

*User Manual*

*Defibrillator Monitor E-HEART*



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## **FOREWORD**

Congratulations for acquiring a US DEFIB equipment.

This product incorporates up to date technology. We are sure you will be very satisfied with E-HEART BIPHASIC DEFIBRILLATOR MONITOR.

**READ ALL OF THE OPERATION INSTRUCTIONS BEFORE operating E-HEART BIPHASIC DEFIBRILLATOR MONITOR.**

This User Manual contains all of the necessary information for a complete interaction with the equipment, from information concerning operation to necessary care for better conservation of E-HEART BIPHASIC DEFIBRILLATOR MONITOR. This equipment should only be used by a well-trained professional to provide **advanced life support**.

After you finish reading the entire User Manual, keep it protected so you can check it at any moment. A future reference could be necessary for new users. The permanent consultation of this manual is a requirement to obtain better equipment performance, correct operation, and more safety for operator and patient.

This manual also contains information related to technical support and Warranty Certificate.

Read carefully the instructions on pages 7-9 of this manual.

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## 1. WARNINGS

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### WARNING!

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR was designed for cardioversion and clinical monitoring applications with guaranteed operation when used correctly, in an appropriate medical place and by qualified personal.



### WARNING!

The operator should proceed to check the equipment conditions and its accessories (regular tests) as well as its operation before use.



### WARNING!

The operator should have knowledge and be aware of all possible collateral effects that can be caused during use of E-HEART BIPHASIC DEFIBRILLATOR MONITOR.



### WARNING!

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR is restricted to one patient at a time and NON FREQUENT USE.



### WARNING!

Do not touch the patient, the bed (stretcher), the equipment or any other accessory connected to the patient and/or DEFIBRILLATOR MONITOR during the electrical discharge (shock).



### WARNING!

When installing the equipment, make sure it is in a place with enough space for ventilation (10cm of upper side, 15cm at rear side and 10cm at sides) and far from heat radiation.



### WARNING!

Equipment and devices connected to E-HEART BIPHASIC DEFIBRILLATOR MONITOR (different equipment connected to same patient), should be connected to perform equal potential among them, to obtain perfect potential equalization, thus preventing damage to them, otherwise the system equipment-patient grounding may be compromised.



### WARNING!

There is risk of electric shock if the equipment case is open. There are no internal fuses to be replaced by the user. All service type or future upgrades of this equipment and its

parts can only be performed by trained personnel and authorized by US Defib Medical Technologies LLC.

 **WARNING!**

There is risk of explosion if this equipment is used in presence of flammable agents, like anesthetic gases, fuels, among others.

 **WARNING!**

When the E-HEART BIPHASIC DEFIBRILLATOR MONITOR is used simultaneously with an electric scalpel, the orientations about equipment operation in the presence of high frequency devices indicated in this manual must be observed.

 **WARNING!**

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR equipment is designed for public network connection, and it does not suffer any interference or electromagnetic disturbances in its modules operation – according to NBR IEC 60601-1-2 / CISPR 11 recommendations – Electromagnetic disturbance characteristics in industrial, scientific and medic equipment radiofrequency measurement limits and methods (ISM).

 **WARNING!**

To prevent fire or shock risks, avoid operating or fitting the DEFIBRILLATOR MONITOR near a water source; also avoid spilling any liquid product on the case.

 **WARNING!**

The protection against the discharge effects of a cardiac defibrillator is present in the modules inside the equipment. The sensors and cables don't have additional protection against a cardiac defibrillator discharge effects or when used simultaneously with an equipment that operates in high frequency.

 **WARNING!**

The materials categorized as disposable should not be reused or even submitted to cleaning process and sterilization. The disposable materials should be discarded in appropriate places according to special procedures for hospital waste.

 **WARNING!**

In general, the EQUIPMENT and ACCESSORIES Parts of E-HEART BIPHASIC DEFIBRILLATOR MONITOR, designed to be in physical contact with biological tissues, cells and corporeal fluids are tested according to ISO 10993-1 guidelines and principles, which deals exclusively with the test of biocompatibility of the applied parts.



 **WARNING!**

If it is necessary to replace any part of equipment, except the disposable materials, the manufacturer or authorized network should be contacted to supply the material and to perform the substitution.

 **WARNING!**

There is risk of environment pollution associated to the use of accessories and consumption materials at the end of its lifecycle. The accessories and consumption materials should be discarded in hospital waste according to environmental laws. The intern batteries should be returned to the manufacturer after substitution due to defect or end of lifespan.

 **WARNING!**

All of the material replacement should be performed according to the specifications included in this manual. US DEFIB only guarantees the equipment perfect operation if the orientations are properly observed.

 **WARNING!**

In special cases, if necessary, US DEFIB will keep available, with agreement, all of the technical material like circuit diagrams, material list, technical information, components list, calibration and benchmarking instructions or whatever is necessary, so the qualified technical personnel can perform repairs in the repairable parts determined by the manufacturer. The maintenance authorization should be formally expressed by US DEFIB MEDICAL TECHNOLOGIES LLC.



## 2. SYMBOLS AND ABBREVIATIONS



Terminal or potential equalization point



Dangerous Electric Voltage



Check attached documents



BF type Equipment applied part with patient isolation



CF type Equipment with defibrillator protection



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



Fragile: indicates that the package should be transported and handed carefully



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



Number 5: indicates maximum piling of five units



Indicates medical device and, therefore, special treatment



Indicates composition with recyclable raw material



Symbol for marking of electrical and electronic devices in accordance to the Directive 2002/96/EC. The device, accessories and packaging must be disposed properly at the end of its use. Please follow local ordinances or regulations for disposal.

## 3. MEASUREMENT UNITS

Symbols	Unit	Description
m, cm, mm	Length	Meter, centimeter, millimeter
h, m, s, mseg	Time	Hour, minute, second, millisecond
kg, g	Mass	Kilogram, gram
°F, °C	Temperature	Fahrenheit degrees, Celsius Degrees
mmHg, hPa	Pressure	Mercury Millimeters, hectopascal
hz, rpm, bpm, ppm	Frequency	Hertz, breeding per minute, beat per minute, pulses per minute
V, mV	Voltage	Volts, millivolts
m/s, mm/s, bps,	Speed	Meter per second, millimeter per second, beat per second, liters per

l/m		minute
$\Omega$	Impedance	Ohms
J	Energy	Joules
$m^3, mm^3$	Volume	Cubic meters, cubic millimeters

#### **4. ACRONYMS USED IN THIS USER MANUAL**

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- ❖ **CLAS:** Cardiology Life Advanced Support;
- ❖ **AHA:** American Heart Association;
- ❖ **BLS:** Life Basic Support;
- ❖ **IDM:** Implantable Defibrillator Monitor
- ❖ **ECG:** Electrocardiogram;
- ❖ **VF:** Ventricular Fibrillation;
- ❖ **Hb:** Hemoglobin (**cHb:** Hemoglobin concentration);
- ❖ **HbO<sub>2</sub>:** Oxihemoglobin (**cHbO<sub>2</sub>:** oxihemoglobin concentration);
- ❖ **PRI:** Printer
- ❖ **INCOR:** Heart Institute;
- ❖ **LDE:** Light Diode Emissor
- ❖ **LCD:** Liquid Crystal Display;
- ❖ **PM:** Pacemaker
- ❖ **SAN:** Sinu-atrial Node;
- ❖ **ABP:** Arterial Pressure
- ❖ **CPA:** Cardio-respiratory Arrest;
- ❖ **NIBP:** Non-Invasive Blood Pressure;
- ❖ **IBP:** Invasive Blood Pressure
- ❖ **DBI:** Defibrillator
- ❖ **CPR:** Cardiopulmonary Resuscitation;
- ❖ **BCS:** Brazilian Cardiology Society;
- ❖ **SPO<sub>2</sub>:** Oxygen Saturation;
- ❖ **VT:** Ventricular Tachycardia;
- ❖ **UTI:** Intensive Care Unit;
- ❖ **VOO:** Pacemaker Asynchronous Mode;
- ❖ **VVI:** Pacemaker on Demand Mode.

## **5. DESCRIPTION OF E-HEART BIPHASIC DEFIBRILLATOR MONITOR AND ITS COMPONENTS**

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### **5.1 PRESENTATION**

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR is a portable and dual phase equipment (truncated dual phase pulse). It can be used in any position in ground hospital environment, in the surgical bed and benches rescue units, by air or land, providing better handling in advanced life support. This equipment was designed to apply electric stimulus to the heart in cases that the cardioversion and/or defibrillation are indicated. This revolutionary defibrillation technology requires less energy than that used by conventional single phase DEFIBRILLATOR MONITOR, producing a better performance.

This equipment is indicated for adult and pediatric use and it integrates several functions like Defibrillation, ECG Monitoring, Non-invasive Blood Pressure – NIBP (optional) and Invasive Blood Pressure – IBP (optional), Oxygen Blood Saturation Scouting (SPO<sub>2</sub>), Capnography monitoring (optional) and an external Pacemaker with non-invasive multi programmable module (asynchronous and by demand and switching for emergency modes, also presents a Thermal Printer - optional). The ECG can be captured by monitoring electrodes and by the external defibrillation paddles, allowing, event memorization (Compact Flash).

The DEFIBRILLATOR MONITOR has a high-resolution and high-contrast liquid crystal display (LCD) that allows perfect visualization in different angles, with the exclusive Lap Top (check page 14, figure 2) for cardiac monitoring. It also has a microprocessor for heart activity analysis, which takes approximately 10 seconds.

ECG analysis (ventricular fibrillation, ventricular tachycardia) and, optionally, it can be supplied with the software for ST Segment and Arrhythmias analysis and software for ventilation / intubation mode, Drugs Calculation.

Easy to use, E-HEART BIPHASIC DEFIBRILLATOR MONITOR offers, through AED mode, the possibility to be used by trained staff and under medical supervision. It is highly safe and presents minimum risks for accidents for patient and operator. In AED mode (optional), it provides a voice and text command to instruct the rescuer during the CPR sequence.

The use of E-HEART BIPHASIC DEFIBRILLATOR MONITOR increases human survival rates in a cardio-respiratory arrest.

The **E-HEART BIPHASIC DEFIBRILLATOR MONITOR** could be configured and adapted according to your necessity and be delivered in the following versions:

**ECG/PRI:**

DEFIBRILLATOR MONITOR of ECG, Defibrillator and 01 channel Thermal Printer and optionally 02 or 03 channels;

**ECG/PM:**

DEFIBRILLATOR MONITOR with ECG, defibrillator and external pacemaker, transthoracic, non-invasive, multi programmable.

**ECG/SPO2/NIBP:**

DEFIBRILLATOR MONITOR with ECG, Defibrillator, Pulse Oximetry and Arterial Pressure Scouting;

**ECG/SPO2/NIBP/PRI:**

DEFIBRILLATOR MONITOR with ECG, Defibrillator, Pulse Oximetry, Arterial Pressure Scouting and single channel thermal printer.

**ECG / AED MODE / DRUG CALCULATION / IBP / CAPNOGRAPHY**

Defibrillator monitor with AED (**voice and text command**), drug calculation, Invasive Blood Pressure (IBP), Capnography and Telemetry.

**NOTE:** The External Transthoracic Pacemaker, AED MODE, Drug Calculation Software, software for ventilation / intubation mode, capnography and Invasive Blood Pressure module can be incorporated into the versions of E-HEART BIPHASIC DEFIBRILLATOR MONITOR. Any option can be assembled, at the discretion of the specific needs of each client, and it does not change the characteristics of the product purpose.

**6. OVERVIEW\***

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*Figure 1 - E-HEART BIPHASIC DEFIBRILLATOR MONITOR Front View*



Figure 2 - Side view with the LAP TOP (45° opening)

## 6.1 PARTS LIST AND INCLUDED ACCESSORIES

- ✓ 01 conductive gel tube 100 ml;
- ✓ 01 Interchangeable and permanent external electrodes pair (Shock Paddles) (adult/infantile);
- ✓ 01 5-way patient cable;
- ✓ 05 Disposable electrodes;
- ✓ 01 Adult NIBP Cuff (only on the versions *with NIBP*);
- ✓ 01 IBP kit (only on the versions with IBP)
- ✓ 01 CO2 kit (Capnography) (only on the versions with Capnography)
- ✓ 01 SpO2 Sensor (*configuration with SpO2*);
- ✓ 01 3-pole power supply cable;
- ✓ 01 Grounding equalization cable;
- ✓ 02 Replacement fuses;
- ✓ 01 User manual;
- ✓ 01 Set of disposable electrodes (only on the versions *with AED mode*);
- ✓ 01 Set of disposable electrodes (only on the versions *with pacemaker*);
- ✓ 01 Roll of printer thermal paper (only on the versions *with thermal printer*);
- ✓ Warranty Certificate.

**NOTE:** The user must observe the parameter modules that have been previously configured in his equipment.

## 6.2 OPTIONAL ACCESSORIES

- ✓ Transport case destined for transport and also safer storage of E-HEART BIPHASIC DEFIBRILLATOR MONITOR;
- ✓ Connection cable for external battery, used in ambulances, aircrafts or occasions where electrical energy is not available for long periods of time;

- ✓ Cables, sensors, paddles (external and internal electrodes) adult, infantile or neonatal;
- ✓ Mobile trolley;
- ✓ Equipment support.

### 6.3 OPTIONAL ACCESSORIES LIST



*Figure 3 - Connection cable for external battery (permanent use accessory - Exclusive)*



*Figure 4 - Conductive gel for ECG (disposable content)*



*Figure 5 - Thermal sensitive paper (disposable)*



*Figure 6 - Adult and Child Shock Paddles for external defibrillation and cardioversion (permanent material - Exclusive)*



*Figure 7 - Adult Shock Paddles for internal defibrillation and cardioversion (permanent use material - Exclusive)*

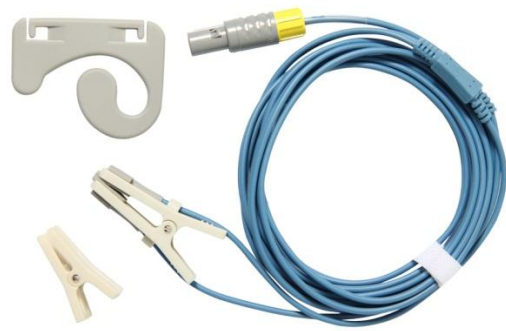


*Figure 8 - Child Shock Paddles for internal defibrillation and cardioversion (permanent use material - Exclusive)*





**Figure 9 - Adult oximetry sensor (permanent use accessory - Exclusive)**



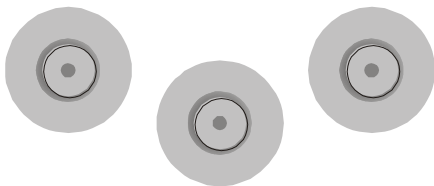
**Figure 11 - Ear Oximetry sensor (permanent use accessory Exclusive)**



**Figure 10 - Pediatric / Neonatal Oximetry Sensor (permanent use accessory - Exclusive)**



**Figure 12 - Capnography Sensors (permanent use accessory - Exclusive)**



**Figure 13 - Permanent ECG electrodes (permanent use accessory - Exclusive)**



**Figure 14 - ECG electrodes (disposable content)**

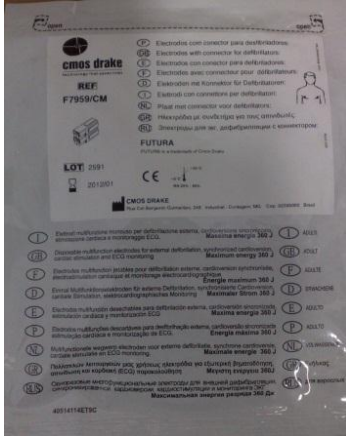


**Figure 15 - 3-way Patient Cable(permanent use accessory - Exclusive)**



**Figure 16 - 5-way Patient Cable (permanent use accessory - Exclusive)**

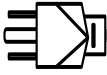




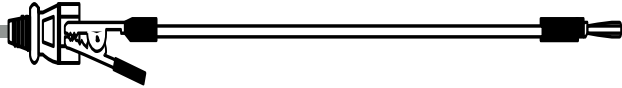
**Figure 17 - Adult Adhesive Electrode Paddles – AED and Pacemaker (disposable)**



**Figure 19 – Adult NIBP Cuff (permanent use accessory – Exclusive)**



**Figure 18 - 3-pole Power Cable (permanent use accessory - Exclusive)**



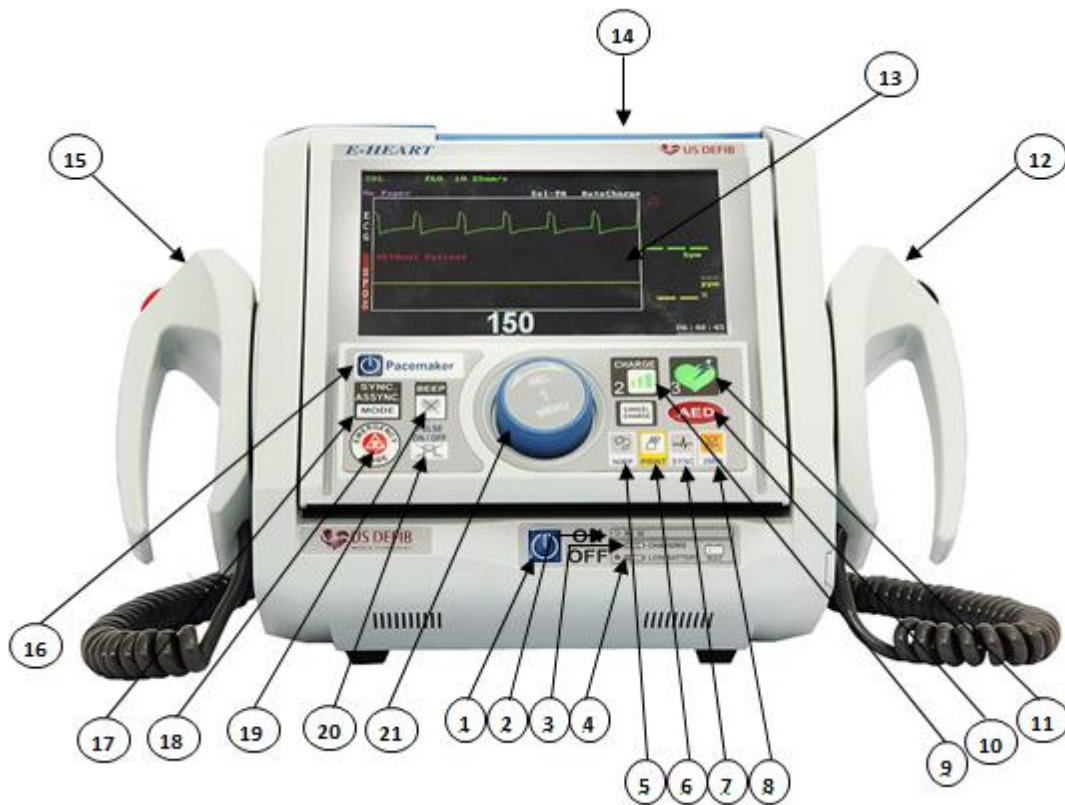
**Figure 20 - Potential equalization cable (permanent use accessory - Exclusive)**

**Important observation:**

All accessories should be stored in a ventilated place and humidity and dust free. In order to clean the paddles and cables use a compress moistened with demineralized water and neutral soap.

**NOTE:** The pictures on this manual are merely illustrative, and they can be changed without previous notice.

## 7. PARTS AND COMMANDS IDENTIFICATION OF E-HEART BIPHASIC DEFIBRILLATOR MONITOR

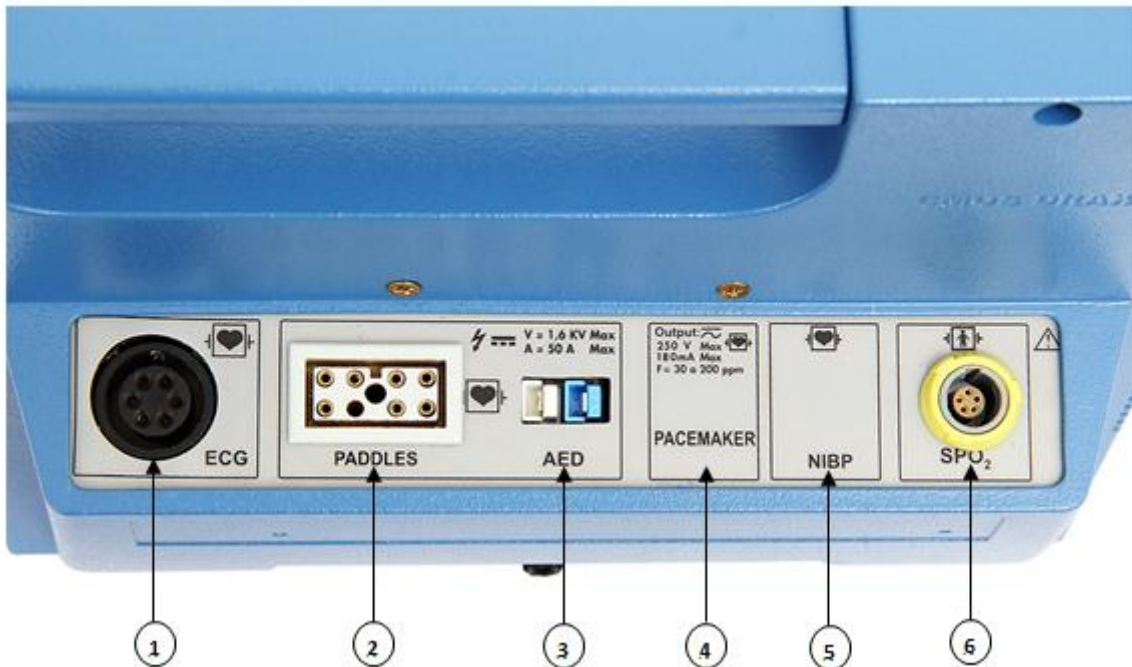


*Figure 21 - Commands identification of the Front Panel*

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>1. Turn the equipment On/Off</li> <li>2. Luminous Alarm Indicator</li> <li>3. Luminous Battery Indicator</li> <li>4. Luminous Battery Charging Indicator</li> <li>5. NIBP</li> <li>6. Printer</li> <li>7. Sync.</li> <li>8. Disables alarm for 2 minutes</li> </ul> | <ul style="list-style-type: none"> <li>9. Defibrillator charge command</li> <li>10. Enables / Disables AED Mode</li> <li>11. Shock trigger command</li> <li>Cancel Charge</li> <li>12. External Paddle for Shock Triggering</li> <li>13. Display</li> <li>14. Transport handle</li> <li>15. External Paddle for Shock Triggering</li> </ul> |
|--|---|

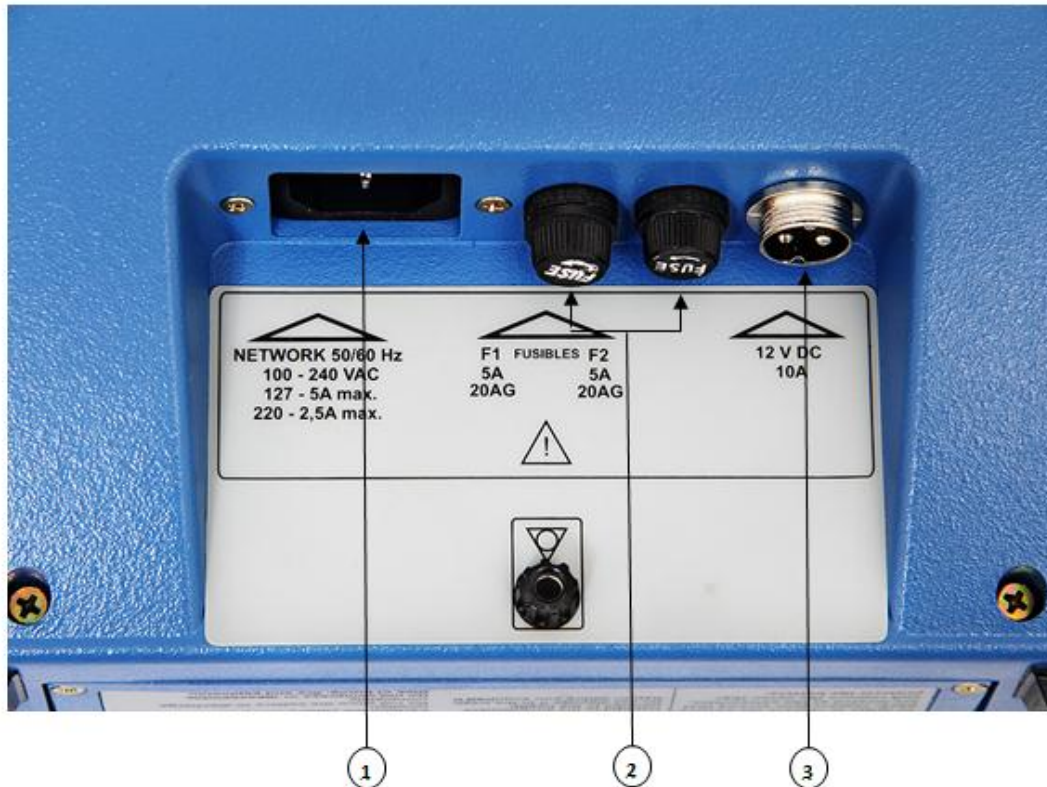
- |  |                                 |
|--|---------------------------------|
| 16. Pacemaker on/off switch                          | 19. Disables Pacemaker Beep     |
| 17. Select between Synchronous and Asynchronous Mode | 20. Disables Pulse              |
| 18. Pacemaker emergency mode                         | 21. Navigation Button (Browser) |

**NOTE: The pictures contained in this manual are merely illustrative and they can be changed without prior notice.**



**Figure 22 - Module Identification**

- |  |   |
|--|---|
| 1- ECG Connector                             | 4- Adhesive Paddles Connector for MP module |
| 2- External Shock Paddles Connector          | 5- NIBP Connector                           |
| 3- Adhesive Paddles Connector for AED module | 6- SPO2 Connector                           |



**Figure 23 - Rear Panel Identification**

- 1- Power Grid Connector
- 2- Fuse Port
- 3- Ambulance Inlet Connector

## **8. E-HEART BIPHASIC DEFIBRILLATOR MONITOR CHARACTERISTICS**

- ❖ Truncated dual phase exponential waveform, with charge of 1 to 200 Joules or optional of 1 to 360 Joules, with operating instructions on the panel of E-HEART BIPHASIC DEFIBRILLATOR MONITOR, or any other energy configuration desired by the user.
- ❖ With the equipment powered by electric grid or even powered by the new battery (and fully charged) its charge time for maximum energy of up to 5 seconds for 200 joules or up to 6 seconds for 360 joules.
- ❖ Adaptable to any patient including intelligent safety system that limits the charge for internal use and pediatric/neonatal use;
- ❖ Patient thoracic impedance analysis, increased defibrillation efficiency and reduced cardiac injuries risk;
- ❖ Automatic internal discharge after 30 seconds if there is no trigger, or manually through the key;

- ❖ Clock, date and shock counter.
- ❖ Clear phase identification: charging, ready, discharging and disarming.
- ❖ Use of reusable electrodes (permanent adult / pediatric / interchangeable paddles), that needs activation of two simultaneous controls, one in each paddle;
- ❖ Performs self-test when switched on;
- ❖ Rechargeable internal battery with manageable charger, with alarms and status indicator for several levels: low level, charging (medium and high) and full charge, with indication in approximately 6 levels on the display.
- ❖ Capacity to perform up to 220 discharges with full load (new battery fully charged).
- ❖ External reserve batteries with internal charger (optional);
- ❖ Electroluminescent liquid crystal display, that shows signal of ECG, SPO2 (optional), Capnography and invasive blood pressure (optional), Non-invasive blood pressure (optional), derivation, cardiac frequency, beep indicator, battery status, alarms, pacemaker pulse, programming parameters, indicating the selected energy for triggering.
- ❖ Event memory including curve, date and hour (optional), of approximately 250 MB, that corresponds to over 100 hours of continuous recording.
- ❖ Indicates mode and charge value on the screen;
- ❖ Informs when the capacitor is discharging: **"CANCELED"**;
- ❖ Charge automatic adjust;
- ❖ Allows continuous ECG registration in memory, critical events and performed procedures;
- ❖ Enables communication with microcomputer, through connection, for memory data visualization (Optional);
- ❖ Allows posterior reading of ECG tracing through the hardware and/or software (Optional);
- ❖ Language: Portuguese (possibility to change language to English or Spanish (optional)).
- ❖ It performs synchronized triggering with QRS complex, with energy time of <20ms when in SYNCHRONIZED MODE.
- ❖ Maximum time for signal stabilization: 5 seconds after ideal connection of sensor on patient;
- ❖ Full system of audible and visual alarms with the possibility of programming maximum and minimum values, including, besides the physiological alarms for loose electrode, asystole, tachycardia, bradycardia, fibrillation;
- ❖ When E-HEART BIPHASIC DEFIBRILLATOR MONITOR is configured in automatic mode, the charge energy follows a trigger sequence of 150J, 200J and 200J;
- ❖ Pacemaker pulse detection and rejection.
- ❖ Impedance detection in the 25 Ohm to 500 Ohm range for the triggering;
- ❖ Software for drug calculation (optional);
- ❖ Software for Ventilation / Intubation Mode (optional);
- ❖ ST Segment and Arrhythmias analysis (optional);
- ❖ Telemetry Software (optional);



- ❖ Memory data card of 250 MB that corresponds to over 100 hours of continuous recording;
- ❖ Charge level selection by the “APEX” Paddle key and charging by the “STERNUM” paddle key and triggering by pressing both paddles keys simultaneously.

### **8.1 ECG CHARACTERISTICS**

- ❖ 3 derivations (DI, DII, DIII), for 3-way ECG cable;
- ❖ 12 derivations (DI, DII, DIII, aVL, aVR, aVF and V1 to 6) for 5-way ECG cable;
- ❖ Capture of ECG signal through defibrillation Pads, adhesive Pacemaker transthoracic Pads, through reusable defibrillator Pads and/or through ECG patient cable
- ❖ Cardiac frequency: Any frequency reading frequency from 10 to 300 rpm, with numerical presentation;
- ❖ Protection against defibrillation and cardioversion;
- ❖ Filter rejects band of 35Hz and 60Hz, pass low frequency: 120Hz and pass high frequency: 0,5Hz;
- ❖ QRS detector;
- ❖ Pacemaker detection and rejection;
- ❖ Synchronized beep with QRS;
- ❖ Display Beep indicator;
- ❖ Cardiac Frequency Indicator on display (bpm);
- ❖ Pacemaker Indicator on display;
- ❖ Speed control for curve tracing;
- ❖ ECG channel gain control;
- ❖ ST Segment and Arrhythmias analysis.

### **8.2 PATIENT ANALYSIS SYSTEM – AED MODE (OPTIONAL)**

- ❖ ECG evaluation automatic system that detect QRS complex and identifies automatically malignant arrhythmia (ventricular tachycardia and ventricular fibrillation) that requires defibrillation;
- ❖ Synchronism with R wave in case of QRS complex presence (when on “synchronized mode”);;
- ❖ Pacemaker detector;
- ❖ Impedance measurement to adjust phases 1 and 2 of dual phase wave and it does not allow triggering with open or short-circuited paddles.
- ❖ It offers voice and text command to instruct the rescuer during the CPR sequence.

### **8.3 THERMAL PRINTER CHARACTERISTICS**

- ❖ High-resolution thermal printer with automatic and manual registration of one channel, with optional of two or three channels, with the possibility of ECG registration with diagnostic-quality with manual or automatic triggering after

defibrillation with annotation of date and time, heart rate, derivation, amplitude of the ECG, etc.

- ❖ It allows manual records, regardless of the defibrillation, by the paddles.
- ❖ This record is made on thermo-sensitive paper of 48 mm (width) x 30 m (length) for GSI printer and 48 mm (width) x 20 m (length) for TR-50 or SP-48 printers.
- ❖ Print speed of 12,5-25-50 mm / sec.

#### **8.4 PULSE OXIMETRY CHARACTERISTICS**

- ❖ Pulse oximetry, with plethysmography curve and saturation indication of numeric oxygen in percentile; plethysmography wave amplitude adjusted automatically on screen; complete alarms system and audio and visual indication of SPO<sub>2</sub> level, through tone of pulse signal; the alarm volumes and pulse audio indicator are adjusted independently; adjustable audiovisual alarms: low and high SPO<sub>2</sub> and low and high cardiac frequency (bradycardia and tachycardia); pulse alarm not detected; low perfusion; disconnected sensor; key for silent alarm for 02 minutes; good behavior in low perfusions,
- ❖ The frequency detected by the equipment is between 30 and 250 ppm with a 3% precision.
- ❖ The pulse oximetry is used in situations where the oxygen saturation (SPO<sub>2</sub>) is essential, in anesthesia, during surgeries and post-surgery, patients under intensive care treatment, in ambulances or at home. It has been proven efficient, with a sample range from 70 to 100% with accuracy up to 3%. The scouted saturation accuracy is undetermined when it is between 0% and 69%.
- ❖ The oxygen saturation, SPO<sub>2</sub>, is defined by the concentration rate of two main forms of blood hemoglobin, the arterial hemoglobin or oxihemoglobin (HbO<sub>2</sub>) and the concentration of HbO<sub>2</sub> + Hb (unsaturated hemoglobin), ie, (cHbO<sub>2</sub>+cHb). The oxygen saturation is expressed in percentage and calculated by the formulae below:
- ❖ Biolight and Nellcor Technology.

$$SPO_2 = \frac{cHbO_2}{cHbO_2 + cHb} \times 100\%$$

#### **8.5 PACEMAKER TECHNICAL SPECIFICATION AND CHARACTERISTICS**

The external pacemaker was designed to stimulate the heart in cases of rhythm disturbance and flaw to conduct internally electric pulse. It is used in cardiac surgeries as emergency cardiac pacemaker. Some indicated transthoracic applications of pacemaker are:



- Treatment of symptomatic bradycardia or bradycardia during emergency
- During and after cardiac surgery
- To ease the insertion of a transvenous stimulator electrode.

### 8.5.1 PACEMAKER CHARACTERISTICS

- ✓ External pacemaker, transthoracic, non-invasive, multi-programmable; in modes on Demand, asynchronous (fixed) and Emergency. It is composed by:
  - One control unit based on micro controller with serial data transmission, and one QRS detection circuit.
  - One high voltage source and stimulation pulse generator with amplitude and pulse width enough to successfully perform a non-invasive transitory stimulation, which requires stimulation rate between 30 and 200 bpm. (Other frequencies may be optionally configured according to the user choice)

**Note:** The operator can control the stimulation process by means of E-HEART BIPHASIC DEFIBRILLATOR MONITOR keyboard. The stimulation pulse application can be visualized through a panel LED.

- ✓ 3 pacemaker operation modes are possible:
  - **VOO:** In this operation mode, the system stimulates the patient continuously, according to frequency parameters, amplitude and width configured in the pacemaker menu.
  - **VVI:** In this mode, the system only stimulates when it detects a cardiac frequency lower than the configured menu value, remaining the stimulus until the patient natural cardiac frequency returns to a value equal or greater to that configured to avoid inhibition of abnormal "T" waves or extra systole. The pacemaker has refractory period of approximately 250ms.
  - **Emergency:** Regardless of the chosen mode, when the EMERGENCY key is pressed, the pacemaker switches to the VOO mode, configured in 100 mA, 70 ppm and 20 ms.

**OBSERVATION:** In VOO and VVI modes the pacemaker will be stimulated and transmitting information to display (amplitude, width, frequency and mode).

- ❖ Stimulation current: Without connected charge: 200 mA; Off: 0 mA
- ❖ Power supply: 12V
- ❖ ECG capture through own adhesive Pads.
- ❖ Stimulation output: Adhesive electrodes (PADs)
- ❖ Frequency: It is possible to adjust the stimulation frequency between 30 and 200 ppm.
- ❖ Amplitude: The amplitude value could be adjusted between 5 and 200 mA.
- ❖ Width: It is possible to select pulse widths between 5 and 50 ms.

### 8.5.2 STIMULATION SYSTEM SPECIFICATION

- ❖ Stimulation frequency: 30 ppm to 200 ppm in steps of 1 ppm
- ❖ Pulse amplitude: 0 mA to 200 mA in steps of 1 mA
- ❖ Pulse width: 0 ms to 50 ms in steps of 1 ms.
- ❖ Stimulation exit: disposable pads
- ❖ ECG capture by the disposable pads
- ❖ Emergency: VOO 70 ppm - 100 mA 20 ms
- ❖ Protection against defibrillation discharge: Up to 400 joules
- ❖ Other specifications may be configured as chosen by the user.

**Observation: The specifications above can be altered according to the user's needs.**



#### ATTENTION!

- The pacemaker operation in the VOO mode is asynchronous. If the patient presents proper cardiac pace the pacemaker may induce ventricular fibrillation, if the pacemaker pulse is regularly applied to the ascendant portion of the T wave.
- In case of a bradycardia support, it must be assured that the stimulation frequency is higher than the patient's own pace, and that the detection is trustable.
- In the VVI mode, the fixation region of the pacemaker electrodes must be verified, once that it is external and presents negative voltage, the stimulation may produce polarizations that change the common mode voltage, compromising the normal detection of the heartbeat.
- This equipment can only be operated by authorized technical staff.
- The non-invasive pacemaker is suitable for use in pre hospital or hospital environments, when urgent cardiac pacemaker use is necessary.

### 8.6 NON-INVASIVE BLOOD PRESSURE (NIBP)

This item was elaborated to make possible a simplified understanding of NIBP channel basic functions. That channel provides diastolic, average and systolic arterial pressure. The automatic measurement time is configured by operator.

The Non-Invasive Blood Pressure module (NIBP) is protected against discharges of cardiac defibrillator, and it does not need specific precaution concerning the equipment. In NIBP use with cuff, which has no metallic wires, therefore it does not cause any interference when used together with other High frequency equipment.

- ❖ Measurement by oscillometer in adult, pediatric, infantile and neonatal patients;
- ❖ Manual and automatic operation mode;
- ❖ Measurements of systolic, diastolic and average arterial pressure;
- ❖ Configurable interval to inflate the cuff;

- ❖ Automatic zero before each measurement;
- ❖ Alarm of minimum, average and maximum pressure;
- ❖ PAR Technology.

## **8.7 INVASIVE BLOOD PRESSURE MODULE (IBP)**

The invasive blood pressure module (IBP) presents on the screen the systolic, diastolic and average pressures (mmHg).

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR is normally supplied with the pressure cable to connect the reusable transducers. In the connection of the transducer to the cable, observe the narrows that are present on the two pieces that indicate the correct fitting position.

All of the IBP system should be fulfilled with saline, if possible with heparin. Make sure that there are no bubbles, especially in the tube that goes to the patient. Do not use latex in the circuit. The transducer must be assembled around the midline of the patient in order to achieve trustable pressure measures.

### **8.7.1 FUNCTIONAL CHARACTERISTICS OF THE IBP**

- ❖ The trace is shown continuously on the screen;
- ❖ Option to select the blood pressure types AP, AO, LV, AE, PVC, AD, RV, PAP, PCP, PIC, Right, Left Esf;
- ❖ Maximum, average and minimum blood pressures shown continuously on the screen (mmHg);
- ❖ Manual control of gain of in several ranges, with baseline variation;
- ❖ Possibility of curve superposing;
- ❖ Alarm for the maximum and minimum blood pressures;
- ❖ Option of continuous recording of the P.I.C. with aid of a thermal printer, with special algorithms for alpha, beta and "C" wave visualization.

## **8.8 CAPNOGRAPHY MODULE (EtCO<sub>2</sub>)**

The Capnography module uses the Sidestream and Mainstream sensors miniaturized, with optional procedure of auto calibration that dismisses the use of specific gases for periodic calibration. It presents to the user the following parameters:

- Exhaled CO<sub>2</sub> curve, showed continuously on the screen;
- Value of the exhaled CO<sub>2</sub>;
- Minimum of inhaled CO<sub>2</sub>;
- Respiratory frequency value.

After connecting the sensor, it is necessary to wait for approximately 1 minute in order to set up to be ready for the measurements. After this while, a light must be observed on the sensor indicating its habilitation. Once connected to the respirator tube, we'll

have the patient information. The Capnography sensor should be on the adaptor to avoid the condensation, if that occurs, interfere on the reading measurement.

### **8.8.1 FUNCTIONAL CHARACTERISTICS OF THE CAPNOGRAPHY**

- ❖ Sensors Sidestream and Mainstream type;
- ❖ Exhaled CO<sub>2</sub> curve showed continuously on the screen;
- ❖ Auto calibration optional procedure that dismisses the specific gases use for periodic calibration;
- ❖ Exhaled CO<sub>2</sub> value, minimum inhaled CO<sub>2</sub> and respiratory frequency value showed continuously on the screen;
- ❖ Miniaturized sensor with auto calibration;
- ❖ Side stream option, Mainstream or both;
- ❖ Disposable water filter;
- ❖ Disposable nasal line;
- ❖ Disposable intubated line;
- ❖ Disposable tube adaptor;
- ❖ Respiration technology.

### **8.9 ST SEGMENT ANALYSIS CHARACTERISTICS**

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

$$\begin{aligned} III &= II - I \\ aVR &= -\frac{(I + II)}{2} \\ aVL &= I - \frac{(II)}{2} \\ aVF &= II - \frac{(I)}{2} \end{aligned}$$

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

After the acquisition, the program measures the ECG as the second phase of the interpretation process. The measurements may be detailed in five steps:

1. QRS Detection: This step is very important, because if it is performed incorrectly, the next steps will be wrong. An auxiliary function is computed for QRS detection, based on eight independent derivations. The complexes are classified as normal or abnormal in order to achieve a

- normal QRS standard from derivation to derivation. Besides, the RR interval is measured and the heartbeat is computed.
2. Identification of the T wave end: This point is very important because it identifies the end of the cardiac cycle and it is used to measure the QT interval.
  3. P wave study: The program looks for the P waves in all segments T-Q (the end of the T wave to the beginning of the next QRS complex) to determine if the duration of the PR interval is varying.
  4. Beginnings and endings: These points are identified for each wave in order to measure its length and find its peaks.
  5. Measure: For each wave amplitude and duration each interval derivation is measured. Also, the deviation of the ST segment such as other parameters is measured.

The result of the measurement process is the following:

- ❖ Duration of normal QRS complex.
- ❖ Duration of PR interval.
- ❖ Length of the QT interval.
- ❖ Heart rate (beats per minute).
- ❖ Duration of PR interval.
- ❖ Length of the P, Q, R and R' waves.
- ❖ Amplitude of the P, P', Q, S, R' and T waves.
- ❖ Amplitude at the beginning, middle and end of the ST segment.
- ❖ Intrinsic deflection (time from start of the QRS complex to the peak of R wave)
- ❖ Projection of the electric axis in the frontal framing (P wave, RS complex and T wave vectors). The ventricular gradient is also measured.

The derivation of the median 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 made. The ST segment analysis has a number of advantages that must be mentioned:

- ❖ Considerable time saving of the cardiology professionals devoted to ECG interpretation in hospitals that offer a large number of these examinations.
- ❖ Stability and uniformity in the ECG interpretation and uniformity in interpreting ECG. Human fatigue or work pressure can cause specialists not to interpret ECGs maintaining the same needed uniformity. The EQUIPMENT always applies the same algorithm and the same rules for ECG interpretation, thus providing more stable findings in a timely manner.
- ❖ The possibility to store all information relating 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 to an ECG database in research applications.

All medical criteria used in this ST segment analysis fluctuate from a mere recommendation or alerting about the ECG results until a complete diagnosis of a specific change. That's why these criteria have varying degrees of specificity and may include phrases such as "**NOT NECESSARILY PATHOLOGICAL**", "**CONSISTENT WITH**", "**PROBABLE...**", "**CONSIDERING ...**", when there isn't absolute certainty about the specific pathology. In these cases, the physician should determine whether the given measures and other complementary factors are conclusive or not.

The EQUIPMENT evaluates all medical criteria taking into account all measurements previously made and determines, in his conclusions, which criteria are unique and which eliminate others due to their greater diagnostic accuracy.

These criteria were grouped as follows:

- ❖ Changes in heart rhythm;
- ❖ Changes in the electrical axis;
- ❖ Left or right ventricular hypertrophy;
- ❖ Intraventricular blockade;
- ❖ Left branch blockade;
- ❖ Changes in the ST segment;
- ❖ Changes in T wave;
- ❖ Heart attack;
- ❖ Other cases.

This type of diagnosis must not be considered a substitute, in any way, for diagnosis by cardiologists, because they simply are not. They should be seen as an efficient tool that assists the physician who specializes in its diagnosis because they are highly efficient in the classification of normality, and they have high sensitivity for the detection of pathological cases. This relieves the physician from reviewing normal cases and it can be used as a guide for the classification of pathological cases. When the electrocardiographic signs are ambiguous or highly complex, the final diagnosis is left to the physician. The following is a list of medical criteria:

 **WARNING!**

The interpretive ST segment analysis report, using the E-HEART BIPHASIC DEFIBRILLATOR MONITOR is one of the valuable tools that helps the physician to interpret ECG efficiently, but only if, combined with a detailed patient history and medical exams. All computerized ECG system is unable to analyze the ECG waveform as the human eye-brain system. The physician should re-read and correct the automatic ECG interpretation report.

 **WARNING!**

The ACC / AHA recommended the computerized interpretation of ECGs to doctors.



*"Several studies have examined the accuracy of computerized ECG interpretation programs and suggested that computer analysis cannot replace the physician's ECGs interpretation. A systematic study of the computerized ECG interpretation performed in 1991 showed that computer programs were, on average, 6.6 % less accurate than the cardiologist in identifying ventricular hypertrophy, myocardial infarction (MI). Rhythm disorders were not assessed in that investigation, and informal experience suggests that computer interpretation has a higher error rate in the analysis of the rhythm than in the diagnosis of MI and hypertrophy. A Japanese study reported that the latest false-positive rate and false-negative was 18 times higher for computer interpretation than trainee doctors in more important ECG diagnosis. However, ECGs computerized interpretation may be useful in the accurate calculation heartbeat, conductive intervals and axis, as long as there is manual review. Thus, despite computerized ECG interpretations that may have useful auxiliary value, and cannot replace the interpretation of experienced electrocardiograms professionals and should not be used to make clinical decisions".<sup>11)</sup>*

## 9. SOME CARDIAC ARRHYTHMIAS CHARACTERISTICS

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The arrhythmia's symptoms are quite variable, and they may be silent (that does not present symptoms).

They can be diagnosed by a physician during a cardiologic exam (pulse exam and auscultation of the heart with a specific device).

The most common symptom is palpitation. Fainting can also occur (quick and spontaneous recovery with no motor abnormalities), dizziness, shortness of breath, discomfort, feeling of heaviness in the chest, weakness, fatigue, chest pain, among others.

Symptoms that indicate gravity are mental confusion, low blood pressure, chest pain and fainting. If any of these symptoms occur, it is necessary to perform EMERGENCY medical treatment to prevent the patient's death.

Cardiac arrhythmias can be classified in various ways, depending on frequency, formation mechanism, place of origin, etc. We will present some terms that are more general, common in everyday life.

Regarding frequency, arrhythmias may be classified as:

- **Bradycardia:** it occurs when the heart beats less than 60 times per minute. In some people, it can be a normal finding, such as athletes. Various types of bradycardia are known, each one with its own peculiar characteristics. Cardiac pacemakers are used in the treatment of this type of arrhythmia.

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



## Types of Bradycardia

There are three basic types of bradycardia, depending on where the heart's electrical system blockage occurs. When blockage occurs in the sinus node, which is the heart's natural pacemaker, it is called the sinus node dysfunction. Besides, the blockade of the electrical impulse may occur in the atrioventricular node or the right or left branch of the heart's electrical system.

The important thing is that all of these types of blocks can lead to reduction of heart rate and cause symptoms such as dizziness and fainting. Depending on the type of block, and of the symptoms shown, it may require a pacemaker implant.

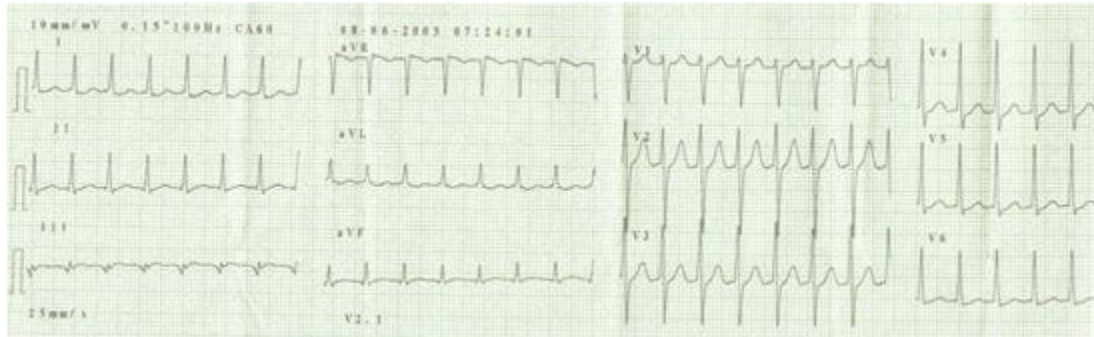
- **Tachycardia:** it occurs when the heart beats 100 times per minute. It usually occurs during physical activity, emotional stress, in the presence of anemia and other diseases. There are several types, some extremely serious.

## Types of Tachycardia

- **Atrial Tachycardia:** it is a rapid heart rhythm that originates in the atrium.
- **Atrial Flutter:** it is an arrhythmia caused by electric circuits of low conduction that originates in the atrium and promotes a rapid and regular rhythm of the heart.
- **Nodal reentrant tachycardia (NRT):** it is an extra electrical pathway, near the atrioventricular node, which causes the electrical impulse to move in a circle and pass through areas that have been previously passed, making the heart beat at a frequency way above normal.
- **Tachycardia by an accessory pathway or Wolff-Parkinson-White Syndrome:** it is an extra electrical pathway that exists from birth and connects the atriums to the ventricles, causing the electrical impulse to reach the ventricle faster.
- **Atrial Fibrillation:** it is an extra electrical impulses originated in the atriums that trigger rapid irregular and disorganized heartbeats.
- **Extra-Ventricular Systole:** it is an extra electrical impulse originated in the ventricle that promotes beat ahead of time.
- **Ventricular Tachycardia:** it is an electrical impulse originated in the ventricles that promotes a rapid potentially life threatening pace. Generally, it is a medical emergency.
- **Ventricular Fibrillation:** it is a fast, disorganized and erratic rhythm, which does not produce ventricular contraction that causes sudden death and requires immediate cardiopulmonary resuscitation and defibrillation (electrical shock).

As the place of origin, these arrhythmias are classified as:

- **Atrial:** as we know, the heart consists of four cameras (or divisions), two atriums and two ventricles. The normal stimulus for the heartbeat is generated in the right atrium. In some arrhythmias, these stimuli are generated in excess or in smaller numbers, by the structure that normally generates them, in others, the stimulus appears elsewhere in the atrium, leading to the occurrence of atrial arrhythmias.



**Figure 24 - Atrial Arrhythmia Electrocardiogram**

- **Junctional:** these arrhythmias occur at the junction between the atriums and ventricles.
- **Ventricular:** it arises within the ventricles, some with great potential to lead to death.



**Figure 25 - Ventricular Arrhythmia Electrocardiogram**

## **10. IMPEDANCE INDICATOR**

The instrument provides a visual indicator related to the total transthoracic impedance between the defibrillation paddles.

The impedance indicator is used to evaluate:

- ✓ Proper placing of the shock PADDLES on the patient;
- ✓ The quality and integrity of the shock PADDLES;
- ✓ The shock PADDLES contact to the patient's skin;
- ✓ The proper connection of the shock PADDLES to the equipment;
- ✓ It provides a rapid assessment of the patient impedance.

**ATTENTION:**

The impedance indicator is only shown in the display when using the ECG reading via shock PADDLES.

The impedance index is divided into 4 (four) sections, where the ideal operating section is Section 2 (impedance range from 30 [Ω] to 150 [Ω]).

Section	Impedance Range [Ω]	Contact Description	Presented Color
1	$20 < IMP \leq 300$	GOOD	Blue
2	$30 < IMP \leq 150$	GREAT	Green
3	$150 < IMP \leq 180$	REGULAR	Yellow
4	$180 < IMP$	BAD	Red

Table 3

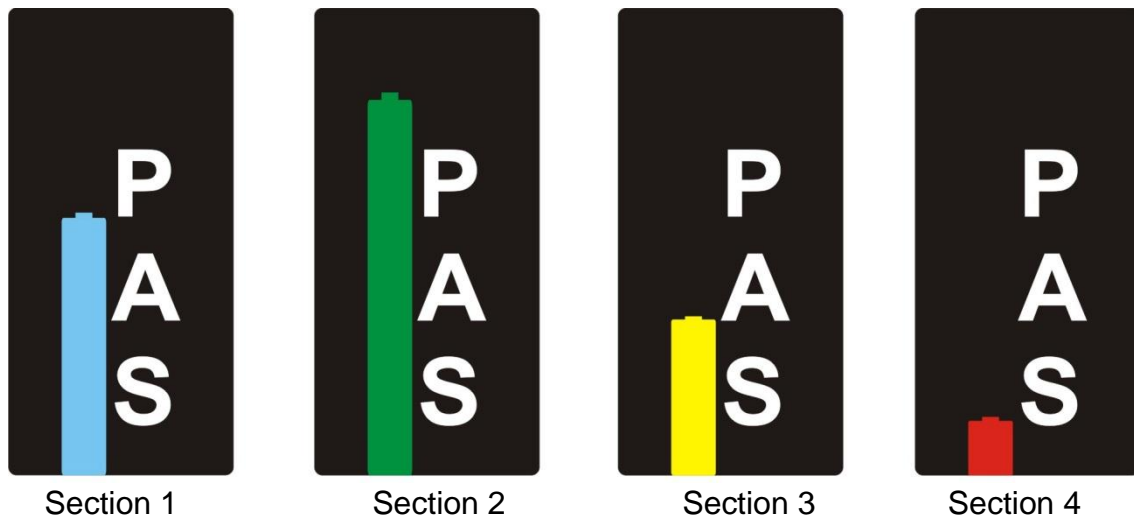


Figure 26 - Impedance Indicator

## 11. EQUIPMENT INSTALLATION

### 11.1 EQUIPMENT UNPACKING AND ADAPTATION

- ✓ Remove the equipment from package;
- ✓ Remove the plastic protection;
- ✓ Adapt on adequate and easy access place;
- ✓ Install the equipment far from other equipment that generates strong magnetic fields, like radiological devices , and others;
- ✓ Make sure that the installation place has an adequate ventilation and is within the pressure and temperature range indicated in this manual (page 68);

- ✓ This equipment was designed to operate in environments without inflammable anesthetic or cleaning agents. Do not operate it in presence of inflammable gases in general.

## **11.2 POWER SUPPLY / BATTERY**

### **11.2.1 LITHIUM-POLYMER (LI-PO)**

Rechargeable Lithium-Polymer (Li-PO) with specific manageable battery charger internal to the equipment. For a long lifespan, keep the charger connected to the equipment and the power grid. With a capacity of up to 150 shocks at 200 J and up to 6 hours of monitoring when the battery is fully charged (new battery fully charged). This device has an internal intelligent battery charging control circuit. Remembering that this battery (LI-PO) should have special attention, as described below:

#### **WARNING!**

- ❖ Do not use any battery charger other than the one recommended by US DEFIB MEDICAL TECHNOLOGIES LLC;
- ❖ Do not short-circuit the battery;
- ❖ Charge in a well-ventilated location;
- ❖ Do not discharge the battery completely;
- ❖ Do not compress or disassemble it;
- ❖ Risk of burns, fire and explosion, if the recommendations above are not followed.

#### 1) Optionally with Lithium-Iron Battery (LI-FE);

Lithium-Iron (LI-IR) rechargeable battery with a proper manageable charger internal to the equipment. For a prolonged lifespan keep the charger connected to the equipment and the power grid. With a capacity of 6 hours of monitoring (battery fully charged) or at least 160 shocks at 360 J or 220 shocks at 200 J, when the battery is fully charged (new battery fully charged). This device has an internal intelligent circuit control of battery charging.

#### 2) Optionally with sealed lead acid battery;

#### 3) Optionally with external battery for ambulances, aircraft:

- ✓ In occasions when there is no power grid available by periods of long use, don't use the network cable when the power supply cable for ambulances is used for ambulance;






- 4) Optionally with external batteries (spare) with its own charger with a maximum charge time of approximately 4 hours:
- ✓ External batteries can be delivered in different charging capacity versions that varies between 2 and 15 hours of monitoring or 50 to 200 consecutive shocks respectively, with a proper charger;
  - ✓ External Batteries are easily replaced (battery interchangeable).

 **WARNING!**

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR can remain connected to the power grid 24 hours a day to keep the battery fully charged and it is also able to operate normally.

### **11.3 DIGITAL STATUS OF BATTERY LOAD**

In the panel of equipment is an LED indicator such as below:

- ✓ Connected to the power grid: ;
- ✓ Battery status  Loading: ;
- ✓ Battery status , Discharged: .

### **11.4 TRANSPORT CONDITIONS**

- ✓ Ambient temperature range from -40° to +70° C
- ✓ Relative humidity range from 10% to 100%
- ✓ Atmospheric pressure range from 700 hPa to 1060 hPa (525mmHg to 795mmHg)

## **12. EQUIPMENT INSTALLATION AND HANDLING RECOMMENDATIONS**

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- ✓ Avoid turning off the equipment if connected to a patient; remove the cable from electrodes before.
- ✓ If the patient is connected to E-HEART BIPHASIC DEFIBRILLATOR MONITOR, with floating isolation (not connected to the power grid grounding), connected to any other device that cannot have the same isolation type, the patient could touch the conductive parts and cancel the equipment protection effect;
- ✓ The connection of E-HEART BIPHASIC DEFIBRILLATOR MONITOR with any other equipment is only allowed when it is not prejudicial to patient, operator and ambient. If the additional equipment specifications does not inform about connection effects, seek for the manufacturer or expert.

- ✓ The E-HEART BIPHASIC DEFIBRILLATOR MONITOR should only be operated by qualified personnel. It is the hospital administration responsibility to make available proper and accessible operation instructions.
- ✓ Do not shock with short circuit paddles, because the trigger device could be damaged.

## **12.1 SAFETY AND PROTECTION**

### **a) Patient**

- The capacitor is charged just before trigger and the charge voltage is connected to electrodes only at shock moment.
- The trigger command is only enabled if capacitor is charged with selected voltage and inside trigger time (30 s). Outside this period or during capacitor charging and/or is detected any anomaly in the relay operation that controls the capacitor discharge is disconnected, causing capacitor discharge.

### **b) Operator**

- Internal battery to isolate the equipment from external electric mains.
- Internal manageable battery charger with external power supply and isolation between power grid, patient and operator.

### **c) Aircrafts**

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

## **13. USING E-HEART BIPHASIC DEFIBRILLATOR MONITOR IN STRONG ELECTROMAGNETIC FIELDS**

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Subways, helicopters and train stations could interfere in DEFIBRILLATOR MONITOR, when it is on the automatic external mode, because they are composed of intense electromagnetic fields in which were observed high alterations in the sensibility and specificity. Do not operate the equipment near cell phones, wet surfaces, high voltage lines or places near strong electromagnetic fields.

## **14. DEFIBRILLATOR MONITOR OPERATION IN HIGH FREQUENCY ENVIRONMENT**

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- ✓ An extreme care should be taken during surgeries that use equipment operating in high frequency, especially in patients with pacemaker. Besides the risk of

pacemaker damages, the electric cauterization currents could cause fibrillation in the patient. Always keep a defibrillator monitor nearby.

- ✓ Respect the minimum distance of 15 cm between ECG electrodes and the electric scalpel or defibrillator, if are used at same time. In case of doubt, disconnect the ECG cable.
- ✓ This equipment may cause radio interference or may interrupt the operation of near equipment. It may be necessary to take migratory actions, like re-orientation or relocation of the defibrillator monitor or the location shielding.

## **15. CARE WHEN APPLYING DEFIBRILLATION / CARDIOVERSION**

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- ✓ Do not place the paddles directly on ECG electrodes. Some care should be taken with patients on pacemaker, in order to avoid damages to device and to patient himself:
  - ❖ The applied energy should be the lowest possible;
  - ❖ Keep an external pacemaker nearby;
  - ❖ Check pacemaker after defibrillation.
  - ❖ Keep distance between the generator and the patient pacemaker and the defibrillator monitor paddles.

### **IMPORTANT:**

- The protection against the defibrillator discharge effects is located in the intern modules of the equipment;
- The cable, electrodes and accessories don't have protection against burn outs caused by the use of high frequency equipment.

## **16. OPERATION MODE**

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### **16.1 EQUIPMENT CONFIGURATION**

When you press the navigation button of E-HEART BIPHASIC DEFIBRILLATOR MONITOR the Configuration Menu modules will appear on the display. A cursor with an arrow shape (>) appears at left of the items of this menu indicating that this is the selected item one. By rotating the navigation button clockwise or anticlockwise, the cursor moves to a new menu item according to rotation sense. To configure the desired module, position the cursor on this module and press the navigation key.

After choosing the module to be configured, a new menu is presented on the display with configuration items of the selected module.

Select the item of the chosen module to be configured proceeding with same manner described previously. When you select the item, notice that it will blink indicating that it



is ready to be altered. Rotate the navigation key to alter the item values, increasing or decreasing them. After choosing the desired value, press the navigation button to hold it.

To exit the menu, place the cursor on the item **Exit** with the browser button.

**NOTE:**

- In the modules Configuration Menu only the ones that are installed in the E-HEART BIPHASIC DEFIBRILLATOR MONITOR (configuration options) will appear.
- It is possible to select the charge to be released in case of treatment(1 to 200 joules or 1 to 360 Joules according to configuration) by rotating the navigation key without pressing it.

***16.1.1 MENU SCREEN***

<b>Settings</b>	
➔	Exit
	Setup
	ECG
	Pacemaker
	SPO2
	Printer
	NIBP
	IBP
	Ventilation
	Drugs
	Capnography

***16.1.2 SETUP SCREEN***

<b>Settings</b>	
➔	Exit
	Sync. ON
	Auto-Charge
	Paddles Selection
	Alarm Volume
	BPM Volume
	Key Volume
	Beep Key
	Date
	Time
	Language

1. Exit - Returns to the previous menu;
2. Alarm Vol. - Set the alarm volume, mute = 001, max = 009;
3. BPM Volume - Sets the beeper volume BPM = 001 mute, 009 = max;
4. Volume key - Sets the volume of the keyboard beep, mute = 001, max = 004;
5. Beep key - Enables (YES) or disables (NO) the beep sound on the keyboard;
6. Language - PTG = Portuguese, English = ENG, SPA = Spanish;
7. Time - Changes the Time;
8. Sync. ON – Enables (YES) or disables (NO) the synchronism with the QRS signal of the ECG sign;
9. Auto-Charge - Enables (YES) or disables (NO) the defibrillator charge automatic sequence;

- 10. Paddles Selection - Enables (YES) or disables (NO) the paddles button command;
- 11. Date – Adjust Day/ Month/Year

**16.1.3 ECG SETUP MENU (ELECTROCARDIOGRAM)**

ECG	
> Exit	Speed
Derivation	Gain
Filter 60Hz	Beep
Filter 35Hz	Alarm
Tachycardia	
Bradycardia	

- 1. Exit – Returns to previous Menu;
- 2. Derivation – Defines the electrocardiogram derivation to be presented on display (CAL = calibration, D1, D2, D3, AVR, AVL, AVF, V);
- 3. Filter 60Hz - Enable (yes) or disable (no) 60 Hertz filter;
- 4. Filter 35Hz – Enable (yes) or disable (no) 35 Hertz filter;
- 5. Tachycardia – Defines the bpm value for alarm operation in tachycardia (100 – 220);
- 6. Bradycardia – Defines bpm value for alarm operation in bradycardia (30 – 60);
- 7. Speed – Select the sweeping speed of ECG for 12.5, 25 or 50mm/s;
- 8. Gain – Select the ECG amplitude for N/2, 1N or 2N;
- 9. Beep - Enable (yes) or disable (no) the synchronism beep with QRS complex of ECG signal;
- 10. Alarm – Enable (yes) or disable (no) any ECG alarm;

**16.1.4 PACEMAKER SETUP MENU**

Pacemaker	
> Exit	Frequency
Mode	Beep
Width	Pulse
Amplitude	

- 1. Exit – Returns to previous Menu;
- 2. Mode – Select Pacemaker operation mode (PM) of the following modes:
  - **VOO**: The PM send pulses according to configured parameters regardless of any ECG signal detected in patient;
  - **VVI**: The PM sends pulses according to configured parameters only if the patient detected signal is outside these parameters range.
- 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 300 ppm (pulse per minute);
- 6. Beep – Enable (yes) or disable (no) pulse beep;
- 7. Pulse – Enable (yes) or disable (no) the PM pulse sending.

8. Alarm - Enables (YES) or disables (NO) any alarm.

**16.1.5 SPO2 SETUP MENU**

<b>SPO2</b>	
> Exit	Gain
Max Sat	Beep
Min Sat	Alarm
Max PPM	
Min PPM	

1. Exit – Returns to previous Menu;
2. Max Sat – Defines the minimum saturation for alarm operation from 40 to 100%;
3. Min Sat – Defines the minimum saturation for alarm operation from 40 to 100%;
4. Max PPM – Defines the pulsation maximum frequency for alarm operation from 40 to 240 ppm;
5. Min PPM – Defines the pulsation minimum frequency for alarm operation from 30 to 120 ppm;
6. Gain – Select the SPO2 amplitude for N/2, 1N or 2N;
7. Beep – Enable (yes) or disable (no) the pulses beep;
8. Alarm – Enable (yes) or disable (no) SPO2 alarm.

**16.1.6 PRINTER SETUP MENU**

<b>Printer</b>	
> Exit	
Automatic	
Report	

1. Exit – Returns to previous Menu;
2. Automatic – Enable or disable Automatic Printing when blade detects ECG;
3. Report – Enable (yes) or disable (no) the report Printing;

**16.1.7 NIBP SETUP MENU**

<b>NIBP</b>	
> Exit	Average
Patient	Diastolic
Mode	Start/Stop
Automatic	Alarm
Systolic	

1. Exit – Returns to previous Menu;
2. Patient – Select patient: Adult or Child;
3. Mode – Select measurement mode: Manual or Automatic;
4. Automatic: defines the measurement time interval when the automatic mode is selected;

5. Systolic – Configures the systolic pressure for alarm triggering; (from 30 to 300 mmHg)
6. Average – Configures the average pressure for alarm triggering; (from 30 to 300 mmHg)
7. Diastolic – Configures the diastolic pressure for alarm triggering; (from 30 to 300 mmHg)
8. Start/Stop – Enable (yes) or disable (no) NIBP module;
9. Alarm – Enable (yes) or disable (no) NIBP alarm.

**16.1.8 DRUGS SETUP MENU**

Drugs		
➔	Exit	Lidocaine
	Adrenaline	Mexiletine
	Amiodarone	Noraadrenaline
	Atropine	Potassium
	Sodium Bicarb.	Procainamide
	Calcium	Sotalol
	Dofetilide	Verapamil

1. Exit - Returns to the previous menu;
2. Procainamide - Selects the level of the injected drug;
3. Lidocaine - Selects the level of the injected drug;
4. Amiodarone - Selects the level of the injected drug;
5. Dofetilide - Selects the level of the injected drug;
6. Sotalol - Selects the level of the injected drug;
7. Verapanil - Selects the level of the injected drug;
8. Drugs 8 - and others used in CPR;
9. Drugs 9 - and others used in CPR.

**16.1.9 IBP SETUP MENU**

IBP	
> Exit	Blood Pressure
Maximum	Gain
Average	Speed
Minimum	Alarm
Patient	Calibrate

1. Exit – Returns to the previous menu
2. Maximum - Allows adjusting the alarm range.
3. Average - Allows adjusting the alarm range.
4. Minimum - Allows adjusting the alarm range.
5. Patient – Select patient: adult or child.
6. Blood Pressure – When activated we have access to the following pressure types: PVC, AD, VD, PAP, PCP, AE, VE, AO, PA, PIC, P1, P2, P3, P4.

7. Gain – The available gains are from 0,5N to 2N.
8. Speed – Allows to vary the scanning speed of the screen to 12,5 mm/s, 25 mm/s and 50 mm/s.
9. Alarm – Enables (YES) or disables (NO) the IBP alarm.
10. Calibrate – When activated it calibrates the pressure channel with the air, measuring subsequently the desired pressure safely.

**16.1.10 CONFIGURATION MENU OF THE CAP (CAPNOGRAPHY)**

CAP	
> Exit	Curve
EtCO2	Gain
Resp	Patient
Insp	Line width
Apnea	Alarm
Speed	

1. Exit – Returns to the previous menu
2. EtCO2 - Allows adjusting the high and low alarm range.
3. Resp - Allows adjusting the high and low alarm range.
4. Insp - Allows adjusting the alarm range.
5. Apnea - Allows adjusting the alarm range.
6. Speed – Allows to vary the scanning speed of the screen to 12,5 mm/s, 25 mm/s and 50 mm/s.
7. Curve – Allows varying between full line or just the line.
8. Gain – The available gains are from 0,5N to 2N.
9. Patient – Select patient: adult or child
10. Line width – the available widths are 1px to 3px.
11. Alarm - Enables (YES) or disables (NO) the Capnography alarm.

**16.1.11 VENTILATION SETUP MENU**

VENTILATION
➡ Exit
Ventilation
Intubation
Peripheral AV.
Central AV.

1. Exit - Returns to the previous menu;
2. Ventilation - Allows you to set the ventilation mode: Spontaneous, Assisted, Controlled;
3. Intubation – Allows you to set between YES or NO and the method of intubation: oral, nasal, tracheostomy;
4. Peripheral AV. – Allows you to set between YES or NO;
5. Central AV. - Allows you to set between: IJV, VSC, OUT, NO;

### ***16.1.12 OTHER FUNCTIONS***

Besides the accessible items on the Configuration Menu, there are other accessible functions on the E-HEART BIPHASIC DEFIBRILLATOR MONITOR panel:

#### ***16.1.12.1 PACEMAKER (OPTIONAL)***

- A) Turns on / off – Enables or disables the pacemaker;
- B) MODE (Sync, or Assync.) – Changes between the VOO and VVI modes;
- C) Inhibits beep – Enables or disables the synchronized beep with the pacemaker pulses;
- D) Inhibits pulse– Enables or disables the pacemaker pulses deflagration;
- E) EMERGENCY – Changes the pacemaker configuration for the ones from the Emergency Mode (VOO, 70 rpm, 150 mA, 40 ms).

#### ***16.1.12.2 PRINTER (OPTIONAL)***

When the key is pressed for the first time the ECG printing gets started, when it is pressed again, the procedure is interrupted.

#### ***16.1.12.3 NIBP (OPTIONAL)***

When the key is pressed for the first time the Arterial Pressure scouting gets started, when it is pressed again, the procedure is interrupted.

#### ***16.1.12.4 SYNC. ON***

Enables or disables the electric discharge with the peak of the R wave. When the equipment is turned on, the synchronism is off, when activated, a “Sync, ON” message will appear on the display (right below the heart frequency indication) and its led will appear on.

#### ***16.1.12.5 CANCEL LOAD***

This key should be activated when the deflagration of the electric discharge is no longer desired, in order to discharge the capacitor.

#### ***16.1.12.6 2 MIN***

It inhibits the sound alarms for 2 minutes.

#### ***16.1.12.7 SELECTION / MENU***

It allows adjusting the load level that is going to be used in the next trigger.



### **16.1.12.8 LOAD / CHARGE**

It charges the capacitor preparing the equipment for the next trigger. If the equipment is not configured for command by the paddles buttons, the capacitor will only be charged if this key is pressed.

### **16.1.12.9 SHOCK TRIGGERING**

When activated, it performs the treatment. The treatment can also occur when both of the blade buttons are activated, simultaneously.

#### **NOTE:**

If the equipment is configured for command through the paddle buttons, there will be the following functions:

1. Sternum → Loads the capacitor;
2. APEX → Select the Load;

The equipment allows you to perform the selection of load level by pressing the APEX key and also charges the capacitor by pressing the STERNUM key and triggers by its own shock paddles by pressing, simultaneously, both the keys of the paddles.

### **16.1.12.10 AED MODE**

When the AED mode is activated, the equipment performs the functions of an AED automatically, to exit the AED mode, you just have to press the AED key again on the control panel.

## **17. ADAPTING CABLES AND ACCESSORIES**

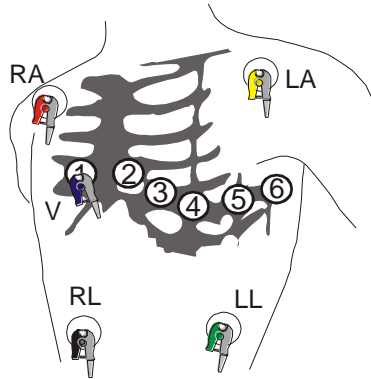
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### **17.1 ECG MODULE**

Connect the patient cable to the defibrillator monitor observing the correct position through 5 ways patient cable tags. Insert the connector until the end so it is firm. The other end will be positioned on the patient chest as described below.

Follow the drawing indicated positions as in figure 31, using the color in the correct place for each wire.

- ✓ **Blue** = V (precordial), represents the six precordial.
- ✓ **Green** = LL (left leg), represents the chest lower left side.
- ✓ **Yellow** = LA (left arm), represents the chest upper left side.
- ✓ **Red** = RA (right arm), represents the chest upper right side.
- ✓ **Black** = RL (right leg), represents the chest lower right side



**Figure 27 - Patient electrodes positioning**

- Use water and neutral soap to clean the reusable electrodes. After dried, disinfect using a moistened compress with ethylic alcohol at 70%. Do not use steel sponges on metallic parts, because the thin silver layer could be removed and make it useless. To clean and disinfect patient cable, use a compress moistened with demineralized water and neutral soap, and other compress moistened with isopropyl alcohol, respectively.
- Do not use abrasive products, because the cable could become dry and brittle. Do not store the patient cable twisted, because it tends to follow this format and consequently break the internal wires and damage it. Just put it on the table with bends corresponding approximately to 1/3 of cable. For disposable electrodes, after its use, they should be discarded in appropriate places following special procedures of hospital waste.

## **17.2 SPO2 OXIMETRY SENSOR**



**Figure 28 - Oximetry sensor positioning.**

Connect the oximetry sensor observing the correct position and in a way that the connector is inserted until the end. Put the sensor on the patient finger as indicated in the above figure.

Some care should be taken in order to obtain the correct reading:

- Remove enamel and dummy nails, because they can block the sensor light blocking the correct reading.

- Do not use adhesive to fix sensor, like plaster, for instance. The sensor is a very fragile device.
- Avoid dropping or leaving it on floor.
- For reusable sensors, after its use, clean the cable and sensor with a cloth moistened with demineralized water and neutral soap. Disinfect with an isopropyl alcohol moistened compress.

### **17.3 ADAPTING THE NIBP CUFF**

This topic was elaborated to the ones that are operating the equipment for the first time. It allows a very simplified basic functions training of NIBP channel. This channel provides diastolic, average and systolic arterial pressure.

The Non-invasive Blood Pressure Module (NIBP) has discharge protection against cardiac defibrillator, and specific precaution concerning the equipment is not necessary.

It was detected damages to the Ulnae nerve during the use of blood pressure automatic cycle in some researches.

A special attention is required not to block the patient's blood circulation:

- Do not leave the cuff over the elbow Ulnae nerve path;
- Select a measurement interval that regulates the adequate venous drain during cuff deflection;
- Check periodically the member that support the cuff to discover "Venous Stasis";
- Avoid compression or restriction of pressure pipes, this can cause the equipment mal-function.

Connect the air hose to the cuff and the socket marked with NIBP and place the cuff on the patient's arm as shown below. Make sure that the following marking "ϕ" on the cuff is placed on the arm's femoral artery and air hose must be positioned below the cuff, to ensure that the hose does not become entangled / enmeshed after exiting the cuff.

The white line on the cuff should be within the range of "↔", otherwise you will need to replace it with a more appropriate cuff (smaller or larger). The cuff should be placed on the same level as the heart in order to avoid false readings caused by the effects of hydrostatic of the blood column between heart and cuff.

If the position of the cuff is higher than the level of the heart, the reading of the ABP measured tends to be lower and if the position of the cuff is lower than the level of the heart, blood pressure reading tends to be far greater.

 **WARNING!**

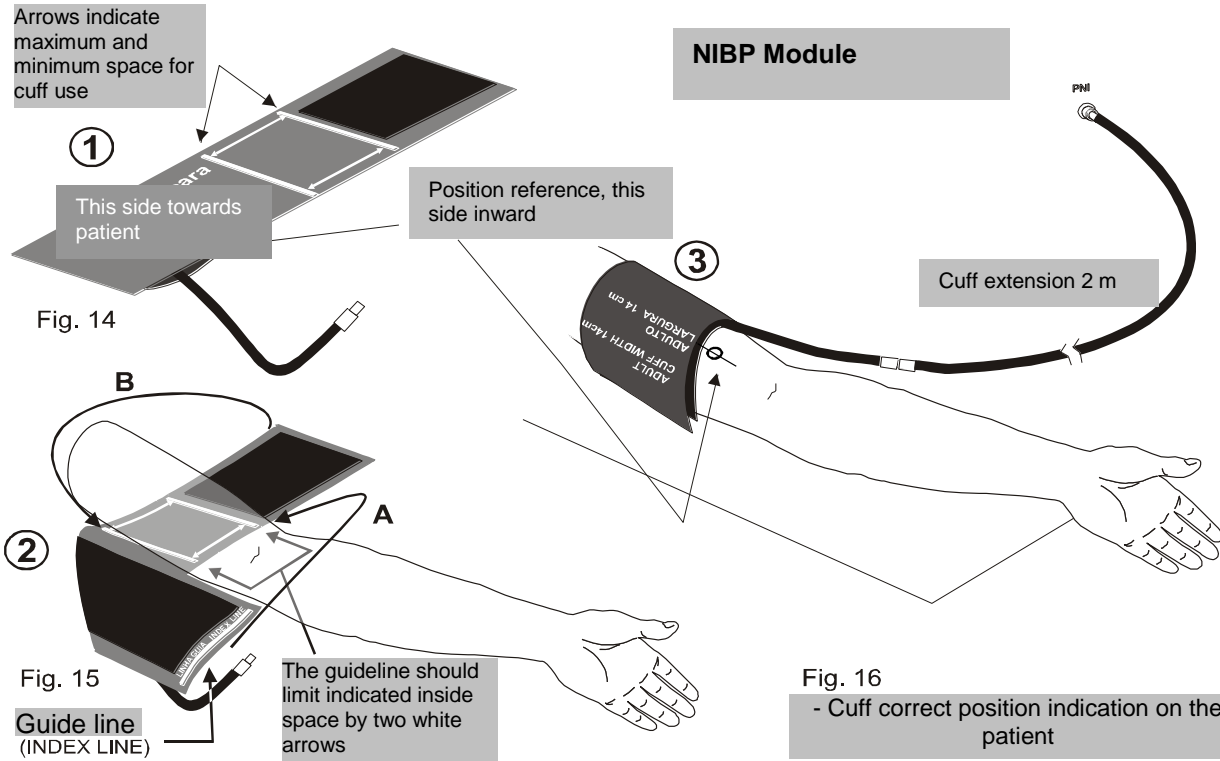
The accuracy of the ABP depends on the adequacy of the cuff. Select the size of the cuff according to the size of the patient's arm. The cuff width should be 40% of arm circumference or 2 / 3 of the arm length.

 **WARNING!**

- You should not perform measurements of NIBP in patients in any condition in which skin is damaged or with the possibility to be damaged.
- For a patient with thrombosis, it is important to determine whether or not the measurement of blood pressure should be performed automatically. The determination should be based on clinical evaluation.
- Prolonged measurement of non-invasive blood pressure in automatic mode may be associated with content, ischemia and neuropathy in the limbs that are using the cuff. When monitoring a patient, examine the ends of the members frequently, if it presents normal color and temperature and sensitivity. If any abnormality is observed, stop the blood pressure measurements.

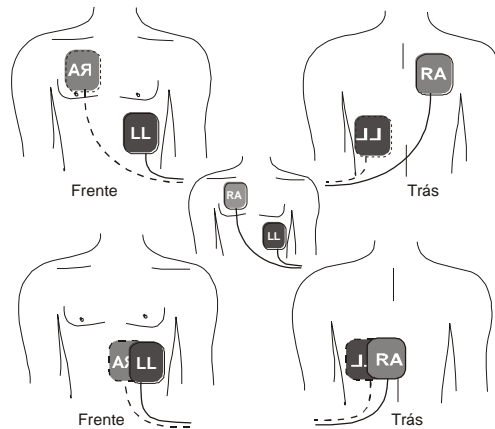
 **WARNING!**

Do not use cuffs and/or pipes with water inside, with risk to damage the equipment. If equipment liquid infiltration occurs, turn it off from the electric power grid, store it and call a technician to check the equipment.



### 17.4 ADAPTING PACEMAKER PADDLES

Connect the extension cable on paddles (PADs), and then insert the other end of the connector to the defibrillator monitor terminal. Insert the connector and fasten with moderate pressure. So the pacemaker will be ready for application.



**Figure 29 - Paddles pacemaker position variants on patient.**

The stimulation electrodes should be positioned in a way that does not interfere in a possible defibrillation. Normally, non-invasive stimulation is performed in the Apex/Front or Front/Back configuration. Nevertheless, we recommend the Front/Back configuration, to ease the defibrillation procedure.

## **17.5 PACEMAKER USE INSTRUCTIONS**

When you turn the equipment on, the pacemaker module begins a self-test routine. In this routine, it checks high voltage circuit and output pulses parameter (Amplitude, Frequency and Width). The pulse Pacemaker generator of E-HEART BIPHASIC DEFIBRILLATOR MONITOR can be used for non-invasive transthoracic stimulation application in a frequency range from 30ppm to 200ppm.



### **WARNING!**

NON-INVASIVE Pacemaker – In the VOO mode, the pacemaker can induce ventricular fibrillation, if stimulation pulse is applied regularly on ascending portion of patient T wave.

### **A – E-HEART BIPHASIC DEFIBRILLATOR MONITOR Pacemaker General Description**

The external multi-configurable pacemaker offers non-invasive stimulation. It could be used during cardiac surgeries, as cardiac stimulator in emergencies.

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR Pacemaker is composed by a control unit based on micro controller with intelligent data transmission capacity to the defibrillator monitor central CPU and one proper circuit for QRS detection and impedance detection circuit, one high voltage power supply and one pulse generator with amplitude, frequency and pulse width enough to execute stimulation in both Pacemaker modes through the membrane keyboard. The equipment produces a sound warning that identifies in audible form the stimulation pulses.

### **B – Non-invasive Stimulation**

As a non-invasive transthoracic stimulation pulse, the Pacemaker of E-HEART BIPHASIC DEFIBRILLATOR MONITOR delivers to patient stimulus that varies from 30 to 200 pulses per minute, in asynchronous mode. You can program the frequency, amplitude and pulse width with the purpose to get reliable stimulation with minimum delivered energy, to minimize patient disturbance.

The Pacemaker stimulator of E-HEART BIPHASIC DEFIBRILLATOR MONITOR was designed to help during emergencies.

By pressing the emergency key, you can turn on the VOO stimulation with the following emergency parameters:

- Frequency = 70 ppm (pulses per minute);
- Amplitude = 100 mA (milliamps);
- Pulse width = 20 ms (milliseconds).



### **C – Applications:**

The non-invasive Pacemaker of E-HEART BIPHASIC DEFIBRILLATOR MONITOR is suitable for pre-hospital and hospital environment.

In general, it is extremely important when fast cardiac stimulation is required.

Some transthoracic applications when continuity is indicated are:

- Symptomatic bradycardia treatment during emergency.
- During and after cardiac surgery.
- To ease the implantation intravenous stimulator electrode.

### **D – Stimulator Operation**



The described procedure is recommended for support stimulation in bradysystole patient (missing intrinsic rhythm). In case of bradycardia support, should assure that the stimulation frequency is higher than the patient own rhythm and the patient QRS capture is reliable. There is risk to induce ventricular fibrillation if the stimulation pulse happens during T wave ascending period.

In order to get reliable QRS capture, the operator has to alter the amplitude and pulse width to lower levels, targeting:

- ❖ The reduction of the energy delivered to the patient, to prolong the equipment battery duration.
- ❖ If the patient is conscious, seek parameter values that cause less inconvenience to him/her.

### **E – Operation Modes**

The Pacemaker of E-HEART BIPHASIC DEFIBRILLATOR MONITOR features two operation modes:

1. VOO;
2. VVI.

- ❖ In the **VOO** and **VVI** modes the Pacemaker will be stimulating and transmitting information to the operator through the display.
- ❖ In the **VOO** mode the pacemaker stimulates the patient continuously.
- ❖ In the VVI mode, stimulation will only be triggered when the patient natural frequency is below the selected by the operator.

## **F – Mode Selection**

You can the operation between “Synchronous” and “Asynchronous” mode by pressing the MODE key.

## **G – Parameter Configuration**

The parameters are configured inside the pacemaker menu. Press the Browser menu to enter main menu, rotate the Browser until the Pacemaker menu, and press it again. Navigate until the desired parameter, press the button again, turn it to alter and select the Navigator to confirm.

## **H – Emergency**

Regardless of the operation mode selected for the E-HEART BIPHASIC DEFIBRILLATOR MONITOR Pacemaker, when you press the EMERGENCY key the pacemaker changes to VOO mode, and takes on the following parameters: 100mA, 20ms, and 70ppm.

**SWITCH ON AND OFF PACEMAKER:** In order to turn the pacemaker on or off you should press the following button (check page 40, item 3.5):



## **I – Pacemaker Specifications**

### **Stimulation configurable parameters:**

Frequency, Amplitude and Pulse width;

Current: stimulation without any charge connected: 100mA, off 3mA;

Power supply: 12V.

### **Stimulation system specifications:**

Stimulation frequency: 30ppm to 200ppm in steps of 1ppm;

Pulse amplitude: 0mA to 200 mA in steps of 1mA;

Pulse width: 0ms to 50ms in steps of 1ms;

Emergency: VOO 70ppm 100mA 20ms;

Defibrillation protection: 400 joules.

### **Location of stimulation electrodes:**

The stimulation electrodes should be positioned in a way that does not interfere with a possible defibrillation. Normally the non-invasive stimulation is performed in the Apex/Front and Front/Back configuration. Nevertheless, we recommend the Front/Back configuration, to ease the defibrillation procedure, if necessary.

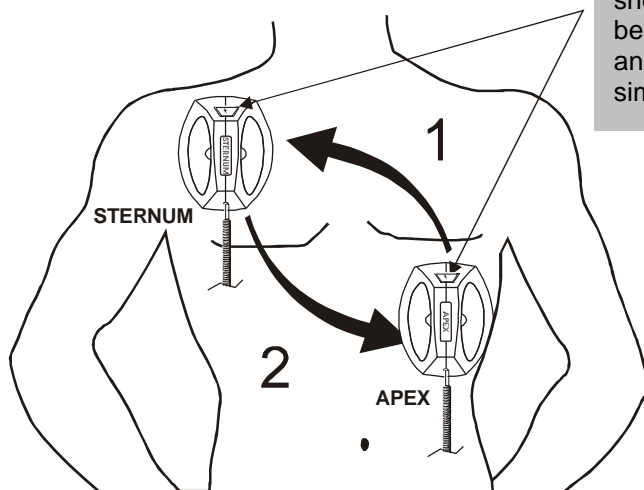
After the connection of both units with interface cable and switching on the pulse generator, you should press the EMERGENCY key to select the more suitable stimulation. In this configuration, the Front Electrode (negative pole) is located on the V3 derivation and the Electrode Back (positive pole) on the left scapula near the spinal column.

### **J – Stimulation Electrodes Application**

The steps to apply the stimulation electrodes (pacing pads) are indicated next:

- ✓ Remove or loosen the patient cloths.
- ✓ Clean and dry the skin area with a dry cloth.
- ✓ Check the expiration date of the stimulation "Pads".
- ✓ Attach them separately following the manufacturer instructions, that normally consists in removing the protective cover and attaching them separately, pressing them only over the adhesive zones.
- ✓ If the electrode does not adhere adequately, discard it and repeat the previous steps with a new pair.
- ✓ Insert the self-fixing connector indicated on the electrodes cable end to the correspondent extension cable connector of E-HEART BIHASIC DEFIBRILLATOR MONITOR
- ✓ In case of doubt, always follow the instructions indicated by the stimulation electrodes manufacturer.

### **17.6 ADAPTING THE DEFIBRILLATOR MONITOR PADDLES**



At the trigger moment conductive gel should be on the paddles, that should be firmly positioned (as on the figure) and the paddles trigger keys pressed simultaneously.

**Figure 30 - Shock Paddles Positioning at trigger moment.**

Connect the external adhesives paddles (electrodes), observing correct position; after the correct paddles connection, to the equipment and to the patient, the ON, CHARGE and TREATMENT key should be pressed to release the electric discharge to the patient.

Connect the adhesive electrodes (AED mode), observing the correct position. After the correct connection of the electrodes, both to equipment and to the patient you must press the ON/OFF, AED and TREATMENT keys to release the electrical charge to the patient.

**Important Observations:**

- ✓ Do not apply shock with short-circuited paddles, because it could damage the trigger device.
- ✓ Always transport equipment with the paddles protected against dropping.
- ✓ There is an adaptor to use disposable paddles with the BIPHASIC E-HEART DEFIBRILLATOR MONITOR.

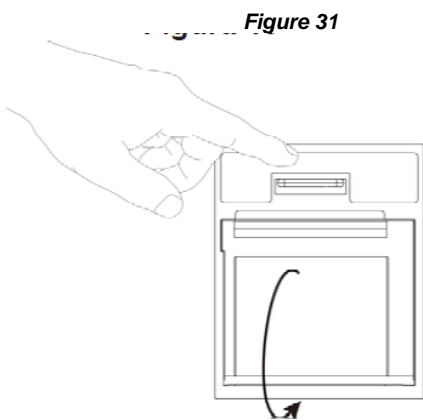
**17.7 INSERTING THERMAL PAPER IN PRINTER**

Use appropriate thermo sensitive paper that is easily found in shops for hospital-medical and surgical equipment or directly with US DEFIB MEDICAL TECHNOLOGIES LLC, so a sharp printing can be warranted.

It should be observed that the thermal paper presents a great variation concerning sensibility and abrasion, therefore, it is possible to find difference in tracing tones from one manufacturer to another or different batch.

To introduce the paper in printer, push the printer lever. When the printer lid releases, insert the paper roll, with the printed millimeter part upward. Place both roll sides (holes) until the side clamps fit inside (depending on the model). After the roll placement, leave some paper spare outside of the printer, and place the lid on horizontal position. Pull the paper outward the printer and position it centralized related to paper passage slot. Push the printer lid so it locks. Then, it is ready to use (see next illustration).

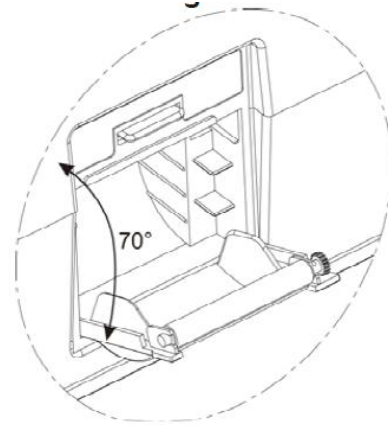
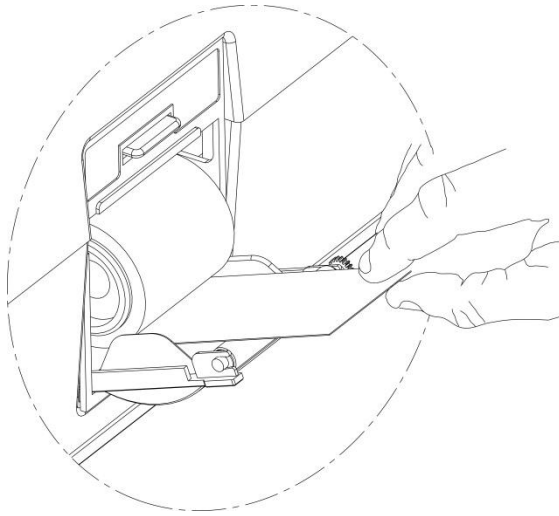
**17.7.1 INSTRUCTIONS TO PLACE THERMAL PAPER IN THE TR-50 OR SP-48 PRINTER**



1 - Press the cover latch;

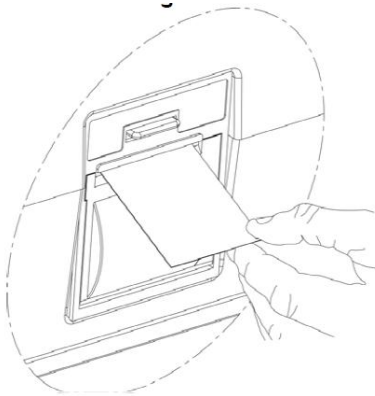
- 2 - Move the lid until it is positioned at 70 °;
- 3 - Enter the print platen in the loop and print side up;
- 4 - Drag out the paper centering;
- 5 - Lift the printer cover in the opposite direction ensuring that it doesn't lock;

**Figure 32**



6 - Set the print paper again so that it centralizes with the printer;

7 - After the correct positioning of the paper, press the printer cover until it locks. After locking the lid, the equipment will be ready for use. If the paper does not move properly during printing, repeat the procedure;



**Figure 33**

## **17.8 USING CAPNOGRAPHY AND SENSORS**

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR can use either the nasal line or intubated for the capnography. To use the capnography in intubated patients, adaptors should be used as shown in pictures below.

The capnography can be damaged because of the reuse of the water filter. Follow the accessories use instructions. The filter should be replaced at every patient according to the manufacturer instructions.

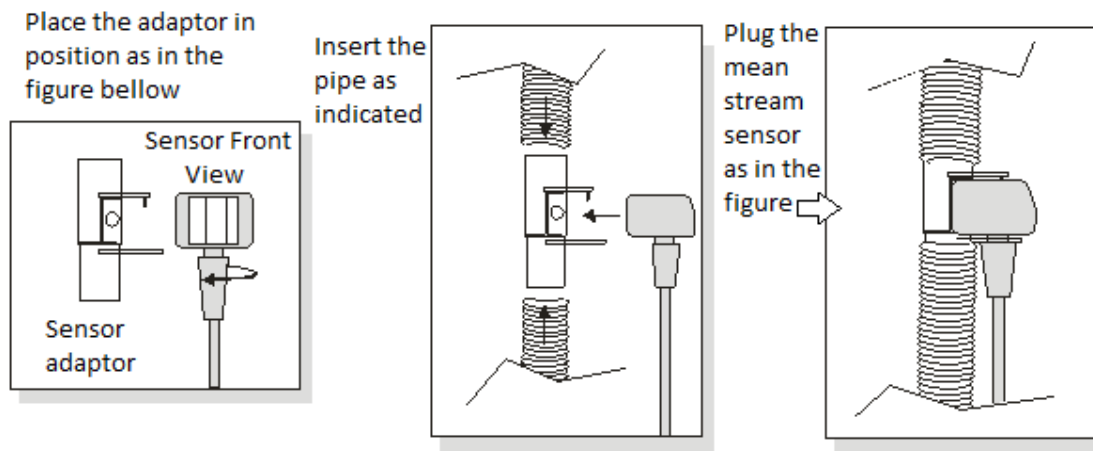
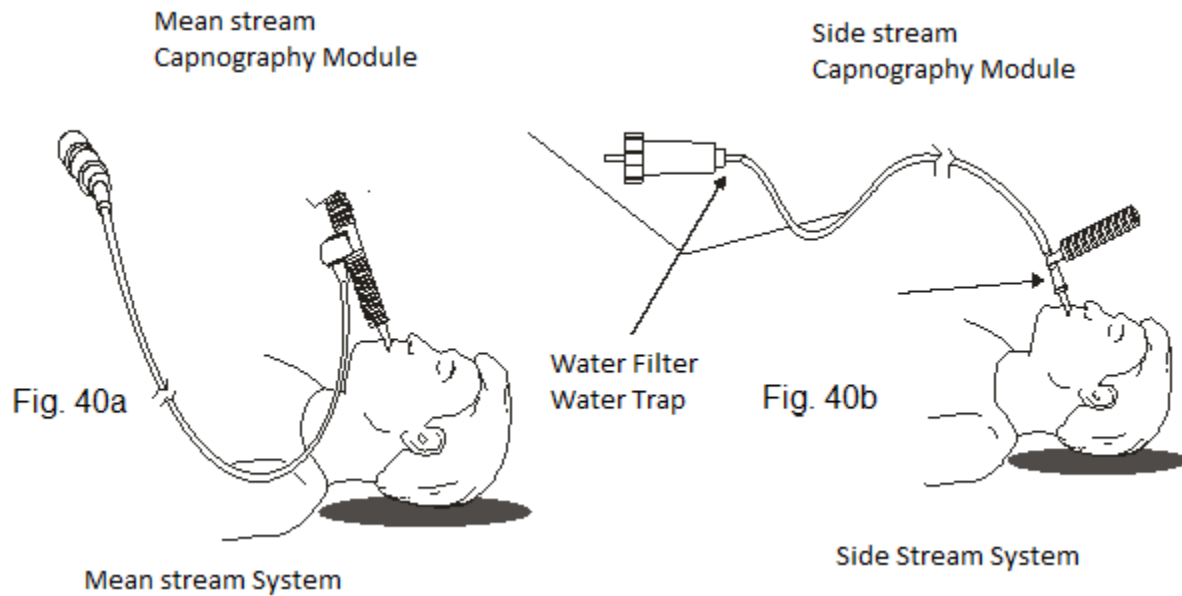


Figure 34 - Mean Stream Assembling Design

### 17.9 USING THE IBP (INVASIVE BLOOD PRESSURE)

In case of using 2 channels of pressure, 2 systems should also be used.

- Material needed:

- 01 disposable dome;
- 01 syringe;
- 02 three-ways;
- 01 extensor;

First, add the two three-ways to the dome (this increases security and makes the work easier). Connect the dome to the pressure transducer.

To connect the dome to the transducer, the system should be opened for the air.

- All of the system bellow should be filled up with the saline, and if possible with heparin.



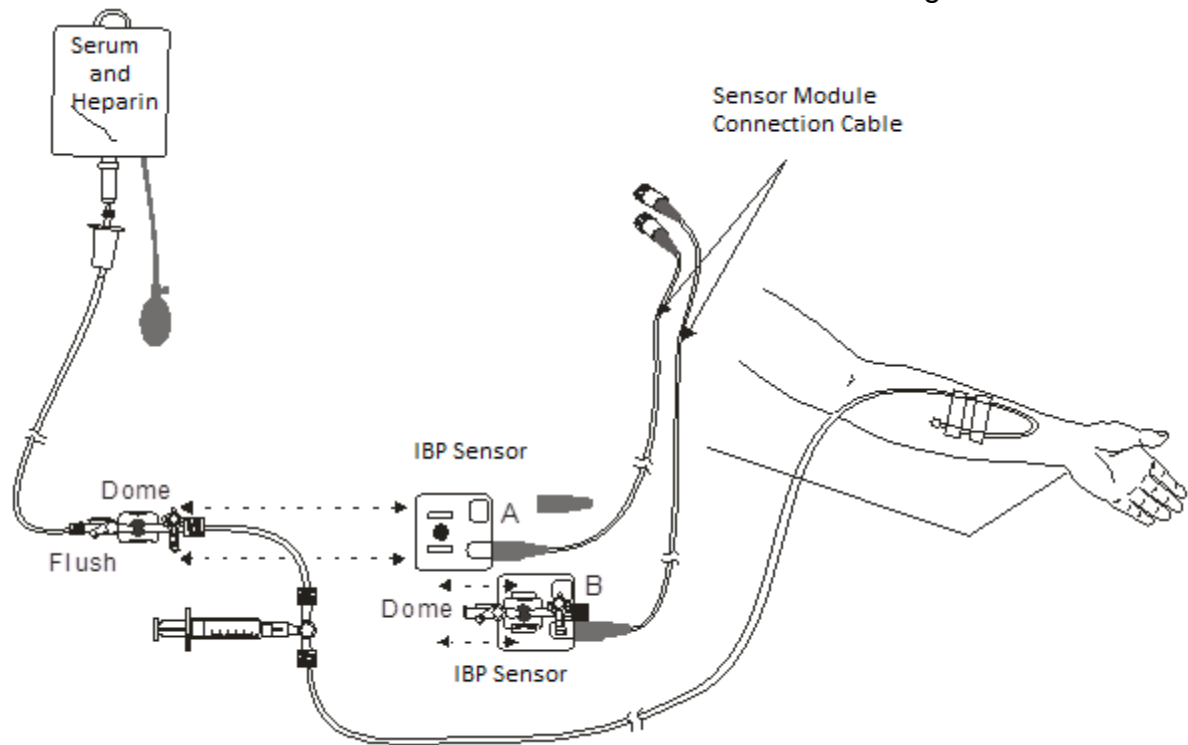
- Make sure that there are no bubbles, especially in the tube that connects to patient.
- Do not use any latex in the circuit.
- The transducer should be placed around the midline of the patient, if not, the values of pressure will not be accurate.

The path of the IBP system should be inspected observing the existence of air bubbles in these ways. If there are air bubbles, they should be eliminated, by letting the saline flow all the way until we can verify that there are no such bubbles in the IBP system.

**For IBP Calibration, we have:**

**NOTE:** Before calibration, check the correct assembly of the blood pressure measurement system.

- Select the channel of the blood pressure and close the 3-way so that the transducer is closed for the patient;
- Open the 3-way for the air and hit ZERO;
- After the ZERO (O) appears, the equipment will be able to measure the pressure. Now, just close the 3-way;
- In order to measure the pressure of the RV (right ventricle) and LV (left ventricle), the pressure to be measured must correspond to the pressure type displayed in the equipment, since that measurements don't have an average pressure value;
- The tolerance for calibration is within the interval of 100 mm/Hg.



*Figure 35 - IBP Assembling Design*

**IMPORTANT:**

The whole IBP system should be filled with saline, if possible with heparin. Make sure that there are no bubbles, especially in the tube that connects to patient. Do not use any

latex in the circuit. The transducer should be placed around the middle line of the patient in order to obtain accurate values of pressure.

### **17.10 INTERNAL BATTERY**

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR has a rechargeable internal battery, which allows operation without power grid cable. The battery charging is automatic when you connect the power cable to electric power grid (127 and 220 V), regardless if equipment is switched on in upper panel. User should proceed to check or replace the internal battery through US DEFIB when observing degradation in the useful charge time.

#### **IMPORTANT:**

The DEFIBRILLATOR MONITOR battery should be returned to manufacturer after a substitution motivated by defect or end of useful life.



#### **WARNING!**

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR should remain connected to the power grid 24 hours a day in order to keep the battery fully charged, the equipment is also able to operate normally when connected to the POWER SUPPLY.

## **18. FOUNDATIONS**

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### **18.1 DEFIBRILLATION CONCEPT**

The Defibrillation is the emergency procedure that consists in the application of an electric current shock non-synchronized on the patient chest (external defibrillation) or directly on the cardiac muscle (internal defibrillation) with the objective to revert the Ventricular Fibrillation or Ventricular Tachycardia without pulsation. It should be differentiated from Cardioversion that consists in an elective or emergency procedure that needs synchronization and is classically indicated in instable tachycardia cases or with medical criteria.

#### **18.1.1 DEFIBRILLATION IMPORTANCE**

The Early Defibrillation it is a link of the Survival Chain. It allows a complete myocardium depolarization, enabling, the cardiac rhythm regulator centers to recover the control of cardiac electrical activity. The defibrillation is the only effective treatment for Ventricular Fibrillation (VF) – the most serious arrhythmia – characterized by irregular wave's presence, in amplitude and frequency, defining the chaotic cardiac rhythm.

In case of VF it is necessary to perform the early defibrillation, because the chance for well succeed treatment in these cases decreases quickly as time goes by – about 7 (seven) to 10 (ten) percent at each minute

## **18.2 THE CARIOVERSION**

The Cardioversion is the other electric therapy modality in order to treat certain cardiac arrhythmia. Different from defibrillation, the cardioversion is performed by applying a synchronized electric discharge with ventricular depolarization. The synchronization is obtained with the detection of QRS complex.

When you choose the synchronized shock (SYNC), every time that the QRS complex is detected by the defibrillator monitor, it provides a visual and sound signal.

Remember that, in certain situations, there is a mechanism to inhibit the energy exit, the signals captured by ECG are difficult to detect, for instance, when there was a wide and short R wave. When the defibrillator monitor is charged in the synchronized mode its discharge only happens if there is R wave, and the patient impedance is within the range from 25Ω to 500 Ω and the paddles buttons are simultaneously operated.

It is necessary to be careful not to apply the charge in asynchronous mode during the vulnerable period, because in this case a ventricular fibrillation (VF) could be induced.

**Recommendations about necessary Energy Levels for arrhythmia treatment (according to *Guideline 2010 of AHA for Truncate Dual Phase Technology*):**

## **18.3 EXTERNAL TRANSTHORACIC CARIOVERSION / DEFIBRILLATION (INDIRECT) ON ADULTS**

❖ Atrial Fibrillation - 100J to 120J;
❖ Atrial “Flutter” - 50J;
❖ Supraventricular paroxysmal tachycardia - 100J;
❖ Ventricular tachycardia monomorphic - 100J

### **Transthoracic External Defibrillation (Indirect) in adults:**

❖ First Defibrillation: 150 J;
❖ Second Defibrillation: 150 to 200 J;
❖ Third and subsequent Defibrillation: 200 J.

### **Transthoracic External Defibrillation (Indirect) in children:**

❖ First Defibrillation: 2 J/Kg;
❖ Subsequent Defibrillation: 2 to 4 J/Kg;

### **Internal Defibrillation (Direct) in children:**

❖ First Defibrillation: to use the lowest energy level available, with the unit about in 2J;
❖ Subsequent Defibrillation: 3 to 10 J;

Table 4

## 19. E-HEART BIPHASIC DEFIBRILLATOR MONITOR CLASSIFICATION

### 19.1 GENERAL CLASSIFICATION

- ✓ Class I Equipment, CF and BF Type ;
- ✓ Equipment internally energized;
- ✓ Equipment should not be used near flammable agents, like nitrous oxide;
- ✓ Intermittent Operation Mode Equipment.
- ✓ Equipment not destined for frequent use.

- ❖ The protection rating **CF or BF** type is according to the module in the equipment and is indicated near the connector of this module.

### 19.2 DETECTOR OF CARDIAC RHYTHM – AED MODE (OPTIONAL)

The E-HEART BIPHASIC DEFIBRILLATOR MONITOR is prepared to recognize and indicate cardiac rhythms defibrillation of ventricular tachycardia (TV) of several frequencies and QRS width, and rhythms of ventricular fibrillation (VF) of several amplitudes, AUTOMATICALLY, remaining for the operator to connect the paddles on the patient chest.

The rhythm detection system of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR analyses the patient ECG and informs if the defibrillator has detected a rhythm that needs to be submitted to shock and contrariwise. The system allows a person, without the training of the ECG rhythm, to use defibrillation measures for ventricular fibrillation and ventricular tachycardia in victims without pulse. The rhythm detection system of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR:

- ❖ Detects contact of the electrode;
- ❖ Analyses automatically the ECG;
- ❖ Provides orientation for the operator during the therapy of defibrillation;
- ❖ It offers voice and text command to instruct the rescuer during the CPR sequence.

The transthoracic impedance of the patient will be measured by the defibrillation electrodes. If the impedance of the base line is greater than the maximum limit value, the E-HEART BIPHASIC DEFIBRILLATOR MONITOR will determine if the electrodes don't have the adequate contact with the patient or haven't been correctly connected to the E-HEART BIPHASIC DEFIBRILLATOR MONITOR. Consequently, the ECG analysis and the release of the defibrillation shocks will be interrupted. The text message on the display will instruct the user *to replace the electrodes at the patient's chest*, if the electrodes contact is not enough.

Optionally, in the AED Mode, for Pediatric use, the charge is limited to  $\frac{1}{4}$  of the energy for adults, automatically. When the PEDIATRIC PADDLE is inserted, the system

automatically limits the energy in the proportion of the sequence of the 1<sup>st</sup>, 2<sup>nd</sup>, and 3<sup>rd</sup> shocks, respectively.

**19.2.1 RECORDING METHODS (FOR AED MODE)**

The possible arrhythmias for TV and VF defibrillation in the equipment, eliminating the necessity for operator configuration, result significant time gain in the treatment.

**19.2.2 RHYTHM SOURCE (FOR AED MODE)**

Through the Defibrillator Analyzer equipment, model QA-40M, of METRON Company, cardiac rhythms likely to defibrillation are simulated, such as TV and VF, the natural rhythms, in several widths and frequencies.

**19.2.3 RHYTHM SELECTION CRITERIA (FOR AED MODE)**

The selected rhythms are the well-known classic indication for defibrillation, such as ventricular fibrillation and ventricular tachycardia.

**20. NOTE METHODS**

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The E-HEART BIPHASIC DEFIBRILLATOR MONITOR is equipped with an electroluminescent liquid crystal display, where the emergency attending procedures and ECG tracing are plotted, allowing cardiac rhythms graph registration.

**20.1 DETECTOR PERFORMANCE RESULTS**

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

**True Positive (A):** Rhythm correct classification possible to be defibrillated.

**True Negative (B):** Organized or in perfusion or asystole rhythm that was classified incorrectly as a possible rhythm to be defibrillated.

**False Positive (C):** It is a VT or VF associated with cardiac stop arrest that was classified incorrectly as not possible to be defibrillated.

**False Negative (D):** Correct classification of all rhythms, in which a shock is not indicated.

## 21. APPLIED TECHNOLOGY

### 21.1 COMPARATIVE: MONOPHASIC X BIPHASIC

The defibrillation pulse waves are classified into monophasic and biphasic. In the monophasic type, the polarity is constant: the biphasic type, the current is conducted in one direction, the polarity is reversed in the opposite direction after a short pause, the waves are also classified according to the form, and they can be truncated or damped sinusoidal, as shown below:

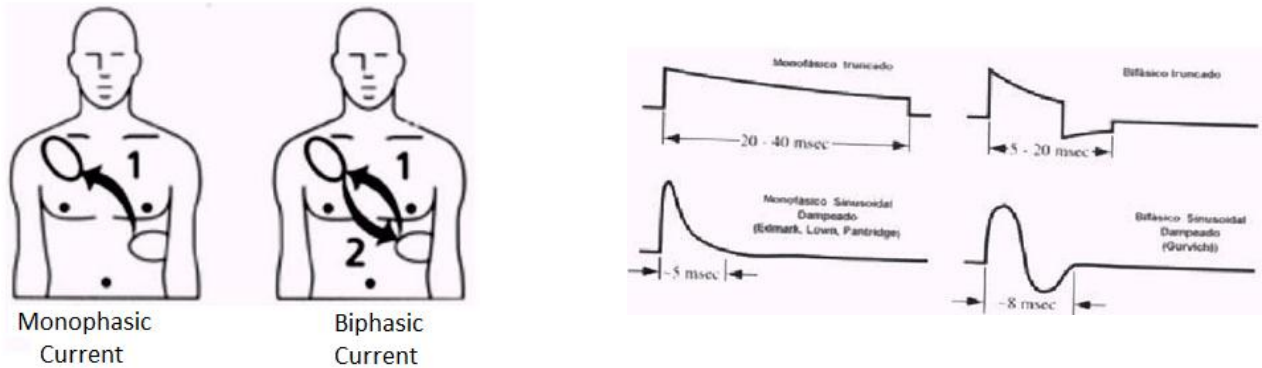


Figure 36 - Pulse wave types: monophasic and biphasic

Biphasic technology is safer and more effective to eliminate VF compared with Monophasic Technology as comparative table below.

<b>Biphasic Technology</b>	<b>Monophasic Technology</b>
<b>Increased</b> survival rate in the reversal of arrhythmia (96% success in the first shock)	<b>Decreased</b> survival rate in the reversal of arrhythmia (59% success in the first shock)
<b>Less</b> energy required (150 to 200J)	<b>More</b> energy required (360J)
<b>Less</b> time required to return to normal heart rate	<b>More</b> time required to return to normal heart rate
<b>Minor</b> occurrence of side effects (minor burn injury)	<b>Greater</b> occurrence of side effects (greater burn injury)
<b>Greater</b> effectiveness when used in cases of Prolonged Ventricular Fibrillation	<b>Minor</b> effectiveness when used in cases of Prolonged Ventricular Fibrillation

Table 6



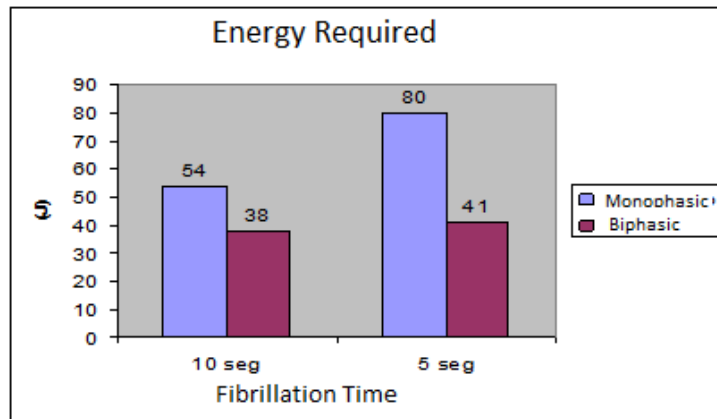


Figure 44 – Energy x Time

### 21.2 TRUNCATED EXPONENTIAL DUAL PHASE WAVEFORM

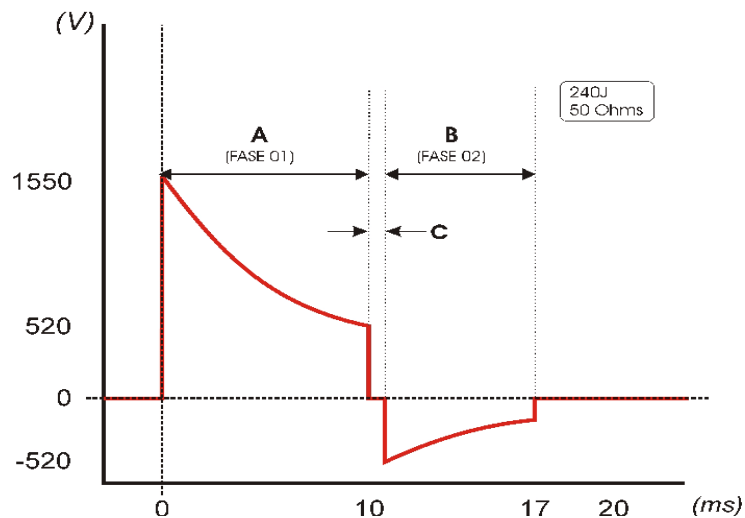


Figure 37 - Truncated Dual Phase Waveform

### 21.3 VARIATION ACCORDING TO PATIENT 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

The phase **B** corresponds to 2/3 of phase **A**

**Maximum width (A+B): 20 ms**

Dead-time (C): 0.5 ms

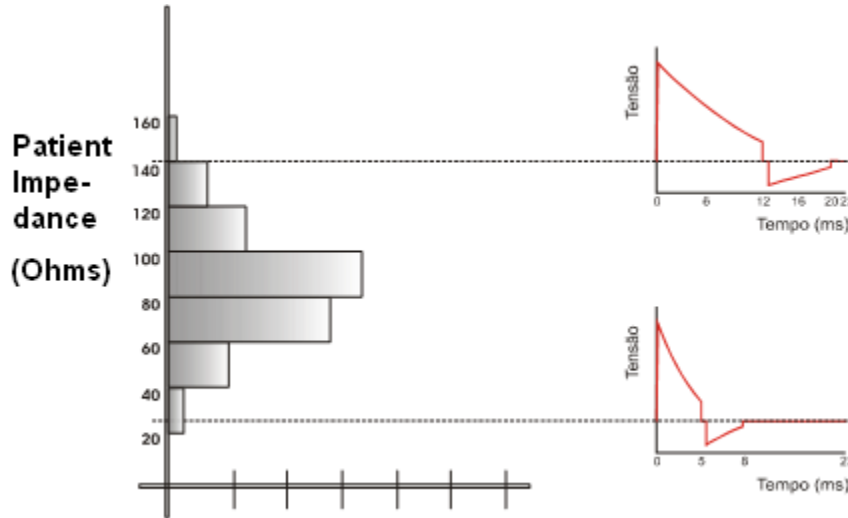


Figure 38 - Variation of waveform according to patient Impedance

**21.4 VARIATION OF DELIVERED ENERGY AND DURATION OF DEFIBRILLATION PHASES PERFORMED WITH TRUNCATE DUAL PHASE WAVEFORM**

Table 8

Capacitor Charge 1237 Volts (150 Joules)					
Impedance $\Omega$	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

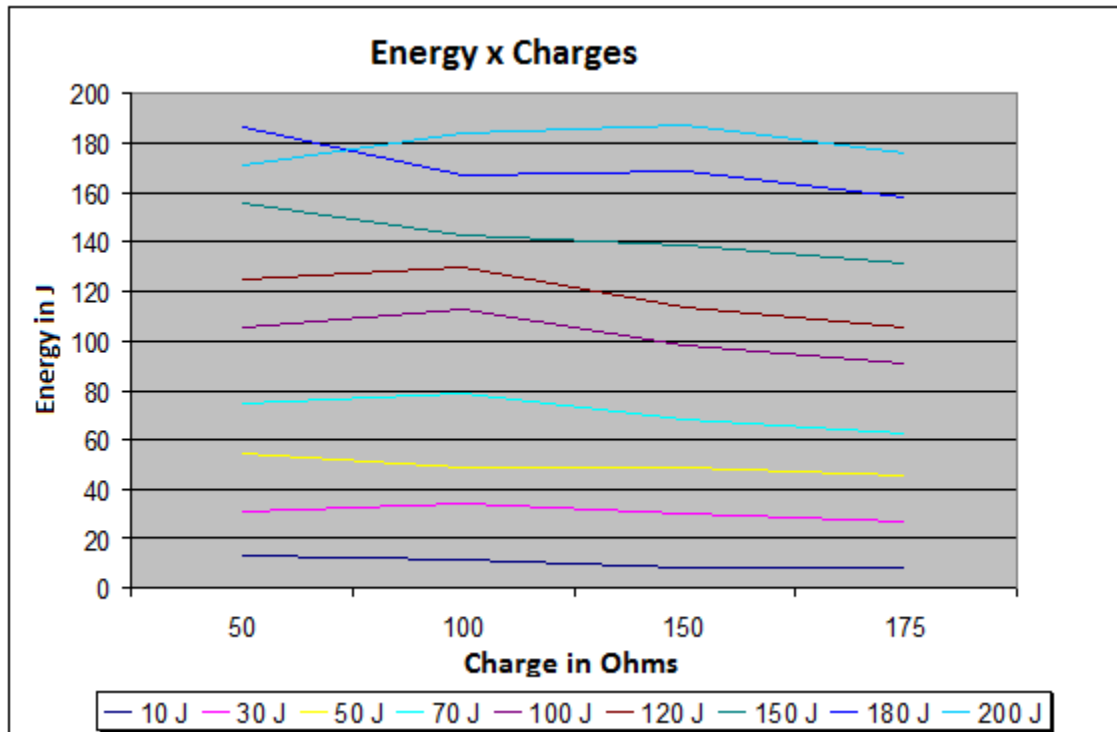
Table 9

Capacitor Charge 1428 Volts (200 Joules)					
Impedance $\Omega$	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

Table 10

Capacitor Charge 1428 Volts (240 Joules)					
Impedance $\Omega$	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

### 21.5 DELIVERED ENERGY X CHARGE



OBS: All of the data is subjected to a tolerance of  $\pm 15\%$

## 22. MAINTENANCE

### 22.1 CORRECTIVE AND PREVENTIVE MAINTENANCE

#### 22.1.1 PRECAUTIONS AND SPECIAL CARE

- Do not place any material on the equipment;
- Do not reuse disposable materials, after its use they should be discarded in appropriate places as special procedures for hospital waste;

- We recommend keeping some auxiliary materials such as surgical scissors, disposable razor to remove hair of the chest and disposable gloves, if needed.

***22.1.1.1 PREVENTIVE INSPECTIONS AND CLEANING***

For longer lifespan of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR and its accessories we recommend that the Inspections and Preventive Cleaning are performed regularly, as in the chart below.

Applied Verification	Frequency
Preventive Inspections	Half yearly
Cleaning	Weekly

Table 12

For each process, make sure that the equipment is switched off and its electrodes disconnected, thus avoiding the risk of shock.

This process should be performed following the criteria below:

***22.1.2 PREVENTIVE INSPECTIONS***

We recommend that an inspection is performed every six months in the E-HEART BIPHASIC DEFIBRILLATOR MONITOR and its accessories regardless of whether the equipment was used or not, following the instructions below:

- Check the validity / expiry date of the (disposable shock paddles) and the accessories functional status. If some of these accessories are near expiration or already expired or in bad conditions of use, we ask you to purchase a new material only by the manufacturer US DEFIBDO NORDESTE LTD. or any representative;
- Check the maintenance of equipment and its accessories, if there is any irregularity in the equipment it needs to be sent to the manufacturer for maintenance and in the case of the accessories, it should be bought new material only by the manufacturer;
- Perform the triggering test at the terminals of the equipment, following the instructions already described in the manual, if there is any irregularity, send it to the manufacturer or any authorized service center.

***22.1.3 CLEANING***

We recommend a cleaning to be performed every three months in the E-HEART BIPHASIC DEFIBRILLATOR MONITOR and its accessories, following the instructions below:

- Use a cloth lightly moistened with a solution of 70% alcohol, and perform the cleaning of equipment and its accessories;
- Do not spill any liquid on the equipment and / or its accessories;

- Do not immerse the equipment and its accessories in any liquid to perform the cleaning;
- To perform these cleanups, the labels contained in the equipment should not be removed.

### **22.1.4 PREVENTIVE MAINTENANCE**

The corrective and/or preventive maintenance of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR must only be performed exclusively by US DEFIBDO NORDESTE LTDA. or any representative, which frequency of this maintenance is up to the customer in accordance to the table below:

<b>Maintenance Frequency</b>	<b>Indication</b>
Every 3 months	Advised
Half-yearly	Recommended
Annually	Mandatory

Table 13

E-HEART BIPHASIC DEFIBRILLATOR MONITOR **requires no periodic calibration** because it is calibrated at the factory according to technical specifications, without the need of new calibrations.

## **23. ADDITIONAL INFORMATION**

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The E-HEART BIPHASIC DEFIBRILLATOR MONITOR is programmed with several security systems for failure detection, following the adequate hardware and software procedure. In order to assure the quality and reliability of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR, US DEFIB Medical Technologies LLC. Relates the procedures to assure security informing the DANGER and RISK according to the Norm NBR, IEC 60601-1-4: 2003 – general security prescriptions – Collateral Norm: Electromedical Programmable Systems, reducing the probability of systematic failure.

For better clarifying, doubts or request for Technical Assistance, please contact US DEFIB MEDICAL TECHONLOGIES LLC:

US DEFIBMEDICAL TECHNOLOGIES LLC.  
[www.usdefib.com](http://www.usdefib.com)

or: [info@usdefib.com](mailto:info@usdefib.com)

## **24. TROUBLESHOOTING**

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The user should always verify the conditions of the equipment. This section has the purpose of solving functionality problems of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR. The solutions suggested here involve common procedures that are easy for

the User to solve. These procedures do not involve the opening of the main cabinet AT ALL, of the modules or the permanent accessories. If the procedures here described do not solve the problems, the User should collect the equipment and contact the Technical Assistance of US DEFIB.

Among the items that should be observed are:

- The conditions of the cabinet (if it is in one piece or presents any cracks or dirty);
- The battery conditions (if it is charged or not);
- Are all the accessories required for the use present? (adults or pediatric electrodes, patient cables, oximetry sensor, among others)
- Are the accessories in good conditions?

<b>PROBLEM</b>	<b>RECOMMENDED ACTION</b>
The E-HEART BIPHASIC DEFIBRILLATOR MONITOR does not turn on.	Check the tripolar supply cable, making sure that it is correctly connected to the electricity.
The supply cable is in perfect conditions, but still the E-HEART BIPHASIC DEFIBRILLATOR MONITOR does not turn on.	Check the security fuse (located at the back part): After disconnecting the equipment from the electricity, open the fuse case and remove the fuse that is inside. Observe if the internal wire of the fuse is broken. If it is, replace the component for another of the same model. If you can't observe this wire, place a new fuse in order to eliminate this possibility (fuse model for replacement: F 3A 20AG) See Appendix A
Instability of the parameter curves	The main causes of the trace instability are: bad sensor and electrodes connection in the patient and the lack of grounding. Therefore, if that occurs, check if the connections on the patients are perfect and if the equipment is correctly grounded. Check for leak in the IBP cuff and the status of the cables and connectors of the other sensors.
Instability and noises in the ECG** trace	The majority of the cases of signal instability and excess of noises in the ECG trace is caused by the following factors: <ul style="list-style-type: none"> <li>➤ Use of damaged or inappropriate electrodes;</li> <li>➤ Inappropriate fixation of the electrodes in the patients;</li> <li>➤ Insufficient grounding of the</li> </ul>

	equipment; ➤ Absence of conductor gel;
--	---

Table 14

**\*\*NOTE:** For better information, check **Appendix B**

ATTENTION: If the recommended actions are not enough to correct the problem, contact the Authorized Technical Assistance by US Defib Medical Technonologies LLC.

IMPORTANT:

Every time that you withdraw or put the fuse in, do it with the equipment off.

## Errors Code in the NIBP Module

When the equipment detects some error related to the NIBP module, it will show a message on the display that should be observed. It can be one of the following:

MESSAGE SHOWN ON THE DISPLAY	ERROR DESCRIPTION	RECOMMENDED ACTION
Insufficient pressure	The module filled up for over 30 seconds	Do not repeat the action, check the connection tube and cuff.
	The pressure is not high enough to produce result.	Check the placement of the cuff.
<10mmHg or >250mmHg	Wrist pressure is smaller than 10mmHg (adult mode).	Check the placement of the cuff.
05mmHg or >150mmHg	Wrist pressure is smaller than 5mmHg (neonatal mode).	Check the placement of the cuff.
Excess movement	Excess movement	Try to calm the patient down.
Irregular measure	Irregular measure	Check waveform
Pulse without rhythm	The pulse measurement could not be performed.	Check the placement of the cuff.
The measure exceeded 90s	It measured for over 90 seconds (60 seconds for neonatal).	Only if the patient is adult, repeat the measurement; do not measure again if neonatal.
+100 neutral pulses	Over 100 pulses without any result were observed.	Check the device configuration.
High blood pressure	High blood pressure	Keep the patient in observation.
Weak pulse	Weak pulse	Check the replacement of the cuff and repeat the operation
Wrong cuff	Wrong cuff	Review the cuff connection

Table 15



## Capnography Messages

MESSAGE SHOWN ON THE DISPLAY	MESSAGE DESCRIPTION	RECOMMENDED ACTION
Initializing ...	Time spent by the capnography module to begin the measuring	None
Calibrating ...	While the sensor is calibrating	Wait approximately 1 minute for the end of the calibration
Check the flow of the entry line! or Check the flow of the outline! (Occlusion) Hit the reset option	These last messages appear when there is some dirt or fold on the tube that impedes the air passage.	Check the conditions of the tube and if necessary replace the filter. Finally, reset the capnography.

Table 16

## 25. PRECAUTIONS AND SPECIAL CARE

### 25.1 EQUIPMENT AND ACCESSORIES CLEANING AND DISINFECTION

- ❖ Do not put serum, needles or objects in general on the equipment.
- ❖ The case cleaning and disinfection should be done with a cloth lightly moistened with demineralized water and neutral liquid soap and other soft cloth moistened with demineralized water with 2% de hypochlorite. Do not use cleaning agents with abrasives, organic solvents, chloride, alcohol or hydrocarbon solvents. To prevent scratches on the panel exhibition screen (display), wipe carefully with a dry flannel or in case of dirty, a cloth lightly moistened in water, and remove dust or dirty particles.
- ❖ The labels existent on equipment are important, and for this reason cannot be removed.
- ❖ The cleaning and disinfection of permanent cables should be done at every equipment use. This cleaning is performed with a cloth lightly moistened with demineralized water and neutral liquid soap. After it dries, disinfect it using a moistened compress with ethylic alcohol at 70%.
- ❖ For *disposable electrodes and accessories*, after use, they should be discarded *in appropriate places* according to special procedures for hospital waste.
- ❖ For the capnography sensor cleaning, after the use, use a cloth moistened in demineralized water with a small quantity of neutral liquid soap and for disinfection, use gauze moistened in isopropyl alcohol.
- ❖ The pipes, water filter (side stream water-trap), mainstream sensor adaptor and miscellaneous are considered disposable, they must not be reused and should be disposed in hospital waste according to each hospital procedure.

- ❖ To clean the NIBP and hose, use a mild solution of soap and water and do not immerse it in chemicals, detergent and water. Accidental entry of fluid in the tubing or bladder can damage the module and equipment.

## **25.2 STORAGE AND TRANSPORT**

- ❖ ***Once you acquire the equipment, make sure that it doesn't have any sign of damage. Store all package materials, because they can be useful in case of posterior transport.***
  - Environment temperature range from -40° to 70° C
  - Relative humidity range from 10% to 100%
  - Atmospheric pressure range from 500 hPa to 1060 hPa (525mmHg to 795mmHg)

**Observation: US DEFIB Medical Technologies LLC**, does not warrant and is not responsible for any damage that occurs in the equipment that has been transported or stored in other package – it should only and exclusively be transported in its original package.

## **25.3 CABLES AND ACCESSORIES HANDLING**

- ❖ Before putting the equipment in contact with the patient, the operator should check if it is in normal operation condition. Observe regularly the expiry date and package integrity of the transthoracic electrodes.
- ❖ Only use accessories, consumable articles and other listed in this manual. US DEFIB does not warrant the equipment good operation with the use of unknown accessories, besides, US Defib is not responsible for equipment operation flaws or possible damages provoked by the unknown accessories.
- ❖ The capnography module could be damaged due to water filter reuse. Follow the accessories use instructions supplied by its manufacturer. The water filter must be replaced after each patient and / or according to the manufacturer use instructions.



### **WARNING!**

- ❖ In general, the EQUIPMENT Parts and ACCESSORIES of E-HEART BIPHASIC DEFIBRILLATOR MONITOR, destined to be in contact with biological tissues, cells or corporeal fluids are tested and analyzed according to the guidelines and principles of ISO 10993-1, which treats exclusively the bio-compatible of applied parts.
- ❖ US Defib warrants all permanent and disposable materials in contact with the patient do not cause any damage type or prejudicial physiological effect, as long as: the described procedures in this manual are respected; it is installed in appropriate medical place; it is used with correct accessories; it is operated by qualified people and that follow all precautions described in this User Manual.
- ❖ The disposable electrodes are ***Single Use***, therefore should not be re-sterilized.
- ❖ Do not use disposable electrodes if its package is damaged.

- ❖ There is risk for patient skin burns when applying defibrillation.
- ❖ Check the Operation Mode and other instructions on this manual.

## **25.4 POWER SUPPLY AND GROUNDING**

When a medical device is connected to the power grid, it may be observed the possibility of a current leakage from some point of its structure to the patient. When that occurs, a current may circulate between the equipment and the patient body that is eventually connected to it. The human body identifies a 1 mA current (on average) as a sensibility threshold. The currents with a superior value tend to cause muscle contractions or even burns and ventricular fibrillation. Currents below 1 mA become imperceptible under the point of view of a shock, but they can become lethal – generating a cardiac arrest or ventricular fibrillation – provided that a current flow in the heart of the order of 20 microamperes.

It is extremely important not to let the conductive part of the electrodes, transducers, connectors and the own patient to be in contact with other conductive parts of the equipment, including the “ground wire”. The safe isolation of the patient can only be assured if the cables and electrodes are correctly used by the operator.

The cable for potential equalization should be used when other equipment are used in the same patient or operator. This way, it is guaranteed that all of the metallic cases are under the same potential. For this, connect the terminal (banana plug) on the E-HEART BIPHASIC DEFIBRILLATOR MONITOR and the other extremity (alligator plug) on another equipment. That should be connected to a third equipment and so on. In case of cable reposition, it should be the same model as the original. The patient safe isolation can only be guaranteed if cables, electrodes, transducers, are listed in the manual.

The adequate grounding is required as a safety measure for the patient. We recommend, for the installation of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR, compliance with the requirements of the standard NBR 13534 – Electrical Installations on Health Assistance Establishments – Requirements for safety, published by ABNT in November, 1995.

In the lack of power supply the E-HEART BIPHASIC DEFIBRILLATOR MONITOR starts to operate through its internal battery (with duration from 30 minutes to 3 hours, depending on the equipment configuration). *When the power supply is normalized, the equipment itself will switch to the option of energy supply by the power grid, and the battery will recharge automatically.*

Even with the interruption of energy and right after its normalization, the equipment will not lose the programmed settings, preventing that the user would be required to set them again.

## **26. PHYSIOLOGICAL EFFECTS**

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In general, the E-HEART BIPHASIC DEFIBRILLATOR MONITOR doesn't offer any damage or causes any physiological effects, provided that it is installed to function in an

appropriate medical location, which it is used with the correct accessories, and that it is operated by qualified staff and that all of the precautions listed in the user's manual are followed.

We accentuate some basic procedures of special care:

### **26.1 ECG MODULE**

- ✓ The appropriate gel should be placed on the electrodes as indicated in this manual only at the moment of the use on the patient;
- ✓ If the electrode is pre gel, do not forget to check the validity date;
- ✓ Use permanent or disposable electrodes of good quality;
- ✓ All of these procedures must be followed independently of the patient (Adult or Pediatric / Neonatal);
- ✓ Other standard procedures should be followed too, already mentioned in the E-HEART BIPHASIC DEFIBRILLATOR MONITOR Description and its components, item: "Presentation" of this manual (see page 11);

### **26.2 NON INVASIVE BLOOD PRESSURE (NIBP)**

- ✓ You must use the appropriate cuff for each type of patient (Adult, teenager, pediatric and neonatal) and install it properly. Certify of the correct equipment configuration so that its use is in accordance with the patient, in order to make the pressure compatible with it and avoid, this way, the circulation interruption.

### **26.3 OXIMETRY MODULE**

- ✓ A sensor composed of LEDs and light sensors is placed on the patient finger (adult or pediatric). The sensor position must be changed every 4 hours to avoid possible skin burns, bruises or lesions to the skin;
- ✓ Neonatal and pediatric patients require special care, using another type of sensor, model on Y format; its position must be changed every 2 hours, to avoid possible skin burn, bruises or lesions to the skin. This application on a neonatal patient is performed by fixating an adhesive tape that cannot be used excessively to avoid lesions to the skin or incorrect readings;
- ✓ Other standard procedures listed in this manual (see pages 19 and 31) should also be followed.

### **26.4 DEFIBRILLATION MODULE**

- ✓ It is necessary to be careful not to discharge the defibrillator during the vulnerable period, because in that case a ventricular fibrillation could be induced;
- ✓ A special care should be taken regarding the different use conditions of the equipment: ***Defibrillation or Cardioversion.***

To use the equipment as a defibrillator, if the synchronism function is on, it will not perform the shock in the cases of ventricular fibrillation – “VF” – or Asystole (even when the paddles contacts are activated), because the applied charge part is waiting the information of the R wave presence, that is not identifiable (because the ECG is not on or because the R wave does not exist).

In this situation, the operator activates the paddle keys, but the equipment does not trigger. This can make the user think that the equipment has a defect, but, actually, the equipment only triggers when there is no sign of the R wave or when the person turns off the synchronism by pressing the synchronism key on the DEFIBRILLATOR MONITOR control panel.

In an opposite situation, if the objective is the cardioversion (synchronized discharge with the R wave) and the equipment is configured for defibrillation, when the buttons of the paddle trigger are pressed, the discharge will occur immediately, regardless of the presence of the R wave. Consequently, in the randomness of the trigger, the shock can occur during the vulnerable period and cause ventricular fibrillation.

## **26.5 INVASIVE BLOOD PRESSURE MODULE**

The reusable transducers cable should be verified to check if they are in perfect condition of use, because they are sealed and sterilized to avoid patient contamination.

## **26.6 CAPNOGRAPHY MODULE**

The adaptors should be verified both in the side stream system and in the mainstream system to check if they are clean, sterilized, in perfect condition to avoid a possible bacterial contamination.

## **27. ADVERSE EFFECTS**

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The US DEFIB, manufacturer of hospital-medical equipment, requests the users, to report possible defects or occurrences of any undesirable event, with the purpose to warrant the equipment quality. Therefore, any flaw or mal-function, contact the nearest Authorized Technical Support or directly with the sale consultant on our web site: [www.usdefib.com](http://www.usdefib.com) or Phone: +1 305 887 7552/ 7541

### **Important Observations:**

- ❖ Do not apply shock with short-circuited paddles in, because the trigger device could be damaged.
- ❖ For the functionality test of the defibrillation trigger at the triggering terminals, there must be an interval between the discharges and charges of at least 30 seconds;
- ❖ Always transport the equipment with Pads inside its transport case.

- ❖ It is recommended maintain the patient totally immobile during ECG analysis, with the purpose to avoid reading errors.

## **28. TECHNICAL SPECIFICATIONS**

According to harmonized technical standards	NBR IEC 60601-1, NBR IEC 60601-1-1, NBR IEC 60601-1-2, NBR IEC 60601-1-4, NBR IEC 60601-2-4, NBR IEC 60601-2-27, NBR IEC 60601-2-30, NBR IEC 60601-2-49, MDD 93/42/EEC, EN ISO 14971:2007, EN ISO 13485:2003 and others.
Protection type against electrical shock	Class I
Protection rating against electrical shock	Applicable of each CF and BF module
Closed equipment with splash protection and projection of water	IPX4
Use safety rating in presence of inflammable anesthetic mixture	Equipment is not adequate to use in presence of inflammable air mixture, O <sub>2</sub> and NO <sub>2</sub>
Operation mode	Continuous operation
Energization	Equipment energized internally
Printing format	1 channel Automatic and Manual
Cardiac frequency	10 – 300 bpm
Input impedance	< 10 MΩ
Frequency response	with filter: 0,5 – 35 Hz without filter: 0,5 – 100 Hz
Filters	AC: 60 – 50 Hz - Muscular: 35 Hz
Gain	5 – 10 – 20 mm/mV
Printing speed (of the Ecg trace)	12.5mm/s, 25 mm/s, 50mm/s
Printing type	Thermal Printer of High Resolution
Paper type	Thermal Paper
Paper dimensions	48 mm (width) x 30m (length) 48 mm (width) x 20m (length)
Liquid Crystal Display - LCD	Electroluminescent Color Display, 7 in ∠45° Opening angle.
AC Power supply	127/220 VAC – automatic – 50/60 Hz
Internal power supply DC (internal battery)	12 VDC 2300 mAh – Lithium-Polimer (LI-PO) - Rechargeable
Internal power supply DC (internal battery - optional)	12 VDC 2400 mAh – Lithium-Iron (LI-IR) - Rechargeable
External DC Power Supply (reserve)	2 to 15 hours of monitoring or 50 to 200 consecutive shocks respectively
AC Current	220V – 2,5 / 127V – 5 A maximum
Pads output voltage	256 - 1570 VDC
Pads output current at 50 ohms	50 A maximum



Charging time	≤5s for 200 J ≤6s for 360 J
Case	High impact with electric isolation
Discharge time	< 240 ms
Discharge time with synchronism	< 20 ms
Operation Temperature	0°C to + 50°C
Operation Humidity	30% to 75%
Dimensions	235 x 260 x 245 mm
Weight	Approximately 6.5 Kg or 14,3 pounds
Operation Atmospheric Pressure	700 Pa to 1060 Pa (525 mmHg 795 mmHg)

Table 17

### 28.1 PACEMAKER TECHNICAL SPECIFICATIONS (PM)

Pacemaker Modes	VVI, VOO, beep option
Protection against defibrillation	Internal suppressor diode, 400 joules
HF Filter	Filter for high frequency interference
Output pulse current	0 to 200 mA Stable in steps of 1mA
Output pulse frequency	30 to 200 ppm, adjustable in steps of 1ppm
Pulse width	0ms to 50ms adjustable in steps of 1ms
Power supply	Internal
Degree of protection against electric shock	CF Type Applied Part defibrillator proof

Table 18

### 28.2 CAPNOGRAPHY TECHNICAL SPECIFICATIONS (EtCO<sub>2</sub>)

Parameter reading method	<i>Side stream and Mainstream</i>
Parameters	EtCO <sub>2</sub> , CO <sub>2</sub> Inhalation, Respiratory frequency
Unit	%
CO <sub>2</sub> 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 seconds.
Compensation	N <sub>2</sub> O, O <sub>2</sub> , and Deflurane
Protection level against electric shock	Applied part CF type defibrillator proof
<b>ALARMS</b>	
Type	Manual for maximum and minimum limits of respiratory frequency, EtCO <sub>2</sub> , stable condition and CO <sub>2</sub> inhalation.
Silent alarm	Sound alarm disabled for 2 minutes
Characteristics	Disables audio, adjust tone and



	volume, alarm delay.
Limits	CO2 Inhalation: 0 to 10 mmHg Respiratory frequency: 0 to 35 RPM EtCO2: 0 to 50 mmHg

**28.3 INVASIVE BLOOD PRESSURE TECHNICAL SPECIFICATIONS (IBP)**

Reading range	- 50 to 300 mmHg
Tolerance	± 2%
Frequency response	0 to 40 Hz
Isolation	± 8000V, 360J defibrillator
Zero adjust	± 50 mmHg
Transformation standard	5µ V/V/mmHg
Digital pressure display	Systolic, Diastolic, average value
Protection level against electric shock	CF type applied type defibrillation proof
Limit values	0 to 300 mmHg
<b>ALARMS</b>	Manual to maximum and minimum value
Silent alarm	Sonorous alarm disabled for 120s
Retard	5 to 75 seconds

Table 20

**28.4 ECG TECHNICAL SPECIFICATIONS**

Input impedance	> 10 Mohms
Frequency response	Monitor: 0,5 to 25 Hz Diagnosis: 0,05 to 100 Hz
Filters	Notch: 60 – 50 Hz Muscular: Low-pass: 35 Hz
Gains	5 – 10 – 20 mm/Vm
Beating reading range	0 to 300 rpm
Tolerance	± 6 rpm
Input	3 or 5 way electrodes cable
Output	Analogical ECG sign 1V/mVpp
Offset (potential)	± 300 mV
Current leak	< 10 uA
Defibrillation protection	Maximum of 360J
Baseline recovery	6 seconds after defibrillation
Systolic indicator (QRS)	Audible beep
Calibration sign	1 mVpp ± 3 %
Protection level against electric shocks	CF type applied part defibrillation proof
<b>ALARMS</b>	
Limits	25 to 220 BPM
Adjust	Manual; maximum and minimum limits

Silent alarm	Sound beep disabled for 120 seconds
Retard	0 to 7 seconds

Table 21

**28.5 NON INVASIVE BLOOD PRESSURE TECHNICAL SPECIFICATIONS (NIBP)**

Reading range	Oscilometric
Operation mode	Manual / automatic
Time programming	1 to 60 minutes
Protection level against electric shock	CF type applied type defibrillation proof
Reading range:	
Adult systolic	40 to 300 mmHg
Adult Diastolic	40 to 300 mmHg
Average Adult	40 to 300 mmHg
Neonatal systolic	20 to 150 mmHg
Neonatal diastolic	20 to 150 mmHg
Average Neonatal	20 to 150 mmHg
Maximum blood pressure:	
Adult	300 mmHG
Neonatal	150 MMhg
<b>ALARMS</b>	
Type	Manual; maximum and minimum limits
Retard	0 to 7 seconds

Table 22

**28.6 OXIMETRY TECHNICAL SPECIFICATIONS**

Pulse reading range	20 to 250 RPM
Tolerance	± 3 rpm
Resolution	1 bpm
SpO <sub>2</sub> reading range	40 to 100 %
Tolerance	70 to 100% ± 2 digits, finger clip 70 to 100% ± 4 digits, ear clip 70 to 95% ± 3 digits, neonatal Under 70%, undefined for all of the sensors
Protection level against electric shock	BF type applied type defibrillation proof
<b>ALARMS</b>	
Type	Manual; maximum and minimum limits
Limits	40 to 100%
Silent alarm	Sonorous alarm disabled for 120s
Retard	0 to 7 seconds

Table 23

### 28.7 DISPOSABLE ACCESSORIES MANUFACTURERS

Accessory / Module	Manufacturer/Model
<b>ECG</b>	
ECG Conductive Gel Register in Ministry of Health od Brazil: 80184040004	<b>Suprimed Industry and Commerce Ltd.</b> Gel In Shape
ECG Disposable Electrode Register in Ministry of Health od Brazil: 10002070152	<b>3M do Brasil</b> Adult Electrode Model Child/Neonatal Electrode Model Adult/Pediatric Electrode Model
Thermal Sensitive Paper Register in Ministry of Health od Brazil: Not required	<b>Daru</b> 48mm x 16mm x 30m thermal paper
<b>Other</b>	
Pacemaker Paddles set (PADs)	<b>FIAB SpA</b> F7959, F7959P
AED Mode Paddles Set (PADs) – exclusive use	<b>FIAB SpA</b> F7959, F7959P
IBP - Complete kit	MEDEX MX9604A
Child Nasal Circuit	RESPIRONICS
Adult intubated line	RESPIRONICS
Adult air adapter	RESPIRONICS
LDS air adapter	RESPIRONICS
Side stream filter (Water strap)	RESPIRONICS
Nasal line	RESPIRONICS

Table 24

### 28.8 PERMANENT ACCESSORIES MANUFACTURERS

Accessory / Module	Manufacturer/Model
<b>ECG</b>	
5 ways patient cable (exclusive use)	BIO-LIGHT or GE DINAMAP
3 ways patient cable (exclusive use)	BIO-LIGHT or GE DINAMAP
Permanent Electrodes	POLIMED / AG802
<b>SPO2</b>	
SPO <sub>2</sub> Adult Sensor	BIO-LIGHT or NELLCOR
SPO <sub>2</sub> Neonatal Sensor	BIO-LIGHT or NELLCOR
SPO <sub>2</sub> Y Pediatric Sensor	BIO-LIGHT or NELLCOR
<b>Others</b>	
3-pole Power cable (MAINS CABLE)	ITALCABOS / Italflex
Ambulance cable	US Defib– n° AM–001–MP
Neonatal External Paddles	US Defib– n° AC–0030
Adult / Pediatric External Paddles	US Defib– n° AC–0011
Extension cable for PADs	US Defib– n° AC–0015–EX
Mainstream CO2 sensor	RESPIRONICS
Invasive Blood Pressure Sensor	MEDEX – n° MX960
Blood Pressure Transducer	MEDEX – n° MX960
Clamp Support (Sergeant)	MEDEX – n° MX260

NIBP Cuff	BAUMANOMETER
Transducer support	MEDEX – n° MX262

Table 25

## 29. APPENDIX A – FUSE REPLACEMENT

### 29.1 FUSE CHANGE PROCEDURE

For the fuse replacement proceed the following steps:

- 1 – Check if the equipment is on. If it is, turn it off by pressing the **ON/OFF** key on the frontal panel.
- 2 – Remove the power cable from the plug and from the equipment;
- 3 – With the help of a screwdriver, remove the cover of the fuse compartment, as shown in **figure A.1** and **figure A.2** below:

**1.a)** Introduce the screwdriver in the fillister of the fuse compartment and press it (moderately) until it reaches the limit.

**1.b)** Still pressing the screwdriver, turn it approximately 45° on the counterclockwise until it reaches the limit. Now, just remove the screwdriver and the set will be released for the fuse removal. Check if the fuse is broken (observing a thin wire in its interior), **figure A.2**. If it is, replace it with the reserve or with another from the same type and characteristic).

**1.c)** To replace the fuse in the fuse compartment, proceed the opposite way, changing only the screwdriver turn (**figure A.1c**) on the opposite way.

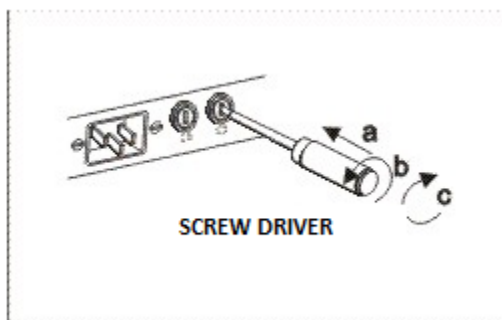


Figure A.1

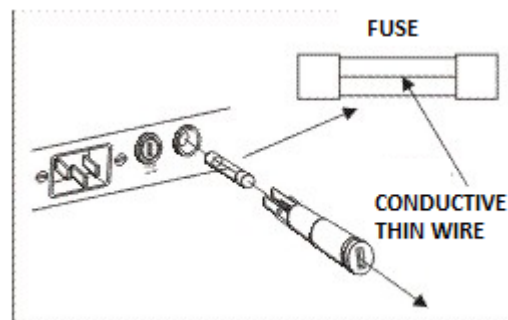


Figure A.2

### Procedure for fuses replacement



**WARNING!**

Always when withdrawing or replacing the fuse, do it with the equipment off.

## 30. APPENDIX B – ECG TRACE INSTABILITY AND NOISES

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When you realize degradation on the output sign, as frequent saturations (sign loss), noise presence juxtaposed to the ECG (even with the filters activation) and wave morphology deformities, check carefully the following items:

1. Status of the electrodes connection cable. Observe the existence of cracks or breaks over the cable that must be homogenous in all its extension.
2. Integrity of cable extremities and junctions, close to the connector, to the connection box and the electrodes. These points are more susceptible to handling and, therefore, more susceptible to breaks.
3. If verified a possible damage to the connection cable, it should be tested by specialized staff and, if necessary, replaced.
4. Status of the clip type electrodes and precordial, observing, especially, the metallic part that stays in contact with the patient skin. There should not be any evidence of oxidation or dirt.
5. Status of the disposable electrodes that should be of good quality and used just once.
6. Type of conductor gel used on electrodes that should be proper for ECG. **Other gel types**, as ultra-sound gel and /or for other aims, **are not indicated**, because they can, not only introduce noises and make the exam unviable, but also cause the early wearing off of the electrodes.
7. Preparation of the patient skin before fixating the electrodes. The excess of skin oil, along with the layer of dead epithelial cells that naturally accumulates on the epidermis, increases the impedance of the electrode-patient interface, causing the degradation of the cardiac sign and introducing noises of several sources on the ECG. Proceed the preparations on the electrodes fixation location according to the usual clinic practice (hair cleaning and shaving, if necessary).
8. Grounding of the power supply plug where the E-HEART BIPHASIC DEFIBRILLATOR MONITOR is installed. Observe the recommendations about power supply and grounding described in this manual (see page 50)
9. Proximity to external interference sources (radio-frequency generators and power lines), if that occurs, move them away.
10. Equipment filters adjustment.
11. For additional support, don't hesitate to contact US DEFIB MEDICAL TECHNOLOGIES LLC.

### 30.1 THE MOST COMMON ECG INTERFERENCES

The ECG signal registered in normal conditions, without noise contamination is shown on figure B1. If the ECG acquisition conditions are not appropriate, four main types of interference may occur: **(1)** AC Power supply interference; **(2)** Muscular artifacts (“muscular tremors”); **(3)** Baseline displacement (drift); and **(4)** Movement artifacts.

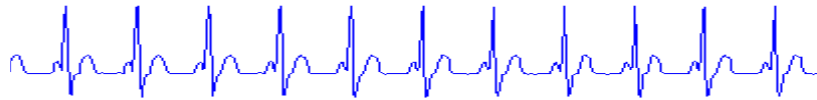


Figure B1: Noiseless Electrocardiogram

### 30.2 AC POWER SUPPLY INTERFERENCE

The power supply induces a specific frequency interference (50 or 60 Hz), which juxtaposes to the ECG signal, as shown in picture B2. The main causes of contamination by the AC network may be related as follows:

- Presence of magnetic fields next to the equipment and electrode cables, as X-ray, electrical transmission lines, reactors for fluorescent lamps and so on;
- Insufficient connection to the grounding;
- Electrode cable of the patient and supply cable crossing;
- Break or disruption of the electrode cable. In this case, the interference is of a high amplitude and appears exclusively on the derivation related to the damaged cable;
- Loose or worn out electrode, lack of conductor gel or insufficient preparation of the patient skin. These conditions increase the impedance of the electrode-skin interface and deregulate the signal impedance read by the equipment, compromising the rejection effect of common mode of the input amplifiers. In these cases, the trace normally appears saturated.

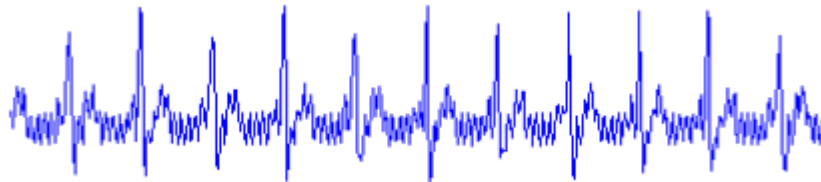


Figure B2: ECG with 60 Hz interference on the AC Power Supply

### 30.3 MUSCLE ARTIFACTS

The muscular activity appears juxtaposed to the ECG as irregular and inconstant waves, as the trace exemplified on figure B3. The main causes are listed below:

- Unquiet patient, due to cold or discomfort during the exam;
- Specific pathologies (for example: Parkinson's Disease).

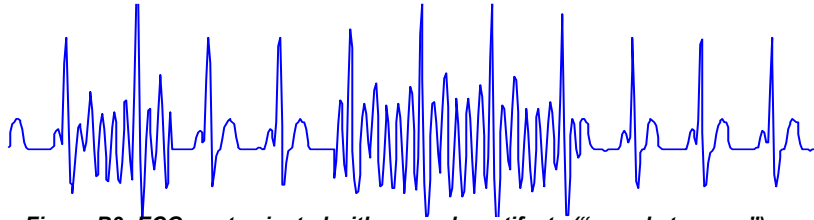


Figure B3: ECG contaminated with muscular artifacts ("muscle tremors")

### 30.4 BASELINE DISPLACEMENTS

This trace disturb causes an ECG baseline displacement regarding the central zero of the graphic (center of the printing paper), taking a while to return to the normal condition (depending on the order of the internal filters of the equipment). The trace can momentarily raise difficulties to the exam (figure B4). The main causes are related as follows:

- Inappropriate connection of the electrode to the patient, with little gel or using worn out electrodes;
- Fixation tape of the electrodes poorly positioned or without adherence;
- Presence of strange particles (dirt, for example) between electrode and patient skin;
- Rupture in the junction between patient and electrode. In this case, normally appears abrupt oscillations between the graphic extremities, with delay on the return to the baseline.

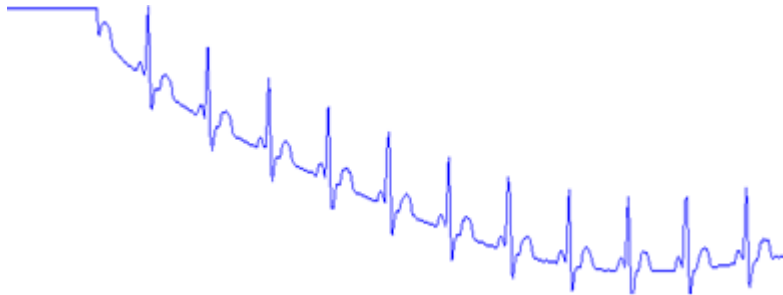


Figure B4: ECG with oscillation on the baseline (drift)

### 30.5 MOVEMENT ARTIFACTS

The movement artifacts have its origin on the interface of contact between the electrode, the conductor gel and the patient skin. Actually, the electrode works, not only as an electric sensor, but performs a more complex electrochemical transduction, the frequency scouted by the equipment is placed between 0 and 300 ppm with a 3% accuracy; transforming the ionic activity of the skin surface – that reflects the internal electrical generators, among them the cardiac activity – in electrical current.



When it is fixed to the patient body, through a layer of conductor gel, the electrode establishes conditions of chemical balance in this interface, generating a double potential layer called half-cell potential. The input amplifier realizes this potential as a constant tension level and it does not interfere on the ECG measuring. However, when the electrode is moved, the interface balance is momentarily altered, so it is necessary to achieve a new condition of balance. This transient disturbance produces an artifact of electrical movement (Figure B5), which may be of the order of several times the biometrical sign to be measured. Still, this type of noise is predominantly of a low frequency, spectrally juxtaposing to the ECG and making impossible its elimination through simple filtering.

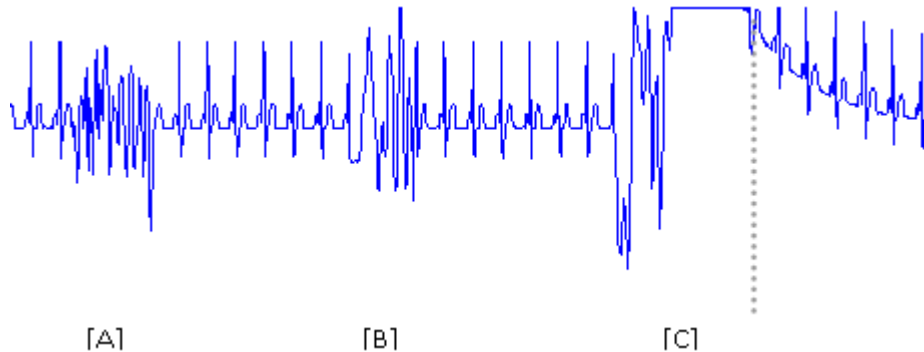
The correct application of the conductor gel between electrode and patient skin and electrode utilization of Ag-AgCl type reduce substantially the movement artifacts generation, stabilizing the electrode-gel-skin interface.

The appropriate preparation of the location of skin contact with the electrode also contributes to obtaining a more defined ECG sign. The superficial layer of the skin (corner extract) is composed of dead epithelial cells, besides having a fat pellicle, presenting high impedance characteristics. After cleaning and abrasion of the location – for example, using gauze moistened with alcohol – the impedance of skin contact may be reduced from 200KOhms to something around 5KOhms in 90% of the patients.

Some practices may help minimize the movement artifacts on the ECG:

1. Always use electrodes in perfect condition, preferentially of Ag-AgCl.
2. The electrodes of all derivations must be made from the same material, to minimize the resultant DC potential and impede the amplifier saturation.
3. Clean the skin with alcohol to remove the oil and layer of dead cells.
4. Use gel or conductive paste with a Cl basis, specific for ECG exams; never use other kind of gels (for example, gel for ultra-sound exam).
5. Apply the gel only under the contact area of the electrode.
6. Never apply abrasive or conductive paste on the injured skin.
7. If it is necessary to remove the hair excess, perform the trimming and not the shaving of the area.
8. Use the proper adhesive tape (micro-pore or patch) on the back of the electrodes and fixate it to the place of contact with the skin, certifying that there is a light pressure of the electrode against the skin.
9. When the connection is well done, if the electrodes are moved, you should observe a little momentary artifact, with a quick restitution of the trace to normal.
10. In long registers, the conductor gel tends to dry, modifying the interface characteristics; in these cases (for example, registers of verge of bed) proceed the periodic replacement of the electrodes on the patient, preferentially in a place slightly different from the previous.
11. Clean the skin after the exam, applying gauze moistened with neutral soap for complete removal of the conductor gel.

12. Clean the electrodes with running water. If necessary, use water under pressure (water pick). Dry them totally before storing them.



*Figure B5: ECG with contamination by movement artifacts: In [A] and [B] the detection of cardiac sign is impossible and in [C] the amplifier even saturates, taking a while to return to the baseline.*

### 31. APPENDIX C – MANUFACTURER GUIDELINES AND DECLARATION – ELECTROMAGNETIC EMISSIONS


<p>The E-HEART BIPHASIC DEFIBRILLATOR MONITOR was designed to operate in any environment presented below. The client or user of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR must assure its operation in one of those environments.</p>			
RF EMISSIONS MEASUREMENT	CONFORMITY	ELECTROMAGNETIC ENVIRONMENT - ORIENTATION	
RF emissions according to ABNT NBR IEC CISPR 11	Group 1	The E-HEART BIPHASIC DEFIBRILLATOR MONITOR uses RF energy exclusively for its internal functions. So, its RF emissions are very low and it's not probable that they cause any interference in electronic equipment nearby.	
RF emissions according to ABNT NBR IEC CISPR 11	Class B	The E-HEART BIPHASIC DEFIBRILLATOR MONITOR is appropriate for use in all of the residential environments and those that are directly connected to the public network of distribution of low voltage electricity that supplies edifications for domestic use.	
Harmonic emissions IEC 61000-3-3	Class A		
Emissions due to Scintillation Tension Float IEC 61000-3-3	Conform		

Table C1

<p>The E-HEART BIPHASIC DEFIBRILLATOR MONITOR was designed to operate in any environment presented below. The client or user of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR must assure its operation in one of those environments.</p>			
Interference resistance test	Essay level of ABNT NBR IEC	Conformity level	Electromagnetic Environment - Orientation

<b>60601</b>			
<b>Static Electricity Discharge (SED) according to IEC 61000-4-2</b>	± 6kV per contact ± 8kV by air	Conform	The floors must be made of wood or cement, and should have ceramic tiles. If the floor is made of synthetic material, the relative humidity must be of at least 30%.
<b>Fast transient electric disturbances / triggers according to IEC 61000-4-4</b>	± 2kV in the supply lines ± 1kV in the input / output lines	Conform	Electricity supply quality should correspond to the voltage supplied in a typical commercial environment or hospital.
<b>Over voltages according to IEC 61000-4-5</b>	± 1kV differential mode ± 2kV common mode	Conform	
<b>Voltage drops, brief interruptions and floatation on the supplied voltage according to IEC 61000-4-11</b>	< 5% Ut ( > 95% of voltage drop in Ut) for 0,5 cycle 40% Ut (60% of voltage drop in Ut) for 5 cycles 70% Ut (30% of voltage drop in Ut) for 25 cycles < 5% Ut ( >95% of voltage drop in Ut) for 5 seconds	Conform	The quality of the supplied voltage quality should correspond to the voltage supplied in a typical commercial environment or hospital. If the user of the <b>E-HEART BIPHASIC DEFIBRILLATOR MONITOR</b> requires continuous operation even when there are interruptions on the electricity supply, the <b>E-HEART BIPHASIC DEFIBRILLATOR MONITOR</b> should receive energy without interruptions or with a battery.
<b>Magnetic field in the supplied frequency (50/60 Hz) according to IEC 61000-4-8</b>	3 A/m	Conform	Magnetic fields in the supply frequency must be in levels that are characteristic of a typical location on a hospital environment or commercial typical.
<b>Note:</b> Ut is the AC supply voltage before applying the essay level.			

Table C2

<b>The E-HEART BIPHASIC DEFIBRILLATOR MONITOR was designed to operate in any environment presented below. The client or user of the E-HEART BIPHASIC DEFIBRILLATOR MONITOR must assure its operation in one of those environments.</b>			
<b>Interference resistance test</b> 	<b>Essay level of ABNT NBR IEC 60601</b>	<b>Conformity level</b>	<b>Electromagnetic Environment – Orientation</b>
<b>Conducted RF IEC 61000-4-6</b>	3 Vrms 150 kHz to 80 Mhz	[V1]V Conform	Portable and mobile RF communication equipment should only be used next to any part of E-

<p><b>Radiated IEC 61000-4-3</b></p>	<p>3 V/m 80 Mhz to 2,5 Ghz</p>	<p>[E1] V/m Conform</p>	<p><b>HEART DEFIBRILLATOR BIPHASIC MONITOR</b>, including cables, with a separation distance smaller than the recommended. This safe distance will be calculated from the equation that is applicable to the transmitter frequency. Recommended Separation Distance: <math>d=[3,5/V1]\sqrt{P}</math> <math>d=[3,5/V1]\sqrt{P}</math> 80 MHz to 800 MHz <math>d=[7/E1]\sqrt{P}</math> 800 MHz to 2,5 GHz where <math>P</math> is the maximum nominal potency of the transmitter output in watts (w), according to the transmitter manufacturer, and <math>d</math> is the recommended separation distance in meters (m). It is recommended that The field intensity established by the RF transmitter, as determined through an electromagnetical inspection on then location, <sup>a</sup> is smaller than the conformity level in each frequency range.<sup>°</sup> It may occur interference around the equipment marked with the following symbol.</p> 
<p><b>Note 1</b> In 80 Mhz and 800 MHz, it is applied a higher frequency range. <b>Note 2</b> These guidelines may not be applicable in all of the situations. The electromagnetic propagation is affected by structures, objects and people absorption and reflection.</p>			
<p><sup>a</sup> The field intensities established by the fixed transmitters, such as radio base, telephone (wireless cell phone) and mobile terrestrial radios, amateur radio, AM and FM radio transmissions and TV transmission may not be theoretically predicted with accuracy. To evaluate the electromagnetical environment due to RF fixed transmitters, it is recommended an electromagnetical inspection on the location. If the field intensity measured on the location that the <b>E-HEART BIPHASIC DEFIBRILLATOR MONITOR</b> is used exceeds the conformity level used above, the <b>E-HEART BIPHASIC DEFIBRILLATOR MONITOR</b> should be observed to check if the operation is normal. If an abnormal performance is observed, additional procedures may be necessary, such as reorientation or replacement of the <b>E-HEART BIPHASIC DEFIBRILLATOR MONITOR</b>. <sup>°</sup> Above the frequency range of 150 KHz to 80 MHz, the field intensity should be smaller than [V1] V/m</p>			

Table C3

## 32. TECHNICAL ASSISTANCE

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### Permanent Technical Assistance

**Mr. Owner,**

The US Defib Medical Technologies LLC has available a large list of representative and technical support.

In order to be able to offer a personalized service, we ask you to send a registering form. It seeks to update our databank to better address authorized technical support service for each region, training and others.

For complaints, doubts, suggestions and technical support, contact with our **CAS** (Customer Assistance Service) bellow:



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Manufacturer: US Defib Medical Techonologies LLC  
Address : 7831 NW 72<sup>nd</sup> Avenue, Medley - Miami  
Zip Code: 33166  
Phone: +1 305 8877552 / +1 305 8877541  
Legal Representative: Amanda Coelho Rodrigues Felix



**OBELIS s.a**  
AV. DE TERVUEREN 34 , BTE 44,  
BRUSSELS CITY – BELGIUM

**CUSTOMERS REGISTERING TEMPLATE**



EQUIPAMENT DESCRIPTION	Serial Number
<b>DESFIBRILLADOR MONITOR E-HEART</b>	

CUSTOMER NAME	
ADDRESS:	
CITY :	STATE:
PHONE:	FAX:

TECHNICAL SUPPORT
<p><b>Attention:</b></p> <p style="text-align: center;"><b>Mr. Owner</b></p> <p>Please fill in the blanks above in order to update our databank for questioning and make sure you send us the registration form in order to get a customized service</p>



**US DEFIB MEDICAL TECHNOLOGIES LLC  
WARRANTY CERTIFICATE**

The US DEFIB MEDICAL TECHNOLOGIES assures Legal Warranty against any manufacturing defect applicable to the following conditions:

1- The valid warranty period lasts 12 (twelve) months from the emission of the sales receipt related to the purchase date of the equipment by the customer with obligatory model identification, serial number and equipment characteristics.

2- US DEFIB does not grant any warranty for equipment that is not accompanied by the customer sales receipt.

**2.1 - Prescribed conditions of this warranty**

- Any defect found during installation and (or) product use, the customer should contact US DEFIB MEDICAL immediately, that will contact the authorized representatives listed on this manual. They, on the other hand, can only perform any intervention with FORMAL AUTHORIZATION, following the validity terms of this authorization.

- The manufacturer is responsible for the replacement of parts and products that present abnormalities proved to be manufacturing defects, besides the involved labor in this process.

- Sensors, cables in general and accessories required for the correct product operation are warranted, against manufacturing defects, by a legal term of 90 (ninety) days from the product purchase date indicated in the customer sales receipt.

**2.2 The warranty will be cancelled when:**

I.

1 – The equipment's serial number is removed or changed in any way.

2 – The equipment was installed or used in a way different than the one indicated in the USER MANUAL.

3 – The equipment was used with cables, sensors, accessories or consumable materials not indicated by US DEFIB or outside normal use conditions, as expiry date or period of use.

4 - The customer will lose his warranty right during the mentioned period of 12(twelve) months if the equipment:

a – had a maintenance or repair performed by a non-authorized professional, according to the list provided by the manufacturer.

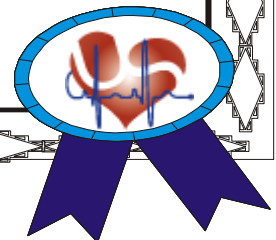
b – was used in a way different than the one described in the user manual.

c – suffer any damages caused by accidents and natural phenomenon.

5 – The manufacturer will not be responsible for expenses related to installations, damaged products or accessories due to transport accident, handling, scratches, kneading, non-operation or flaws caused by electric energy supply shortage.

In places where there isn't a US DEFIB authorized technical support, the expenses of device transport or authorized technician displacement to the place where the equipment is, it will be charged at the service petitioner Customer.

Serial N°





## **33. VERSION CONTROL**

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### **USER MANUAL**

PROJECT NAME: E-HEART BIPHASICO DEFIBRILLATOR MONITOR  
CODENOME ENG<sup>a</sup>: CBI400

### **VERSION CONTROL**

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<b>Ver</b>	<b>Date</b>	<b>Author</b>	<b>Description</b>
1.0	Nov, 06, 2011	Luara Delfin	First Issue