disables (NO) the transmition of the PM pulse.



PICTURE 38 - Pacemaker command pannel

The Pacemaker is a parameter separated from the others used in the Defibrillator Monitor E-HEART. In order to use it, simply press the On/Off key, located on the front pannel or press the emergency button. Besides the setup through the Menu, the pacemaker has some setup shortcut keys:

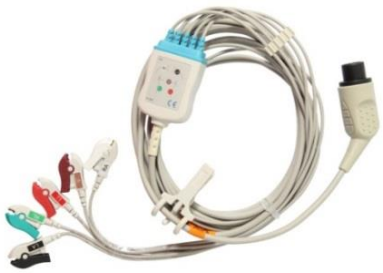
1. On–Off – Activates and disables the pacemaking function;
2. MODE (Sync. or Asynchronous) – Alternates between the modes VOO and VVI;

3. EMERGENCY – Changes the pacemaker settings to the Emergency mode (VOO, 70 ppm, 150 mA, 40 ms);
4. Inhibits Beep – Activates or disables the beep synchronized with the pulses of the pacemaker;
5. Inhibits Pulse – Activates or disables the transmition of the pacemaker pulses.

⚠**By pressing the emergency key with the pacemaker mode turned off the following message will be displayed on the device's screen: *"Emergency key was pressed. This option will initialize the VOO mode of the pacemaker. Press the MENU button to confirm or any other key to cancel."***

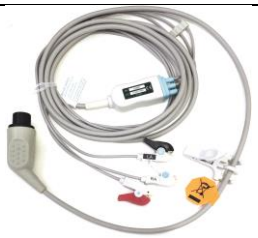
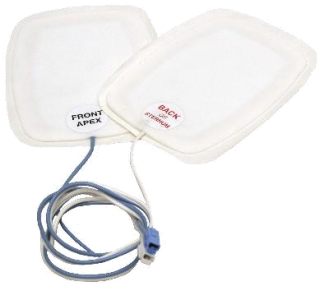
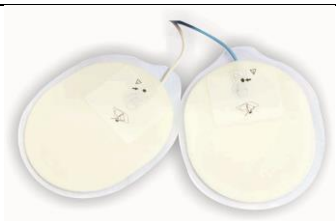
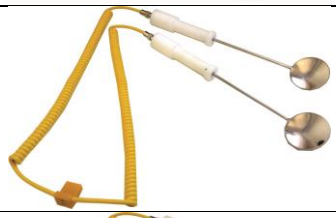
9. ACCESSORIES DESCRIPTION

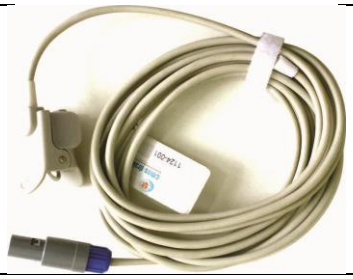
Basic Accessories

Description	Code / Ref.	Supplier	Picture
TRIPOLAR POWER CABLE	LT7031 / 021	ITALCABOS ITALFLEX ECA ELCOA	
ADULT/PEDIATRIC REUSABLE SHOCKING PADDLES	LT27275	US DEFIB exclusively	
5-LEAD ECG CABLE	2540 RP	US DEFIB/ Unimed Medical Suplies	
ADULT DISPOSABLE ECG ELECTRODES	SF10	US DEFIB/ S&W ELECTRODES	
CONDUCTIVE ECG GEL	4861 / GEL PARA ECG	US DEFIB/ Signagel	
USER MANUAL CD	15496	US DEFIB exclusively	

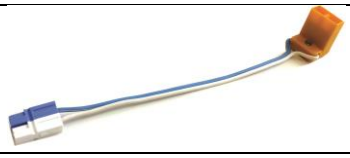
QUICK PRINTED GUIDE.	38385	US DEFIB exclusively	
DEVICE WARRANTY CERTIFICATE	33778	US DEFIB exclusively	

Parameter Accessories

Parameter	Description	Code / Ref	Manufacturer	Picture
ECG	3-LEAD ECG CABLE	LT483	USDEFIB/ Unimed Medical Supplies Inc	
AED MODE PACEMAKER	ADHESIVE DISPOSABLE SHOCKING PADS - **ADULT**	F7959W/CM	US DEFIB /FIAB	
	ADHESIVE DISPOSABLE SHOCKING PADS - **PEDIATRIC**	F7959P/CM	US DEFIB/FIAB	
INTERNAL REUSABLE SHOCKING PADDLES	INTERNAL REUSABLE SHOCKING PADDLES– ADULT**.**	P320	US DEFIB exclusively	
	INTERNAL REUSABLE SHOCKING PADDLES– PEDIATRIC.	P336	US DEFIB exclusively	
	INTERNAL REUSABLE SHOCKING PADDLES– NEONATE.	P342	US DEFIB exclusively	

NIBP	NIBP CUFFS – NEONATE, PEDIATRIC, ADULT AND OBESE SIZES.	1005 / 1882 SSNL 4305 / 1881 SSNL 12671 / 1880 SSNL	PAR MEDIZINTEC	
CAPNOGRAPHY	NASALCANNULA ADULT/PEDIATRIC	3468ADU-00	RESPIRONICS DISTRIBUTORS	
	CAPNOGRAPHY TUBE ADAPTOR	34371	RESPIRONICS DISTRIBUTORS	
OXIMETRY	OXIMETRY SENSOR – FINGER CLIP MODEL - ADULT.	U410-62D	USDEFIB/ Unimed Medical Supplies Inc	
	OXIMETRY SENSOR – FINGER CLIP MODEL – PEDIATRIC.	U210S-62D	USDEFIB/ Unimed Medical Supplies Inc	
	OXIMETRY SENSOR – Y MODEL	U810-62D	USDEFIB/ Unimed Medical Supplies Inc	

	OXIMETRY SENSOR – EAR CLIP MODEL	LT224 / A0212-SE125 PU	USDEFIB/ Unimed Medical Supplies Inc	
MASIMO RAINBOW SET	ADULT SENSOR – FINGER CLIP MODEL: SpO2, SpCO, SpMet Weight>30Kg.	LT32922/ DCI-DC3 2407	USDEFIB/ Masimo	
MASIMO RAINBOW SET	PEDIATRIC SENSOR – FINGER CLIP MODEL: SpO2, SpCO, SpMet Weight10kg - 50kg	LT36015/ DCIP-DC12 2070	USDEFIB/ Masimo	
	DISPOSABLE ADULT SENSOR: SpO2, SpCO, SpMet. Weight>30Kg.	LT36021 / R25 2221	USDEFIB/ Masimo	
	DISPOSABLE PEDIATRIC SENSOR: SpO2, SpCO, SpMet Weight3kg - 30kg	LT36051 / R20L2220	USDEFIB/ Masimo	
	DISPOSABLE ADULT/NEONATE SENSOR:SpO2, SpCO, SpMet Weight<3kg ou >30kg	LT36038/ R25L 2219	USDEFIB/ Masimo	
	EXTENDER CABLE FOR MASIMO DISPOSABLE SENSOR.	LT36044/ RC-12 2404	USDEFIB/ Masimo	

BAG	TRANSPORTBAG	1838	USDEFIB exclusively	
RACK	RACK FOR STRECHER OR HOSPITAL BED	33927	USDEFIB exclusively	
RACK	RACK FOR MOBILE CARE UNIT	33927	USDEFIB/ exclusively	
PRINTER	THERMAL PAPER ROLL	490	USDEFIB/ Daru	
POWER CABLE	EXTERNAL POWER CABLE	33324	USDEFIB/ exclusively	
AED MODE EXTENDER CABLE	DISPOSABLE ADHESIVE PADS EXTERNDER CABLE	35576	USDEFIB/ exclusively	
MEMORY STICK	256MB MEMORY STICK	LT603	USDEFIB/ exclusively	

10. CLEANING

Clean the Defibrillator Monitor after every use. If not used, it is recommended a quarterly cleaning. Follow the instructions below:

- Disconnect the unit from the power grid before cleaning.
- The cleaning and disinfection of the cabinet should be made with a slightly damp cloth in demineralized water and mild liquid soap and another damp cloth in demineralised water with 2% hypochlorite. Do not use abrasive cleaning agents, organic solvents, chlorine, alcohol or hydrocarbon solvents. To prevent scratches on the screen (display), carefully pass a dry flannel or in case of dirt, a slightly damp cloth in water, and remove dust or dirt particles.
- The labels on equipment and accessories are important, and therefore should not be removed nor damaged.
- The cleaning and disinfection of permanent cables must be made for every use of the equipment. This cleaning is done with a slightly damp cloth in demineralized water and mild liquid soap and another slightly soft, damp cloth in demineralized water. Once dry, disinfect them using gauze soaked in ethyl alcohol 70%.
- After the use of disposable electrodes and accessories, despose them at appropriate locations as per special disposing procedures for medical waste.
- To clean the capnography sensor after use, use a damp cloth in demineralised water with a small amount of mild liquid soap and disinfecting, use a gauze moistened with isopropyl alcohol.
- The tube, the water filter (water-trap Side-etream), Main-stream sensor adapter and miscellaneous are considered disposable, should not be reused and must be disposed as medical waste at a hospital procedure.
- The cleaning and disinfection of the NIBP cuffs should be made after every use of the equipment. This cleaning is done with a slightly damp cloth in demineralized water and mild liquid soap and another slightly soft, damp cloth in demineralized water. Once dry, disinfect it using gauze soaked in ethyl alcohol 70%.
- After using the permanent shock paddles, with a paper towel, remove the conductive gel from the surface of the blades; with a clean cloth dampened with 70% ethanol, wipe the shock paddles. If the pediatric pads have been used, perform the same procedure and then reattach the adult blades to the shock paddles.
- To clean the internal paddles:

1. Remove the cables from the shock paddles handle; wipe them with a clean cloth damped in 70% ethyl alcohol.
2. Do not use a brush on the internal paddles;
3. Protect the internal paddles individually before and after sterilizing them, to prevent any damage to their surfaces.
4. Examine the paddles, cables and connector to check for damage or signs of wear (loose connectors, exposed wires and oxidized cable connection).
5. Examine the electrodes to ensure they are not scratched, punctured or cracked or if the surfaces of the electrodes are blistered, scratched or chipped with epoxy coating. If any of these situations occur, immediately discontinue the use of the affected component.
6. The internal pads should be placed in the sterilizer so as to allow the insertion of drainage area (lumen) of the electrode. Sterilization exposure time of 4 minutes. Drying time up to 30 minutes.

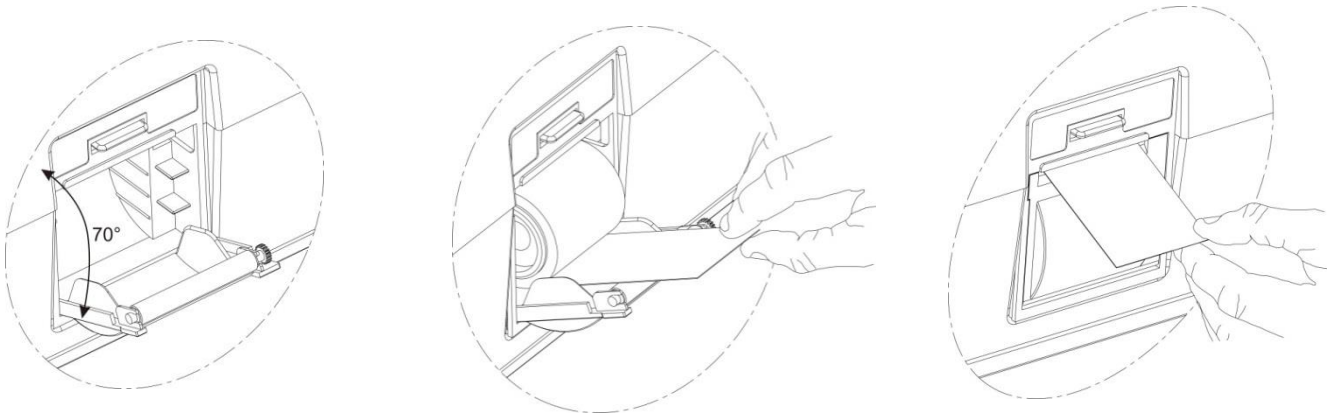
11. SETUP OPTIONS

INSERTING THE THERMAL PAPER INTO THE PRINTER

Use appropriate heat-sensitive paper that is easily found in medical equipment and surgical stores or directly with US DEFIB. This guarantees a clear impression of the unit.
It should be noted that the thermal papers have a wide variation in sensitivity and abrasion, so it is possible to have a difference in the waveform tone during printing, according to the different manufacturers, or batch.

Instructions for the insertion of the thermal paper in the TR-50 or SP-48 printers.

1 - Press the lid latch;
2 - Move the lid until it is open in a 70º angle;
3 - Insert the paper roll with the printable side facing up;
4 - Pull out the paper and centralize it as indicated in the picture;
5 - Push the printer lid up without locking it;
6 - Adjust the printing paper again so that it is in a centralized position;
7 - After adjusting the position of the paper, push the printer lid so that is locks. After locking it, the device will be ready to use. If the paper does not come out properly diring the printing process, repeat the operation;



PICTURE 39 - Inserting paper into the printer

The printer has two LED's with the following indications:

Led Error (Yellow): Open lid or lack of paper indication;
Led Power (green): Indicates that the printer is turned on.

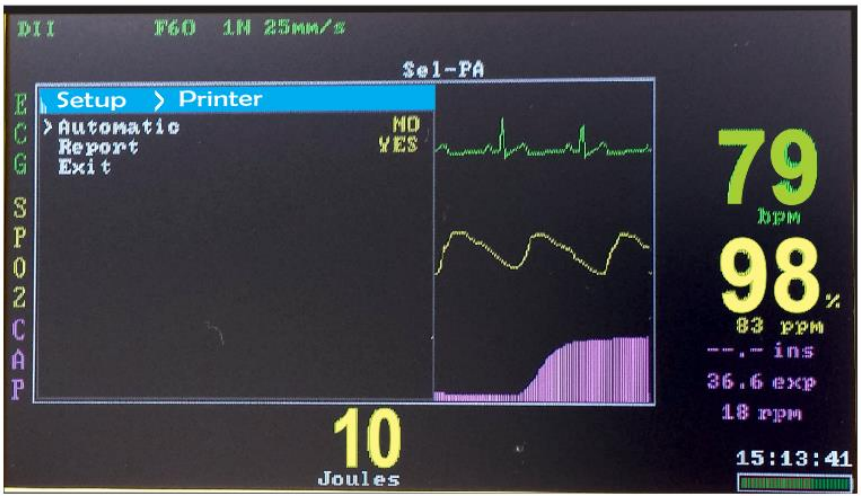
Thermal Printer Features

- High reolution thermal printer, with automatic and manual recording of one channel, with option of two and three channels. Possible to record the ECG with diagnose quality, with manual or

automatic operation after defibrillation. It has information on time and date, cardiac frequency, derivation, ECG amplitude and etc

- Enables independent manual recordings of cardioversion through the paddles.
- The recording is printed on thermal paper of 48 mm (width) x 20 m (length) or 50 mm (width) x 20 m (length) for TR-50 or SP-48 printers;
- Printing speed of 12,5-25-50 mm/sec.

Printer Setup Menu



PICTURE 40- ***Printer Menu***

2. Exit – Returns to the previous Menu;
3. Automatic – Activates (YES) or disables (NO) automatic printing when the use the of shock paddles is detected;
4. Diagnostic – Ativates (YES) or disables (NO) the diagnostic printing;

Data that will be printed once the diagnostic is activated:

- Signature field;
- Patient's name field;
- Field to enter patient's age and weight;
- Date and time;
- Time of printing start and end;
- Number of applied shocks;
- Indication of the sync. status (activated or disabled);
- NIBP - Mean/ Diastolic/Systolic;
- SPO2 blood saturation (%);
- ECG: Curve amplitude/ Derivation/ speed/ cardiac frequency;
- Other data may be implemented if required by the purchaser.

The Defibrillator Monitor has a shortcut key on the front pannel to start/stop printing.

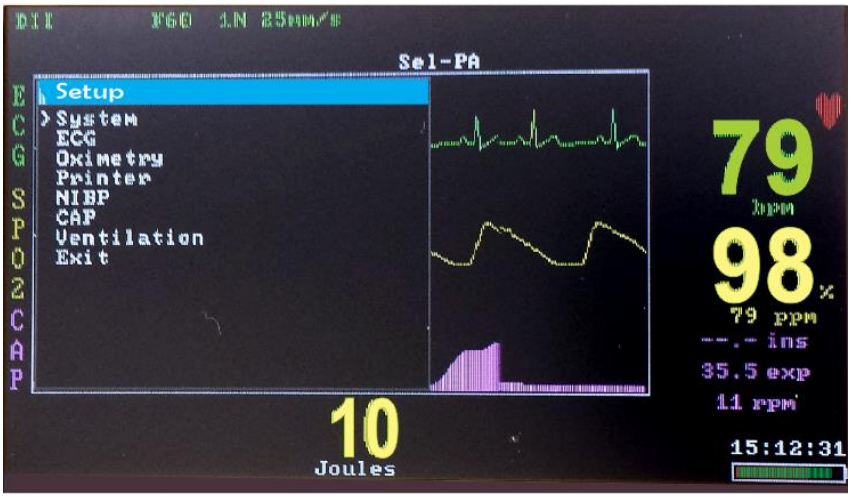
By pressing the printing key  once, the device will start printing; if the key is pressed again, it will stop the printing process.

⚠**If the setup menu is open and the printing key is pressed, the Menu screen will be automatically closed.**

⚠**During the printing process, it is not possible to enter the Setup Menu. The message "Printing...Menu locked" will be shown on the display . In order to access the Menu again, just stop printing.**

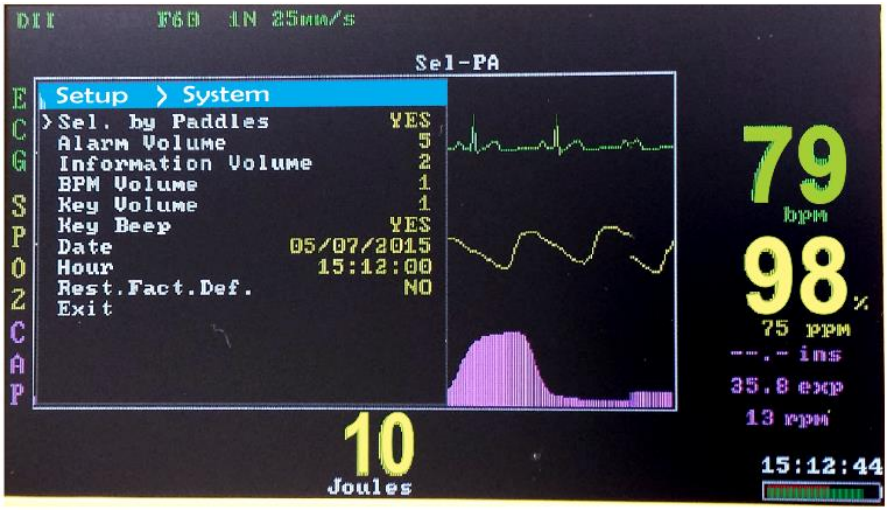
MAIN SCREEN

In order to access the main screen, press the Menu/Select button.



PICTURE 41 - *Main Screen*

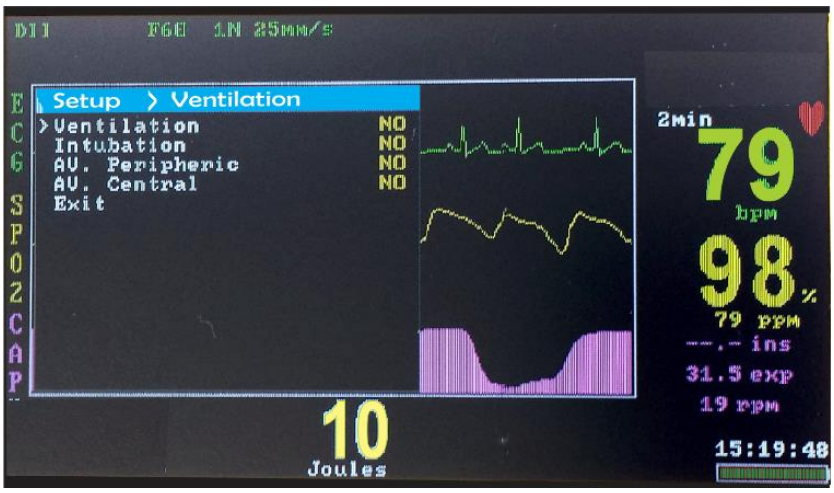
General Settings Screen



PICTURE 42 - *General Settings*

1. Exit – Returns to the previous Menu;
2. Sync. ON – Activates (YES) or disables (NO) the synchronism with the ECG QRS complex;
3. Auto Charge – Activates (YES) or disables (NO) the automatic defibrillation charge sequence;
4. Sel. through paddles – Activates (YES) or disables (NO) the commands through the paddles buttons;
5. Alarm Volume – Configures the alarm volume, 001 = minimum, 009 = maximum;
6. BPM Volume– Configures the volume of BPM, 001 = minimum, 009 = maximum;
7. Key Vol – Configures the keyboard beeping volume, 001 = minimum, 004 = maximum;
8. Beep Key – Activates (YES) or disables (NO) the sound of the keyboard;
9. Date – Ajusts the day/month/year.
10. Reest. Factory Default – Reestablishes all of the device's settings.

VENTILATION SETTINGS MENU



PICTURE43 – Ventilation *Menu*

1. Exit – Returns to the previous Menu;
2. Ventilation - Allows the selection of the ventilation mode: Spontaneous, Assisted, Controled;
3. Intubation - Allows the definition between YES or NO and the intubation mode: Oral, Nasal, tracheostomy;
4. Periferical AV. - Allows the definition between YES or NO;
5. Central AV.– Allows the definition between: VJI, VSC, OUT, NO;

DRUG SETTINGS MENU

The Defibrillator Monitor E-Heart, optionally, offers a drug level recording used during the patient treatment.

1. Procainamide – Selects the level of injected drug;
2. Lidocaine – Selects the level of injected drug;
3. Amiodarone – Selects the level of injected drug;
4. Dofetilide – Selects the level of injected drug;
5. Sotalol – Selects the level of injected drug;
6. Verapanil – Selects the level of injected drug;
7. Drug 8 – and others used in the CPR;
8. Drug 9 – and others used in the CPR.

12. DATA MANAGEMENT

It is possible to record and store the data and events that occur during the use of the Defibrillator Monitor through a memory stick (compact flash) or through internal memory:

- To record and store data, just connect it to the identified port (side of the device). The input connector only allows the connection of the stick on the correct side, which makes it unnecessary to indicate the correct side of the stick. In order to visualize the stores data just disconnect it from the device and connect it to the memory stick port of a computer or, in case it is not possible, use a memory stick/USB adapter to download the data in the Phoenix Software.
- For internal memory recording, it is not necessary to previously set the device.

To visualize the data stored in the device's internal memory:

- Turn on the device;
- With the aid of the USB A/B extensor calbe - connect the B side to the Defibrillator MOnitor and the A side to the computer;
- Open the Phoenix Software and download the data.

⚠ **The Compact flash memory stick is supplied by US DEFIB. In case of use of a card other than the one supplied by the manufacturer, the purchaser or user will lose the device's warranty.**

PHOENIX SOFTWARE

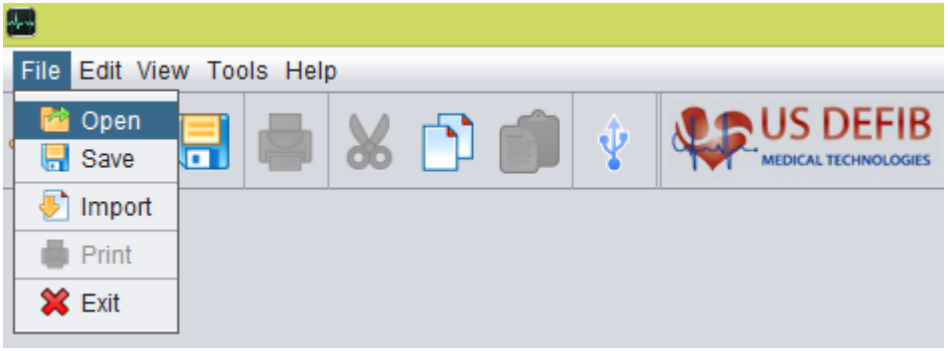
With the Phoenix Software it is possible to visualize all the events occurred during the use of the US DEFIB products.
Through a memory stick or USB cable it will be possible to transmit the data and detailed analysis of the events ocurred during the use of the AED mode to the Phoenix Software.

Installing the Phoenix Software

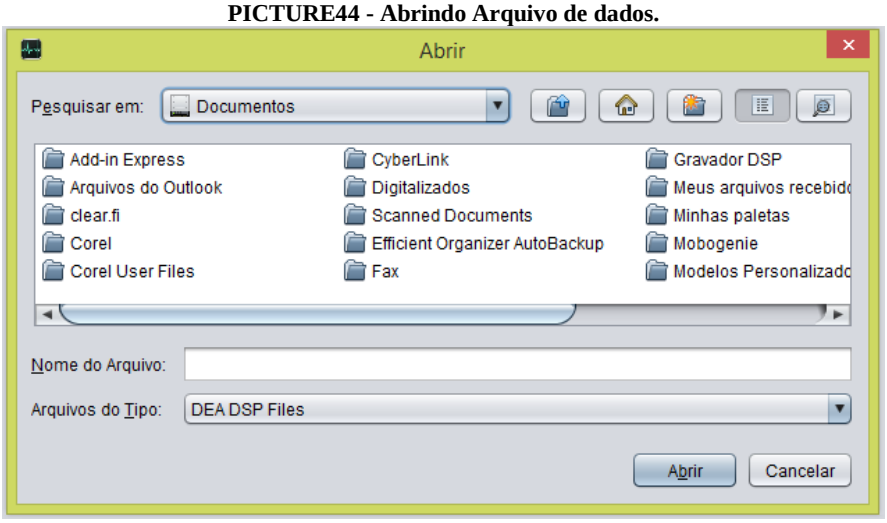
- Insert the program CD on the CD/DVD ROM drive;
- The installation will be automatically initialized;
- Follow the instructions that are shown on the screen;
- At the end of the installation of the Phoenix Software an installation window of the Java software, which must also be installed, will be shown on the screen;
- After the installation process is finished, a shortcut will be created on the user's desktop. Just double click on the icon in order to open the device.

Stored Data Visualization

In order to visualize the stored data, just access the "File' menu and click "Open", or simply click on the "Open" icon on the toolbar and select the desired file.

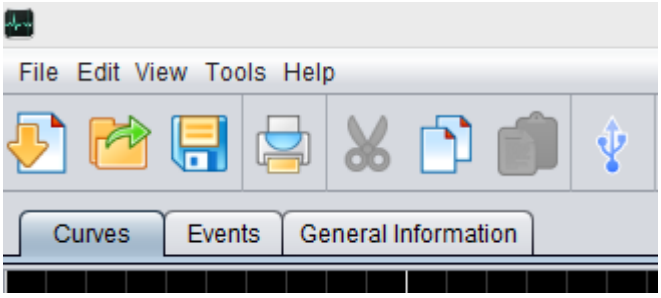


PICTURE44 - Abrindo Arquivo de dados.



PICTURE 45- By clicking on the"Open" icon, a window for the file selection will open.

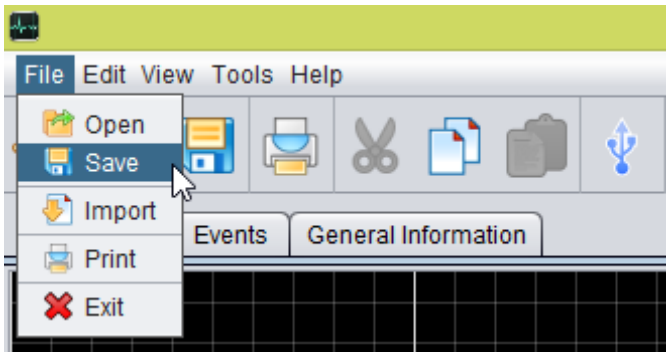
3 tabs will be displayed on the screen: curves, events, general information. To change the tabs just click directly on the tab, or via the "View" menu and choose one of the tabs.



PICTURE 46 – Data exhibition tabs.

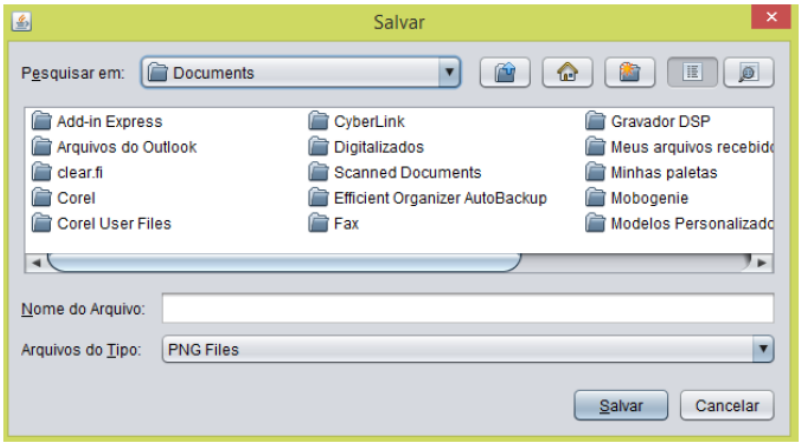
Saving ECG Images

To save the image the user must click on the icon "Save" or go to the "File" menu and click "Save".



PICTURE 47 - Saving a file.

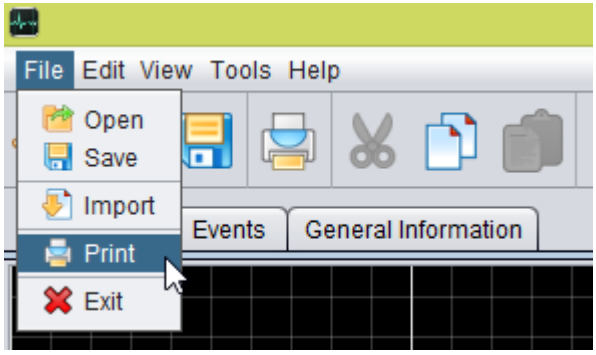
A screen to select the folder and file name will be shown. After selecting the folder and the file name the user must click "Save".



PICTURE 48 - Screen for the selection of the file to be saved.

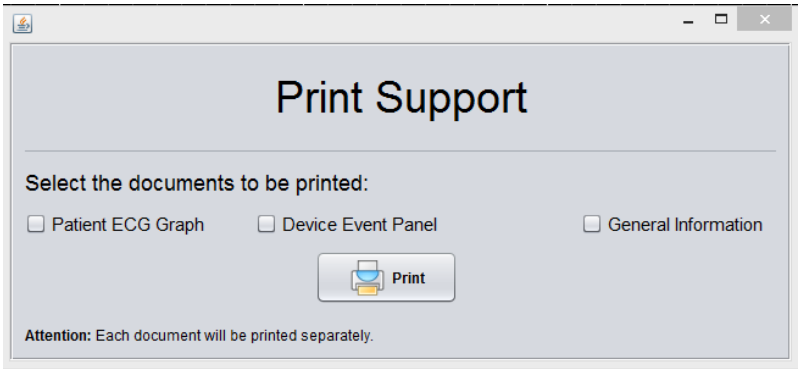
Print file

To print the data, simply click the "Print" icon, or via the "File" menu - "Print".



PICTURE 49 - Printing file through the "File" - "Print" Menu.

A window for selecting the file to be printed will be shown. Although you can select more than one file to print, the files will be printed individually.



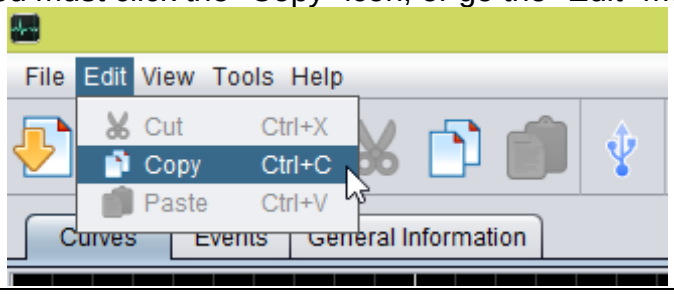
PICTURE 50 - Window for the selection of the file to be printed.

Copying Data from the Program

The "Copy" function will make a copy of the tab currently displayed in the following way:

- ECG tab – An image will be copied to the transference area.
- Event tab – The text on the selected table cell will be copied.
- General Information tab – The text on the selected area will be copied.

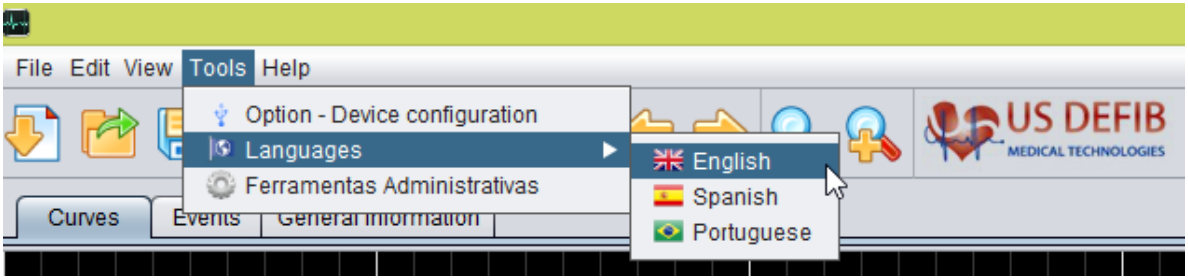
To use this function, you must click the "Copy" icon, or go the "Edit" menu and click "Copy."



PICTURE51 - Copiando conteúdo da tela.

Change Language

To change the language you must click "Tools" - "Language" and select the desired language. The Phoenix software is available in English, Spanish and Portuguese.



PICTURE 52 – Language Selection.

Change Page

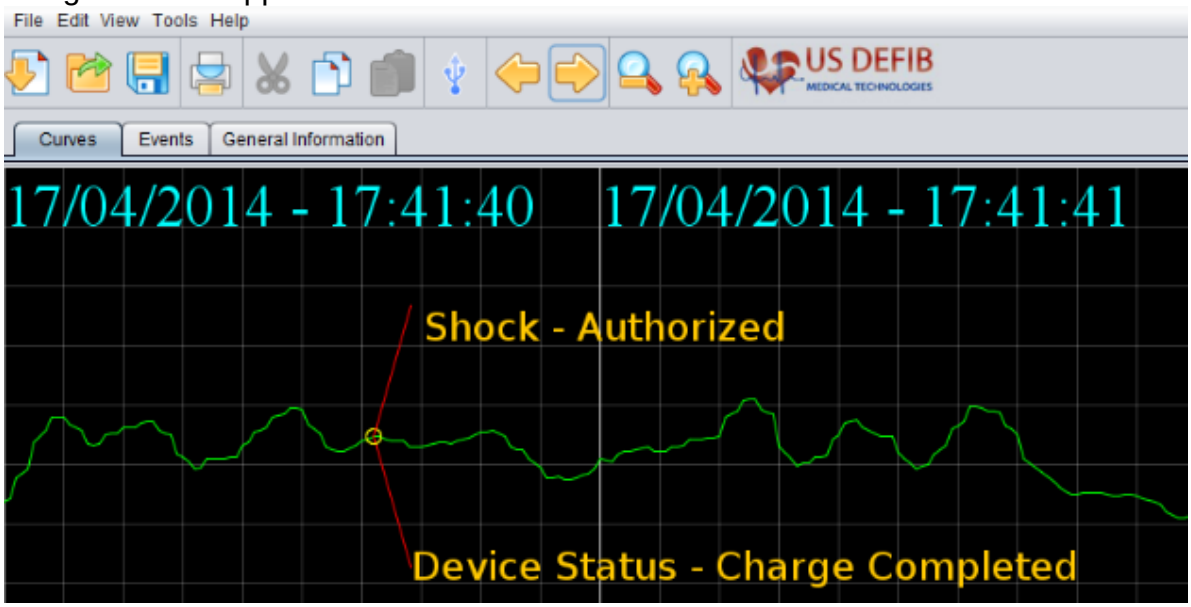
On the toolbar, Click the yellow arrow to the right. Pages will be changed in the chronological sequence in which they were recorded.

PICTURE 53 - Next Page – (arrow to the right).

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

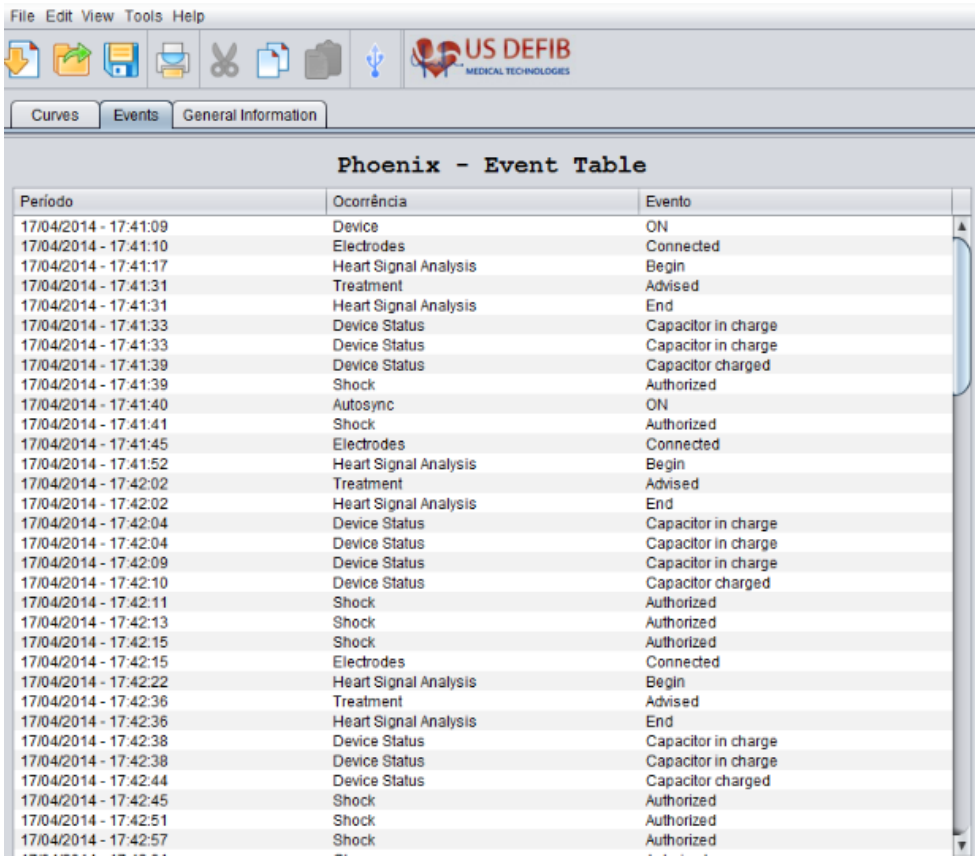
Visualize Events

With the right mouse button, click directly on the curves and select events.
Event messages should appear marked at the time of the event



PICTURE 54 – Description of the occurred events.

In the Events tab you can view all the events with date, time and description of the event.



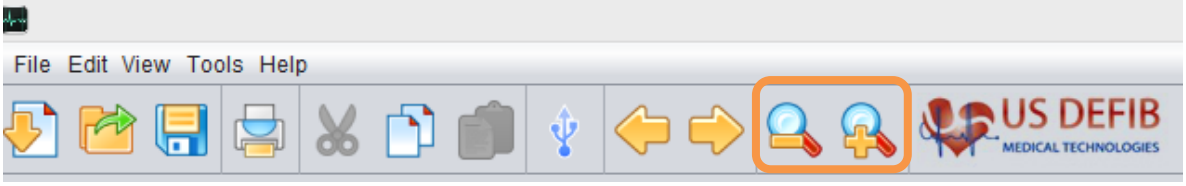
Período	Ocorrência	Evento
17/04/2014 - 17:41:09	Device	ON
17/04/2014 - 17:41:10	Electrodes	Connected
17/04/2014 - 17:41:17	Heart Signal Analysis	Begin
17/04/2014 - 17:41:31	Treatment	Advised
17/04/2014 - 17:41:31	Heart Signal Analysis	End
17/04/2014 - 17:41:33	Device Status	Capacitor in charge
17/04/2014 - 17:41:33	Device Status	Capacitor in charge
17/04/2014 - 17:41:39	Device Status	Capacitor charged
17/04/2014 - 17:41:39	Shock	Authorized
17/04/2014 - 17:41:40	Autosync	ON
17/04/2014 - 17:41:41	Shock	Authorized
17/04/2014 - 17:41:45	Electrodes	Connected
17/04/2014 - 17:41:52	Heart Signal Analysis	Begin
17/04/2014 - 17:42:02	Treatment	Advised
17/04/2014 - 17:42:02	Heart Signal Analysis	End
17/04/2014 - 17:42:04	Device Status	Capacitor in charge
17/04/2014 - 17:42:04	Device Status	Capacitor in charge
17/04/2014 - 17:42:09	Device Status	Capacitor in charge
17/04/2014 - 17:42:10	Device Status	Capacitor charged
17/04/2014 - 17:42:11	Shock	Authorized
17/04/2014 - 17:42:13	Shock	Authorized
17/04/2014 - 17:42:15	Shock	Authorized
17/04/2014 - 17:42:15	Electrodes	Connected
17/04/2014 - 17:42:22	Heart Signal Analysis	Begin
17/04/2014 - 17:42:36	Treatment	Advised
17/04/2014 - 17:42:36	Heart Signal Analysis	End
17/04/2014 - 17:42:38	Device Status	Capacitor in charge
17/04/2014 - 17:42:38	Device Status	Capacitor in charge
17/04/2014 - 17:42:44	Device Status	Capacitor charged
17/04/2014 - 17:42:45	Shock	Authorized
17/04/2014 - 17:42:51	Shock	Authorized
17/04/2014 - 17:42:57	Shock	Authorized

PICTURE 55 – Events tab

Zoom

Zooming out

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



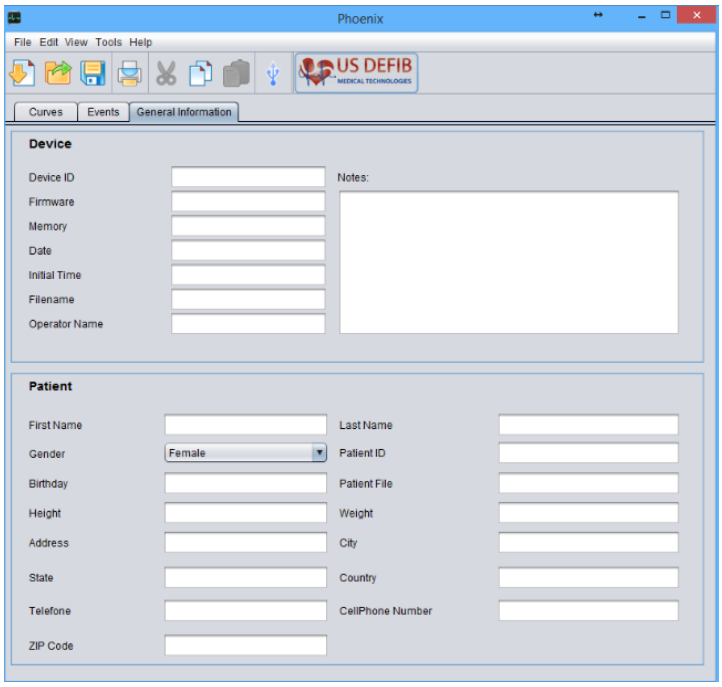
PICTURE 56 – Zooming out.

Zooming in

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

General Information

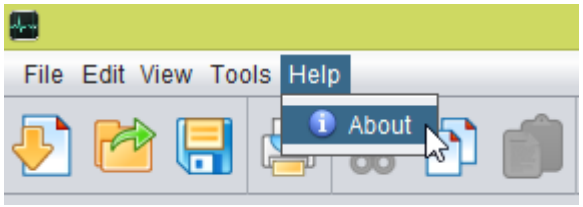
In the General Information tab the user can fill out the patient and operator data. There is also a comments field that can be used to include additional information.



PICTURE57 – General Information Tab

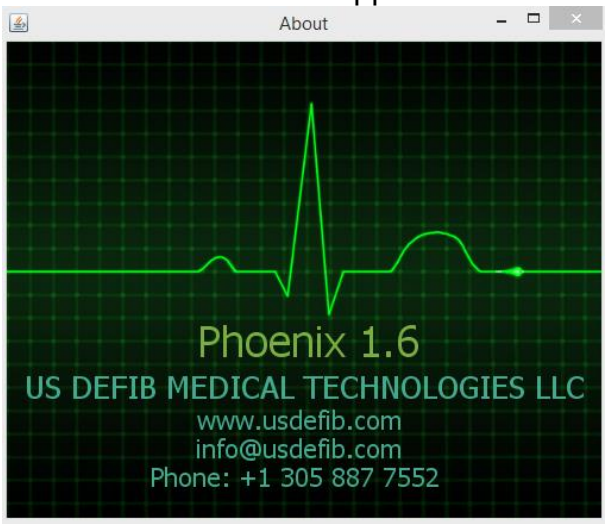
Help

Click "Help" - "About".



PICTURE 58 - Help Menu.

A window with the software version information and support contact in case of doubt will be shown.



PICTURE 59 - Help Menu.

Exit Program

Click the “File” Menu – “Exit”. The software will stop running.

13. MAINTENANCE

CORRECTIVE AND PREVENTIVE MAINTENANCE

Precautions and Special Cares

- Do not place any type of material on top of the device;
- Keep the Biphasic Defibrillator Monitor E-HEART in a dry room, avoiding locations where liquids can be spilled over the equipment. Do not use the device if it is wet or excessively humid;
- The Biphasic Defibrillator Monitor E-HEART must not go through maintenance or technical assistance during use on a patient;
- Do not reuse the disposable materials. After use they should be disposed at the appropriate locations according to local regulations on medical waste;
- We recommend that the users keep some auxiliary materials such as surgical scissors, disposable shaving blades to remove hair from the patient's chest and disposable rubber gloves, if necessary.

Preventive Inspections and Cleaning

For an extended durability of the Biphasic Defibrillator Monitor E-HEART and its accessories, we recommend that the preventive inspections and cleaning be made periodically according to the table below:

Applied Measure	Frequency
Preventive Inspection	Semiannually
Cleaning	Semiannually

For each process, make sure that the device is off and its electrodes disconnected, avoiding risk of shocks.
This process should follow the criteria below:

Preventive Inspections

We recommend a semiannual inspection of the Biphasic Defibrillator Monitor E-HEART and its accessories, not matter if the device has been used or not, as per the instructions below:

- Check the expiration date of the disposable shock pads and the functionality of the accessories. If any of these accessories are close to their expiration date or already expired, we suggest that new material be purchased with the manufacturer or one of its representatives;
- Check the conditions of the device and its accessories. In case of any Verificar a conservação do equipamento e seus acessórios, if there are any irregularities in the device , it should be sent to the manufacturer for maintenance, and if the accessories are not in good conditions, new ones should be purchased;
- Perform the shocking test on the pins located close to the handle of the device, as per the instructions on this manual. In case of any irregularities, send the device to the manufacturer or to an authorized technical assistance.

Preventive Maintenance

The maintenance and periodic tests are preventive measures that help avoid and detect possíble electrical and mechanical failures . During the maitenance schedule recommended US DEFIB, if the tests show a possible abnormality with the device, accessories and sensors, discontinue its use immediately and contact the manufacturer or authorized technical assistance.

Tests and Maintenance Schedule

The tables below should be used in association witht the quality control program of the hospital or facility where the device is being used. A check-list will help the operator take the recommended corrective measures should a problem occur.
The defibrillator analyzer electrical safety tests, calibration and performance tests must be carried out by US DEFIB or any authorized technical assistance.
These tables should be kept close to the device for control by the operating staff.

Programação	Antes do uso	Após o uso	Se necessário	Diariamente	Semanal mente	3 meses	6 meses	12 meses
Checar a validade dos eletrodos de ECG, do Marcapasso e DEA	x							
Inspecionar o Cardioversor (visual e mecânica)	x	x						
Limpar o Cardioversor		x	x					
Limpar os acessórios		x	x					
Checar se todos os materiais e acessórios necessários estão completos				x				
Auto teste diário				x				
Teste de descarga interna em 20 Joules					x			
Verificações das Funções:								
Modo DEA (checar mensagem na tela e comando de voz)						x		
Monitorização das pás permanentes adulto/inf							x	
Monitorização pelo cabo do paciente					x		x	
Verificação de cardioversão sincronizada pelas pás permanentes							x	
Teste de segurança elétrica								x
Teste de segurança elétrica pós intervenção técnica	x							
Teste com o Analisador do desfibrilador no primeiro e segundo ano								x
Teste com o Analisador do desfibrilador no terceiro ano em diante							x	
Checar o nível de carga da bateria		x	x					

Check List

Cardioversor Bifásico VIVO

Nº de Série da unidade: _____

Localização _____

Objetivo:

Recomendamos que este aparelho seja inspecionado e testado diariamente.

Autorizamos a reprodução deste formulário do Check List.

Instrução	Ação Corretiva Recomendada	Data / Iniciais
		Insira um V na caixa após executar cada instrução concluída
1- Inspecione as condições físicas para procurar por:		
Substâncias estranhas	Limpar o aparelho	
Danos ou rachaduras	Entre em contato com a área técnica qualificada	
2- Inspecione a fonte de alimentação para procurar por:		
Cabo de força conectado a unidade e a rede elétrica; o LED não esta aceso	Cheque as conexões no aparelho e na tomada, se o LED permanecer apagado troque o cabo de força, Se continuar apagado cheque os fusíveis e por ultimo entre em contato com a assistência técnica qualificada e autorizada.	
Cabo de força quebrado, frouxo ou gasto	Substitua as peças danificadas ou quebradas	
3- Verifique os eletrodos ECG e Eletrodos de marcapasso e modo DEA		
Data de validade	Substitua se estiver vencido	
Eletrodos de reserva disponíveis	Reponha os eletrodos	
4- Examine os cabos para saber se há rachaduras, danos, partes ou pinos quebrados ou tortos, e as superfícies das pás para saber se há danos	Substituas as peças danificadas ou quebradas	
5- Desconecte o aparelho da rede elétrica, pressione a tecla LIGA e verifique por:		
Nível de carga da bateria	Se estiver baixa, conecte o cabo de força até que a carga esteja plena. Repita o procedimento, se a carga ainda permanecer baixa, entre em contato com a assistência qualificada e autorizada.	
Execute o teste da descarga em 20 Joules	Se o teste falhar repita, se falhar duas vezes entre em contato com a assistência qualificada e autorizada.	
6- Verifique a impressora de ECG procurando:		
Suprimento de papel adequado	substitua se necessário	
Capacidade de impressão	Se não estiver funcionando entre em contato com a assistência técnica	
Observação:		
Testar rotineiramente o Cardioversor consome energia, por isso execute o teste de disparo de descarga com o aparelho conectado a rede elétrica.		

CUIDADO!

Possibilidade de danos ao equipamento.

Não limpe nenhuma parte deste aparelho ou de seus acessórios com alvejante, diluição de alvejante ou compostos químicos a base de fenol. Não utilize agentes de limpeza abrasivos ou inflamáveis. Não tente esterilizar este aparelho ou qualquer um de seus acessórios.

ADVERTÊNCIA!

Possibilidade de danos a pá e queimaduras no paciente.

Quando estiver efetuando testes de descarga, pressione firmemente as pás nos bornes de teste, para evitar centelhas e a formação de furos nas superfícies das pás. Pás furadas ou danificadas podem causas queimaduras na pele durante a desfibrilação.

Durante o teste de descarga a energia descarregada passa pelo conector e pelos cabos. Conecte os conectores com segurança e garanta que o contato está perfeito.

Every 12 months the device should be sent to an authorized technical assistance so that the preventive maintenance can be performed. This procedure ensures that all of the device's fucntionalities are fully operational.
It is not necessary to run a periodic calibration of the Defibrillator Monitor because it is calibrated by the manufacturer according the technical especifications, which makes additional calibrations unnecessary.
The oximetry parameter is calibrated after its manufacturing process is concluded. Therefore, there is no need for new calibrations over its lifespan. it was calibrated between 70 and 100%, which means that under these values it is not possible to assure the parameter's accuracy. In the range of 70-100% there is an error margin of ±2%.

SOFTWARE VERSION

To check the software version of your device, simle press the Cance Charge key for 30 seconds. After this time the device will display its software version on the screen.

Battery Replacement

At the end of its lifespan the battery should be replaced according to the procedures below:

The battery compartment is located at the bottom of the device. To access it, tilt the device sideways or on its back.

1. With a philips screw driver remove the 4 screws from the battery compartment lid;
2. Pull out the battery compartment;
3. Disconnect the battery from the device.

PICTURE 60 – Replacing the battery pack

⚠**Do not remove the battery if the device is running on it, before you turn off the device.**

⚠**The user must order with US DEFIB a new battery for the replacement of the old one in case of end of lifespan or malfuncitioning.**
If the device's performance decreases, due to low battery autonomy, contact US DEFIB 's technical assistance or an authorized representative.

⚠**The batteries lifespan is of at least 600 cycles (fully charged and discharged).**
If the Defibrillator Monitor E-HEART is not used for a long period of time, the battery will have to be recharged. To recharge it, plug its power cord to the grid.
The battery replacement is recommended every two years or when the autonomy time is lower than 1 hour.

⚠**If you are using extra batteries, do not use a charger that is not supplied by US DEFIB;**

- **Do not short circuit the battery;**
- **Do not completely discharge the battery;**
- **Do not compress or disassemble it;**
- **Risk of burns, fires and explosion if the above recommendations are not followed;**
- **Keep the device connected to the power grid at all time to save battery. If the device is stored for a period longer than 60 days, it is recommended that the battery is removed from it to avoid leaks and damages;**
- **In case it is necessary to dispose the battery, contact the manufacturer for further information.**

⚠**The Defibrillator Monitor E-HEART has an automatic battery charging system and it can be continually connected to the power grid.**

FUSE REPLACEMENT

To replace the fuses proceed with the following steps:

1 - Check if the device is on. If it is, turn it off by pressing for 3 seconds the ON/OFF key on the front pannel;
2 - Remove the power cord from the grid and from the device's input;
3 – On the backside of the device, unscrew the fuse compartment and remove it;
4 - Screw the new fuse compartment back.

CABLES AND ACCESSORIES HANDLING

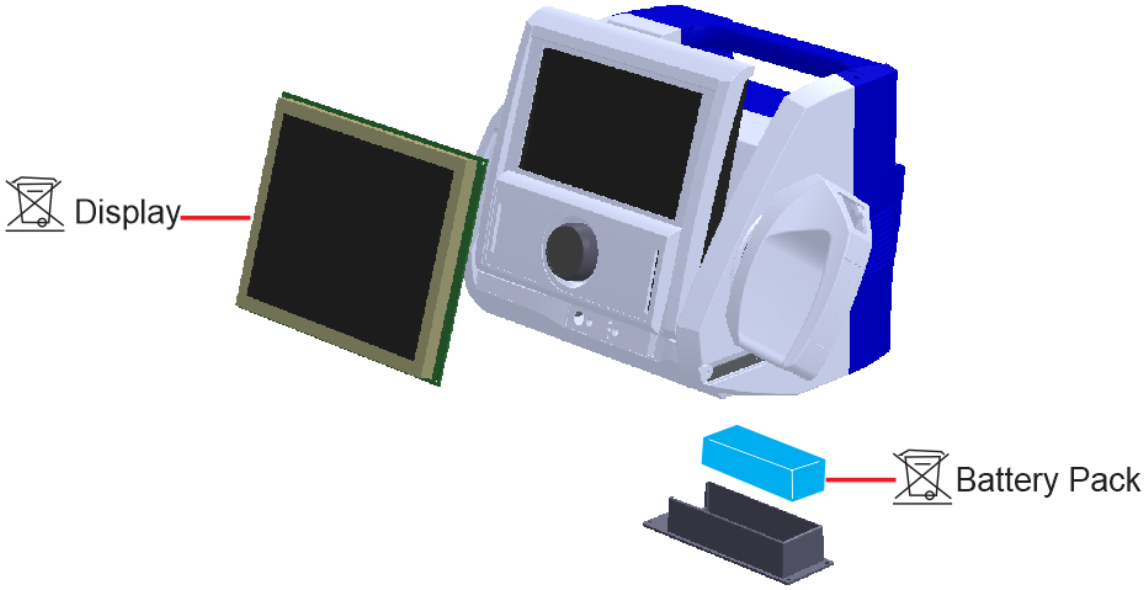
- Before the device is in contact with the patient, the user must make sure that it is in good operating conditions. Check the expiration date and the integrity of the electrodes package on a regular basis;
- Use only the accessories, consumables and other items listed on this manual. US DEFIB does not guarantee the perfect functioning of the device if other accessories and items are used;
- The capnography set may be damaged by the reuse of the water filter. Follow the use instructions provided by the manufacturer. The water filter must be replaced at each patient or according to the manufacturer's intructions.
- In general, the part of the device and its accessories are designed to come into contact with biological tissues, cells or body fluids and they are all tested according to the guidelines and principles of the ISO 10993-1, which deals exclusively with applied parts biocompatibility report;
- US DEFIB assures that all materials, permanent and disposable, will not cause any type of harm or harmful physiological effect as long as: the procedures described on this manual are followed; they are installed in an appropriate medical area; that the device is used with the proper accessories; that the device and accessories are operated by trained and qualified personnel and finally that all precautions described on this user manual are followed;
- The disposable electrodes are to be used one time only. Therefore, they should be disposed after each and every use and cannot be sterilized. Não utilizar os eletrodos descartáveis se a embalagem do mesmo estiver danificada;
- Risk of burn on the patient's skin at the momento of the defibrillation;
- Refer to the operating mode instructions as well as additional information on this manual.

POWER SUPPLY AND GROUNDING

When a medical device is connected to the power grid, there is a possibility of current leakage at some part of its structure to the patient. When this occurs, a current may go through the patient's body and the device to which the patient is connecte. In the case of an inadequate grounding, dangerous currents may go through the patient's body from the device if an internal electrical failure occurs. The grounding must be executed according to the regulations for electrical installations. In addition to the power cord with plug and three-pin connector, the third conductor (connected to the protection contact through the power plug) is only used as a functional grounding, since the Defibrillator Monitor E-HEART is a class II device.
If there is no power grid available, the device will operate on its internal battery (with a duration of 30 minutes to 4 hours, depending on the device's configurations). When the power supply is reestablished the device will automatically switch to the power grid and the battery will start charging.

14. DISPOSAL OF THE BIPHASIC DEFIBRILLATOR MONITOR E-HEART AT THE END OF ITS LIFESPAN

At the end of the useful life of the equipment, the disposal of the equipment should be performed by specialized companies, according to the local laws of each country. Special attention should be given to the display and the battery pack equipment.



PICTURE 61 – Special attention

DISPOSING ACCESSORIES OF THE DEVICE

In order to dispose parts and accessories, follow the local regulations for medical waste.


Electrical and electronic devices waste materials. Dispose separately from other items of the organization. Consult the local regulations for waste (consult the European Guidelines 2002/96/CE).

15. TROUBLESHOOTING

The user should frequently check the conditons of the device. This section aims to solve problems the user might have with the Defibrillator Monitor E-Heart. The solutions suggested herein involve common procedures that can be solved by the user. This procedures do not involve the opening of the device's main case, or its modules and permanent accessories. If the procedures described herein do not solve the problems, the user must contact the manufacturer or an authorized technical assistance.

Among the items to be noted are the following:

- The main case conditions (if it is intact or it has cracks or dirty spots);
- The battery conditions: if it is charged and operational or not;
- Does it have all accessories required for its use? (Adult and/or pediatric electrodes, ECG cable, oximetry sensor, and others);
- Are these accessories in good state?

PROBLEM	ACTION RECOMMENDED
The Defibrillator Monitor E-HEART will not turn on.	Check the conditions of tripolar power cord and make sure that it is connected to the device and to the power grid.
The power cord is in perfect conditions but the device still won't turn on.	Check the coditions of the safety fuses (located on the backside of the device): After disconnecting the device from the power grid, open the fusebox and remove the fuse in its interior. Try to see if the internal wire is broken. If it is, replace the component with another one of the same model. if you cannot see whether the wire is broken or not, replace with a new fuse to eliminate the possibility of a damaged fuse anyway. (Model for fuse replacement (fast type): F L5A 20AG).
Battery cannot hold charge	Check whether the low battery indicator LED located on the device's pannel is flashing. If it is, contact the manufacturer or an authorized technical assistance.
Instability of the parameters' curves	The main causes of curves instabilities are: poor connection of the sensors to the patients and inadequate grounding. So, if this happens, make sure the sensor connections are OK and if the device is properly grounded. Also, make sure that there are no leaks on the NIBP cuff and hose and verify the conditions of the other sensors.
Instability and interference of the ECG wave**	In most of the cases, ECG wave instabilities and excessive interference are caused by the following: Use of inadequate or damaged electrodes; Inappropriate attachement of the electrodes to the patient; Insuficient grounding; Conductive gel was not used.
Selected energy is limited to 50Joules	Make sure that the adult paddle blades are firmly attached to the pediatric paddle blades at the base of the paddles. There is a small

	black sensor close to the pediatric blades. When the adult blades are attached and this sensor is activated, it allow the energy to be selected to its limit (commonly 200 Joules). For pediatric use, the energy is limited to 50 joules, because the black sensor will not be activated.
Does not show SPO2 value	Make sure the sensor is correctly attached to the patient; Make sure the patient's finger is not cold - if it is, switch it to another finger; Make sure there is no excessive light onto the sensro, as it may interfere in the reading. The continuous and long-term monitoring may increase the risk of undesired skin abnormalities such as, rashes, blisters or burns. Check the area where the sensor is applied every two hours and change areas if the skin is not normal. For neonates with poor periferical blood circulation or sensitive skin, check the area to which the sensor is applied more.
When in AED mode, the device does not identify the shock pads.	Check the expiration date on the pads and in case they are expired, replace them with new ones. The device will not identify the pads because the contact between the pads gel was not made. Before attaching the shock pads the rescuer needs to shave excessive hair and remove any oily substances from the patients chest area.
The device does not charge the capacitor through the shock paddles.	Check on the device's display the indication Se*l. Paddles*. If it does not show, press the Select/Menu button and access the *Setup Menu - Sel. through paddles - Yes.*
The device does not measure NIBP in adult patients.	For safet reasons the NIBP parameter is set for neonatal patients. In order to measure the NIBP in adults, press the Select/Menu button, access *NIBP - Patient – Adult.*

If the recommended procedures cannot solve the problems, contact US DEFIB or an authorized technical assistance.

NIBP Module Erros Codes

When the device detects any errors or failures related to the NIBP parameter, it will display one of the following messages on the screen:

MESSAGES DISPLAYED ON THE SCREEN	ERROR DESCRIPTION	RECOMMENDED ACTION
Insuficient Pressure	Module inflated for more then 30 seconds.	Do not measure again, check the cuff and hose connection.

	Pressure is not high enough to produce results.	Check the cuff positioning.
<10mmHg or >250mmHg	Wrist pressure is lower than10mmHg (Adult mode).	Check the cuff positioning.
05mmHg or >150mmHg	Wrist pressure is lower than 5mmHg (Neonate mode).	Check the cuff positioning.
Excessive movement	Excessive movement.	Try to calm down the patient.
Irregular Measurement	Irregular Measurement.	Check waveform.
Arrhythmic pulse	Could not measure pulse.	Check the cuff positioning.
Measurement exceeded 90sec	Measured for more than 90 seconds (60 seconds for Neonates).	Measure again if it is an adult patient. Do not measure again if it is a neonatal patient.
+100 neuter pulses	More than 100 pulses without results were detected.	Check the device configurations.
High pressure	High pressure.	Keep the patient under observation.
Weak pulse	Weak pulse.	Check the cuff positioning and repeat the measurement.
Wrong cuff/hose	Wrong cuff/hose.	Check the cuff/hose connection.

CAPNOGRAPHY MESSAGES

MESSAGES DISPLAYED ON THE SCREEN	ERROR DESCRIPTION	RECOMMENDED ACTION
Initializing...	Time needed for the capnography module to start operating.	None.
Calibrating...	While the sensor is calibrating	Wait for approximately 1 minute for the calibration conclusion.
Check the line Inhaled Flow !, or Check the line exhaled flow! (Obstruction) Press the Reset option	These messages are displayed when there is something blocking the air flow through the tubes.	Check the tube conditions and replace the filter, if necessary. Reset the capnography module.

16. BIPHASIC DEFIBRILLATOR MONITOR E-HEART APPLIED PARTS

Applied part - any part that comes into physical contact with the patient so that the device can carry out its functionalities.

The applied parts of the Biphasic Defibrillator Monitor E-Heart are:

Applied Part	Protection Degree
❖ ECG Cable	CF defibrillation proof
❖ Oximetry Sensor	BF defibrillation proof
❖ NIBP Cuff	BF defibrillation proof
❖ Capnography Cannula	BF defibrillation proof
❖ Permanent Shock Paddles	CF defibrillation proof
❖ Internanl Permanent Shock Paddles	CF defibrillation proof
❖ Disposable AED mode shock pads	CF defibrillation proof
❖ Disposable pacemaker shock pads	CF defibrillation proof

Dispite performing different functions the permanent shock paddles, the disposable shock pads and the ECG cable have the same protection degree.

⚠ **Do not simulteneously use the permanent shock paddles, ECG electrodes and disposable shock pads, to avoid damages in case of shocks.**

17. TECHNICAL SPECIFICATIONS

The Defibrillator Monitor is portable, has a transport handle, is microprocessed, it is used for cardiac monitoring of the vital signs, has paddle holders. The device works in a simple 3-step way.
By accessin the menu through the round spinning button (Select/Menu), it is possible to setup all parameters. Used in adult, pediatric and neonatal patients.

According to the Harmonized Technical Regulations	EN 980:2008, EN 1041:2008, EN ISO 10993-1:2009, EN ISO 13485:2012, EN ISO 14155-1:2009, EN ISO 14971:2012, EN ISO 15255:2007, EN 60601-2-4:2003, ABNT NBR IEC 60601-1:2010, ABNT NBR IEC 60601-2-27:2011, ABNT NBR IEC 60601-2-49:2001, ABNT NBR IEC 60601-1-2:2007, ABNT NBR IEC 60601-2-30:2000, ABNT NBR IEC 60601-1-6:2010, ABNT NBR IEC 60601-1-8:2010, EN 62304:2008 and others.
Protection type against electrical shock	Class II
Protection degree against electrical shock	Applicable to every module. ECG/ Defibrillator/AED Mode/ Pacemaker - CF defibrillation proof applied part. SPO2/ NIBP/ EtCO2 – BF defibrillation proof applied part.
Protection against harmful ingress of liquids and particles.	IP22
Operation Mode	Applicable to every module.
Safety degree of use in the presence of flammable anesthetic gases.	Not adequate to use in the presence of flammable mixtures with air, O_2 and N2O.
Printing format	1 channel, automatic and manual
Input impedance	<10 MOhm
Impedance detection range	25Ohm - 500Ohm
Frequency response	with filter: 0,5 – 35 Hz without 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
Display	Liquid crystal colored display around 6” in size, with high resolution. Optional: Touch Screen around 8,2¨ in size Optional: Contrast adjustments.
Display indicators for visualization	Clear indication of phases: charging, ready, discharging. Indicates the charge mode and value on the screen. Automatic charge adjust. Programmable indicators of beep, battery statusand others.
Paddles contact indicators	Indicates the contact between the shock paddles and patient chest througha bargraph on the display or through LED's on the paddles.

Data visualized on the display	ECG, SPO2 and ETCO2 waves, NIBP data , derivations, cardiac frequency, beep indicator, pulse oximetry range with saturation values, pulse, battery status, maximum and minimum alarms for all parameters, pacemaker pulse, selected energy, delivered energy, filter, wave speed, amplifier, battery charge indicator, charged or charging indicating LED. NOTE: In order to be albe visualize the parameters above on the display, your device must have them in its configuration. Every US DEFIB Defibrillator Monitor has the basic parameters of ECG and DEFIBRILLATOR.
Audible and visual alarms	Alarms for disconnected electrodes, assystole, bradycrdia, tachycardia, high and low SPO2, disconnected sensor, disconnected cuff, high and low NIBP, ETCO2, low battery. It has a key that silences the alarms for 2 minutes. All alarm systems strictly comply with the IEC 60601-1-8 regulations. General requirements for basic safety and essential performance - Colateral Regulation: General requirements, reports and guidelines for alarming systems in electromedical and eletromedical devices.
Chronometer	Seconds counting meter, date and shock counter.
Device test	Performs an auto test when turned on.
Memory	It has an internal memory of 256 MB, including curve, data and time. That corresponds to over 100 hours of continuous monitoring. It is also possible to record ECG events, critical occurances and procedures.
External memory stick – OPTIONAL	Enables the communication with a computer through connection for memory data visualization with possible future readings of the ECG waves and events through a specific software (optional).
USB connection	USB port only for firmware updating.
Softwares – Optionals	Software for drug calculation and intubation / ventilation procedures.
ST Segment	Optional
ECG signal detection	Through the permanent defibrillator paddles or adhesive pads and through the ECG cable.
Energy	100 - 240 VAC – Automatic – 50/60 Hz Internally Energized – Internal battery. External DC: 10 - 16 VDC
Mean used to separate the device from the power grid.	Power grid plug
Tripolar power cord.	Flexible round cable 750V - 3 X 0,75 mm2 10A - 2,5mts- Male/Female 180º NBR12349
Consumption (maximum)	Power Grid:

	100V – 5A 240V – 2,5A Battery: 10A
Internal DC power supply (internal battery)	Type: Rechargeable Lithium-Polymer (LI-PO), 11,1 VDC, 2200mAh Time to completely charge the battery (completely discharged): 4 hours Temperature: +10ºC to +60ºC
Externa DC power supply (spare)	10 to 15 hours of continuous monitoring or 100 to 150 consecutive shocks.
AC current	100 VAC – 5A / 240V – 2,5A maximum
Paddles output voltage	256 - 1570 VDC
Paddles output current at 50 ohms	50 A maximum
Maximum charging time	Depends of configuration
Fast type fuse	20AG F L5A, 250V 20AG F L5A, 250V
Defibrillation escale	Depending on configuration
Plastic case	High impact index, electrical and thermal insulation (anti-flames – Rohs Directive)
Discharging time	< 240 ms
Synchronized discharging time	< 20 ms
Medium priority audible alarm	Approximately +78,0 dB
High priority audible alarm	Approximately +85,0 dB
Verbal alarm signal	Approximately +81,0 dB
Beeping signal (SPO2/ECG)	Approximately +78,0 dB
High Priority Alarms	Number of pulses per sequence: 10 pulsos Interval between sequences of pulses: 3 seconds - variation between sequences +/- 5%. Pulsing espace: Between 1º and 2º: 87ms Between 2º and 3º: 87ms Between 3º and 4º: 291ms Between 4º and 5º: 87ms Between 5º and 6º: 0,81s Between 6º and 7º: 87ms Between 7º and 8º: 87ms Between 8º and 9º: 286ms Between 9º and 10º: 87ms x and y variations between sequences: +/- 5% Amplitude difference between 2 pulses: max. of 10dB
Medium Priority Alarms	Number of pulses per sequence: 3 pulsos Interval between sequences of pulses: 13 seconds - variation between sequences +/- 5%. Pulsing espace: Between 1º and 2º: 200ms

	Between 2º and 3º: 200ms x and y variations between sequences: +/- 5% Amplitude difference between 2 pulses: max. of 10dB
Operating Temperature	10ºC to + 40ºC
Operating Humidity	30% to 75%
Storage Temperature	0 to 60 ºC.
Storage Humidity	10 to 95%, without condensation.
Transport Conditions	Range of room temperature from 0º to + 50º C; Range of relative humidity from de 10% to 95%; Range of atmospheric pressure from 700 hPa to 1060 hPa (525mmHg to 795mmHg). Maximum stacking of 5 boxes. Transport in the devices' original box. US DEFIB does not warrant or can be held liable for any damages that may occur to the device, if it is transported in a box other than its own.
Dimensions	Approximately H-125 xL-355 x W-280 mm
Weight	Approximately 4,3 kg including accessories.
Operating Atmospheric Pressure	700 to 1060 Pa (525 mmHg 795 mmHg)
Software Version	CBI450_A002_05
Available Languages	Portuguese, Spanish and English

DEFIBRILLATOR TECHNICAL SPECIFICATIONS

Wave form	Biphasic truncated exponential
Permanent Paddles	Interchangeable adult and pediatric, multifunctional.
Energy	From 1 to 200 joules biphasic
	Optional up to 360 joules biphasic
	Optional from 1 to 270 joules biphasic
	Limited to 50 Joules for pediatric mode – interchangeable shock paddles;
Maximum voltage applied to the patient	1450V (200J)/ 1850V (360J)
Manual Energy Selection	Versiios 200 Joules: 1,2,3,4,5,6,7,8,9,10, 15, 20, 25, 30, 35, 40, 45, 50 joules for pediatric defibrillation (external paddles) 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 paddles).
	Versions 270 Joules: 1, 2,3,4,5,6,7,8,9,10, 15, 20, 25, 30, 35, 40, 45, 50 joules for pediatric defibrillation (external paddles) 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 e 270 joules for adult defibrillation (external paddles).
	Versions 360 Joules:

	1,2,3,4,5,6,7,8,9,10, 15, 20, 25, 30, 35, 40, 45, 50 joules for pediatric defibrillation (external paddles) 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 e 360 joules for adult defibrillation (external paddles).
	Pediatric charge: Is automatically limited to 50 joules when the adult paddle blades are disconnected in any version.
Pre-set energy sequence	When in auto mode the device will follow the shock sequence of 150-200 and 200 joules.
Delivered Energy Accuracy	1 to 10 Joules - +/- 2J 11 to 360 Joules - +/- 15%
Ways to activate the energy shocking discharge	The energy (joules) can be selected through the paddles, pannel and Select/Menu button. When selected by the paddles the APEX button is used to select the energy and the APEX button is used to charge. Both buttons must be pressed simulteneously to apply the electrical shock, which minimized the chances of accidental shocks to the user Through the pannel, the 1-2-3 system is used, 1 to select the energy, 2 to charge and 3 to shock (shock key).
Paddles Test	Performs a working test with lighting indication.
Thoracic Impedance	Automatically analyzes the thoracic impedance of the patient, increasing the efficacy of the defibrillation and reducing injury risks Detection of impedance in the range of 25 Ohm to 50 Ohm for shocking treatments.
Cancel Charge	The shocking charge will be canceled by pressing the "cancel charge" key or after 30 seconds if the shock is not applied.
Sync.	Performs synchronized shoks with the QRS comples, with delivery time lower than 20ms. Maximum delay time for signal stabilization of 5 seconds after ideal attachment to the patient.
Operation Mode	Non continuous operation.

AED Mode Technical Specifications

Voice and text messages shown on the display, instruct the rescuer/user during the ressuscitation sequence according to the 2010 Guidelines by the American Heart Association. It has an automatic ECG evaluation system that detects the QRS complexes and malignant arrhythmias (ventricular tachycardia and ventricular fibrillation) that require defibrillation, informing the user if the shock treatment will be needed or not. Measures the impedance for adjustments of the phases 1 and 2 of the biphasic wave, avoiding short circuits between paddles.

Wave form	Biphasic truncated exponential
Disposable pads	Disposable AED mode and pacemaking pads.
Maximum energy	200J
Maximum voltage applied to patient	1450V
Signal Analysis	Automatic analysis of the patient's ECG signal and decision if the shock treatment is necessary or not.
AED mode delivered energy	Default setting: 1st shock 150J, 2nd shock 150J and 3rd shock 200J.
Accuracy of the delivered energy	+/- 15%
Cancel charge	The shocking charge will be canceled by pressing the "cancel charge" key or after 30 seconds if the shock is not applied.
Operating mode	Non continuous operation.

PACEMAKER (PM) TECHNICAL SPECIFICATIONS

Operation	Assynchronous, demand and emergency/ VOO, VVI and emergency.
Disposable pads	Disposable AED mode and pacemaking pads.
Stimulation output	Thorough the adhesive electrodes.
Defibrillation protection	Internal supressing diode, 400 joules
HF Filter	Filter against interferences of high frequency.
Output pulse current	5mA to 200mA Stable in 1mA degrees - accuracy of 10%
Output pulse frequency	30ppm to 200 ppm, adjustable is 1ppm degrees - accuracy of 10%
Pulse width	5 ms to 50ms adjustable in 1ms degrees
Frequency	30 ppm to 200 ppm accuracy of ±1,5%
Leakage interval	Time between detected beat or a pulse and subsequent non-synchronized pulse of the pacemaker - Accuracy ± 10%
Refractory period	340 ms (from 30 to 80 ppm); 240 ms (from 90 to 200 ppm).
Power supply	12 V
Operating mode	Continuous operation
Protection degree against electrical shock	CF defibrillation proof applied part
ALARMS	
Limits	30 to 200 BPM
Adjuste	Manual; maximum and minimum limits
Silent Alarm	Beep disabled for 120 sec
Delay	0 to 7 sec

CAPNOGRAPHY TECHNICAL SPECIFICATIONS (ETCO2)

Parameter reading method	*Sidestream and Mainstream*
Parameters	EtCO2, CO2 inhaled , Respiratory frequency
Wave	Exhaled Co2 wafe continually shown on the screen
Procedures	Auto calibration optional, which makes the use of specific gases for calibration unnecessary.
Unit	%
CO_2 concentration reading range	0 to 50 mmHg
Respiratory frequency reading range	0 to 35 RPM
Stable condition	Graphic line and numerical values 0 to 99 mmHg with ± 3 Sec
Compensation	N_2O, O_2 and Desflurane
Protection degree against electrical shock	BF defibrillation proof applied part.
Operating mode	Continuous operation
ALARMS	
Type	Manual. For maximum and minimum limits of respiratory frequency, $ETCO^2$, estable conditon and CO^2 inhaled.
Silence Alarm	Beep disabled for 120 sec
Features	Disables audio, adjusts tone and volume, dalays alarm.
Limits	CO2 inhalation: 0 to 10 mmHg Respiratory Frequency: 0 to 35 RPM EtCO2: 0 to 50 mmHg

ECG TECHINICAL SPECIFICATIONS

Derivations	DI, DII, DIII, aVL, aVR, AVF, V1 to V6
ECG cable	05 lead
Input impedance	> 10 Mohms
Frequency response	Monitor: 0.5 to 25 Hz Diagnosis: 0.05 to 100 Hz
Rejection	In regular mode is higher than 90 dB
Sensitivity	ECG amplification phases , 5,10,15,20,30 and 40 mm/mv
Filters	*Notch:* 60 - 50 Hz Muscular: below 35 Hz
Gains	5 - 10 - 20 mm/mV
Beats reading range	10 to 300 BPM - accuracy of 01 BPM with numerical display
Tolerance	± 3 %
Output	Analogical ECG signal 1V/mVpp
Offset (potencial)	± 300 Mv
Leakage current	< 10 uA

Defibrillation Protection	Maximum of 360 J
Base line recovery	Below or at 4sec after defibrillation
Systolic indicator (QRS)	Audible beep
Calibration signal	1 mVpp ± 3 %
Protection degree against electrical shock	CF defibrillation proof applied part.
Operating mode	Continuous operation
ALARMS	
Limits	25 to 220 BPM
Adjust	Manual; maximum and minimum limits
Silence alarm	Beep disabled for 120 sec
Delay	0 to 7 sec

NON INVASIVE BLOOD PRESSURE TECHNICAL SPECIFICATIONS

Measuring Method	Oscilometric
Operating mode	Manual / automatic Non continuous operation
Auto mode time programming	1 to 480 minutes
Protection degree against electrical shock	BF defibrillation proof applied part.
Reading Ranges:	
Systolic adult	40 to 300 mmHg
Diastolic Adult	40 to 300 mmHg
Mean Adulto	40 to 300 mmHg
Systolic Neonatal	20 to 150 mmHg
Diastolic Neonatal	20 to 150 mmHg
Mean Neonatal	20 to 150 mmHg
Maximum Pressure:	
Adult	300 mmHg
Neonatal	150 mmHg
Resolution	1mmHg
Reading Accuracy	Innacuracy of ± 5 mmHg Standard deviation of 8 mmHg
Reading time	Regular: 20sec Adult: 90sec max. Neonatal:60sec max.
Accessories	Complete Adult Hose/cuff, Complete Pediatric Hose/cuff, Complete Neonatal Hose/cuff.
ALARMS	
Type	Manual; maximum and minimum limits
Delay	0 to 7 sec

OXIMETRY TECHNICAL SPECIFICATIONS

Curve/Waveform	Plethysmographic, with oxygen saturation and cardiac frequency indication and numerical values display on the screen numerically.
Display visualization	Oxygen saturation and cardiac frequency displayed numerically and in percentage. Wave/curve amplitude can be adjusted on the screen.
Volumes	Adjusted separately
Accessories	Adult/pediatric finger sensor, neonatal finger sensor.
Pulse reading range	10 to 300 BPM
Tolerance	± 2 %
Resolution	1 BPM
SpO_2 reading range	00 to 100 %
Tolerance	70 to 100 % ± 2 digits, finger clip 70 to 100 % ± 4 digits, ear clip 70 to 95 % ± 3 digits, neonatal Below 70 %, undefined for all sensors
Protection degree against electrical shock	BF defibrillation proof applied part.
Operating mode	Continuous operation
ALARMS	
Type	Manual; maximum and minimum limits
Limits	00 to 100 %
Silence alarm	Beep disabled for 120 sec
Delay	0 to 7 sec

MASIMO RAINBOW SET TECHINICAL SPECIFICATIONS

Waveform	Plethysmographic with adjustable amplitude; Quality of signal
Display features	Arterial oxygen saturation, arterial carboxyhemoglobin saturation and saturation of blood methemoglobin in percentage; heart rate numerically.
Pulse Readings Range	25 to 240 BPM
Tolerance	± 3 digits without movement ± 5 digits in movement
Resolution	1 BPM
SpO^2Reading Range	00 to 100%
Tolerance	70 to 100%: ±2 digits without movement; ±3 digits in movement. <70% - Undetermined
PI Reading Range	00 to 20%
Resolution	00 to 1 – 0.01%

	1 to 10 – 0.1% 10 to 20 – 1%	
SpCO Reading Range	00 to 100%	
Resolution	1 digit	
Tolerance	±3 digits	
SpMet Reading Range	0 to 100.0%	
Resolution	0.1 to 2 – 0.1% 2 to 100 – 0.5%	
Tolerance	±1 digit	
Protection degree against electrical shock		
Operation Mode	Continuous Operation	
ALARMS		
Type	Manual; maximum and minimum limits	
Limites	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%
Silent Alarm	Audible alarm is shut off for 120 seconds	
Delay	0 to 7s SpO_2audible alarm settings 0 - 15s	

PRINTER TECHNICAL SPECIFICATIONS

Channels	1 or 03 channels
Resolution	High
Activation	Automatic or manual after each shock. It is also possible to print if no shcok treatments were administered.
Printing	On thermal paper of: 48 mm (wide) x 20m (long) or; 50 mm (wide) x 20m (long) or; 75 mm (wide) x 20 m (long)
Printing type	Prints diagnosis through manual or automatic mode, after defibrillation or any other alarm triggering event. It registers time and date, cardiac frequency, level of energy selected, sync. defibrillation, alarm triggering,

	derivation, ECG amplitude number of administered shocks.
Speed	12,5, 25, 50 mm-sec.
Accessories	Paper roll
Operating mode	Operating mode
Delay	0 to 7 s

18. CARDIOVERSION/DEFIBRILLATION BASICS

DEFIBRILLATION DEFINITION

Defibrillation is the emergency procedure that consists of applying a non-synchronized electrical shock to a patient's chest (external defibrillation) in order to revert ta ventricular fibrillation or pulseless ventricular tachycardia. It differs from ***cardioversion***, which consists of either an optional or emergency procedure that requires a synchronized electrical shock and it is typically recommended in the event of unstable tachycardias or at a doctor's discretion.

THE IMPORTANCE OF DEFIBRILLATION

The early defibrillation is one of the links of the survival chain. It allows a complete depolarization of the myocardium, which in turn, gives way to the control of the normal electrical activity by the other regulatory parts of the heart. When ventricular fibrillations occurs, it is necessary to perform the defibrillation immediately, since the chances of a successful treatment rapdly dicreases as time goes by – around 7 (seven) to 10 (ten) percent every minute.

CARDIOVERSION

Cardioversion is another electrical therapy type that aims to treat certain cardiac arrhythmias. Unlike the defibrillation, it is performed by applying a synchronized electrical discharge with the ventricular depolarization. The synchronization is obtained with the detection of the QRS complex.
Once the user chooses a synchronized shock (SYNC), everytime the QRS complex is detected the device will emit an audible and a visual signal.
It is important to point out that there is a mechanism to inhibit the energy discharge in certain situations. The QRS signals are difficult to be detected by the ECG. For example, when there is a wide and a narrow R wave. When the device is charged in the SYNC mode, the shock will only occur if it detects the R wave and the impedance is between 25Ω and 500Ω and the paddle buttons are pressed simultaneously. Extra care must be taken not to apply the shock on the asynchronous mode during the vulnerable period, since it can lead to a ventricular fibrillation (VF).

APPLIED TECHNOLOGY

Recording Methods (for the AED mode)

The arrhythmias that can be defibrillated (VT and VF) are pre-programmed in the device, eliminating the need to be programmed by the user and resulting in significant time saving for an earlier treatment.

Rhythm Source (for the AED mode)

With the help of a defibrillator analyzer, model QA-40M, by METRON, shockable cardiac rhythms (such as VT and VF) and regular cardiac rhythms of different amplitudes and frequencies are simulated.

Rhythm Selection Criteria (for the AED mode)

The selected rhythms are the ones widely known and typically indicated for defibrillation: Ventricular fibrillation and ventricular tachycardia.

Recording Methods

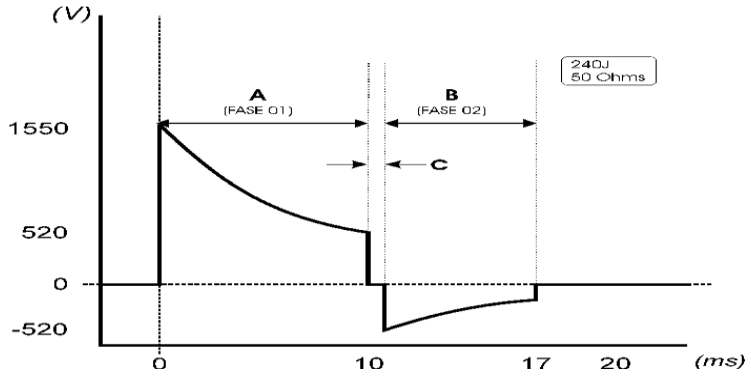
The Defibrillator Monitor E-Heart is equiped with a liquid crystal display where the emergency procedures and the ECG waves can be visualized, making it possible to graphically record the cardiac rhythms.

Detector's Performance Results

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

True positive (A): Correct classification of shockable rhythm.
True negative (B): Organized rhythm, or in perfusion or in assystole that was mistakenly classified as a shockable rhythm.
False positive (C): A VT or a VF combined with a SCA that was mistakenly classified as a non-shockable rhythm.
False negative (D): Correct classification of all non-shockable rhythms.
.

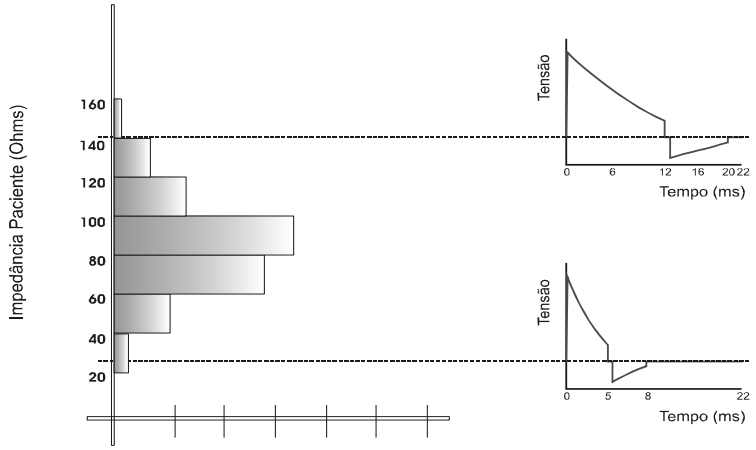
BIPHASIC TRUNCATED EXPONENTIAL WAVEFORM



PICTURE 61 - Biphasic Truncated Exponential 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



PICTURE 62 - Waveform variations according to the patient's thoracic impedance

Phase B corresponds to 2/3 da phase A
Maximum width (A+B): 20 ms
Dead-time (C): 0,5 ms

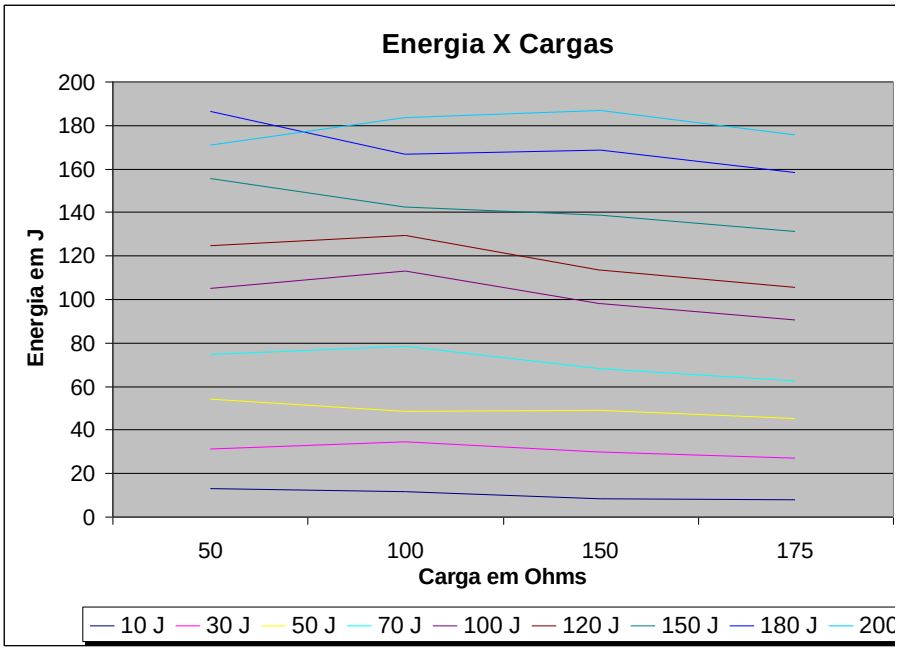
Variation of delivered energy and duration of defibrillation phases performed with Biphasic Truncated Exponential Waveform

Capacitor Charge 1237 Volts (150 Joules)					
Impedance Ω	**Phase 1 – A ms**	**Phase 2 – B ms**	**A + B ms**	**%A – %B**	**Delivered energy in Joules**
25	5,0	3,3	8,3	60% – 40%	149,9
50	10,0	6,7	16,7	60% – 40%	147,4
75	12,0	8,0	20,0	60% – 40%	140,1
100	12,0	8,0	20,0	60% – 40%	130,5
125	12,0	8,0	20,0	60% – 40%	120,7
150	12,0	8,0	20,0	60% – 40%	111,5
175	12,0	8,0	20,0	60% – 40%	103,2

Capacitor Charge 1428 Volts (200 Joules)					
Impedance Ω	**Phase 1 – A ms**	**Phase 2 – B ms**	**A + B ms**	**%A – %B**	**Delivered energy in Joules**
25	5,0	3,3	8,3	60% – 40%	199,94
50	10,0	6,7	16,7	60% – 40%	196,62
75	12,0	8,0	20,0	60% – 40%	186,84
100	12,0	8,0	20,0	60% – 40%	174,02
125	12,0	8,0	20,0	60% – 40%	160,92
150	12,0	8,0	20,0	60% – 40%	148,70
175	12,0	8,0	20,0	60% – 40%	137,69

Capacitor Charge 1428 Volts (240 Joules)					
Impedance Ω	**Phase 1 – A ms**	**Phase 2 – B ms**	**A + B ms**	**%A – %B**	**Delivered energy in Joules**
25	5,0	3,3	8,3	60% – 40%	239,96
50	10,0	6,7	16,7	60% – 40%	236,00
75	12,0	8,0	20,0	60% – 40%	224,30
100	12,0	8,0	20,0	60% – 40%	208,95
125	12,0	8,0	20,0	60% – 40%	193,40
150	12,0	8,0	20,0	60% – 40%	178,73
175	12,0	8,0	20,0	60% – 40%	165,37

Delivered Energy X Charge



NOTE: All data is subject to a tolerance of +/-15%.

RECOMMENDATIONS ON THE NECESSARY LEVEL OF ENERGY FOR THE TREATMENT OF ARRHYTHMIAS

According to the 2005 Guidelines of the AHA for Biphasic Truncated Technology:

External Transthoracic Cardioversion/ Defibrillation (indirect) in adults:
❖ Atrial Fibrillation - 100J to 120J;
❖ Atrial "Flutter" - 50J;
❖ Paroxysmal supraventricular tachycardia - 100J;
❖ Monomorphic ventricular tachycardia - 100J
External Transthoracic Defibrillation (indirect) in adults:
❖ First Defibrillation: 150 J;
❖ Second Defibrillation: 150 to 200 J;
❖ Third and subsequent Defibrillations: 200 J.
External Transthoracic Defibrillation (indirect) in children:
❖ First Defibrillation: 2 J/Kg;
❖ Subsequent Defibrillations: 2 to 4 J/Kg;
Internal Defibrillation (Direct) in children:
❖ First Defibrillation: use the lowest possible, with unit around 2J;
❖ Subsequent Defibrillations: 3 to 10 J;

19. ST SEGMENT ANALYSIS FEATURES

The first step to run an ST segment analysis is to digitize the signal for 10 seconds at a rate of 500 samples per seconds. Eight derivations are directly acquired (I, II and V1 up to V6). The 4 remaining derivations (III, aVR, aVL and aVF) are derived via Einthoven 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 interference and achieving better results. The result of these stages is the digital ECG.

Following the acquisition, the program measures the ECG in the second stage of the interpretation process. The measures can be detailed in 5 steps:

1. QRS detection: This is a very important stage, because if it is performed incorrectly, the next steps will also incorrect. An auxiliary function for the QRS detection is computed, based on 8 independent derivations. The complexes are classified as normal and abnormal with the objective of getting a normal QRS pattern from derivation to derivation. This way, the RR interval is measured and the cardiact beat computed.
2. Identification of the end of the T wave: This is a very important point because it identifies the end of the cardiac cycle and it is used to measure the AT interval.
3. P wave study: The program searches for the P wave in all T-Q segments (from the end of the T wave to the beginning of the next QRS complex) to determine if the duration of the P-R interval is changing.
4. Beginnings and endings: These points are identified for each wave to measure their duration and find their peaks.
5. Measurement: For each wave the amplitude and duration are measured, derivation by derivation. This way, the deviation of the St segment is measured, as are other parameters.

The measuring process result is the following:

- Duration of the normal QRS complex;
- Duration of the PR interval;
- Duration of the QT interval;
- Cardiac beating (beats per minute);
- Duration of the PR interval;
- Duration of the P, Q, R, and R waves';
- Amplitude of the waves P, P', Q, S, R' and T;
- Amplitude of the beginning, middle and end of the St segment;
- Intrinsic deflection (time from the befinning of the QRS complex to the peak of the R wave);

- Projection of the electrical axis on the front planel (P wave, RS complex and T wave vectors). The ventricular gradient is also measured.

The derivation of the average cardiac cycle is also stored as it is useful for printed reports.

The last step is the evaluation of medical reports from the ECG measurements. The analysis of the ST segment has a number of advantages, among which the following can be mentioned:

- Considerable time saving of cardiology professionals devoted to ECG interpretation in hospitals that offer a large number of these tests. Stability and uniformity in ECG interpretation and homogeneity in ECG interpretation. Human fatigue or working pressure can cause specialists to not interprete ECG's, making it impossible to maintain the same homogeneity required. The equipment always applies the same algorithm and the same rules for ECG interpretation, thus providing more stable results in a timely manner. The possibility of storing all information related to a patient allows you to get the same examination report several times without any need to repeat the ECG. This information is a valuable component of an ECG database for research applications.

All medical criteria used in this ST segment analysis varies from a simple recommendation or warning about the ECG results to a complete diagnosis of a specific change. That is why these criteria have varying degrees of specificity and may include phrases such as: **"NOT NECESSARILY PATHOLOGICAL", "CONSISTENT WITH", LIKELY ... "** when there is no absolute certainty of a specific pathology. In these cases, the physician must determine whether the given measures and additional factors are conclusive or not.

The equipment evaluates all medical criteria, taking into account all the measurements made previously, and determines in its conclusions, the criteria that are unique and the criteria that eliminate others because of their greater diagnostic accuracy. These criteria were grouped as follows:

- Changes in the cardiac rhythm
- Changes in the electrical axes
- Left or right ventricular hypertrophy
- Intraventricular obstruction
- Bloqueio do ramo esquerdo
- Changes is the ST segment
- T wave modifications
- Heart attacks
- Other case

No way should these types of diagnosis be considered a substitute for diagnosis of cardiologists; simply because they are not. They should be seen as an efficient tool that assists the specialized physician in the diagnosis because they are highly efficient in normal situations, and have high sensitivity for the detection of pathological cases. This relieves doctors from reviewing normal cases and serves as a guide for the classification of pathological cases. When electrocardiographic indications are ambiguous or extremely complex, the final diagnosis is left to the doctor. The following is a list of medical criteria:

The interpretation of ST segment analysis report using the Biphasic Defibrillator Monitor E-Heart is one of the valuable tools that help the doctors efficiently interpret ECG, but only when combined with a detailed patient history and medical examinations. All computerized ECG systems are unable to analyze the ECG waveform as the human eye-brain system. The physician should re-read and correct the automatic interpretive ECG report.
The ACC/AHA recommended the computerized ECG interpretation to doctors.

"Several studies have examined the accuracy of computerized ECG interpretation programs and suggested that computer analysis can not replace the interpretation of ECGs by the doctor. 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 and myocardial infarction (MI). Rhythm disorders were not evaluated in that investigation, and the informal experience suggests that computer interpretation has a higher error rate in the analysis of rhythm 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 computer interpretation than for medical trainees in major ECG diagnoses. However, computerized ECG interpretation can be useful in the accurate calculation of heart beat intervals and conductive axes, since a manual review is conducted. Thus, despite the computerized interpretation of ECGs may have useful value, they cannot replace the interpretations of experienced electrocardiographs and should not be used to make clinical decisions.[1]"

CHARACTERISTICS OF SOME TYPES OF CARDIAC ARRHYTHMIAS

Symptoms of arrhythmias are variable and can be silent (no symptoms). They can be diagnosed by the doctor during cardiac examination (examination of the pulse and heart auscultation with specific device).
The most common symptom is palpitation. Fainting may also occur (fast, spontaneous recovery and without motor abnormalities), dizziness, shortness of breath, discomfort, heaviness in the chest, weakness, fatigue, chest pain, among others.
Symptoms indicating severity are: mental confusion, low blood pressure, chest pain and fainting. If any of these symptoms are noted, a doctor must be seen urgently to prevent death of the patient. Cardiac arrhythmias can be classified in various ways, depending on the frequency, formation mechanism, place of origin, etc. We will present some more general terms, common in people's daily lives.
Regarding frequency, arrhythmias can be classified into:

- Bradycardia: occurs when the heart beats less than 60 times per minute. In some people it may be a normal aspect, such as in athletes. There are several types of bradycardia, 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 bradycardia, depending on where the obstructionof the electrical system of the heart takes place. When the obstruction occurs in the sinus node, which is the natural pacemaker of the heart, it is called the sinus node dysfunction. Furthermore, the electrical impulse obstruction can occur in the atrioventricular node or the left or right branches of the electrical system of the heart. The important thing is that all these types of problems may cause the decrease in the number of

heartbeats and lead to symptoms such as dizziness and fainting. Depending on the type of obstruction, and its causing symptoms, there may be the need to implant an artificial pacemaker.

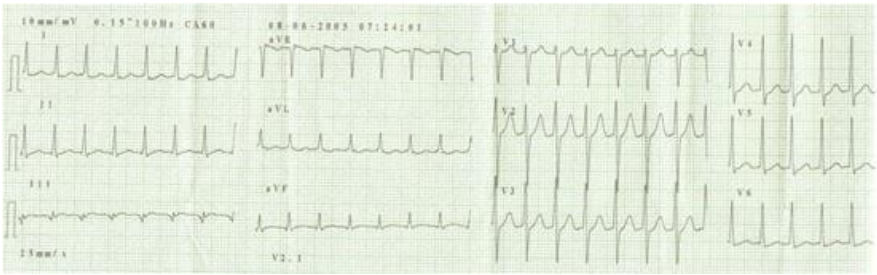
- Taquicardia: occurs when the heart beats more than 100 times per minute. Normally occurs during physical activity, emotional stress, in the presence of anemia and other diseases. There are several types, some extremely serious.

Types of Tachycardia

- Atrial Tachycardia: is a rapid heart rhythm that originates in the atria.
- Atrial Flutter: is an arrhythmia caused by electrical circuits of slow conduction that originate in the atria and promote a rapid and regular heart rhythm.
- Nodal reentrant tachycardia (NRT): an extra electrical pathway, near the atrioventricular node, which causes the electrical impulse to move in a circle and pass through areas that had passed before, making the heart beat at a much higher frequency than usual.
- Accessory pathway Tachycardia or Wolff-Parkinson-White syndrome: extra electrical pathway that exists since birthday and connects the atria to the ventricles, causing the electrical impulses to arrive faster to the ventricle.
- Atrial fibrillation: extra electrical impulses originating in the atria that trigger rapid, disorganized and irregular heartbeat.
- Ventricular extra-systole: extra electrical impulse originated in the ventricle that promotes beat ahead of time
- Ventricular Tachycardia: electrical impulse originated in the ventricles that promotes a rapid pace and is potentially threatening to life. Generally, it is a medical emergency.
- Ventricular Fibrillation: is a rapid, disorganized and erratic pace, which does not produce ventricular contraction and causes sudden death. Needs immediate CPR and defibrillation (electric shock).

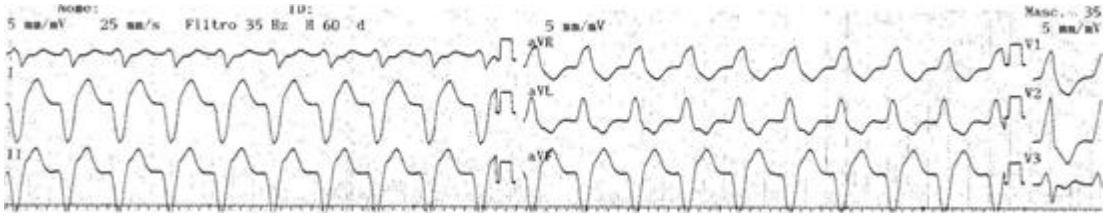
Regarding the place of origin, arrhythmias are classified into:

- Atrial: as we know, the heart consists of four chambers (or divisions), two atria and two ventricles. The normal stimulus to the heartbeat is generated in the right atrium. In some arrhythmias, these stimuli are generated in excess or insufficiency, by the structure that normally generates; In other words, the stimulus appears somewhere else in the atria, leading to the occurrence of atrial arrhythmias.



PICTURE 63 - Electrocardiogram of atrial arrhythmias

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



PICTURE 64 - Electrocardiogram of atrial arrhythmias

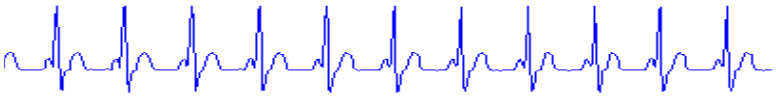
20. APENDIX A – INSTABILITY AND INTERFERENCE TO THE ECG WAVE

If degradations in the output signal, such as frequent saturation (loss of signal), the presence of interferences overlapping the ECG (even with the filter activated) and deformation of the wave morphology, check carefully the following items:

- Conditions of the electrodes connecting cable. Note the existence of cracks or breaks along the cable, which must be homogeneous throughout its length.Integridade das extremidades and cable joints, next to the connector, the connection box and the electrodes. These points are more susceptible to handling and, therefore, more likely to break.
- If a possible damage to the cable is observed, it should be tested by qualified personnel and, if necessary, replaced.
- Conditions of electrodes type clip and precordial, noting in particular the metal part of contact with the patient's skin. There should be no oxidation evidence or dirt.
- Condition of the disposable electrodes, which must be of good quality and used just once
- The type conductive gel used in the electrodes, which should be suitable for ECG. Other types of gel such as gel for ultrasound and / or for other purposes, are contraindicated as they can not only introduce interference and ruin the exam, but also cause premature wear of the electrodes themselves.
- Patient skin preparation before attaching the electrodes. The excessive skin oiliness, together with the layer of dead skin cells that naturally accumulate in the epidermis, increases the impedance of the patient-electrode interface, degrading the cardiac signal and introducing interference from various sources in the ECG. Proceed with the preparation of the areas where the electrodes will be applied according to the usual clinical practices(cleaning of the skin and shaving hair, if necessary).
- Power outlet grounding where the Biphasic Defibrillator Monitor E-Heart is installed. Note the recommendations on power and grounding in this manual.
- Proximity to sources of external interference (radio frequency generators and power lines), if this happens, move them away.
- Adjuste the device's filters.
- For additional support, do not hesitate to contact US DEFIB.

MOST COMMON ECG INTERFERENCETYPES

The ECG signal recorded under normal conditions, without contaminations, is shown in the picture B1. If the conditions of acquisition of the ECG are not adequate, four main types of interference can occur: (1) Power supply interference (AC); (2) muscle artifacts ("muscle tremors"); (3) shift of the base line ("drift"); and (4) motion artifacts.

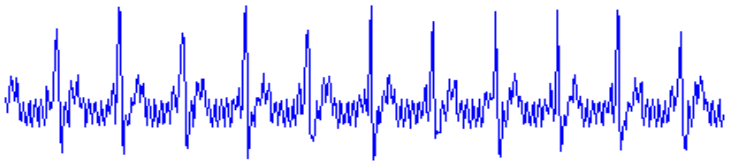


PICTURE 65 - E*lectrocardiogram without contaminations.*

AC POWER SUPPLY INTERFERENCE

The AC power supply leads to a specific frequency interference (50 Hz or 60 Hz) overlaps the ECG signal as shown in the picture B2. The main causes of contamination by the AC power supply are listed as follows:

- presence of electromagnetic fields close to the unit and electrode cables, such as X-rays, power lines, fluorescent lamp ballasts and etc;
- Poor connection to grounding;
- Weaving patient electrodes cable and power cord;
- Electrodes or cable break. In this case, the interference is of high amplitude and only appears in the lead related to the damaged cable;
- Loose or worn electrode, lack of conductive gel or insufficient preparation of the patient's skin. These conditions increase the impedance of the electrode-skin interface and disrupt the signal impedance detected by the equipment, jeopardizing the regular mode rejection effect of the input amplifiers. In these cases, the waves typically appears saturated.

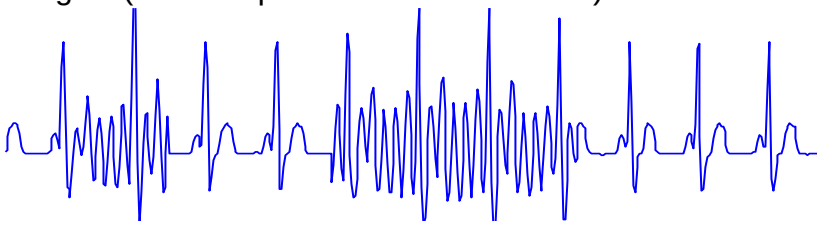


PICTURE 66 - ***ECG with a 60 Hz AC power suppl interference.***

MUSCLE ARTIFACTS

Muscle activity overlaps the ECG as irregular and unstable waves, according to the picture B3 shown below. The main causes are listed below:

- Restless patient, due to cold feeling or discomfort during the exam;
- Specific pathologies (for example Parkinson's disease).



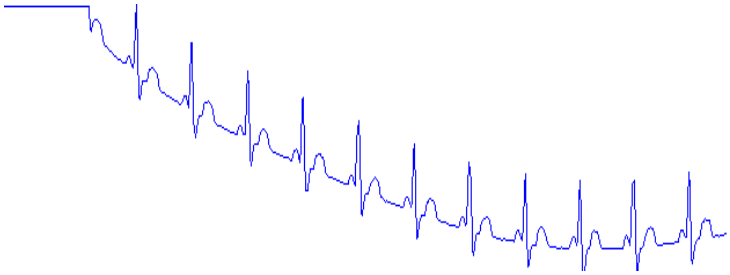
PICTURE 67 - **E*CG contaminated with muscle artifacts (“muscle trembling”).***

BASELINE SHIFTING

This disorder causes a shifting of the ECG baseline in relation to the central zero-chart (center of the printing paper), taking some time to return to a normal condition (depending on the internal order of the filters of the equipment). The wave may momentarily saturate, hindering the examination (B4 picture). The main causes are listed below:

- Incorrect connection of the electrodes to the patient, with insufficient gel or worn electrodes;

- Tapes of poorly attached electrodes or electrodes without adherence;
- Presence of foreign particles (dirt, for example) between the electrode and the patient's skin;
- Breaks at the junction between the patient cable and electrode. In this case, sharp oscillations generally appear between the ends of the graph, and it takes longer than usual to return to the baseline.



PICTURE 68 - E*CG base line shifting ("drift").*

MOTION ARTIFACTS

Motion artifacts have their origin in the contact interface between the electrode, the conductive gel and the patient's skin. In fact, the electrode functions not only as an electric sensor, but performs more complex electrochemical transduction, the frequency measured by the equipment is between 10 and 300 ppm with a precision 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 conductive gel layer, the electrode set chemical balance conditions to this interface, generating a potential double layer called half-cell potential. The input amplifier identifies this potential as a constant voltage level, that does not interfere with the measurement of the ECG. However, when moving the electrode, the balance of the interface is changed momentarily, and makes it necessary to achieve a new balance condition. This disorder produces a transient electrical artifact motion (Picture 40), which can be of the order of several times the biomedical signal to be measured. Still, this type of intereference is predominantly of low frequency, spectrally overlapping the ECG and preventing its removal by simple filtration.

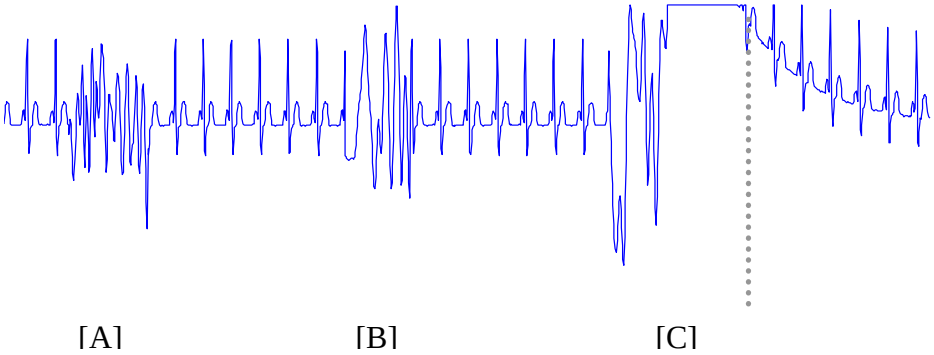
The correct use of conductive gel between the electrode and the patient's skin and the use of electrodes of Ag-AgCl type, substantially reduces the generation of motion artifacts, stabilizing the electrode gel-skin interface.

Proper preparation of the skin area of contact with the electrode also contributes to obtain a more precise ECG signal. The surface layer of the skin (stratum corneum) is composed of dead skin cells, in addition to having a thin layer of fat, with high impedance characteristics. After cleaning the area by rubbing it - for example, with a gauze soaked in alcohol - The skin contact impedance may be reduced from 200 kOhms to around 5 kOhms in 90% of patients.

Some practices can help minimize motion artifacts in ECG:

1. Always use electrodes in perfect conditions, preferably of Ag-AgCl type.

2. The electrode leads must be all of the same material in order to reduce the resulting DC potential and prevent saturation of the amplifier.
3. Clean skin with alcohol to remove oil and dead cell layer.
4. Use gel or Cl-made conductive paste, specific for ECG examinations; never use other gels (e.g.,ultrasound examination gel).
5. Apply the gel only on the electrodes contact areas.
6. Never apply the gel or conductive paste to injured skin areas.
7. If necessary to remove hair excess from the skin, cut it, do not scrape the area.
8. Use the appropriate tape (micropore or tape) on the back of the electrode and secure it to the place of contact with the skin, making sure that there is a slight pressure of the electrode against the skin.
9. When the connection is well made, the electrodes movement should cause a minor motion artifact, with fast recovery of the normal wave.
10. In long records, the conductive gel tends to dry off, modifying the interface characteristics; in these cases (eg, bedside records) conduct periodic replacement of the electrodes on the patient, preferably in different areas.
11. Clean the skin after the examination by applying a wet sponge with mild soap for a complete removal of the conductive gel.
12. Clean the electrodes with water. If necessary, using water under pressure (waterpick). Dry them thoroughly before putting them away.



PICTURE 69 - ***ECG contaminated by motion artifacts:***

In [A] and [B] the detection of the cardiac signal is impossible and in [C] the amplifier reaches saturation, and it takes some time to return to the baseline.

21. APENDIX B - PERFORMANCE CHARACTERISTICS

USE OF THE BIPHASIC DEFIBRILLATOR MONITOR E-HEART IN INTENSE ELETROMAGNETICS FIELDS

Subways, helicopters and train stations can interfere with the device's normal operation when in AED mode, for their high electromagnetic fields. In these places, major sensitivity and specificity changes were noted. Do not operate the machine near cell phones, wet surfaces, high-voltage lines or near strong electromagnetic fields.

Operation of the Defibrillator Monitor in High Frequency Areas

- Extreme care must be observed when performing surgeries using equipment operating at high frequencies, especially in patients with pacemakers. Besides the risk of damage to the pacemaker, the electrocautery currents can cause fibrillation to patients. Keep a defibrillator around.
- Respect the minimum distance of 15 cm between the ECG electrodes and the Harmonic scalpel or defibrillator, if used at the same time. If in doubt, disconnect the ECG cable.
  This equipment can cause radio interference or may disrupt nearby equipment operation. It may be necessary to take mitigation measures, such as reorienting or relocating the Defibrillator Monitor or shielding the location.

SAFETY AND PROTECTION

a) Patiente

- The capacitor is charged shortly before the shock treatment and the voltage is only passed on the electrodes at the time of shock.
- The shooting command is only activated if the capacitor is charged with the selected voltage and within the shooting time (30 s). Exceeding this period or the capacitor's limits and/or if any anomalies are detected, the relay which controls the discharge of the capacitor is disconnected, causing the internal discharge of the capacitor.

b) Operator

- Internal battery to insulate the device from the external power supply.
- Internal manageable battery charger with external power supply and insulated between power grid, patient and operator.
- Do not apply the shock with the paddles facing one another, because the shooting mechanism may be damaged.

c) Aircrafts

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

PHYSIOLOGICAL EFFECTS

In general, the Biphasic Defibrillator Monitor E-Heart does not offer any harm or causes any physiological effect, provided it is installed for operation in appropriate medical location, it is used with the correct accessories, and operated by trained staff and all the precautions described in the user manual are followed.
We point out some basics of special care:

ECG Module

- The adequate and recommended gel must be applied to the patient only at the moment of use of the electrodes;
- If the electrode is of pre-gel type, check the expiration date first;
- Use only quality disposable and reusable electrodes;
- All of these procedures are to be follow, no matter who the patient is (Adult or Pediatric / Neonatal);
- Other standard procedures, previously mentioned in this manual under the "Presentation" topic must be observed.

Non Invasive Blood Pressure (NIBP) Module

- The use of appropriate cuff for each patient type (adult, adolescent, pediatric, neonatal) and adequate positioning must be observed. Make sure that the correct configuration of the equipment is on so that its use is consistent with the patient, so that the pressure is compatible with each individual, avoiding the interruption of the blood flow.
- When using the Auto Mode function, in intervals of less than 15 minutes between measurements, the equipment, for safety reasons, automatically reconfigures to perform measurements of 120 in 120 minutes after the first 15 minutes have elapsed. This prevents damage to the patient in case of long periods of monitoring. Timer imprecision (intervals between measurements): 10ms / min.

Oximetry Module

- A LED and light emitting and receiver sensor is used. It is placed on the patient's finger (adult or pediatric). The sensor should be changed position every 4 hours to avoid possible skin burns, bruises or skin lesions;
- Pediatric and neonatal patients deserve special care, using sensor model type Y, which should be changed position every two hours to avoid possible skin burns, bruises or skin lesions. This use in neonatal patient is made by fastening a tape to he sensor. Be careful not to use excessive tape, to avoid skin lesions or incorrect readings.

Prolonged Use of the Sensor

The oximetry sensors (adult, child or universal) are not suitable for prolonged use, due to the heat emitted by the sensor and the continuous pressure to the patient. While monitoring for a longer period, repositioning the sensor in another area is recommended every two (02) hours or 4 hours depending on the type of sensor.

Defibrillation Module

- It is necessary to be careful not to discharge the defibrillator during vulnerable period, in which case one can induce ventricular fibrillation;
- Special care must be taken as to the different conditions of use of the equipment: defibrillation or cardioversion.

For the use of the device as a defibrillator, if the SYNC. mode is on, the shock will not be delivered in Ventricular Fibrillation - VF - or assystole (even when pressing the paddle buttons), for the charge applied part awaits the information of R wave presence, which is not detectable (because the ECG is not on or because the R wave does not exist). In this situation, the user presses the paddle buttons, but the shock is not applied. This may cause the user to think that the device is not working well but, in fact, the device will only apply the shock when the SYNC. mode is turned off by pressing the SYNC. key on the device's pannel. On the other hand, if the cardioversion is the objective (electric shock at the R wave peak) and the device is configured for defibrillation, when the paddle buttons are pressed, the shock will be immediately delivered, regardless the R wave. As a consequence, if the shock is delivered during a vulnerable period, it may lead to ventricular fibrillation.

Capnography Module

The user must make sure that the adapters of both Sidestream and Mainstream systems are clean, sterilized and in perfect conditions to avoid a possible bacterial contamination.

ADVERSE EFFECTS

As a medical device manufacturer, US DEFIB asks that the users report any undesirable or odd occurance in order to assure the quality of the device. Therefore, in the event of any failures or malfunctionsc, contact US DEFIB or any of its authrized technical assistance partners. The company's website is: www.usdefib.com

Important Notes:

- Do not apply the defibrillation or cardioversion shock with the paddles in short circuit as they may be damaged
- A break of at least 30 seconds should be taken between the shocks to the test pins;
- Always carry the device with its paddles inside the transport bag;
- In order to avoid misreadings, it is recommended to keep the patient still during the ECG analysis.

22. APENDIX C - MANUFACTURER'S DIRECTIVES AND DECLARATIONS –ELETROMAGNECTIC EMISSIONS

The Biphasic Defibrillator Monitor E-Heart as designed for operation in any of the anvironments list below.
The user must secure its use in one of the following locations.

RF EMISSION MEASUREMENTS	COMPLIANT	ELETROMAGNECTIC ENVIRONMENT - ORIENTATION
RF emissions according to ABNT NBR IEC CISPR 11	**Group 1**	The Biphasic Defibrillator Monitor E-Heart only uses RF energy for its internal functions. So, the RF emissions are very low and unlikely to cause interference to electronic devices around.
RF emissions according to ABNT NBR IEC CISPR 11	**Class B**	The Biphasic Defibrillator Monitor E-Heart is suitable for domestic use as well as in any other facility connected to low voltage public power supply buildings as the ones intended for domestic use.
Harmonic emissions IEC 61000-3-2	**Class A**	
Emissions due to voltage variation / scintillation IEC 61000-3-3	**Compliant**	

The Biphasic Defibrillator Monitor E-Heart as designed for operation in any of the anvironments list below.
The user must secure its use in one of the following locations.

Interference resistance test	Level of ABNT NBR IEC 60601 test	Level of Compliance	ELETROMAGNECTIC ENVIRONMENT - ORIENTATION
Static electricity discharge (ESD) de aCOLORdocom a IEC 61000-4-2	± 6kV through contact ± 8 kV by air	**Compliant**	Floors should be wooden or cement covered with tiles. If the floor is made of synthetic material, the relative humidity should be at least 30%
Fast electrical Disorders / discharges according to IEC 61000-4-4	±2 kV in the power lines ±1 kV in the input/ output lines	**Compliant**	Quality of the power supply must match the voltage provided in a typical commercial or hospital environment
About voltages according to IEC 61000-4-5	± 1 kV diferential mode ± 2 kV regular mode	**Compliant**	
Voltage failures, brief	< 5% Ut	**Compliant**	The quality of the supplied

interruptions and supplied voltage variations according to IEC 61000-4-11	(> 95% voltage failure in Ut) for 0,5 cycle. 40% Ut (60% voltage failure in Ut) for 5 cycles. 70% Ut (30% voltage failure in Ut) por 25 cycles. <5% Ut (> 95% voltage failure in Ut) for 5 seconds.		voltage should correspond to the voltage provided in a typical commercial or hospital environment. If the Biphasic Defibrillator Monitor E-Heart user requires continuous operation even when there are interruptions in the supply of energy, the device must receive power without interruptions or from a battery.
Magnetic field in the AC frequency (50/60 Hz) according to the IEC 61000-4-8	3 A/m	**Compliant**	Magnetic fields in the AC frequency should be at levels characteristic of a typical commercial or hospital environment.

Nota *Ut is the AC voltage before undergoing the test level.*

Tabela C2

The Biphasic Defibrillator Monitor E-Heart as designed for operation in any of the anvironments list below.
The user must secure its use in one of the following locations.

Interference resistance test	**Level of ABNT NBR IEC 60601**	**Level of Compliance**	**ELETROMAGNECTIC ENVIRONMENT - ORIENTATION**
Conducted RF IEC 61000-4-6 **Radiated RF IEC 61000-4-3**			Portable and mobile RF communications equipment should only be used near any part of the Biphasic Defibrillator Monitor E-Heart, including cables, with a separation distance below the recommended. This safe distance is 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 maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the distance separation recommended in meters (m) It is recommended that the field intensity established by the RF transmitter, as determined by an electromagnetic inspection at the location, should be lower than the compliance level in each frequency range. Interference may occur around devices marked with the following symbol:
	3 Vrms 150 kHz up to 80 Mhz 3 V/m 80 Mhz up to 2,5 Ghz	[V1]V **Compliant** [E1] V/m **Compliant**	

Nota 1 *At 80 MHz and 800 MHz, applies the highest frequency range.*
Nota 2 *These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.*

[a] *Field intensities from fixed transmitters, such as base stations, telephone (cellular wireless) and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, it is recommended that an electromagnetic area be inspected. If the measured field strength in the location in which the* ***Biphasic Defibrillator Monitor E-Heart*** *is used exceeds the level of conformity used above, the* ***Biphasic Defibrillator Monitor E-Heart*** *should be observed to verify whether the operation is normal. If abnormal performance is observed, additional measures may be necessary, such as reorientation or replacement of the* ***Biphasic Defibrillator Monitor E-Heart.***

[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 RF communications equipment and the Biphasic Defibrillator Monitor E-Heart

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

Immunity Test	**Level of ABNT NBR IEC 60601**	**Level of Compliance**	**ELETROMAGNECTIC ENVIRONMENT - ORIENTATION**
Maximum output power rating of the transmitter (W)	Separation distance according to frequency of transmitter (meters)		
	50 kHz up to 80 MHz d=1,2√P	80 MHz up to 800 MHz d=1,2√P	800 MHz up to 2,5 GHz d=2,3√P

0,01	0,1m	0,1m	0,2m
0,1	0,4m	0,4m	0,7m
1	1,2m	1,2m	2,3m
10	3,8m	3,8m	7,3m
100	12 m	12 m	23 m

For transmitters with a nominal maximum power output not listed above, the recommended separation distance "d" in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where "P" is the maximum output power the transmitter in watts (W) according to the transmitter manufacturer.
NOTE 1: At 80 MHz and 800 MHz, applies the highest frequency range.
NOTE 2: These guidelines may not apply in all situations.
Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

23. TECHNICAL ASSISTANCE

Permanent Technical Assistance

Dear Owner,

US DEFIB has a wide range of representatives and technical assitance partners throughout Brazil.

In order to provide you with a customized service, we ask you to send us the registration form (below). The forms aims to keep our database updated so that we can recommend the closest technical assistance partners, as well as keep you posted of trainings and other important information.

For complaints, doubts, suggestions and technical assistance service, contact our Customer Service department below:

US DEFIB MEDICAL TECHNOLOGIES LLC
7831 NW 72ND AVENUE, MEDLEY FL
33166
Phone: +1 305 887 7552

24.REGISTRATION FORM

DEVICE DESCRIPTION	SERIAL NUMBER

CUSTOMER NAME:
ADDRESS:

CITY:	**STATE:**
TELEPHONE:	**FAX:**

MANUFACTURER NAME:
TECHNICAL ASSISTANCE PARTNER:

ATTENTION:

Dear Owner,
Please fill out the fields above and send us through email or fax so that we can register you.
It is very important that you send us your information so that we can refer you to the closest technical assistance partner and give you other important information.

25. WARRANTY CERTIFICATE

US DEFIB WARRANTY CERTIFICATE

US DEFIB MEDICAL TECHNOLOGIES LLC ensures Legal Warranty against any manufacturing damage applicable under the following conditions:

1. The term beginning of the warranty period occurs from the date of issue of the bill of sale related to the equipment purchased by the consumer with mandatory identification of the model, serial number and features of the equipment.

2- The term duration of warranty is twelve (12) months from the date corresponding to the item above.

3. US DEFIB MEDICAL TECHNOLOGIES LLC does not grant any form or any kind of warranty for the equipment without the bill of sale to the consumer.

Prescribed conditions of this warranty

- In case of any defect diagnosed during installation and (or) use of the product, the consumer should immediately contact US DEFIB MEDICAL TECHNOLOGIES LLC. The same will contact the accredited representatives listed at the end of this manual, which can only proceed an intervention with a FORMAL APPROVAL, following the expiry date of this release.

The replacement of parts and products that present anomalies detected as manufacturing defects, plus the labor involved in this process, will be liability of the manufacturer.

- Sensors, cables in general and accessories required for the proper operation of the product are guaranteed against manufacturing defects for the legal period of ninety (90) days, beginning from the date of product purchase prescribed in the bill.

- Accessories marked as disposable and consumable (non-durable) will have its warranty in accordance with the Art. 26, item I of the Consumer Protection Code.

The warranty will be terminated when:

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

2- The equipment is installed or used differently from the provided in the USER MANUAL.

3 - The equipment is used with cables, sensors, accessories or consumables not recognized by US DEFIB or out of normal conditions of use, as expiry date or period or use.

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

a - receives maintenance or repair by professional not accredited by the manufacturer.

b - is used differently from the use described in the operation instructions,

c - is damaged by accidents or natural phenomena.

5- The manufacturer is not liable for expenses with facilities, products or accessories damaged due to traffic accident, handling, scratches, dents, non operation or failure due to problems in the supply of electricity.

In locations where there is no authorized service of US DEFIB MEDICAL, the transport costs of the device or of the authorized technician to the location where the equipment is will be payable by the Consumer requesting the service.

Serial Number: