User Manual

CardioStart Defibrillator Monitor

US DEFIB
MEDICAL TECHNOLOGIES

Manufacturer: US Defib Medical Technologies
Address : 7831 NW 72nd AVENUE, MEDLEY - MIAMI
Zip Code: 33166
Phone: +1 305 8877552 / +1 305 8877541
Legal Representative: Amanda Felix

EC REP

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

GMP Good Manufacturing Practice Compliant

ISO 9001:2008 SGS

ISO 13485:2003 SGS

CE 0120

FOREWORD

Congratulations for acquiring the US DEFIB equipment.

This product incorporates up to date technology. We are sure you will be very satisfied with the CARDIOSTART DEFIBRILLATOR MONITOR.

READ ALL OF THE OPERATION INSTRUCTIONS BEFORE operating CARDIOSTART DEFIBRILLATOR MONITOR.

This User Manual contains all of the required information for a full interaction with the equipment, from information concerning operation to necessary care for better conservation of CARDIOSTART DEFIBRILLATOR MONITOR. This equipment should only be used by a qualified professional to provide **advanced life support.**

After you finish reading the entire User Manual, keep it in a protected location so you can refer to it at any moment. A future reference could be required for new users. The permanent consultation of this manual is a requirement to obtain the equipment best performance, correct operation, and provide additional safety to the operator as well as to the patient.

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

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

SUMMARY

1. WARNINGS

WARNING!
The CARDIOSTART DEFIBRILLATOR MONITOR was designed for clinical monitoring applications with guaranteed operation when used correctly, in an appropriate medical place and by qualified staff.

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 CARDIOSTART DEFIBRILLATOR MONITOR.

WARNING!
CARDIOSTART 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 the defibrillator monitor during electrical discharge (shock).

WARNING!
When installing the equipment, make sure that 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 CARDIOSTART DEFIBRILLATOR MONITOR (different equipment connected to same patient), should be connected to the equalization terminals in order to perform equally the potential among them, 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 sorts of services or future equipment upgrades and its

parts can only be performed by professionals trained 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 CARDIOSTART DEFIBRILLATOR MONITOR is used simultaneously with an electric scalpel, the orientations about equipment operation indicated in this manual in the presence of high frequency devices must be observed.


WARNING!
The CARDIOSTART DEFIBRILLATOR MONITOR equipment is destined for connection to a public network. And it doesn't suffer any interference or electromagnetic disturbance in its module operation – according to the recommendations from NBR IEC 60601-1-2 / CISPR 11 – Limits and methods of measuring the characteristics of electromagnetic disturbance in radio-frequency of industrial, scientific and medical equipment (ISM).


WARNING!
The CARDIOSTART DEFIBRILLATOR MONITOR equipment is designed for public network connection, and it does not suffer any interference or electromagnetical 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!
In order to prevent fire or shock risks, avoid operating or fitting the defibrillator monitor near a water source; 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 the discharge effects of a cardiac defibrillator or when used simultaneously with an equipment that is operating in high frequency.


WARNING!
The protection against the effects of a cardiac defibrillator electrical discharge is contained in the modes inside the equipment. The sensors and cables do not have additional protection against electrical discharge of the cardiac defibrillator or when used simultaneously with another equipment operated with 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 CARDIOSTART DEFIBRILLATOR MONITOR, designed to be in physical contact with biological tissues, cells and corporeal fluids are tested according to the guidelines and principles of ISO 10993-1, 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 lifespan. 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 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 provide, with agreement, all 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.

2. SYMBOLS AND ABBREVIATIONS


Grounding terminal for protection


Dangerous Electric Voltage


Attention! Check accompanying documents


Continuous Current


Defibrillation proof, BF type applied part.


Defibrillation proof, CF type applied part.


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


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


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


Minimum and maximum temperature

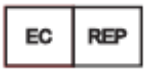
Number 5: indicates maximum pilling of five units

Indicates medical equipment and, therefore, it deserves special treatment


Indicates composition with recyclable raw material


Manufacturer


Manufacturing date



Representative in the European Community

Symbol of compliance with the European Community

Electrical and Electronic Equipment Waste - Dispose it separate from other objects.

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, l/m	Speed	Meter per second, millimeter per second, beat per second, liters per minute
Ω	Impedance	Ohms
J	Energy	Joules
m3, mm3	Volume	Cubic meters, cubic millimeters

4. ACRONYMS USED IN THIS USER MANUAL

- **CLAS:** Cardiology Life Advanced Support;
- **AHA:** American Heart Association;
- **BLS:** Life Basic Support;
- **IDM:** Implantable Defibrillator Monitor
- **ECG:** Electrocardiogram;
- **VF:** Ventricular Fibrillation;
- **Hb:** Hemoglobin (**Hbc:** Hemoglobin concentration);
- **HbO_2:**Oxihemoglobin (**$cHbO_2$:**oxihemoglobin concentration);
- **PRI:** Printer
- **INCOR:** Heart Institute;
- **LDE:** Light Diode Emissary

- **LCD:** Liquid Crystal Display;
- **PM:** Pacemaker
- **SAN:**Sinu-atrial Node;
- **ABP:** Arterial Pressure
- **CRA:** Cardio Respiratory Arrest;
- **NIBP:** Non-Invasive Blood Pressure;
- **IBP:** Invasive Blood Pressure
- **DBI:** Defibrillator
- **CPR:** Cardiopulmonary Resuscitation;
- **BSC:** Brazilian Cardiology Society;
- **SPO_2:** Oxygen Saturation;
- **VT:** Ventricular Tachycardia;
- **ICU :** Intensive Care Unit;
- **VOO:** Pacemaker Asynchronous Mode;
- **VVI:** Pacemaker on Demand Mode.

5. THROWING AWAY THE EQUIPMENT

To prevent the contamination of the environment, people or other equipment, be sure to have disinfected and decontaminated the equipment properly before you dispose of it, according to the national laws for equipment with electrical content and electronic parts. To discard parts and accessories, follow local regulations concerning medical waste.

Electrical and electronic equipment waste. Discard it separately from other objects of the establishment. Refer to local regulations for waste disposal (consult the European Directive 2002/96/EC).

6. DESCRIPTION OF CARDIOSTART DEFIBRILLATOR MONITOR AND ITS COMPONENTS

6.1 PRESENTATION

The CARDIOSTART DEFIBRILLATOR MONITOR is a portable with dual phase equipment able to reverse arrhythmias of ventricular fibrillation or ventricular tachycardia with no pulse in adult and pediatric patients, as well as cardioversion of arrhythmias which may be required.

The Dual-Phase defibrillation technology requires less energy than that used by the conventional single-phase producing a better performance in patient treatment. This equipment can be used in any hospital and rescue units, air and ground, providing excellent care in advanced life support.

This equipment includes several functions like patient defibrillation and vital signs monitoring. It is possible to visualize on the equipment screen: ECG curve, Non-Invasive Blood Pressure (NIBP), Invasive Blood Pressure (IBP), Oxygen Blood Saturation Scouting (SPO2), Capnography (CO2), external multi programmable Pacemaker (to reproduce or regulate the cardiac rhythm).

The CARDIOSTART DEFIBRILLATOR MONITOR features high resolution colorful liquid crystal display (LCD), which allows perfect visualization from different angles. It also features the optional touch screen display.

It is possible to record all of the events occurred on the equipment in two ways, at the client discretion:

- Through the memory card (compact Flash).
  - In order to visualize the data, just connect the card to the computer and transfer the data through the AEDRescue software;

- By recording the events in the internal storage of the device.
  - To visualize the data just use the USB port to transfer the data to the AEDRescue software.

With all these parameters the CARDIOSTART DEFIBRILLATOR MONITOR assists in monitoring the patient and increases the rate of human survival in a cardiac arrest.

6.2 CHARACTERISTICS

CARDIOSTART DEFIBRILLATOR MONITOR features factory default settings:

- ECG Monitoring and cardiac frequency;
- Dual-Phase Defibrillator Monitor;
- Rechargeable Battery.

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

- Functional arterial oxygen saturation monitoring (SPO2);
- Non-invasive transcutaneous external pacemaker;
- Non-invasive pressure monitoring (NIBP);
- Capnography (CO2);
- Invasive Blood Pressure (IBP);
- Automated external defibrillator monitor mode (AED) with voice and text commands;
- Thermal Printer;
- Drug software;
- Ventilation / intubation Software.

NOTE: Any of the mentioned parameters can be integrated to the Defibrillator Monitor at the discretion of the specific needs of each client, and it does not change the intended features of the product.

7. OVERVIEW*

CARDIOSTART DEFIBRILLATOR MONITOR

Image1 - CARDIOSTART DEFIBRILLATOR MONITOR

7.1 PARTS LIST ACCESSORIES

- 01 conductive gel tube 100 ml;
- 01 Interchangeable and permanent external electrodes pair (Paddles) (adult/child);
- 01 5-way patient cable;
- 50 AG/AGCL Disposable electrodes;
- 01 Adult NIBP Cuff - only in versions with NIBP;
- 01 Pediatric NIBP Cuff - only in versions with NIBP;

- 01 IBP kit - only in versions with IBP;
- 01 CO2 kit - only in versions with Capnography;
- 01 Adult SpO2 Sensor Clip - only in versions with SpO2;
- 01 3-pole power supply cable;
- 01 Grounding equalization cable;
- 01 CD with User manual;
- Software for card reading (in versions with Data Card);
- 01 Pair of Adult / Pediatric Disposable External Electrodes - only in versions with pacemaker and AED Mode;
- 01 Roll of Thermal Printer Paper - only in versions with Thermal Printer;
- Warranty Certificate.

7.2 OPTIONAL ACCESSORIES

- 3-way Patient cable (ECG);
- Pediatric oximetry sensor type clip;
- Ear oximetry sensor;
- Adult / Pediatric / Neonatal type Y oximetry sensor;
- Shock paddles for Internal adult / pediatric defibrillation and cardioversion;
- Compact Flash Memory Card;
- Transport Case destined for transport and also safer storage of CARDIOSTART 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, pediatric or neonatal;
- Mobile Crash Cart;
- Equipment support.

The images contained herein are merely illustrative

7.3 ACCESSORIES PHOTO

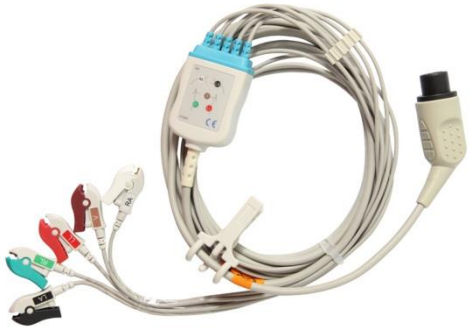


Image2 - 5-Way Patient Cable (permanent use accessory)

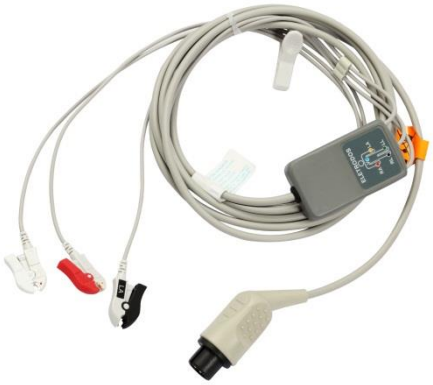


Image3 - 3-Way Patient Cable (permanent use accessory) - optional

Image4 -ECG Contact Gel (disposable content)

Image5 - Disposable ECG Electrodes

Image6 - Shock Electrodes for defibrillation and cardioversion shock (permanent material)

Image7–Pediatric Disposable Adhesive Electrodes Paddles – AED MODE (single-use material)

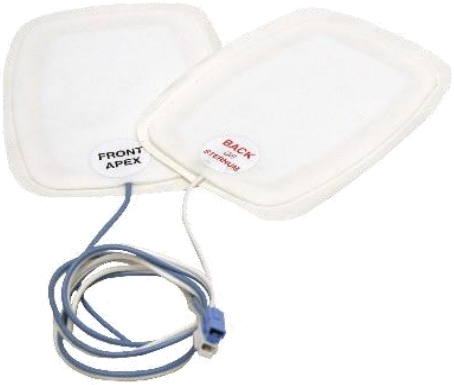


Image8–AdultDisposable Adhesive Electrodes Paddles– External paddle Model F7959W (single-use material)

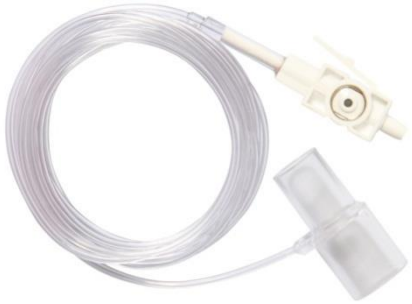


Image9–Capnography Intubation Line– optional accessory

Image10 - Capnography tube adaptor – Optional accessory

Image11 - Capnography nasal line – optional accessory

Image12 - Adult oximetry sensor (permanent use accessory)- optional

Image13 - Adult /Pediatric / Neonatal oximetry sensor (permanent use accessory) - optional

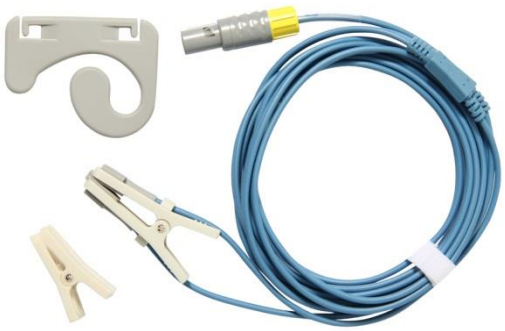


Image14 - Ear Oximetry Sensor (permanent use accessory) – optional

Image15 - Disposable Oximetry Sensor – Optional

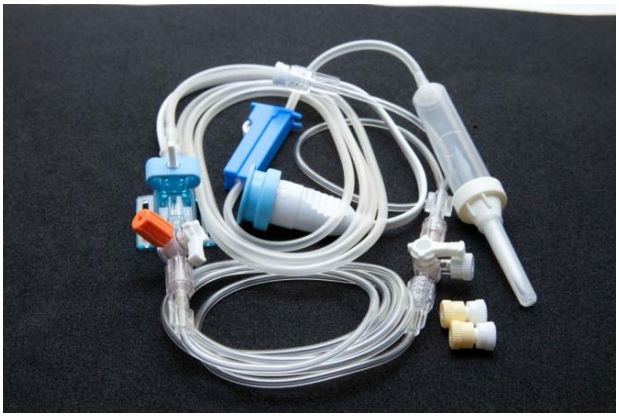


Image16 - Invasive pressure transducer - optional

Image17 - Medex Invasive Blood Pressure Communication Cable - Optional

Image18 - Invasive Pressure Transducer Support

Image19 - NIB Cuff– Optional in Neonatal, Pediatric, Adult and obese sizes (permanent use accessory).

NOT AVAILABLE

Image20–Transportation Bag – optional

Image21–Tripolar Power Cable (permanent use accessory- Exclusive)

Image22 - Thermal sensitive paper (disposable)– optional

Image23 - External Battery Interconnection Cable (permanent use accessory)- optional

Image24–Compact Flash 256MB Memory Card - Optional accessory.

8. PARTS AND COMMANDS IDENTIFICATION OF CARDIOSTART DEFIBRILLATOR MONITOR

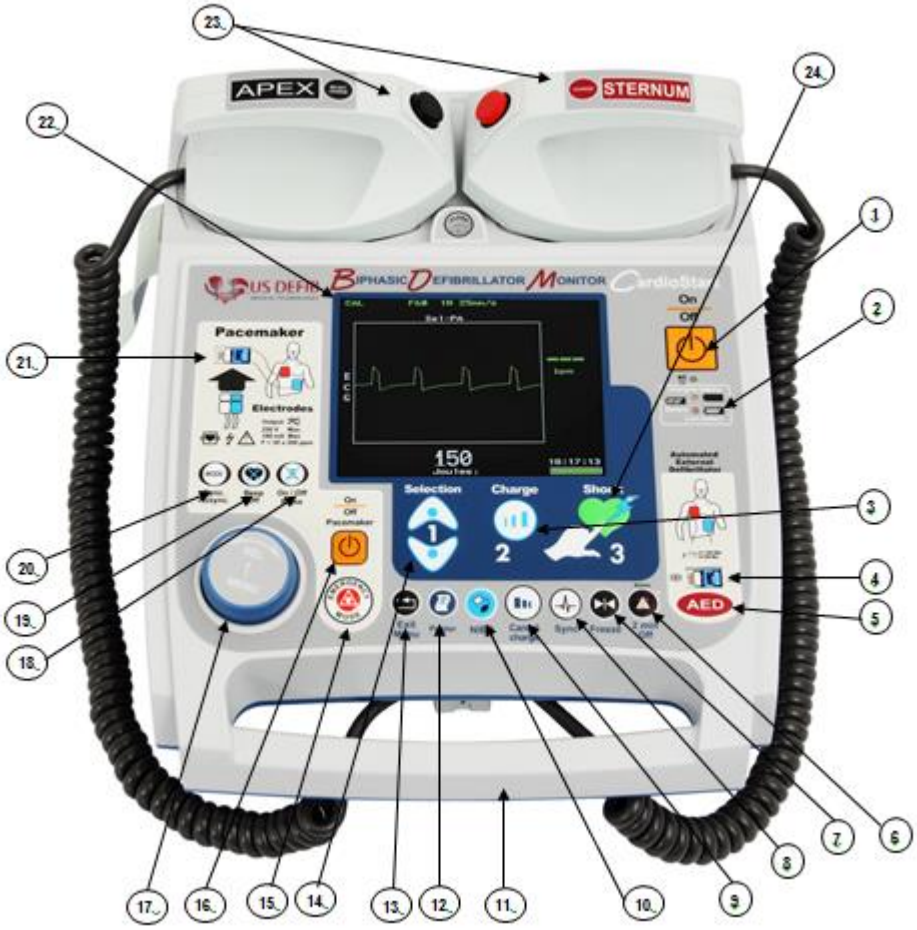
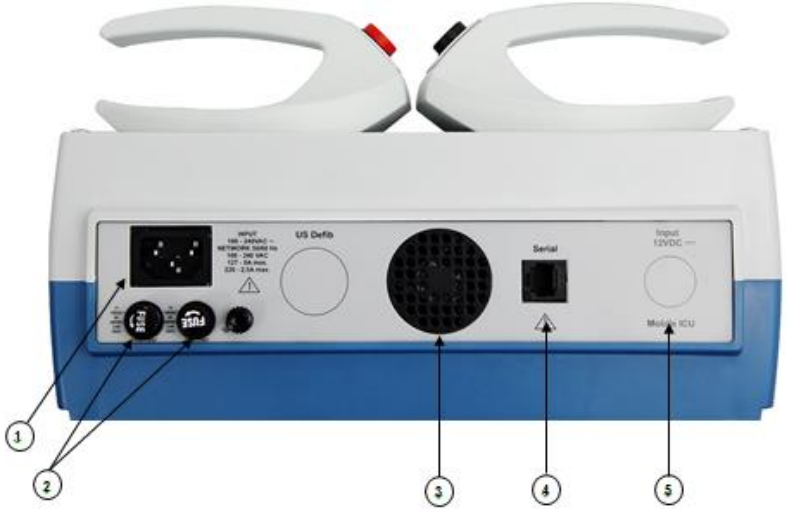


Image25 - CARDIOSTART DEFIBRILLATOR MONITOR Command Identification

1 - On/Off;
2 –Battery Status Indicator;
3 –AED Mode Electrode Entry Connector;
4 - AED Mode On/Off;
5 - Disables Alarm for 2 minutes;
6 – Freeze screen;
7 – Enable / Disable Synchronism;
8 – Charge Erase;
9 –NIBP Trigger;
10- Print;
11- Exit Menu;
12- Pacemaker Emergency Mode;
13- . Pacemaker On/Off switch;
14- Navigation Button;
15- Pacemaker Pulse On/Off;
16- Disables Pacemaker Beep;
17- Select between Synchronous and Asynchronous Mode;
18- Pacemaker Electrodes Entry Connector;
19- 5,7”Color Display;
20- Adult /Pediatric Shock Paddles;
21- Treatment Button;
22- Charge Button;
23- Charge Selection Key;
24- Transportation Handle;
25- Test Born;
26 –Compact Flash Card Entry;
27- Trigger Button;



1 –Tripolar Power Connector;
2 – Fuse Port;
3 – Cooling Fan;
4 –RJ 45 Connector;
5 – Ambulance Connector Cable.

Image26 - CARDIOSTART DEFIBRILLATOR MONITOR Parts Identification – Side and Rear View

8.1 CARDIOSTART DEFIBRILLATOR MONITOR CHARACTERISTICS

- Defibrillation with truncated dual phase exponential waveform, with charge of 1 to 200 Joules and optional of 1 to 360 Joules, with operation instructions on the panel of CARDIOSTART DEFIBRILLATOR MONITOR;

- Defibrillation Range / Scale:

✓200Joules Version:

- Pediatric Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50 Joules.
- Adult Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200 Joules.

✓270Joules Version:

- Pediatric Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50 Joules.
- Adult Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200, 270 Joules.

✓ 360Joules Version:

- Pediatric Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50 Joules.
- Adult Mode: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 15, 20, 25, 30, 35, 40, 45, 50, 70, 90, 100, 110, 120, 150, 180, 200, 240, 360 Joules.

- Cardiostart Defibrillator Monitor features intelligent safety system that limits the charge for internal use for 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 Erase Charge Key, at the user discretion at any time;
- Trigger indicator for the equipment routine tests through flash (neon lamp);
- Clock/Date;
- Shock Counter;
- It features interchangeable adult/pediatric permanent paddles;
- The shock paddles are fixed on the equipment through ima;
- Visual indicator of contact on the PADDLES(optional); It monitors the contact of the paddles on the patient's chest via barragraph on the display and optionally on the paddles itself via led;
- Performs self-test when it is switched on;
- Rechargeable internal battery;
- External reserve batteries with specific charger (optional);
- Battery Status Indicator– Low, charging and charged;
- Capacity to perform up to 150 shocks (200J) with full load (new battery fully charged);
- Color liquid crystal display, which shows the ECG Trace, SPO_2, NIBP, Pacemaker, AED Mode, Printer, Capnography and Invasive Blood Pressure (IBP) - optional, beep indicator, battery status, alarms, pre and post shock programming parameters, indicating the selected energy for trigger, PADDLE contact and impedance indicator;
- Event memory, via Data Card, including curve, date and time, of approximately 256 MB, that corresponds to over 100 hours of continuous recording (optional).
- Internal event memory with transference though the USB port including curve, date and time, with approximately 6hours of continuous recording - optional;
- Charge Automatic Adjustment;
- Available in the following language: Portuguese, English or Spanish;
- It features voice and text command with volume control (optional) to instruct the rescuer during CPR sequence;
- When in "SYNCHRONIZED MODE", it performs synchronized triggering with QRS complex, with energy delivery time of <20ms;

- Maximum time for signal stabilization: approximately 6 seconds after ideal connection of the cable to the patient;
- It features beep for CPR orientation (100 Comp/min) in AED MODE;
- Full system of sound and visual alarms with the possibility to setup maximum and minimum values, including besides the technical for Loose Electrode and physiological alarms for Asystole, Tachycardia, Bradycardia and Fibrillation;
- When CARDIOSTAR DEFIBRILLATOR MONITOR is configured in automatic mode, the energy charge follows a trigger sequence of 150J, 200J and 200J;
- Charging Time of 3 seconds for 200J and 5 seconds for 360J;
- Pacemaker pulse detection;
- 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 Arrhythmia's Analysis Software (optional);
- Software with impedance and PADDLES contact indicator(Optional);
- Charge level selection by the "APEX" paddle key and charge by pressing the "STERNUM" paddle key.

8.2 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 Paddles, adhesive Pacemaker transthoracic Pads, through reusable defibrillator Pads and/or through ECG patient cable;
- Cardiac frequency reading: from 10 to 300 rpm;
- Protection against defibrillation and cardioversion;
- Filter rejects frequency band of 35Hz and 60Hz, pass low frequency 120Hz and pass high frequency 0,5Hz;
- QRS detector;
- Pacemaker pulse detector and rejection;

- Synchronized beep with QRS;
- Beep indicator on display;
- Cardiac Frequency Indicator on display (bpm);
- Pacemaker Indicator on display;
- Speed control for curve tracing (12.5, 25.0 or 50.0 mm/s);
- ECG channel gain control in ½, 1 and 2N; optionally gains of ¼, and 4N may be setup.

8.3 PATIENT ANALYSIS SYSTEM – AED MODE

- Automatic system of ECG evaluation that detects QRS complexes and automatically identifies malignant arrhythmias (ventricular tachycardia and ventricular fibrillation) that require defibrillation;
- Synchronism with "R" wave in case of QRS complex presence (when in "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 features voice and text command with volume control and to instruct the rescuer during CPR sequence.

8.4 THERMAL PRINTER CHARACTERISTICS

- High-resolution thermal printer with automatic and manual registration of one channel, with optional of two 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;
- It allows manual records, independent of the defibrillation by the paddles;
- This record is made on thermal-sensitive paper of 48 mm (width) x 30 m (length) for GSI printer; 48 mm (width) x 20 m (length) or 75 mm (width) x 20 m (length) for TR-50 or SP-48 printers;
- Print speed of 12,5-25-50 mm / sec, or others speeds at the User discretion, when requested.
- Data that are printed on thermal paper:
  - Field for signature;

- Field to write the patient's name;
- Field to write the patient's age and weight;
- Date and time;
- Printing Beginning and Ending Time;
- Number of applied shocks;
- NIBP - Average / Diastolic / Systolic;
- Blood saturationSPO2 (%);
- ECG: Amplitude on the Curve / Bypass / Speed / Heart Rate;
- Other data may be deployed if requested by the client.

8.5 PULSE OXIMETRY CHARACTERISTICS

- Pulse oximetry, with plethysmographic curve and saturation indication of numeric oxygen in percentile;
- Amplitude of the plethysmographic wave adjusted on the screen;
- It features complete alarms system and audio and visual indication of the level of SPO_2, though the pulse signal tone; the alarms volumes and the audio pulse indicator are adjusted independently; audiovisual adjustable alarms: low and high level of $SPO_2$and cardiac frequency (bradycardia and tachycardia); non-detected pulse alarms; disconnected sensor; searching for pulse;
- Good response at low perfusion;
- The frequency measured by the equipment is situated approximately between 10 and 300 bpm, with a precision of 3%;
- The pulse oximetry is used in situations where the oxygen saturation (SPO_2) is essential, in anesthesia, during surgeries and in post-surgery, patients under intensive care treatment, in ambulances or even at home. It has been proven efficient, with a sample range from 70 to 100% with accuracy of 3%. The scouted saturation accuracy is undetermined when it is between 0% and 69%
- The oximetry used in the equipment measures the functional saturation where oxygenated hemoglobin is expressed as a percentage of the hemoglobin that can transport oxygen.
- The oxygen saturation, SPO2, is defined by the concentration rate of two of the main forms of blood hemoglobin: the arterial hemoglobin or oxyhemoglobin (HbO2) and the concentration of HbO2 + unsaturated hemoglobin (Hb), i.e., cHbO2+cHb. The oxygen saturation is expressed in percentage and calculated by the formulae below:

$$SPO2 = \frac{cHbO2}{cHbO2 + Hbc} \times 100\%$$

Available technologies (optional): Masimo, Nellcor

8.6 PACEMAKER TECHNICAL SPECIFICATION AND CHARACTERISTICS

The external pacemaker was designed to stimulate 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 bradyasystole during emergency;
- During and after cardiac surgery;
- To favor the insertion of a transvenous stimulator electrode.

8.6.1 PACEMAKER CHARACTERISTICS

The external pacemaker applies, in the heart, a square wave of variables frequency and current intensity. Its function is to stimulate the organ to perform the heartbeat. The pacemaker uses electrical stimulation to reproduce or regulate the rhythm of the heart. Its function is to provide pulses for cardiac stimulation. These pulses have two characteristics to be adjusted: the number of pulses per minute (PPM) and current intensity (mA). It features three possible modes of operation of the pacemaker:

- **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 value on the menu, maintaining the stimulus until the patient natural cardiac frequency returns to a value that is equal or greater to that configured to avoid inhibition of abnormal or extra systole “T” waves. The pacemaker has a 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.

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

- Stimulation current: Without connected charge: 200 mA; Off: 0 mA;
- Power supply: 12V;
- ECG capture through its adhesive Paddles;

- Stimulation output through the adhesive paddles;

External pacemaker, transthoracic, non-invasive, multi-programmable; in modes of 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 10 and 300 bpm. Other frequencies may be optionally configured according to the user choice.

NOTE: The operator can control the stimulation process by means of CARDIOSTART DEFIBRILLATOR MONITOR keyboard. The stimulation pulse application can be visualized through a LED panel.

8.6.2 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;
- Emergency: VOO 70 ppm - 100 mA 20 ms;
- Protection against defibrillation discharge: Up to 400 joules;
- Other specifications may be configured at user discretion.

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 must only be operated by qualified technical staff;

8.7 NON-INVASIVE BLOOD PRESSURE (NIBP)

The parameter of noninvasive pressure uses the oscillometric method for the calculation of non-invasive blood pressure and provides systolic, mean and diastolic blood pressure. A cuff is used for transmitting changes in blood pressure caused by blood flow.

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

- It may be used in adult, pediatric, child 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;
- Resolution 1mmHg.

⚠ Only use cuffs supplied by US DEFIB or US DEFIB. Other brands may compromise the equipment precision.

. ⚠ The cuff must not be applied on the same limb or extremity of the SPO_2 sensor. When the cuff inflates, the SPO_2monitoring may be affected.

⚠ Do not place the cuff on any limb or extremity where intravenous infusion is being used or any other area where the blood circulation is compromised.

8.8 INVASIVE BLOOD PRESSURE MODULE (IP)

The most accurate way of measuring blood pressure, it is performed by using the invasive method. This method is performed through a catheter inserted into the artery which is connected to a fluid column. The pressure measurement is obtained by means of a pressure transducer that performs the reading. By this method, there are numerical values and curves that correspond to blood pressure measurement.

8.8.1 FUNCTIONAL CHARACTERISTICS OF THE IBP

- The trace is shown continuously on the screen;
- Selection/Visualization of the curve/blood pressure values: PA, AO, VE, AE, PVC, AD, VD, PAP, PCP, PIC, Right, Left. Esf.

- Maximum, average and minimum blood pressures shown continuously on the screen (mmHg);
- Manual control of gain 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;

8.9 CAPNOGRAPHY MODULE (ETCO2)

The CO2 produced during the cellular metabolism is transported by the venous system to the atrium and to the right ventricle, gets to the loans and diffuses itself from the capillaries to the alveoli. From the alveoli, this gas is finally eliminated with the exhaled mixture. The amount of CO2 that reaches the alveolar spaces is proportional to the cardiac output and to the pulmonary blood flux. The elimination of this gas for the environment depends on the ventilation accuracy. Thus, the measurement of carbon dioxide in exhaled at the end-tidal (ETCO2) allows continuous monitoring and noninvasive alveolar gas, indirectly reflecting its circulating.

The Capnography is a non-invasive measurement, which graphical presentation is held according to the patient's respiratory rate (rpm) and involves the measurement of exhaled carbon dioxide to the end of expiration (EtCO) and the inspired (FICO).

CO2 detection can be performed through two types of sensors: Side stream and Mainstream. Both sensors have self-calibration system that does not require the use of specific gases for periodic calibration.

8.9.1 FUNCTIONAL CHARACTERISTICS OF THE CAPNOGRAPHY

- Side stream and Mainstream type Sensors;
- Exhaled CO2 curve showed continuously on the screen;
- Auto calibration optional procedure that dismisses the specific gases use for periodic calibration;
- Disposable water filter;
- Disposable nasal line;
- Disposable intubated line;
- Disposable tube adaptor.

8.10 ST SEGMENT ANALYSIS

The acute myocardial infarction is a necrosis of a part of the heart muscle by interrupting the blood flow in the coronary arteries. Early diagnosis is a fundamental factor for the reduction of mortality and of the possible consequences for the patient. One of the most accurate for this diagnosis is the identification of anomalies in ST segment though the electrocardiogram. Patients with ST Segment positive deflection may be suffering a myocardial infarction and patients with ST Segment depression in aVR and v1 can be suffering a myocardial ischemia (malnutrition of a certain part of the myocardium)

8.10.1 ST SEGMENT ANALYSIS CHARACTERISTICS

The first step in order to make the analysis of the ST segment is to digitize 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:

$$III = II - I$$

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

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

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

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 whether the duration of the PR interval is varying or not.

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 of 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 QRS complex normal.
- 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 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. This ST Segment analysis 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 assists the physician in 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 final diagnosis must come from the physician.

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

"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."

8.11 CARDIAC ARRHYTHMIAS ANALYSIS

The arrhythmia's symptoms are quite variable, and they may be silent and can be diagnosed by a physician during a cardiologic. The most common symptom is palpitation, fainting, dizziness, shortness of breath, discomfort, feeling of heaviness in the chest, weakness, fatigue, chest pain, among others.

Cardiac arrhythmias can be classified in various ways, depending on frequency, formation mechanism, place of origin, etc. 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.

There are 3 basic types of bradycardia, depending on the location where the electrical system of the heart occurs. When blockage occurs in the sinus node (the heart's natural pacemaker), it is called the sinus node dysfunction. In addition, the electrical impulse can occur in the atrioventricular node or in the right or left of the electrical system of the heart.

The important thing is that all of these blockages can lead to a decrease in the number of heartbeat and cause symptoms such as dizziness and fainting. Depending on the type of blockage, and the symptoms that it is causing, there may be a need to deploy an artificial pacemaker.

- **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.
  - **Atrium Tachycardia:** it is a rapid heart rhythm that originates in the atrium;
  - **Atrium 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;
  - **Atrium 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:

- **Atrium:** 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 atrium arrhythmias.

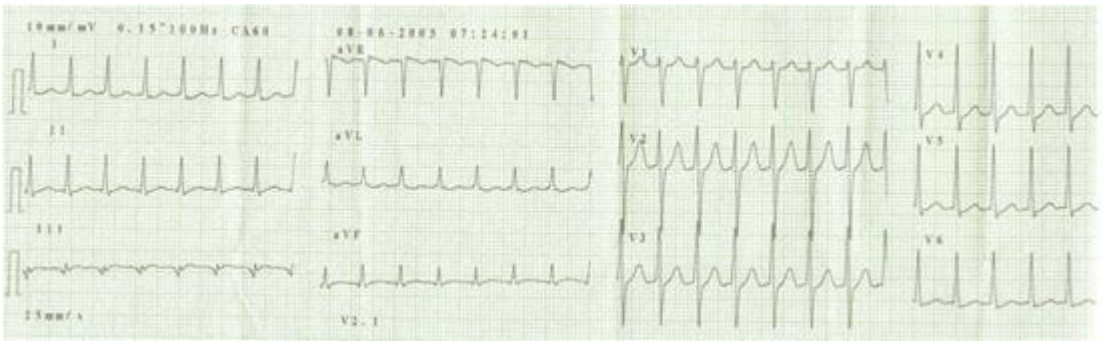


Image27 - Atrium Arrhythmia Electrocardiogram

- **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.

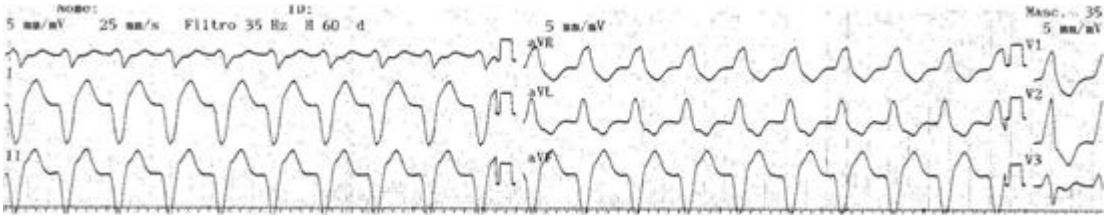


Image28 - Ventricular Arrhythmia Electrocardiogram

9. 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;
- Quality and integrity of the shock PADDLES;
- Shock PADDLES contact to the patient's skin;
- Proper connection of the shock PADDLES to the equipment;
- It provides a rapid assessment of the patient impedance.

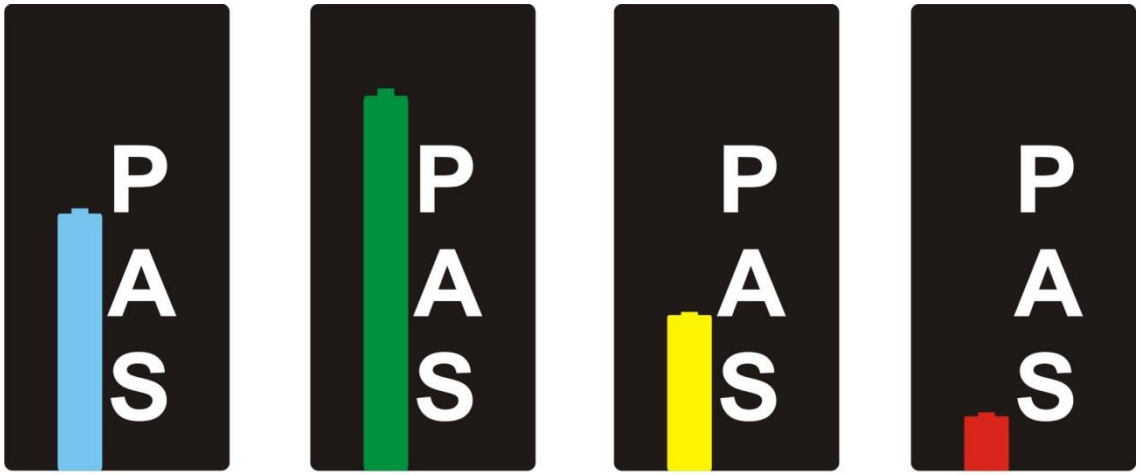
Attention:

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 [ç] to 150 [ç])

Section	Impedance Range [ç]	Description Contact	Presented Color
1	20 < IMP ≤ 300	GOOD	Blue
2	30 < IMP ≤ 150	GREAT	Green
3	150 < IMP ≤ 180	REGULAR	Yellow
4	180 < IMP	LOW	Red

Impedance Indicator



Section 1 **Section 2** **Section 3** **Section 4**

In addition to the indicator in the display of the equipment, the STERNUM paddle contains an indicator of contact with the patient (Image 22). This led assists in positioning the paddles at the time of the shock.

- Green: Good Contact;
- Red blinking: Low / Bad Contact.

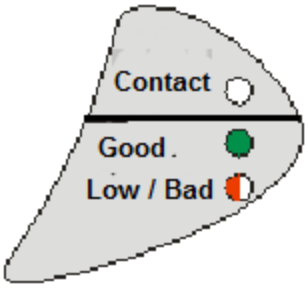


Image29 - Indicator of paddle contact to the patient

10. COMPACT FLASH CARD SLOT (OPTIONAL)

It is possible to record the curves, date and time of the events occurred during the use of CARDIOSTART DEFIBRILLATOR MONITOR, is this just connect the memory card in the indicated location. The input connector only allows the card to be connected to the right side; it is not necessary indication of the mating. Each time the equipment is initialized the information will be recorded for approximately 100 hours of continuous recording.

In order to view the information recorded on the card just disconnect it from the equipment though the strap and connect it to the card input of the computer or if not possible just use an UBS / compact flash adapter for download the data in AED rescue software.

NOTE: Compact Flash Memory Card (256MB) is provided by CMOS Drake / US DEFIB. The uses of a different card other than the one provided by the manufacturer will void the warranty of the card reader.

10.1.1 INSTALLING THE RESCUE EAD SOFTWARE

- Insert the program CD into the CD / DVD ROM;
- If the installer does not start automatically, locate the file "Setup.exe" on the program CD and double-click;
- Follow the instructions that appear on the screen;
- Once installation is complete, click on the software icon which will appear in the start menu of your computer. The image below shows the AEDRescue screen.

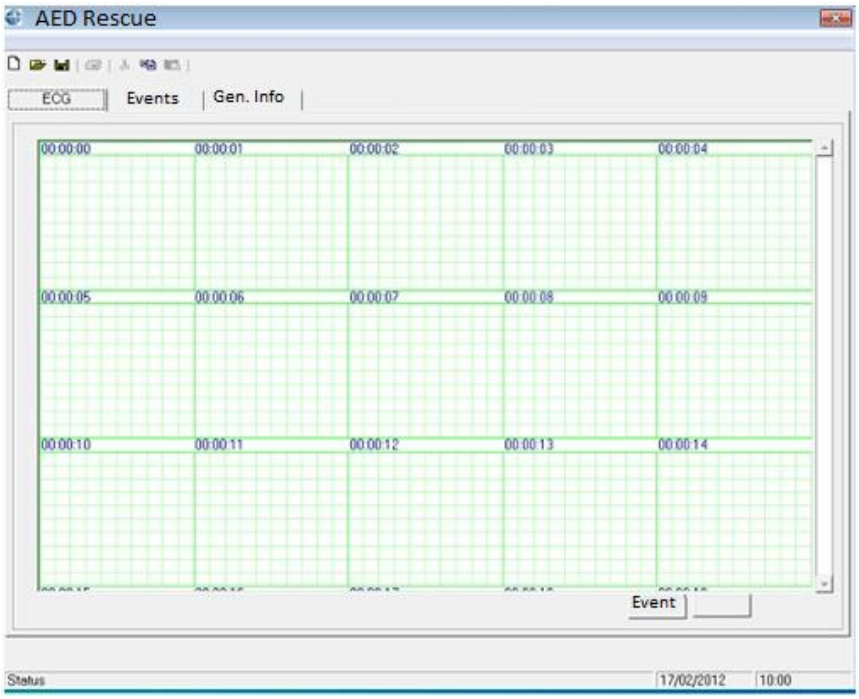


Image30–AED Software Main Screen

- In order to visualize the information contained in the memory card, just connect it to the computer; enter the menu File – Import. The information will appear on the screen with the ECG curve, date and Time of the event;

- In the Event tab all of the occurred events will be presented, with date and time;

- In the General Information tab (image below). All of the equipment data will be presented automatically and it is possible to insert comments. The patient information should be filled by the rescuer, or professional who operates the software;

- To print the information, just click on the print icon on the screen.

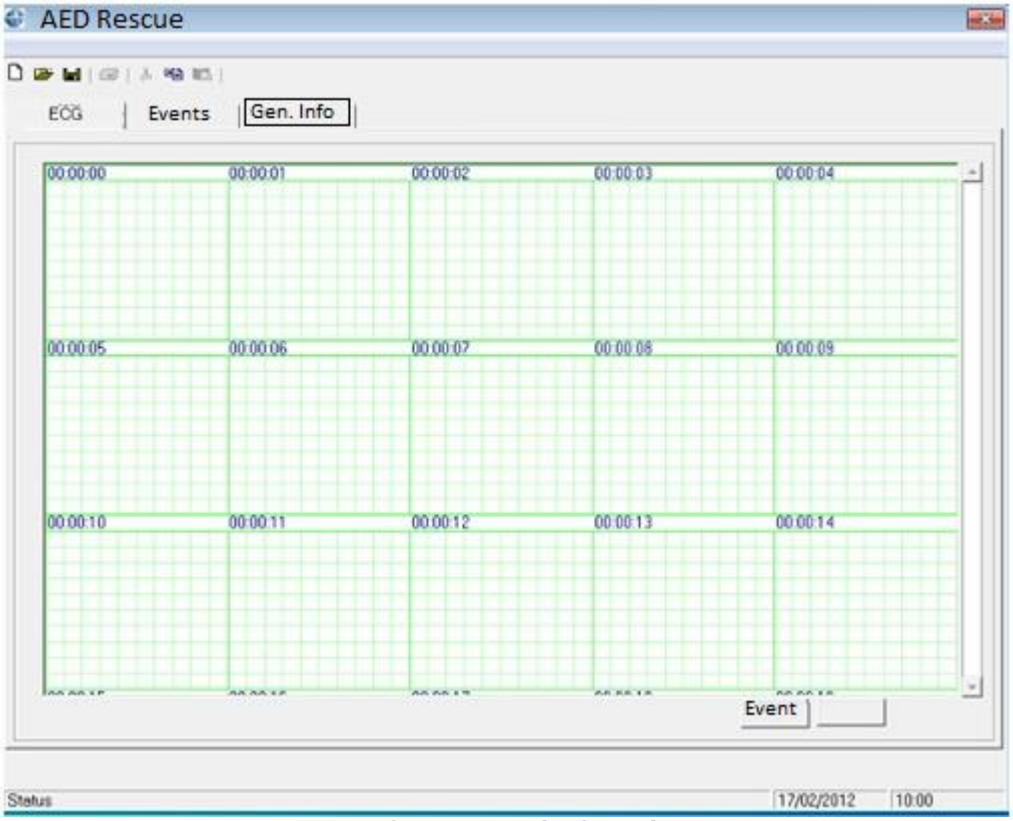


*Image31 - **AED Software General Information Screen***

11. EQUIPMENT INSTALLATION

11.1 EQUIPMENT UNPACKING AND ADAPTATION

- Remove the equipment from the package;
- Accommodate it on an adequate and easy access location;
- Install it away from other equipment which generates strong magnetic fields, like radiological devices, air-conditioning system and others;
- Ensure that the installation place has an adequate ventilation and is within the pressure and temperature range indicated in this manual (item 31);
- This equipment was designed to operate in environments without flammable anesthetic e cleaning agents. Do not operate it in presence of flammable gases in general.

11.2 POWER SUPPLY/BATTERY

CARDIOSTART DEFIBRILLATOR MONITOR features a Lithium-Steel or Lithium-Polymer, both batteries with capacity of up to 150 shocks (trigger) at 200 J; 50 shocks (triggers) at 360J or up to

6 hours of monitoring. This device has an internal battery charger that performs all of the battery charging control internally with charging time of approximately 6 hours.

Optionally, to increase the shock capacity and monitoring time, it is also possible to use external batteries or additional external power supply, as follows:

a) The equipment has a connector for power supply in ambulances and aircrafts. In occasions when there is no power grid available for long periods of use, just connect the equipment to the external power supply, thus preserving equipment battery for situations where it is necessary to move the equipment to the location where the patient is. Don't use the network cable when the power supply cable for ambulances is being used (optional accessory);

b) Easy replacement external batteries (reserve) with a proper charger a maximum charging period of approximately 4 hours.

1. External batteries can be delivered in versions of different charge capacities which vary between 2 hours to 15 hours of monitoring or 50 shocks to 150 consecutive shocks, respectively with proper charger.

ATTENTION!

- In case of reserve batteries,do not use any charger other than the one supplied by US DEFIB;
- Do not short-circuit the battery;
- Charge the battery in a well-ventilated environment;
- Do not discharge the battery completely;
- Do not compress or disassemble it;
- Risk of burns, fire and explosion, if the recommendations listed above are not followed.

ATTENTION!

The CARDIOSTART DEFIBRILLATOR MONITOR features an automatic system for battery charge and it may remain connected to the power grid continuously.

11.2.1 DIGITAL STATUS OF THE BATTERY CHARGE

On the equipment panel there is a battery indicator as shown below:

- Connected to the power grid: 

;

- Battery charging: 

;

- Battery discharged: 

.

11.2.2 TRANSPORT CONDITIONS

- Ambient temperature range from 0º a + 50º C;
- Relative humidity range from 10% to 95%;
- Atmospheric pressure range from 700 hPa to 1060 hPa (525mmHg to 795mmHg).

NOTE: US DEFIB does not warrant and shall not be liable for any damage that occurs to the equipment which is transported or stored in another packaging - must only and exclusively be transported in its original box.

11.3 EQUIPMENT INSTALLATION AND HANDLING RECOMMENDATIONS

- If the patient is connected to CARDIOSTART DEFIBRILLATOR MONITOR, with floating isolation, is connected to any other device that cannot have the same type of isolation, the patient could touch the conductive parts and cancel the equipment protection effect
- It features a isolation protection to the patient, for connection 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 interconnection of CARDIOSTART DEFIBRILLATOR MONITOR with any other equipment is only allowed when it is not harmful to the patient, to the operator and for the environment. If the additional equipment specifications do not inform about interconnection effects, contact the manufacturer or an expert.
- The CARDIOSTART DEFIBRILLATOR MONITOR should only be operated by dully qualified personnel;
- Don't shock the patient with short circuited Paddles;
- For the normal activities operation with all of the possible parameters, the external shock paddles (adult/pediatric module) should remain connected to the equipment.

12. SAFETY AND PROTECTION

a) **Patient**

- The shock capacitor is charged just before the trigger and the charge voltage is transferred to the electrodes only at moment of the shock (moment in which the physician presses the trigger button);
- The trigger command is only enabled when the capacitor is charged with the selected voltage. If the trigger is not performed within 30 seconds after the capacitor charge, the equipment cancels the charge automatically through the internal discharge circuit;
- With the pacing module on and the paddles connected to the patient, the function of defibrillation of the equipment is automatically disabled.

b) **Operator**

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

c) Aircrafts

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

13. USING CARDIOSTART DEFIBRILLATOR MONITOR IN STRONG ELECTROMAGNETIC FIELDS

This equipment is designed for providing resistance to electromagnetic interference. However, its operation may be affected in the presence of strong sources of electromagnetic interference or radio frequency as, for example, mobile phones, radio communicators, etc.

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

13.1 CARDIOSTART DEFIBRILLATOR MONITOR IN HIGH FREQUENCY ENVIRONMENT

- An extreme care should be taken during surgeries that use equipment operating with high frequency, especially in patients with pacemaker. Besides risk of pacemaker damages, the electric cauterization currents could provoke fibrillation to 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 they 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 shielding of the location.

14. CARE WHEN APPLYING DEFIBRILLATION/CARDIOVERSION

- Do not place the Paddles directly on ECG electrodes;

- In patients with pacemakers, some care should be taken in order to prevent damage to the device and to the patient himself:

    - The applied energy should be the lowest possible;

    - Check pacemaker right after defibrillation;

    - Keep proper distance between the generator and the patient pacemaker and the DEFIBRILLATOR MONITOR paddles

 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 burns caused by the use of high frequency equipment.

15. TRIGGERING TEST OF DELIVERED ENERGY

The CARDIOSTART DEFIBRILLATOR MONITOR is equipped with borne for energy trigger testing, which are positioned on the side of the paddle attachment places.

The User must select a charge (advisable a load between 10 and 50 joules), the 1 key - Selection, press the 2 key - Charge, after issuance of the beep that will identify that the charge is ready for triggering, run the process of shock triggering with the paddles placed upon the borne, applying a pressure of about 10 kg.

As soon as the trigger buttons are pressed, a luminous flash will be triggered stating the proper functioning of the charge delivery. This procedure can be performed daily as means of preventive maintenance.

This test is important as it ensures that the selected energy is delivered to the patient when the equipment used in actual operation.

16. OPERATION MODE

16.1 EQUIPMENT CONFIGURATION

When you press the navigation button of CARDIOSTART DEFIBRILLATOR MONITOR the Configuration Modules Menu will appear on the display. A cursor with an arrow shape (>) will appear on the left of the menu items indicating it is the selected one. By rotating the navigation button clockwise or counterclockwise, the cursor moves to a new menu item according to rotation sense. In order 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 will be presented on the display with the configuration items of the selected module.

Select the item to be configured of the chosen module proceeding the same way as described previously. When you select the item, observe that it will flash indicating that it is ready to be altered. Rotate the navigation key to change the item values, increasing or decreasing them. After you choose the desired value, press the navigation button to keep it altered.

To exit the menu, place the cursor on the item **"Exit**" or press the **Exit** shortcut key located on the panel on the side of the navigation button.

NOTE:

- In the modules Configuration Menu only the ones that are installed in the Cardiostart Defibrillator Monitor will appear (configuration options);
- Rotating the navigation key without pressing it will allow the selection of the charge to be released in case of treatment (1 to 200 joules or other as requested).

16.1.1 SETUP SCREEN

Menu	
➡	Exit
	Setup
	ECG
	Pacemaker
	SPO2
	Printer
	NIBP
	IBP
	Capnography
	Ventilation
	Drugs

16.1.2 SYSTEM SCREEN

	Settings
➡	Exit
	AED Mode
	Sync. ON
	Auto-Charge
	Sel. by Paddles
	Volume Alarm

BPM Volume Volume Key Beep Key Date Time Language

2. Exit - Returns to the previous menu;
3. Alarm Vol. - Set the alarm volume, mute = 001, max = 009;
4. BPM Volume - Sets the beeper volume BPM = 001 mute, 009 = max;
5. Volume key - Sets the volume of the beeper keyboard, mute = 001, max = 004;
6. Beep key - Enables (YES) or disables (NO) the beep sound on the keyboard;
7. Language - PTG = Portuguese, English = ENG, SPA = Spanish;
8. Year - Changes the Year;
9. Month - Changes the Month;
10. Day - Changes the Day;
11. Time - Changes the Time;
12. Minute - Changes Minutes;
13. AED Mode - Enables (YES) or disables (NO) AED mode.
14. Sync. ON - Enables (YES) or disables (NO) the synchronism with the QRS complex of the ECG signal;
15. Auto-Charge - Enables (YES) or disables (NO) the automatic charging of the defibrillator;
16. Sel. by Paddles - Enables (YES) or disables (NO) the command by the paddles buttons;
17. Date - Set the day / month / year.

NOTE:

When you select the AED Key, the equipment will enable the AED MODE automatically. In order to exit the AED MODE, press the AED key again.

16.1.3 ECG SETUP MENU

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

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 – 200);
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, N 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;

Note: Gains: N2 = 0,5 cm, N = 1,0 cm and 2N = 2,0 cms.

16.1.4 PACEMAKER SETUP MENU

Pacemaker
➡ Exit
Mode
Width
Amplitude
Frequency
Beep
Pulse

1. 1. Exit – Returns to previous Menu;
2. 2. Mode – Select Pacemaker operation mode (MP) of the following modes:
   - ❖ **VOO**: The PM sends 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 10 to 300 ppm (pulse per minute);
6. Beep - Enables (yes) or disables (no) pulse beep;
7. Pulse - Enables (yes) or disables (no) the PM pulse sending.

16.1.5 SPO2 SETUP MENU

SPO2
➡ Exit
Max Sat
Min Sat
Max PPM
Min PPM
Gain

Beep Alarm

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 30 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 - Enables (yes) or disables (no) the pulse beeps;
8. Alarm – Enables (yes) or disables (no) the SPO2 alarm.

16.1.6 PRINTER SETUP MENU

Printer
➡ Exit Automatic Grid Report

1. Exit – Returns to previous Menu;
2. Automatic – Enables (YES) or disables (NO)Automatic Printing when paddle detects ECG;
3. Grid – Enables (YES) or disables (NO) Grid Printing;
4. Report – Enables (YES) or disables (NO)Report Printing;

16.1.7 NIBP SETUP MENU

NIBP
➡ Exit Patient Mode Automatic Systolic Average Diastolic Start/Stop Alarm

1. Exit – Returns to the previous Menu;
2. Patient – Selects patient: Adult or Pediatric;
3. Mode – Selects the measurement mode: Manual or Automatic;
4. Automatic: defines the measurement time interval when automatic mode is selected;
5. Systolic – Configures the systolic blood pressure for alarm triggering: (from 30 to 300 mmHg);
6. Average – Configures the average blood pressure for alarm triggering (de 30 a 300 mmHg);
7. Diastolic – Configures the diastolic blood pressure for alarm triggering (de 30 a 300 mmHg);

8. Start/Stop – Enables (YES) or disables (NO)the NIBP module;
9. Alarm – Enables (YES) or disables (NO) NIBP alarm.

16.1.8 DRUGS SETUP MENU

Drugs
➡ Exit
Adrenaline
Amiodarone
Atropine
Sodium Bicarb.
Calci
Dofetilide
Lidocaine
Mexiletine
Noradrenalin
Potassium
Procainamide
Sotalol
Verapamil

1. Exit – Returns to the previous Menu;
2. Procainamide – Selects the level of injected Drug;
3. Lidocaine – Selects the level of injected Drug;
4. Amiodarone – Selects the level of injected Drug;
5. Dofetilide – Selects the level of injected Drug;
6. Sotalol – Selects the level of injected Drug;
7. Verapanil – Selects the level of injected Drug;
8. Drug 8 – and other used in CPR;
9. Drug 9 – and other 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 – Selects patient: Adult or Pediatric;
6. Blood Pressure – When activated we have the following pressure types: PVC; AD; VD; PAP; PCP; AE; VE; AO; PA; PIC; P1; P2; P3 and P4;
7. Gain – The available gains are from 0,5N to 2N (or other optional);
8. Speed – Allows varying the scanning speed of the screen to 12,5mm/s, 25mm/s and 50mm/s (or other optional);
9. Alarm – Enables (YES) or disables (NO)IBP alarm;

10. Calibrate – When activated it calibrates the pressure channel with air, measuring subsequently the desired pressure safely;

16.1.10 CAP (CAPNOGRAPHY) CONFIGURATION MENU

CAP	
➡ Exit	Curve
EtCO2	Gain
Response	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. Response – 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 varying the scanning speed of the screen to 12,5mm/s, 25mm/s and 50mm/s;
7. Curve – Allows varying between full line and just the line;
8. Gain – The available gains are from 0,5N to 2N;
9. Patient – Selects patient: Adult or Pediatric;
10. Line Width – The available widths arefrom1px to 3px;
11. Alarm – Enables (YES) or disables (NO)Capnography alarm.

16.1.11 SETUP MENU OF VENTILATION

VENTILAÇÃO
➡ 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, and Tracheotomy;
4. Peripheral AV. - Allows you to set between YES or NO;
5. Central AV. – Allows you to set between: VJI, VSC, OUT, NO;

16.1.12 OTHER FUNCTIONS

Besides the accessible items on the Configuration Menu, there are other accessible functions on CARDIOSTART DEFIBRILLATOR MONITOR panel.

16.1.12.1 PACEMAKER

A) On-Off – Enables or disables the Pacemaker function;

B) MODE (Sync. or Async.) – Alternates between the VOO and VVI modes;
C) Inhibits the beep – Enables or disables the beep synchronized with the pacemaker pulses;
D) Inhibit pulse– Enables or disables the pacemaker pulses deflagration;
E) EMERGENCY – Changes the pacemaker configuration to the ones from the Emergency Mode (VOO, 70 rpm, 150 mA, 40ms).

16.1.12.2 PRINTER

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

16.1.12.3 NIBP

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

16.1.12.4 SYNC. ON

Enables or disables the electric discharge with the R wave peak. 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 lead will appear lit.

The synchronism is performed either by shock paddles as the ECG cable. When used simultaneously in the patient (ECG cable and shock paddles) the Cardiostart Defibrillator Monitor prioritizes the synchronism by the shock paddles.

 In order to defibrillate (unsynchronized shock), never press the SYNC key, because if so, the trigger will not occur. Only requires defibrillation, ventricular fibrillation and ventricular tachycardia, and in these cases are not synchronized.

16.1.12.5 CANCELS 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 FREEZES

This key, when activated, freezes the curves that are on the display. To unfreeze, press it again.

16.1.12.7 BEEP

It inhibits the identification beep of the “R” wave.

16.1.12.8 2 MIN

It inhibits the sound alarms for 2 minutes.

16.1.12.9 SELECTION

It allows adjusting the charge level that is going to be used in the next shock.

16.1.12.10 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.

16.1.12.11 TREATMENT

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

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

1. STERNUM →Loads the capacitor;
2. APEX →Selects 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 pressing, simultaneously, both the keys of the paddles.

16.1.12.12 AED MODE

When the AED mode is activated, the equipment performs the functions of an AED automatically, featuring voice and text command with optional volume control to instruct the rescuer during CPR sequence. To exit the AED mode, just press the AED key on the equipment panel.

17. ADAPTING CABLES AND ACCESSORIES

17.1 ECG MODULE / PADDLE CONNECTOR

Connect the patient cable to the defibrillator monitor observing the correct position through 5-way 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 positions indicated in the drawing below, using the color in the correct place for each wire.

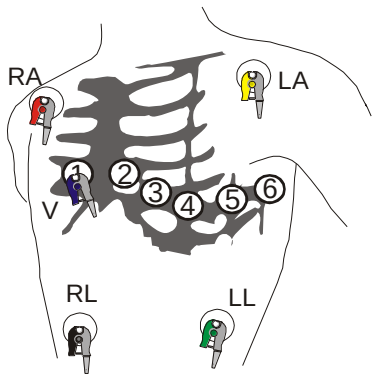


Image32 - Patient Electrodes Positioning

There are two color patterns for ECG cables, Cardiostart Defibrillator Monitor uses IEC standard. View table below.

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

- To clean and disinfect the 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 use, they should be discarded in appropriate places following to special procedures of hospital waste.

17.2 SPO2 OXIMETRY SENSOR

Image33 - Oximetry sensor positioning.

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

Some care should be taken so that the correct reading is performed:

- 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 use, clean the cable and sensor with a moistened cloth with demineralized water and neutral soap. Disinfect with an isopropyl alcohol moistened compress.
- Oximetry sensor Expiration: Undetermined.

17.3 ADAPTING THE NIBP CUFF

A special attention is required not to jeopardize the patient blood circulation when the blood pressure is being measured:

- 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 supports the cuff to discover "Venous Stasis";
- Avoid compression or restriction of pressure pipes, this can cause mal-function;
- NIBP Cuff Expiration: Undetermined.

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

NIBP cuff must be placed on the patient according to the following instructions.

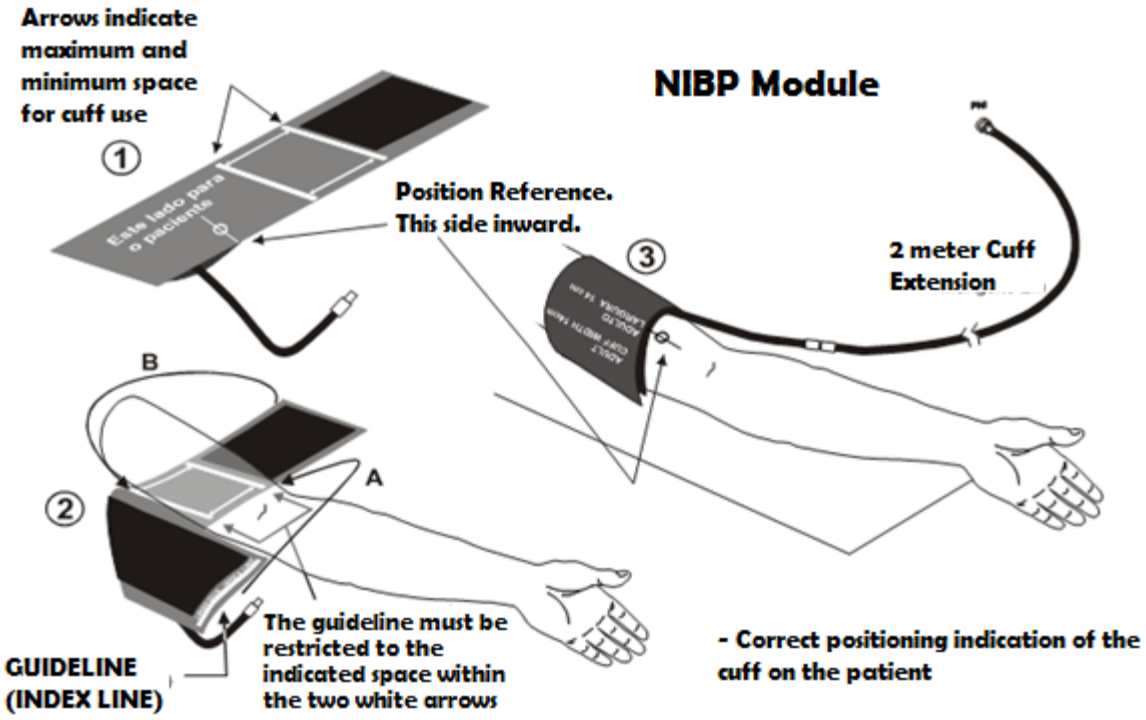


Image 34 - Adjusting the cuff to the patient

17.4 ADAPTING PACEMAKER PADDLES

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

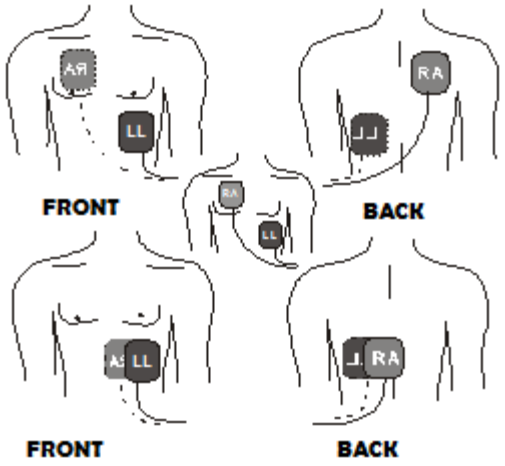


Image35–Paddles Positioning Variations of Pacemaker on the patient

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

17.4.1 PACEMAKER USE INSTRUCTION

When equipment is turned 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). If the result is OK, it emits a sound signal "beep". Then, the module turns off automatically and the message "pacemaker off" appears on the display. The pulse Pacemaker generator of CARDIOSTART DEFIBRILLATOR MONITOR can be used for non-invasive transthoracic stimulation application in a frequency range from 30ppm to 240ppm.

ATTENTION!
NON-INVASIVE Pacemaker – In the VOO mode, the pacemaker can induce ventricular fibrillation, if the stimulation pulse is applied regularly on the ascending portion of the patient's T wave.

A –CARDIOSTART DEFIBRILLATOR MONITOR Pacemaker General Description

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

CARDIOSTART 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 by membrane keyboard. One LED on the equipment panel identifies in visual form the stimulation pulses.

B – Non-invasive Stimulation

As this is about non-invasive transthoracic stimulation pulse, the Pacemaker of CARDIOSTART DEFIBRILLATOR MONITOR delivers to the patient stimulus that varies from 30 to 200 pulses per minute, in asynchronous mode. It is possible to program the frequency, amplitude and pulse width with the purpose to obtain reliable stimulation with minimum delivered energy, to minimize patient disturbance.

C – Applications:

CARDIOSTART DEFIBRILLATOR MONITOR non-invasive Pacemaker is appropriate for pre-hospital and hospital ambient.

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

Some indicated transthoracic applications are:

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

D – Stimulator Operation

ATTENTION!

The described procedure is recommended for support stimulation in bradyasystole patient (missing of intrinsic rhythm). In case of bradycardia support, you should make sure that the stimulation frequency is higher than the patient own rhythm and that 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:

- Reduction of the energy delivered to the patient, prolonging the equipment battery duration;

- Search of parameters values which cause less discomfort to the patient, in case of unconscious patients.

E – Operation Modes

CARDIOSTART DEFIBRILLATOR MONITOR Pacemaker features three operation modes:

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

- 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 occur when the patient's natural frequency is lower than the one selected by the operator.

F – Modes Selection

You can select the operation between "Synchronous" and "Asynchronous" mode by pressing the MODE key.

G – Parameter Configuration

The parameters are configured in the pacemaker menu. Press the Navigator menu to enter main menu, rotate the Navigator until the Pacemaker menu, and press it again. Navigate until the desired parameter, press the button again, turn to alter and select the Navigator to confirm. (Check item 15.1.4).

H – Emergency

Regardless of where the Pacemaker operation mode of CARDIOSTART DEFIBRILLATOR MONITOR, is running, when you press the EMERGENCY key the pacemaker changes to VOO mode, and takes on the following parameters: 100mA, 20ms, and 70ppm.

SWITCHING THE PACEMAKER ON AND OFF: In order to turn the pacemaker on or off you should press the Pacemaker On/Off Button.

Location of stimulation electrodes:

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

After the connection of both units with the interface cable and after switching on the pulse generator, you should press the EMERGENCY key to select the most suitable stimulation. In this configuration, the Front Electrode front (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:

1. Remove or loosen the patient cloths.
2. Clean and dry the skin area with dry cloth.
3. Check the expiration date of the stimulation "Paddles".
4. 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.
5. If the electrode does not adhere properly, discard it and repeat the previous steps with a new pair.

6. Insert the autoclaving connector indicated in the electrodes cable end to the correspondent extension cable connector of CARDIOSTART DEFIBRILLATOR MONITOR.
7. In case of doubt, always follow the instructions indicated by the stimulation electrodes manufacturer.

17.5 ADAPTING CARDIOSTART DEFIBRILLATOR MONITOR PADS

1. Ensure that the paddles are connected to the Cardiostart Defibrillator Monitor. If not, plug the cable into the paddles located below the carrying handle of the equipment;
2. Place conductive gel electrodes on the paddles;
3. Place paddles as image bellow.

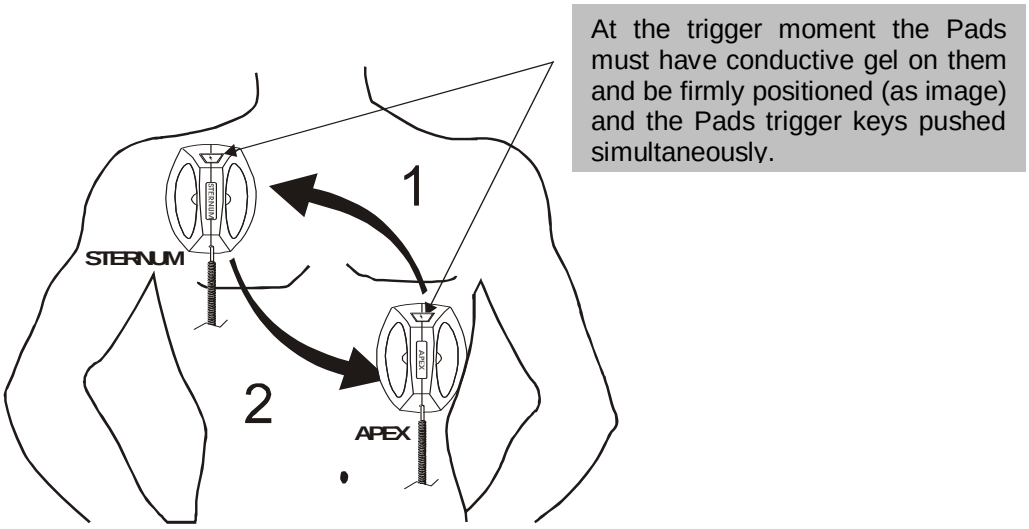


Image36 - Positioning of shock Paddles at trigger moment.

For shocking, the operator should press the Select, Charge and Load simultaneously to release the electric discharge to the patient.

Cardiostart Defibrillator Monitor automatically identifies the operation in pediatric mode and limits the energy to 50 Joules.

Important Observations:

- ✓ Never shock with short-circuited paddles;

17.6 INSERTING THERMAL PAPER IN THE PRINTER

Use appropriate thermal sensitive paper that is easily found in shops for clinical-medical and surgical equipment or directly with US DEFIB / US DEFIB. Thus, it warrants equipment clear printing.

You should observe that the thermal paper has presents a great variation concerning sensibility and abrasion, therefore, it is possible to observe differences in tracing tones of a manufacturer or different batch.

17.6.1 Instructions to Place Thermal Paper In the TR-50 or SP-48 Printer

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

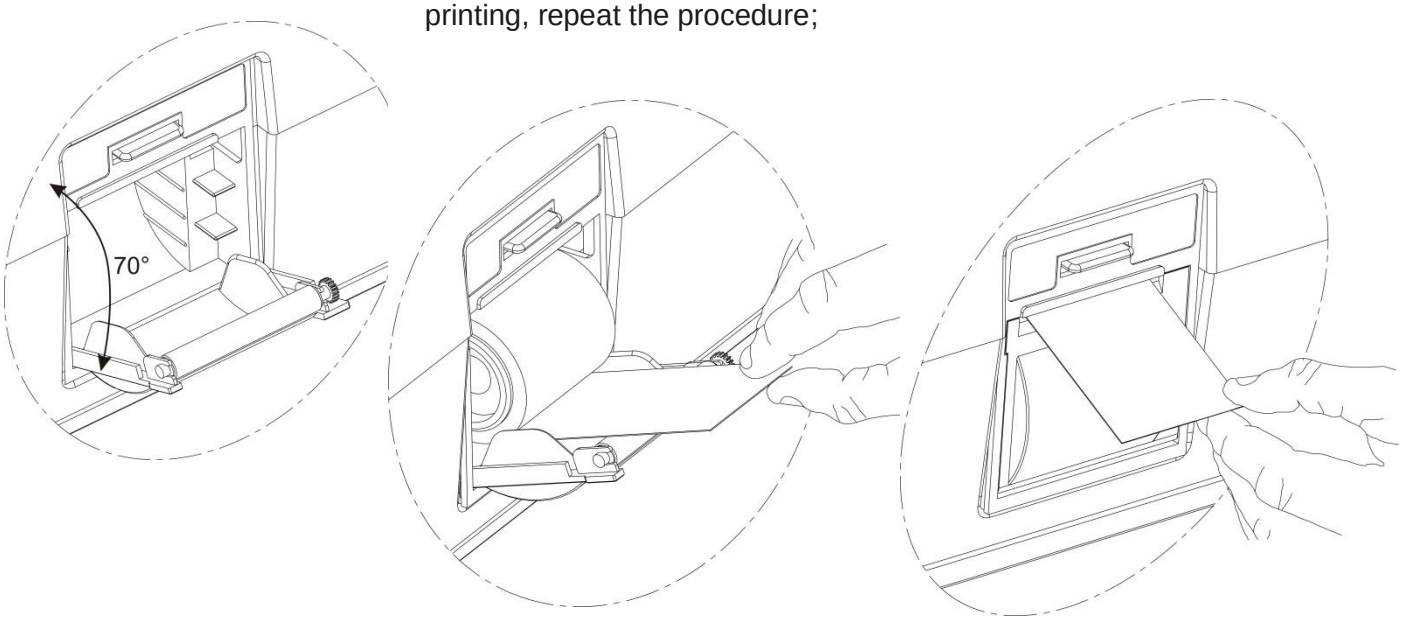


Image37–Placing the Paper on the Printer

17.7 Using Capnography and Sensors

CARDIOSTART DEFIBRILLATOR MONITOR can use either the nasal line or intubated for the capnography. In case of capnography use on intubated patients, one of the adaptors shown in the images below should be used.

The capnography can be damaged due to the reuse of the water filter. Follow the instructions of accessories use supplied by its manufacturer. The filter should be replaced at each patient according to the use instructions of the manufacturer.

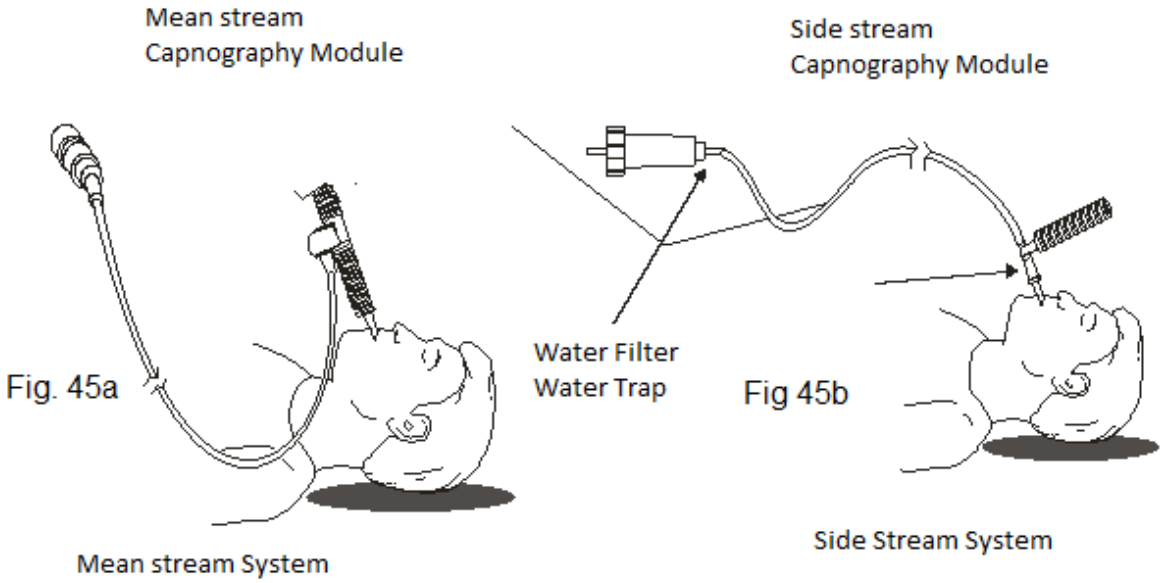


Image38 - Placing the CO2 sensor

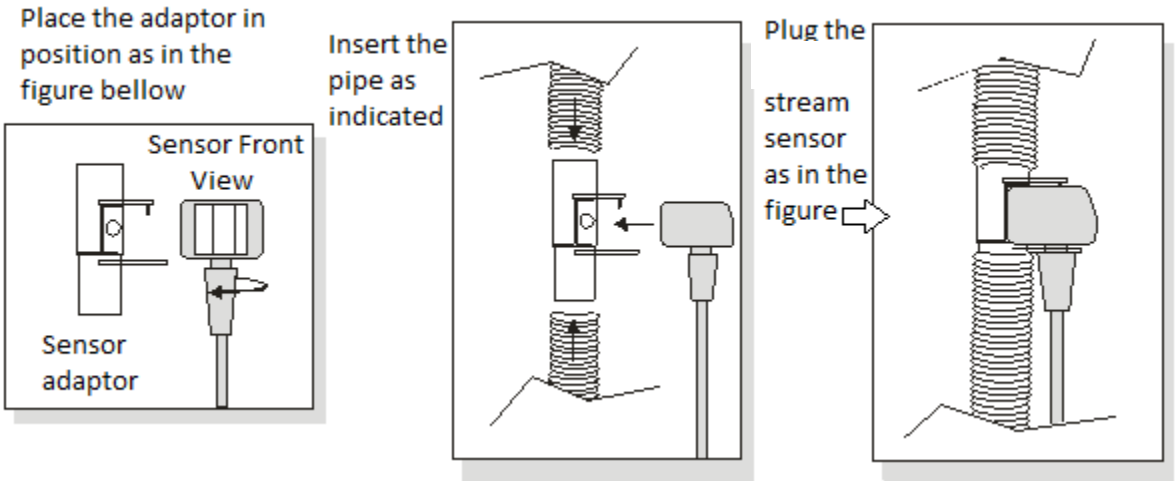


Image39- Mean Stream Assembling Design

17.8 USING THE IBP (INVASIVE BLOOD PRESSURE)

In case of using two channels of pressure, assemble two systems.

- Material:
  - ❖ 01 disposable dome;
  - ❖ 01 syringe;
  - ❖ 02 three-ways;
  - ❖ 01 extensor.

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

To make the connection from dome to transducer, the system should be opened for 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 patient midline; otherwise, 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 the air bubbles exist, it should be eliminated by allowing the saline to flow all the way until we can verify that there are no such bubbles in the IBP system.

17.8.1 RESETING IBP

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

- Select the channel of the blood pressure and close the T2 three-way so that the transducer is closed for the patient;
- Open the T1 3-way for the air and hit ZERO;
- After the ZERO (O) appears, the equipment will be able to measure the pressure. Just close T1 and open T2;
- To measure the pressure of the RV (right ventricle) and LV (left ventricle) it is necessary that the pressure to be measured corresponds to the type of pressure showed in the equipment, because they don't have an average pressure value;
- The tolerance for calibration is within the interval of approximately 100 mm/Hg.

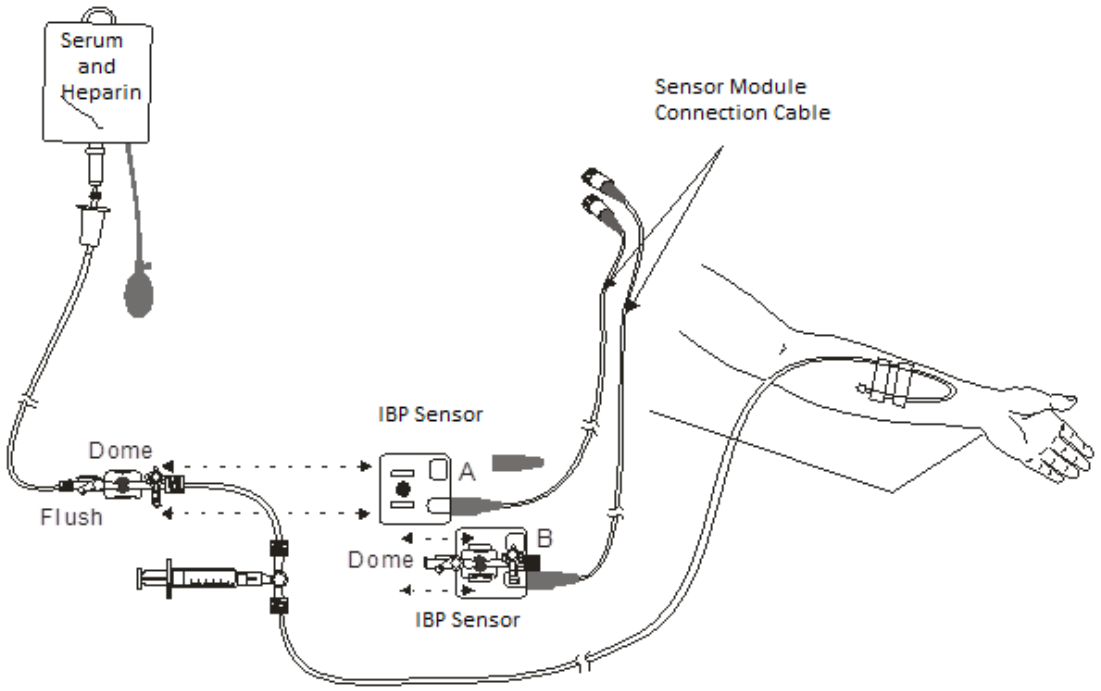


Image40- IBP Assembling Design

18. FOUNDATIONS

18.1 DEFIBRILLATION CONCEPT

The **Defibrillation** is the emergency procedure that consists in applying a non-synchronized electric current to 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 pulse. It must be differentiated from **Cardioversion** that consists in an elective or emergency procedure that requires synchronization and that is classically indicated in instable tachycardia cases or depending on medical criteria.

18.2 DEFIBRILLATION IMPORTANCE

The Early Defibrillation is a link of the Survival Chain. It allows a complete myocardium depolarization, allowing that 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 more serious arrhythmia – characterized by irregular wave's presence, in amplitude and frequency, defining the chaotic cardiac rhythm.

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

18.3 THE CARDIOVERSION

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 the QRS complex is detected by the DEFIBRILLATOR MONITOR, it provides a visual and sound signal.

Remember that, there is a mechanism to inhibit the energy exit in certain situations, the signals captured by ECG are difficult to detect, for instance, when there is 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 Pads buttons are simultaneously pressed.

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.

19. GUIDELINES 2010 - AMERICAN HEART ASSOCIATION

1. The importance of the Chain of Survival is the Emergency Cardiovascular Care (ECC) proposed by the American Heart Association (AHA) has been strengthened in the new guidelines. Besides the emphasis on high-quality CPR, the chain has added another link - Care after cardiopulmonary arrest (CPA). The first link in the chain remains the immediate recognition of the situation of emergency, including CRP and the activation of the Emergency Medical Service as image bellow.

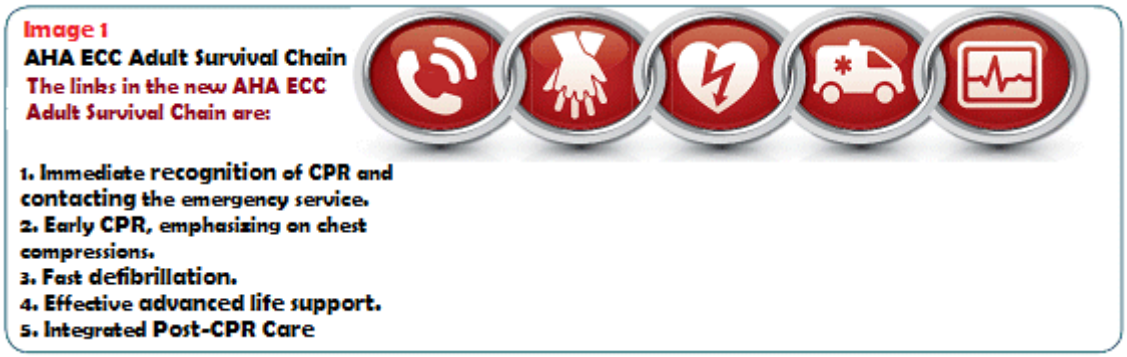


Image41 - Reproduced from American Heart Association: Highlights of American Heart Association 2010 for CPR and ECC Guidelines. [Translated from the Portuguese version].

2. The new guidelines only encourage CPR with chest compressions (RCPSCT) for the layman who witness a sudden cardiac arrest. RCPSCT is easier to be performed by untrained people and can be easily instructed by phone by an attendant of the Emergency Medical Service (EMS).

3. The assessment of breathing "See, hear and feel" was removed from the BLS algorithm. These steps were shown to be inconsistent, as well as time consuming..

4. The sequence for recommended for a first responder attendance that acts alone was modified. Now the recommendation is to start chest compressions before rescue breath. The old sequence AGC (airway - Good ventilation - Chest Compression) is now CAG. The sequence AGC remains for neonatal care, because almost always the cause of CRP in the newborn is asphyxiation.

5. There was no change in the recommendation concerning compression-ventilation ratio of 30:2 for a single rescuer of adults, children and infants / babies (excluding newborns).

6. The greater emphasis of the 2010 Guidelines is the need for a high-quality CPR:

- Minimum compression frequency of 100/minute (instead of "approximately" 100/minute, as before);
- Compression depth of at least 5 cm in adults;
- Total Return after each chest compression;
- Minimizing interruptions in chest compressions;
- Avoid excessive ventilation.

7. The new guidelines minimize the importance of checking the pulse by trained health professionals. The pulse detection can be difficult even for experienced providers, especially when blood pressure is very low. When executed, checking the pulse cannot take more than 10 seconds.

8. Previous recommendations to use the Automatic External Defibrillator (AED) as soon as possible, in cases of off-hospital witnessed cardiac arrest, was reinforced. When the CRP is not witnessed, EMS staff should start CPR (if not already held by the layman) while the AED verifies the pace. In such cases, one may consider 1 to 3 minutes of CPR before the first defibrillation shock..

9. It was encouraged to implement programs that establish AED accessible in public places where there is a relatively high probability of CRP witnessed. The AHA recommends that such programs are accompanied by planning, training and integration with EMS for better effectiveness.

10. The post - CRP care include: optimization of cardiopulmonary function and perfusion of vital organs after the return of spontaneous circulation, transport for a proper hospital or ICU which has resources for post-CPR care, including the ability to intervene in cases of acute coronary syndromes, temperature control to improve neurological prognosis, and treatment and prevention of multiple organ dysfunction.

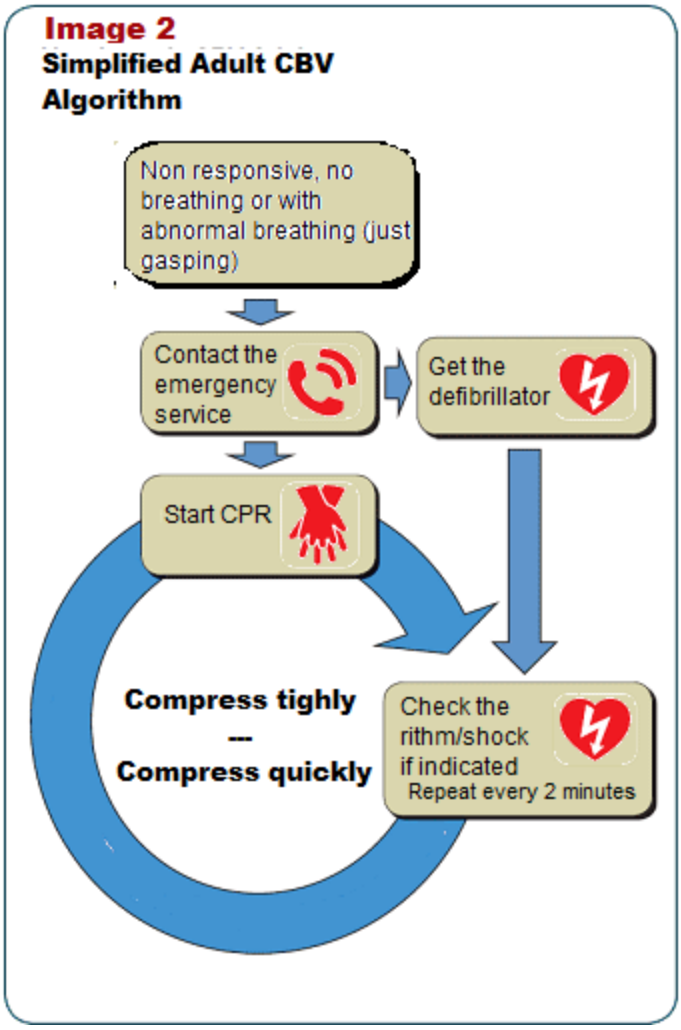


Image42–Reproduced from American Heart Association: Highlights of American Heart Association 2010 for CPR and ECC Guidelines. [Translated from the Portuguese version].

19.1 REFERRALS

This text was based in the new guidelines for CPR of AHA, available in:

http://www.heart.org/idc/groups/heart-public/@wcm/@ecc/documents/downloadable/ucm_317343.pdf

20. HEART PACE DETECTOR – AED MODE (OPTIONAL)

The CARDIOSTART DEFIBRILLATOR MONITOR is prepared to recognized and indicate cardiac rhythms defibrillation of ventricular tachycardia (VT) of several frequencies and QRS width, and rhythms of ventricular fibrillation (VF) of several amplitudes, AUTOMATICALLY, remaining to operator to connect the Pads on the patient chest.

The rhythm detection system of the CARDIOSTART DEFIBRILLATOR MONITOR analyses the patient ECG and informs in case 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 actions for ventricular fibrillation and ventricular tachycardia in victims without pulse.

The rhythm detection system of the CARDIOSTART DEFIBRILLATOR MONITOR::

- Detects contact of the electrode;
- Analyses automatically the ECG;
- Provides orientation for the operator during the defibrillation therapy;
- It features 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 CARDIOSTART DEFIBRILLATOR MONITOR will determine if the electrodes don't have the adequate contact with the patient or haven't been correctly connected to CARDIOSTART 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 50J, automatically. When the PEDIATRIC PADS are inserted, the system automatically limits the energy in proportion of the sequence of 1st, 2nd, and subsequent shocks, respectively.

20.1 Recording Methods (for AED Mode)

The possible arrhythmias for VT and VF defibrillation are pre-setup in the equipment, eliminating the necessity for operator configuration, resulting in significant gain in treatment time.

20.2 Rhythm Source (for AED Mode)

Through the Defibrillator Analyzer equipment, cardiac rhythms subject to defibrillation are simulated, such as VT and VF, the natural rhythms, in several widths and frequencies.

20.3 Rhythm Selection Criteria (for AED Mode)

The selected rhythms are the well-known classic indication for defibrillation, such as Ventricular Fibrillation and Ventricular Tachycardia.

20.4 Annotation Methods

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

20.5 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 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.

20.6 APPLIED TECHNOLOGY

Truncate Exponential Dual Phase Waveform:

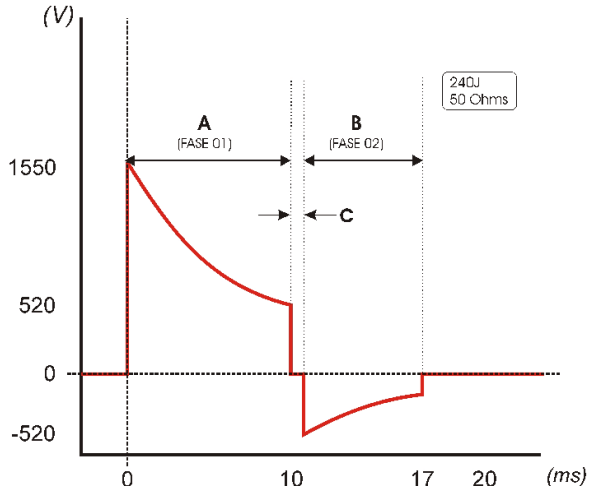


Image43 - Truncate Dual Phase Waveform

Variation according to Patient Thoracic Impedance

Table 1

IMPEDANCE	A (PHASE 01)	B (PHASE 02)
= 25 Ohms	4,9 ms	3.2ms
= 30 Ohms	5,8 ms	3,9ms
= 40 Ohms	7,8ms	5.2ms
= 50 Ohms	10,0ms	6,7 ms
≥ 60 Ohms	12,0ms	8,0ms

*The phase **B** corresponds to 2/3 of phase **A, Maximum width (A+B): 20 ms***
Dead-time (C): 0.5 ms

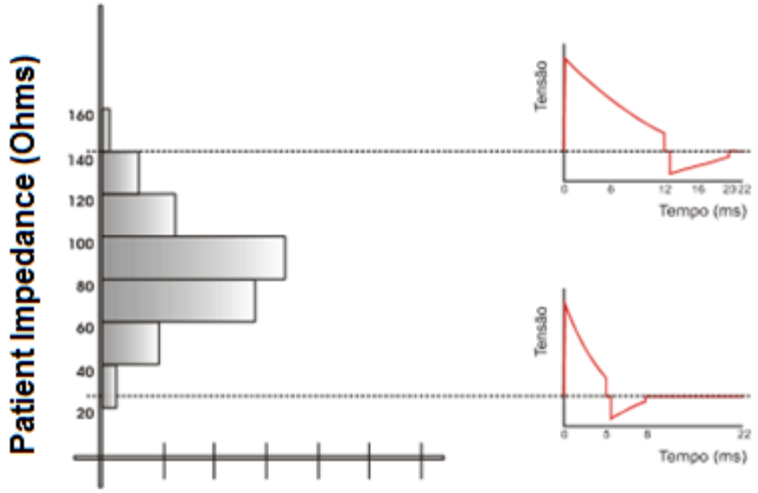


Image44 - Variation of waveform according to patient Impedance

Delivered energy Variation and duration of defibrillation phases performed with Truncate Dual Phase Waveform.

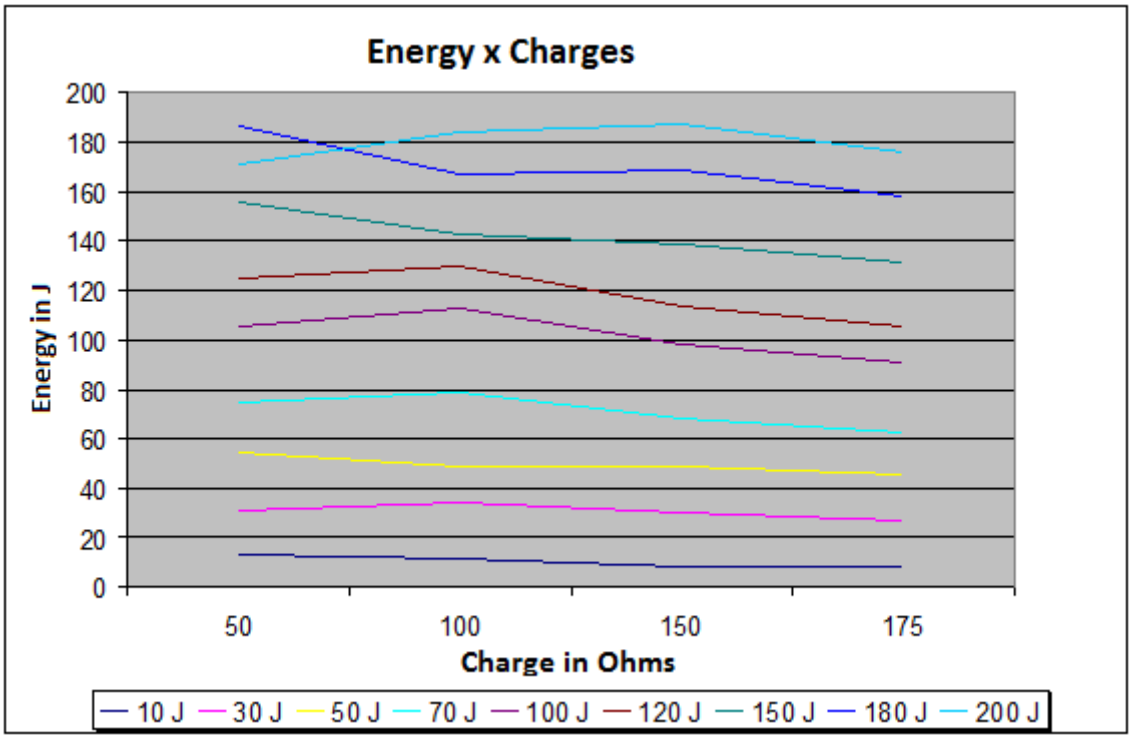
Table 2

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

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

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

Delivered Energy X Charge



NOTE: All of the data is subjected to a tolerance of approximately 5%.

21. MAINTENANCE

21.1 CORRECTIVE AND PREVENTIVE MAINTENANCE

21.1.1 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 necessary.

21.1.2 PREVENTIVE INSPECTIONS AND CLEANING

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

Applied Verification	Schedule
Preventive Inspections	Half Yearly
Cleaning	Weekly

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:

21.1.2.1 PREVENTIVE INSPECTIONS

We recommend that an inspection is performed every six months in CARDIOSTART DEFIBRILLATOR MONITOR and its accessories 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 through the manufacturer US DEFIB or any authorized 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, you should buy new material only through 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 (item 15).

21.1.3 CLEANING

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

- Cleaning and disinfection of the cabinet should be performed with a cloth slightly moistened with demineralized water and neutral liquid soap and another a cloth slightly moistened with demineralized water with 2% of hypochlorite. Do not use cleaning agents

with abrasive, organic solvents, chlorine, alcohol or hydrocarbon solvents. To prevent scratches on the panel display screen, carefully wipe, with a dry flannel, or in case of dirt, a cloth slightly moistened with water, and remove the dust or particles of dirt.

- The tags on the equipment are important, and for that, should not be removed..
- Cleaning and disinfection of the permanent cables should be performed at each equipment use. This cleaning is performed with a cloth slightly moistened in demineralized water and neutral liquid soap and another cloth slightly soft and moistened in demineralized water. After it is dry, disinfect them using gauze moistened with 70% ethyl alcohol.
- For electrodes and disposable accessories, after its use, they should be discarded in appropriate locations according to special procedures for hospital waste.
- To clean the capnography sensor, after its use, use a cloth moistened in demineralized water with a small amount of neutral liquid soap and for disinfection, use gauze moistened with isopropyl alcohol.
- The tubing, water filter (Side-stream water-trap), Main-stream adaptor sensor and miscellaneous are considered disposable, should not be reused and should be discarded in hospital waste according to each hospital procedure.
- Cleaning and disinfection of NIB Cuff should be performed at each equipment use. This cleaning is performed with cloth slightly moistened in demineralized water and neutral liquid soap and another cloth slightly soft and moistened in demineralized water. After it is dry, disinfect it using gauze moistened with 70% ethyl alcohol.

21.1.4 PREVENTIVE MAINTENANCE

Corrective and / or preventive maintenance of CARDIOSTART DEFIBRILLATOR MONITOR must only be performed by US DEFIB or any representative. The frequency of this maintenance is up to the customer in accordance to the table below:

Maintenance Frequency	Indication
Every 3 months	Advised
Half-yearly	Recommended
Annually	Mandatory

Every 12 months the equipment must be submitted to an authorized service, so that a preventive maintenance is performed. This procedure ensures that all the features of the equipment are in full working condition.

CARDIOSTART DEFIBRILLATOR MONITOR does not require periodic calibration, because it is factory calibrated as technical specifications, requiring no new calibrations

Pulse oximetry parameter is calibrated after the manufacturing process is finalized. So there is no need for recalibration of the equipment during its lifespan. It was calibrated between 70 and

100%, and in lower values it is not possible to ensure the accuracy of the calibration. In the range of 70-100% for an error of ± 2%.

22. ADDITIONAL INFORMATION

CARDIOSTART 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 CARDIOSTART DEFIBRILLATOR MONITOR, US DEFIB, lists 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 risks.

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

US DEFIB MEDICAL TECHNOLOGIES LLC

WWW.USDEFIB.COM
INFO@USDEFIB.COM
PHONE: +1 305 887 7552
FAX: +1 305 887 7541

1. TROUBLESHOOTING

The user should always check the equipment conditions. This section has the purpose of solving functionality problems of CARDIOSTART DEFIBRILLATOR MONITOR. The solutions here suggested 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?

PROBLEM	RECOMMENDED ACTION
CARDIOSTART DEFIBRILLATOR MONITOR does not turn on.	Check the tripolar supply cable, making sure that it is correctly connected to the electricity.
Power supply cable is in perfect	Check the security fuse (located at the rear side): After

conditions, but the equipment still does not turn on.	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 5A 20AG)→See **Appendix A**
Instability of 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 NIBP 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: ➢ Use of damaged or inappropriate electrodes; ➢ Inappropriate fixation of the electrodes in the patients; ➢ Insufficient grounding of the equipment; ➢ Absence of conductor gel.

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

⚠ If the recommended actions are not enough to correct the problem, contact the Authorized Technical Assistance by US DEFIB.

⚠ Only remove or replace the fuse while the equipment is turned 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 inflated 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.

Movement excess	Movement excess.	Try to calm the patient down.
Irregular measure	Irregular measure	Check waveform
Pulse without rhythm	The pulse measurement could not be performed.	Check the cuff placement.
The measure has 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.	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.

Capnography Messages

MESSAGE SHOWN ON THE DISPLAY	MESSAGE DESCRIPTION	RECOMMENDED ACTION
Initializing …	Time spent by capnography module to begin the measurement.	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.

2. CABLES AND ACCESSORIES HANDLING

- Before using the equipment on 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;

- Never use accessories, consumables that are not supplied by U.S. DEFIB. We are not responsible for the operation of the equipment if not with the use of all original accessories provided by the U.S. DEFIB;

- Do not buy similar accessories on the market;

- 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.

ATTENTION!

- In general, CARDIOSTART DEFIBRILLATOR MONITOREQUIPMENT Parts and ACCESSORIES, designed 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 that 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 followed; it is installed in appropriate medical place; it is used with correct accessories; it is operated by qualified people and that all precautions described in this User Manual are followed.

- 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 burning when applying defibrillation.
  .

3. POWER SUPPLY AND GROUNDING

When a medical device is connected to the power grid, the current leak possibility should be observed 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 bellow 1 mA become imperceptible under the point of view of a shock, but they can become lethal – generating a cardiac arrest or ventricular fibrillation – as long as a current of the order of 10 microamperes circulates in the heart

It is extremely important not to let the conductive part of the electrodes, transducers, connectors and the own patient to contact 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 equipment features a protection grounding terminal, located on the rear side of the equipment (banana terminal).

In the lack of power supply CARDIOSTART DEFIBRILLATOR MONITOR starts to operate through its internal battery (with approximate duration of 6 hours, depending on the battery level). 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.

4. PHYSIOLOGICAL EFFECTS

In general, CARDIOSTART DEFIBRILLATOR MONITOR doesn't offer any damage or causes any physiological effects, as long as it is installed to operate 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:

4.1 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 expiry date;
- Use permanent or disposable electrodes of good quality;
- All of these procedures must be followed regardless of the patient (Adult or Pediatric / Neonatal);

4.2 NON-INVASIVE BLOOD PRESSURE (NIBP) MODULE

- 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 to be compatible with it and avoid, this way, the circulation interruption;
- Only use the cuff supplied by US DEFIB.

4.3 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 deserve special care, using another type of sensor, model on Y format; its position must be changes every 2 hours, to avoid possible skin burn, bruises or lesions to the skin. This application on a neonatal patient is done by the fixation of an adhesive tape that cannot be used excessively to avoid lesions to the skin or incorrect readings;

NOTE: The use of oximetric sensors is not recommended during a MRI, because the sensors may affect the image or affect the oximetry accuracy.

4.3.1 SENSOR PROLONGED USE

Oximetry sensors (adult, pediatric or universal) are not suitable so prolonged use due to the heat emitted by the sensor and the continuous pressure applied to the patient. For a longer period of monitoring, it is recommended repositioning it to another location in every patient 2 (two) hours or 4 hours in accordance to the type of sensor.

4.3.2 SENSOR CLIP UTILIZATION

To place the finger sensor on the patient, open the posterior fins of the sensor so that it does not chafe or rub on the finger. If the indicator cannot be used for the sensor connection, use preferably a small finger, do not use the finger sensor on the thumb. The sensor should be positioned so that its cable crosses at the top of the hand (image below). When selecting a location for the sensor, choose an extremity / limb free from other devices, such as arterial catheter, blood pressure gauge or intravascular infusion lines.

Image45–Placing the Oximetry Sensor (adult).

When faults are found in the reading, the user must accommodate the patient to correct his posture and to return the normal blood circulation, thus being able to restore the quality of the signals.

In the presence of bright light sources such as direct sunlight, surgical lamps, infrared heating, cover the area where the sensor is placed with opaque material. With that the possibility of interference from ambient light (which could cause erroneous readings) will be minimized.

Avoid applying adhesive tape, or adhesive bandage onto reusable the sensor. This reduces the risk of venous pulse, and saturation wrong measurements and possible damage to the area caused by pressure. However, the application of an adhesive bandage over the cable can help prevent the sensor to move.

- Sensor Expiration: Undetermined.

4.3.3 Y TYPE SENSOR UTILIZATION

The recommended sensor for pediatric / neonatal application is the Y model. This sensor is fixed by using an adhesive tape around the foot; other areas may not provide acceptable results because of an incorrect infusion or inadequate light. Ensure that the fixing tape is secured, but not too much, avoiding interference in blood flow which may cause inaccurate readings or skin lesions. If the sensor is not positioned properly (alignment between transmitter and receiver),

there may be inaccuracies and instabilities in reading and plethysmographic curve. Prevent the radiant light of radiotherapy equipment to exceed the tissue and interfere with the measurement of SPO2.
Movements of the patient's foot may misalign the transmitter-receiver joint (Y sensor) and result in inaccuracies in SPO2. The correct placement of the sensor is essential for a good performance of the oximeter.

Y Sensor Important Features:

- Pediatric: Weight of 15-40 Kg;
- Index finger is the ideal applying area, with the cable along the back of the hand. Such as alternative areas, we recommend the thumb or another finger, big toe, with the cable along to the bottom of the foot;
- For patients who weight over 30Kg, another alternative would be: the ear lobe outer ear / ear flag;
- Move location between 02 to 04 hours;
- Sensor Expiration: Undetermined.

ATTENTION
When positioning the sensors, the patient physiological conditions should always be observed. Patients with burns that may present greater sensibility to heat and pressure, should receive special care, such as moving the area in which the sensor was applied more frequently.

ATTENTION
Do not use the oximeter in continuous monitoring.

4.4 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 blades 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 lead the user to 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 R wave presence. Consequently, in the randomness of the trigger, the shock can occur during the vulnerable period and cause ventricular fibrillation.

4.5 INVASIVE BLOOD PRESSURE MODULE (IBP)

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;

4.6 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 and in perfect condition to avoid a possible bacterial contamination.

5. ADVERSE EFFECTS

US DEFIB, manufacturer of clinical-medical equipment, requests to users to report possible defects or occurrences of any undesirable event, in order to warrant the equipment quality. Therefore, any flaw or mal-function, contact the nearest Authorized Technical Support or directly with the sale consultant US DEFIB MEDICAL TECHNOLOGIES LLC, www.usdefib.com, info@usdefib.com, Phone: +1 305 887 7552, Fax: +1 305 887 7541.

6. TECHNICAL SPECIFICATIONS

According to harmonized technical standards	NBR IEC 60601-1-1:2004, NBR IEC 60601-1-2:2010, NBR IEC 60601-1-4:2004, NBR IEC60601-2-4:2005, NBR IEC 60601-2-27:1997,NBR IEC 60601-2-30:1997, NBR IEC 60601-2-49:2003, MDD 93/42/EEC:2007, EN ISSO 14971:2007, EN ISO 13485:2003, and other.
Relevant Certifications	Product Certification - INMETRO
Type of protection against electrical shock	Class I
Protection rating against electrical shock	Applicable to each module. ECG/ Pacemaker – Defibrillation proof CF applied part. Defibrillator/ SPO2/ NIBP/ CO2/ AED Mode/ Invasive

	Blood Pressure – Defibrillation proof BF applied part.
Protection against liquids and solids	IP22
Utilization protection rating in the presence of anesthetic flammable mixture	Equipment not suitable to be used in the presence of inflammable air mixture, O_2 and N_2O.
Operation mode	Continuous operation with intermittent charge. Minimum interval between shocks – 30 seconds
Printing format	1 channel Automatic and Manual
Input impedance	< 10 MΩ
Impedance detection range	25Ω - 500Ω
Frequency response	w/ filter: 0,5 – 35 Hz w/o/ filter: 0,5 – 100 Hz
Filters	AC: 60 – 50 Hz - Muscular: 35 Hz
Gain	5 – 10 – 20 mm/mV
Printing Speed (of ECG tracing)	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 20m (length) or; 48 mm (width) x 30 m (length) or; 75 mm (width) x 20 m (length)
Liquid Crystal Display – LCD	LCD 5,7 inches (of visible area) Colored with contrast adjustment in several sizes and resolutions – 5,5to 7,2 inches.
Powering	100 - 240 VAC – Automatic – 50/60 Hz External DC: 10 to 16 VDC
Consumption (maximum)	Power Grid - 635 VA Battery – 10A
Internal DC Power Supply (internal battery)	Typo: Rechargeable Lithium-Steel(LiFe), 14VDC, 2300mAh Battery full charging time (completely discharged): 6 hours Temperature +10ºC a +60ºC Typo (optional): Rechargeable Lithium-Polymer (LI-PO), 11,1 VDC, 2200mAh Battery full charging time (completely discharged): 4hours Temperature +10ºC a +60ºC

DC External Power Supply(reserve)	2 hours to 15 hours of monitoring or 50 shocks to 100 consecutive shocks respectively
AC Current	127 VAC – 5A / 220V – 2,5A maximum
Pads output voltage	256 - 1570 VDC
Pads output current at 50 ohms	50 A maximum
Maximum charging time	As configuration
Defibrillation Scale	As configuration
Cabinet	High Impact with electric and thermal isolation (anti-flame –Rohs Directive)
Discharge time	< 240 ms
Discharge time with synchronism	< 20 ms
Operation Temperature	10ºC a + 40ºC
Operation Humidity	30% a 75%
Dimensions	ApproximatelyH-125 x D-355 x W-280 mm
Weight	Approximately 4,500 kg
Atmospheric Operation Pressure	700 to 1060 Pa (525 mmHg 795 mmHg)
Equipment Software Version	CBI400_A011

6.1 PACEMAKER TECHNICAL SPECIFICATIONS

Pacemaker Modes	VVI, VOO, with 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	30ppm to 240 ppm, adjustable in steps of 1ppm
Pulse width	0ms to 50ms adjustable in steps of 1ms
Power supply	12 V
Degree of protection against electric shock	CF Type Applied Part defibrillator proof

6.2 CAPNOGRAPHY TECHNICAL SPECIFICATIONS (ETCO2)

Parameter Reading Method	*Side stream and Mainstream*
Parameters	EtCO2, CO2 Inhalation, Respiratory frequency
Unit	%
CO_2 Concentration reading range	0 to 50 mmHg
Respiratory Frequency Reading Range	0 to 35 RPM
Stable condition	Graphic line and numerical values 0 to 99 mmHg with ± 3 seconds.
Compensation	N_2O, O_2 and Deflurane
Protection level against electric shock	CF Type Applied Part
ALARMS	
Type	Manual for maximum and minimum limits of respiratory frequency, EtCO2, stable condition and CO2 inhalation.
Silent alarm	Sonorous 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

6.3 INVASIVE BLOOD PRESSURE TECHNICAL SPECIFICATIONS (IBP)

Reading range	- 50 to 300mmHg
Tolerance	± 2%
Frequency response	0 to 40 Hz
Isolation	± 8000V, 360J defibrillator
Zero adjustment	± 50mmHg
Transformation standard	5µV/V/mmHg
Digital pressure display	Systolic, Diastolic, average value
Protection level against electric shock	BF Type Applied Part
Limit values	0 to 300 mmHg
ALARMS	Manual for maximum and minimum limits
Silent alarm	Sonorous alarm disabled for 120s
Delay	05 to 75 seconds

6.4 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 bpm
Tolerance	± 3%
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	≤ 4 seconds after defibrillation
Systolic indicator (QRS)	Audible beep
Calibration sign	1 mVpp ± 3 %
Protection level against electric shocks	CF type applied part defibrillation proof
ALARMS	
Limits	25 to 220 BPM
Adjust	Manual; maximum and minimum limits
Silent alarm	Sonorous beep disabled for 120 seconds
Delay	0 to 7 seconds

6.5 NON INVASIVE BLOOD PRESSURE TECHNICAL SPECIFICATIONS (NIBP)

Reading Technique	Oscillometric
Operation mode	Manual / automatic
Time programming	1 to 60 minutes
Protection level against electric shock	BF Applied Part
Reading range	
Adult Systolic	40 to 300 mmHg
Adult Diastolic	40 to 300 mmHg
Adult Average	40 to 300 mmHg
Neonatal Systolic	20 to 150 mmHg
Neonatal Diastolic	20 to 150 mmHg
Neonatal Average	20 to 150 mmHg
Maximum Blood Pressure:	
Adult	300 mmHg
Neonatal	150 mmHg
Resolution	1mmHg
ALARMS	
Type	Manual; maximum and minimum limits
Delay	0 to 7 seconds

6.6 OXIMETRY TECHNICAL SPECIFICATIONS

Pulse reading range	10 to 300 BPM
Tolerance	± 3 %
Resolution	1 BPM
SpO2 reading range	00 to 100 %
Tolerance	70 to 100% ± 2 digits, finger clip 70 to 100% ± 4 digits, ear clip 70 to 95% ± 3 digits, neonatal Under 70%, undefined for all sensors
Protection level against electric shock	BF Type Applied Part
ALARMS	
Type	Manual; maximum and minimum limits
Limits	00 to 100 %
Silent Alarm	Sonorous alarm disabled for 120s
Delay	0 to 7 seconds

7. DISPOSABLE ACCESSORIES MANUFACTURERS

Accessory / Module	Manufacturer/Model
ECG	
ECG Conductive Gel	US DEFIB/Suprimed / Gel In Shape
ECG Disposable Electrode	US DEFIB/ Kendall / Medi Trace 200
Thermo Sensitive Paper	US DEFIB/ Daru / ECG
Other	
Pacemaker Paddles set (PADs)	US DEFIB exclusively
AED Mode Paddles Set (PADs)	US DEFIB exclusively

IBP - Complete kit	US DEFIB/MEDEX MX9604A
Child Nasal Circuit	RESPIRONICS Distributors
Adult Intubated Line	RESPIRONICS Distributors
Adult Air Adapter	RESPIRONICS Distributors
LDS Air Adapter	RESPIRONICS Distributors
Side Stream Filter (Water strap)	RESPIRONICS Distributors

7.1 PERMANENT ACCESSORIES MANUFACTURERS

Accessory / Module	Manufacturer/Model
ECG	
5 ways patient cable (exclusive use)	US DEFIB exclusively
3 ways patient cable (exclusive use)	US DEFIB exclusively
SPO2	
SPO2 Adult Sensor	US DEFIB/ BIO-LIGHT or NELLCOR
SPO2 Neonatal Sensor	US DEFIB/ BIO-LIGHT or NELLCOR
SPO2 Y Pediatric Sensor	US DEFIB/ BIO-LIGHT or NELLCOR
Other	
3-pole Power cable (MAINS CABLE)	ITALCABOS / Italflex
Ambulance cable'	US DEFIB
Neonatal External Paddles	US DEFIB
Adult / Pediatric External Paddles	US DEFIB
Extension cable for PADs	US DEFIB
Mainstream CO2 Sensor	RESPIRONICS
Invasive Blood Pressure Sensor	MEDEX / nº MX960
Blood Pressure Transducer	MEDEX / nº MX960
Clamp Support (Sergeant)	MEDEX / nº MX260
NIBP Cuff	BAUMANOMETER

8. APPENDIX A – FUSE REPOSITION

8.1 FUSE REPOSITION 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 – On the rear panel, unscrew and pull out the fuse support, remove the damaged fuse, replace for a new one and repeat the opposite operation, screwing the support on the rear panel frame.
.

9. APPENDIX B – ECG TRACE INSTABILITY AND NOISES

When you notice 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 if there are cracks or breaks along 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 you realize a possible damage to the connection cable, it should be tested by specialized staff and, if necessary, replaced.

4. Status of the clip and precordial (chest) type electrodes, 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 to ECG. **Other gel types**, as ultra-sound gel and /or for other aims, **are not indicated**, because they can, not only introduce noises and the exam unviable, but also cause the early wearing off of the electrodes.

7. Preparation of the patient skin before fixing 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 fixing location according to the usual clinic practice (hair cleaning and shaving, if necessary).

8. Grounding of the power supply plug where the CARDIOSTART DEFIBRILLATOR MONITOR is installed. Follow the recommendations about power supply and grounding described in this manual (see item 25).

9. External interference sources proximity (generators of radio-frequency and power lines), if it occurs, move them away.

10. Equipment filters adjustment.

11. For additional support, don't hesitate to contact US DEFIB.

9.1 THE MOST COMMON ECG INTERFERENCES

The ECG sing 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.

Image B1: Noiseless Electrocardiogram.

9.2 AC Power Supply Interference

The power supply induces a specific frequency interference (50 or 60 Hz), which juxtaposes to the ECG sign, 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 sign impedance read by the equipment, compromising the rejection effect of common mode of the input amplifiers. In these cases, the trace normally appears saturated

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

9.3 Muscular 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).

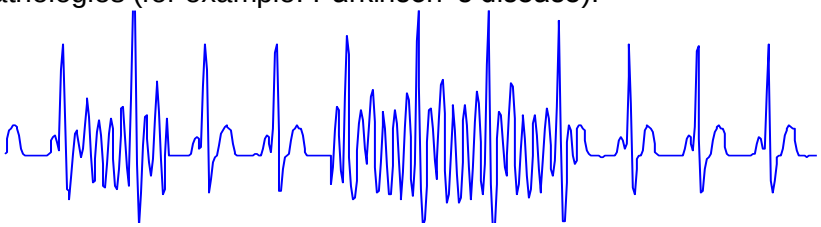


Image B3: ECG contaminated with muscular artifacts ("muscle tremors").

9.4 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 raising 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.

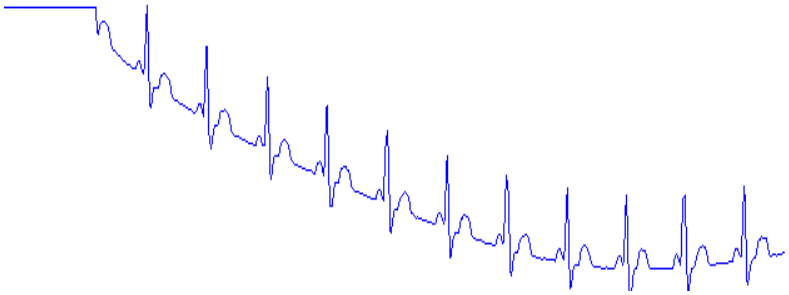


Image B4: ECG with oscillation on the baseline (drift).

9.5 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 30 and 300 ppm with a 3% accuracy; transforming the ionic activity of the skin surface – that reflect 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 of 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. Never apply abrasive or conductive paste on the injured skin.
6. If it is necessary to remove the hair excess, perform the trimming and not the shaving of the area.
7. Use the proper adhesive tape (micro-pore or patch) on the back of the electrodes and fix it to the place of contact with the skin, making sure that there is a light pressure of the electrode against the skin.
8. When the connection is well done, when the electrodes are moved, you should observe a little momentary artifact, with a quick restitution of the trace to normal.
9. 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.
10. Clean the skin after the exam, applying gauze moistened with neutral soap for complete removal of the conductor gel.

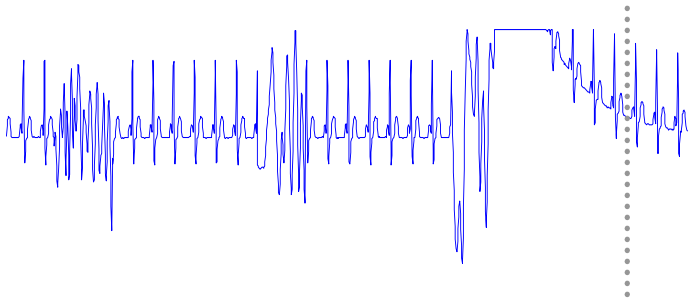


Image B5: ECG with contamination by movement artifacts: In [A] and [B] the detection of cardiac sign is impossible and in [C] the amplifier even saturates, taking a while to return to the baseline.

10. APPENDIX C – MANUFACTURER GUIDELINES AND DECLARATION – ELECTROMAGNETIC EMISSIONS

CARDIOSTARTDEFIBRILLATOR MONITOR was designed for operation in any environment presented below. The client or user of CARDIOSTART DEFIBRILLATOR MONITOR must assure its operation in one of those environments.		
RF EMISSIONS MEASUREMENT	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - ORIENTATION**
RF emissions according to ABNT NBR IEC CISPR 11	Group 1	CARDIOSTART 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 A	CARDIOSTARTDEFIBRILLATOR MONITOR is suitable 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 61000-3-2	Class A	
Emissions due to Scintillation Tension Float IEC 61000-3-3	Compliant	
RF emissions according to ABNT NBR IEC CISPR 14	Compliant	CARDIOSTARTDEFIBRILLATOR MONITOR is suitable for interconnection with other equipment.
RF emissions according to ABNT NBR IEC CISPR 15	Compliant	

CARDIOSTART DEFIBRILLATOR MONITOR was designed for operation in any environment presented below. The client or user of CARDIOSTART DEFIBRILLATOR MONITOR must assure its operation in one of those environments.			
Interference resistance test	**Essay level of ABNT NBR IEC 60601**	**Compliance Level**	**ELECTROMAGNETIC ENVIRONMENT - ORIENTATION**
Static Electricity Discharge (SED) according to IEC 61000-4-2	± 6kV per contact ± 8kV by air	Compliant	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%.
Fast transient electric disturbances / triggers according to IEC 61000-4-4	± 2kV in the supply lines ± 1kV in the input / output lines	Compliant	Electricity supply quality should correspond to the voltage supplied in a typical commercial environment or hospital.
Over voltages according to IEC	± 1kV differential mode ± 2kV common mode	Compliant	

61000-4-5			
Voltage drops, brief interruptions and floatation on the supplied voltage according to IEC 61000-4-11	< 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	Compliant	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 **CARDIOSTART DEFIBRILLATOR MONITOR** requires continuous operation even when there are interruptions on the electricity supply, the **CARDIOSTART DEFIBRILLATOR MONITOR** should receive energy without interruptions or with a battery.
Magnetic field in the supplied frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	Compliant	Magnetic fields in the supply frequency must be in levels that are characteristic of a typical location on a hospital environment or commercial typical.
Note: *Ut is the AC supply voltage before applying the essay level.*			

CARDIOSTART DEFIBRILLATOR MONITOR was designed for operation in any environment presented below.
The client or user of CARDIOSTART DEFIBRILLATOR MONITOR must assure its operation in one of those environments.

Interference resistance test	**Essay level of ABNT NBR IEC 60601**	**Compliance Level**	**ELECTROMAGNETIC ENVIRONMENT - ORIENTATION**
Conducted RF IEC 61000-4-6 **Radiated RF IEC 61000-4-3**	3 Vrms 150 kHz to 80 Mhz 3 V/m 80 Mhz to 2,5 Ghz	[V1]V Compliant [E1] V/m Compliant	Portable and mobile RF communication equipment should only be used next to any part of **CARDIOSTART DEFIBRILLATOR MONITOR**, 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: $d=[3,5/V1]\sqrt{P}$ $d=[3,5/V1]\sqrt{P}$ 80 MHz to 800 Mhz

			d=[7/E1] √P 800 MHz to 2,5 GHz where *P* is the maximum nominal potency of the transmitter output in watts (w), according to the transmitter manufacturer, and *d* 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, [a] is smaller than the conformity level in each frequency range.[b] Interference may occur around the equipment marked with the following symbol. 

Note 1 *In 80 Mhz and 800 MHz, it is applied a higher frequency range***.**
Note 2 *These guidelines may not be applicable in all of the situations. The electromagnetic propagation is affected by structures, objects and people absorption and reflection***.**

[a] *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 VT 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 measure on the location that the* ***CARDIOSTART DEFIBRILLATOR MONITOR*** *is used exceeds the conformity level used above, the* ***CARDIOSTART DEFIBRILLATOR MONITOR*** *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* ***CARDIOSTART DEFIBRILLATOR MONITOR.***

[b] *Above the frequency range of 150 KHz to 80 MHz, the field intensity should be smaller than [V1] V/m.*

11. TECHNICAL ASSISTANCE

Permanent Technical Assistance

Mr. Owner,

US DEFIB has available a large list of representative and technical support all around the Brazilian territory.

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

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

Manufacturer: US Defib Medical Techonlogies
Address : 7831 NW 72nd AVENUE, MEDLEY - MIAMI
Zip Code: 33166
Phone: +1 305 8877552 / +1 305 8877541
Legal Representative: Amanda Coelho Rodrigues Felix

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

Mr. Final Customer,

It is with great satisfaction that we deliver the most modern technology in defibrillation and cardioversion.

But, in order for this equipment to provide the best attendance and utilization, we request that the following measures are taken:

- **Register your product**;

Why register: this registry is necessary to identity the final costumer of the equipment, for the cases of preventive and corrective maintenance, we will know who and where to contact, besides it affirms our commitment regulatory priority assistance to the final user.

12. CUSTOMERS REGISTERING TEMPLATE

US DEFIB MEDICAL TECHNOLOGIES

EQUIPMENT DESCRIPTION:	**SERIAL NUMBER:**
CARDIOSTART DEFIBRILLATOR MONITOR	

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

TECHNICAL SUPPORT:
ATTENTION Mr. Owner, 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.

13. VERSION CONTROL

USER MANUAL

PROJECT NAME: Cardistart Defibrillator Monitor
CODENAME ENG[a]: CBI300

VERSION CONTROL

Rev	Date	Author	Description
1.0	Nov, 8th,2011	Luara Delfin	First Issue