User Manual

DEFIBRILLATOR DEFIBSTART

Version 05 rev.02

US DEFIB
MEDICAL TECHNOLOGIES

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INTRODUCTION

Congratulations on the purchase of the Defibrillator DEFIBSTART - AED of USDEFIB.
This product incorporates the state-of-art technology designed to aid patients in a medical emergency and resuscitation thereof.
The full reading of the operation instructions should precede the use of the equipment. All necessary data for the safe and correct use of the equipment is contained in this manual, as well as information on the essential care for preservation of the Defibrillator DEFIBSTART - AED and clarifications related to Customer Services and the Warranty Certificate.
After reading the manual, keep it close to the equipment for future reference.

If you would like to receive this user manual printed, please get in contact by email (info@usdefib.com). US DEFIB has 7 days, after received the request, to ship the user manual.

This User Manual is available to download on website: www.usdefib.com

SUMMARY

1. FIGURE

2. INTRODUCTION

PRESENTATION

The Automatic External Defibrillator AED, DEFIBSTART model, is a compact, lightweight and portable electronic equipment developed and designed for applications in early defibrillation procedures on victims of cardiopulmonary arrest, aiming to combat the sudden death in an effectively and accurately manner.
Controlled electric shocks are applied in the patient's chest using defibrillator electrodes (disposable Adhesive paddles) with instructions to the rescuer by voice and text commands (self-explanatory).
The equipment offers micro processed circuits that perform cardiac mapping and automatically identify shockable cardiac arrhythmias such as VT - ventricular tachycardia and VF - Ventricular Fibrillation.
The AED can be used in adults and infant patients in all places, in this first examination, the basic life support, considerably increasing the survival rate.

USE INDICATION

The Defibrillator DEFIBSTART has the basic function of reversing cardiac arrhythmias. The equipment is intended to be used by lay people (trained in BLS - Basic Life Support, since the equipment operates automatically independently from prior knowledge of the operator) and physicians and rescuers trained to basic and/or advanced life support.Voice and text commands shall guide the operator during the patient resuscitation procedure.

AED MODE

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

DISCLAIMERS

The company will be free from any and all liability that may arise related to personal injury or property damage caused as a result of:

- Application different from the intended purpose.
- Improper use and repairs in the equipment.

- ❖ Failure to follow instructions in this manual regarding use, repair and maintenance of equipment.
- ❖ Use of accessories and spare parts manufactured by other companies (not authorized by USDEFIB).
- ❖ Not permitted interventions, repairs or structural changes in the equipment.

3. SAFETY INFORMATION

WARNINGS

⚠ **The Defibrillator DEFIBSTART shall be used by properly personnel trained in basic or advanced life support, or by personnel authorized by physicians for emergency defibrillation therapy in patients with heart failure.**

⚠ **The operator must examine the equipment and its accessories conditions (regular testing), as well as the operation of them before use.**

⚠ **The operator must have knowledge and science of all possible side effects during the defibrillator use.**

⚠ **When installing the equipment and battery charger, make sure they are in place with enough space for ventilation and away from the heat radiation.**

⚠ **The Defibrillator DEFIBSTART was developed for use in defibrillation procedures, enabling the application of electrical stimulation to the heart. It can be used in any hospital or extra hospital environment, including air or land rescue units, providing advanced life support.**

⚠ **Always disconnect the Defibrillator DEFIBSTART from the battery charger before connecting the equipment.**

⚠ **To prevent fire or improper shock, avoid the operation or accommodation of the defibrillator near to water source and/or flammable products; do not leave any liquid product on the cabinet and/or battery charger.**

⚠ **Risk of explosion if the equipment and the battery charger are used in the presence of flammable anesthetic gases.**

⚠ **The electrodes may be left on the patient for a few hours, depending on the skin condition.**

⚠ **Risk of electric shock if the cabinets of the equipment and battery charger are open. Every type of service or future updates of this equipment, battery charger and its parts can only be performed by personnel appropriately trained and authorized by USDEFIB.**

⚠ **Avoid use of cell phone or any devices that capture radio frequency near the equipment. The high level of electromagnetic radiation emitted by these devices may**

result in significant interference, impairing the normal operation of the equipment and risking the patient's safety.

⚠ **These disposable materials should not be reused even after being subjected to a cleaning and sterilization process. They should be disposed in the appropriate locations as special procedures for medical waste.**

⚠ **If the replacement of any part of the equipment and battery charger is required, excluding disposable materials, you should contact the manufacturer or the authorized network to provide the material and perform the replacement of it, when necessary. If the accessories are made by different suppliers from those suggested by USDEFIB, the company is not responsible for operation of the equipment and may have a void warranty.**

⚠ **Overall, the EQUIPMENT and ACCESSORIES Parts of the Automatic External Defibrillator - AED, intended to come into contact with biological tissues, cells or body fluids are tested and analyzed in accordance with guidelines and principles of ISO 10993-1, which AEDls exclusively with biocompatibility test of the parts applied.**

⚠ **No change in this equipment and battery charger is allowed.**

⚠ **There is a risk of polluting the environment associated with the use of accessories and consumables at the end of the life cycle. Accessories and consumables must be disposed in the hospital waste according to environmental law. The batteries must be returned to the manufacturer after replacement due to defect or end of life cycle thereof.**

⚠ **Do not use the battery charger within the patient environment.**

⚠ **Do not use another battery charger if not provided by the USDEFIB.**

⚠ **Do not place the battery charger connected to extensions or additional MULTIPLE SOCKETS directly on the ground, so to prevent the liquid from entering in the contacts and prevent electrical and mechanical damage.**

⚠ **This equipment delivered electric shock (if indicated) for the treatment of arrhythmias. If other equipment connected to the patient at the time of the shock, they may be damaged by electrical discharge. When using this equipment disconnect other devices.**

⚠ **If the equipment is exposed in environment where the protection against harmful penetration of water is higher than IP56, do not used the equipment and contact immediately US DEFIB.**

⚠**This equipment is not intended for use in environments with a high electromagnetic field. Never use in electromagnetic resonance rooms.**

⚠**This equipment is not intended for use in environments with a high radiation. Never use in X ray rooms while in use.**

4. RATING AND SYMBOLS

 Hazardous electrical voltage.

 Continuous Current.

 Alternating Current.

 Class II equipment

 Warning!

 Refer to the manual / instruction booklet.

 Do not sit.

 Do not step on the surface.

 On / Off button.

 Shock triggering button to treatment.

Low battery indicator.

 Polarity of Battery Charger AED.

 Heart beat indicator on the equipment display.

 Defibrillation-proof Applied Part Type CF.

 Defibrillation-proof Applied Part Type BF.

 Consult instructions for use.

 This side up: indicates the correct position for the box to be carried.

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

 Keep dry: indicates that the packaging must be kept dry.

 Number 5: indicates the maximum stacking of five overlapping units.

 Minimum and maximum temperature.

 Indicates if it is medical equipment and, therefore, deserves special treatment.

 Manufacturer.

 Indicates that it consists of recyclable raw materials.

 Waste of electrical and electronic equipment - Separate disposal of other objects.

IP56 Protection against harmful penetration of water and particles.

5. MEASUREMENT UNITS

Symbols	Unit	Description
m, cm, mm	Length	Meter, centimeter, millimeter
h, m, s, ms	Time	Hour, minute, second, millisecond
Kg, g	Mass	Kilogram, gram
°F, °C	Temperature	Fahrenheit, Centigrade
mmHg, hpa	Pressure	Mercury millimeters, hectopascals
hz, rpm, bpm, ppm	Frequency	Hertz, breaths per minute, beats per minute, pulse per minute
V, mV	Voltage	Volts, millivolts
m/s, mm/s, bps, l/m	Speed	Meter per second, millimeter per second, beats per second, liters per minute
Ω	Impedance	Ohms
J	Power	Joules
m3, mm3	Volume	Cubic meters, cubic millimeters

Table 1 - Measurement Units

6. ACRONYMS USED IN THIS USER MANUAL

- ACLS: Advanced Life Support in Cardiology;
- AHA: American Heart Association;
- BLS: Basic Life Support;
- CDI: Implantable Cardioverter-Defibrillator;
- AED: Automatic External Defibrillator;
- ECG: Electrocardiogram;
- VF: Ventricular Fibrillation;
- LCD: Liquid Crystal Display;
- PCR: Cardiopulmonary Attack;
- CPR: Cardiopulmonary Resuscitation;
- VT: Ventricular Tachycardia;
- ICU: Intensive Care Unit;

7. CONTRAINDICATIONS

- AED should not be used by lay people without proper training and capacitation;
- Asynchronous defibrillation is contraindicated in patients who have one or any combination of the following conditions:

    - Consciousness;
    - Spontaneous breathing;
    - Palpable pulse.
    - Child under 8 years old or weighing less than 25 kg (according to AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care).

- This equipment does not indicate shock treatment in asystole. In case of asystole, defibrillation can inhibit the recovery of natural pacemakers in the heart and completely eliminate any chance of recovery. Therefore, shock in asystole shall not be applied;
- This equipment is not able to be use in resonance of electromagnetic rooms;
- This equipment not suitable for use in the presence of flammable mixture with air, O2 and N2O;
- This equipment is not able to be use in environment where the protection against harmful penetration of water is higher than IP56.

8. BASIC GUIDELINES OF DEFIBRILLATOR DEFIBSTART

The Defibrillator DEFIBSTART - AED with voice and text command can be configured according to customer's needs in the following ways:

- Defibrillator DEFIBSTART – AED Basic
- Medical Mode - Software that makes it possible, when enabled, to change the assessment control and the exclusive decision to perform the treatment for the medical rescuer;

Any option can be assembled at the discretion of the specific needs of each client, not changing the purpose of the product features.

GENERAL FEATURES

- Automatic System of analysis of the ECG signal with detection of malignant arrhythmias (ventricular tachycardia and ventricular fibrillation) that require defibrillation;
- Synchronism with "R" wave in case of presence of QRS complex (as in "synchronous mode");
- Pacemaker Detection;
- Biphasic truncated exponential waveform;
- Automatic system for triggering in 150, 200 and 200 J in Adult mode (as setting) and 50 J fixed in the Infant Mode (as setting);
- The AED for pediatric use (infant mode), limits the load on 1/4 power applied to adults in an automatic form. When entering the PEDIATRIC PADDLE, the system automatically limits the power in proportion to the sequence of the 1st, 2nd and other shocks, respectively;
- Analysis of the patient's thoracic impedance with time setting and shock electric current level, increasing the efficacy of defibrillation and reducing the risk of damage to the heart;
- Charging time in 150J less than 5 seconds;
- Internal automatic discharge after 30 seconds if there is no triggering;
- Ability to perform up to 140 discharges at full load (new battery fully charged);
- Electroluminescent liquid crystal display which displays the ECG trace;
- Cabinet in high impact ABS electrically isolated;
- Cronometer (seconds' counter);
- Daily self-test;

- Possibility of use of rechargeable or non-rechargeable battery;
- Battery charger (for rechargeable batteries);
- Battery charge indicator;
- Low battery indicator - audible and visual;
- Heart Rate: reading range from 10 to 300 bpm with numerical display;
- Enables shock only if the patient is in ventricular fibrillation or tachycardia;
- Charge possibility for up to 360 joules (optional);
- Enables memory registration of continuous ECG and events (optional);
- Internal event memory including curve, date and time (optional) of 2GB;
- Enables, through PC connection, the visualization of data recorded in the internal memory;
- Text and voice commands;
- Language: English e Spanish (Possibility of language change through the software);
- ECG with beep;
- Beep for guidance of compressions frequency during CPR;
- The ECG is monitored by paddles during and after the shock.

9. INSTALLING THE DEFIBRILLATOR DEFIBSTART

UNPACKING AND ACCOMMODATING THE EQUIPMENT

- Remove the equipment from the packing box;
- Place it in an appropriate and easily accessible location;
- Install it away from other equipment that generate strong magnetic fields such as radiological devices, air conditioning systems and others;
- Make sure that the installation location has appropriate ventilation and is within the pressure and temperature ranges indicated in this manual.

⚠ **Always keep the Defibrillator DEFIBSTART packed in its transport bag or Emergency Cabinet, thus, avoiding damage;**

⚠ **This equipment is not designed to work in environments constituents of anesthetic agents and flammable cleaning. Do not operate it in the presence of flammable gases.**

10. IDENTIFICATION OF PARTS AND COMMANDS

Figure 1 - Front Identification of the Defibrillator DEFIBSTART - AED

1. Display (displays the treatment time, route of ECG, text commands to the user according to the voice commands);
2. Treatment button used for the shock triggering. When flashing, confirms that the shock is ready to be applied in the patient;
3. On/Off button;
4. Carrying handle;
5. Low battery indicator.;
6. Connector of shock paddles (electrodes);

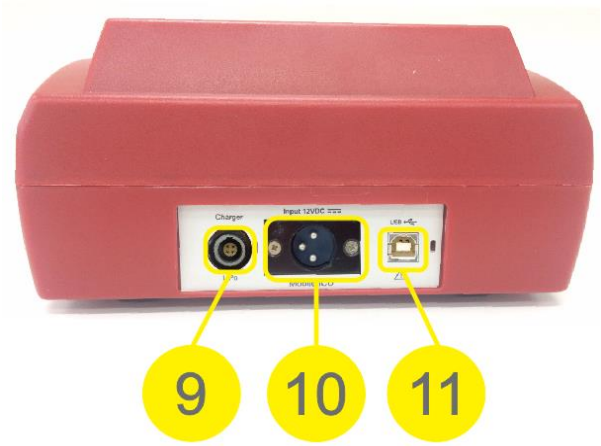


Figure 2 - ***Front Identification DEFIBSTART***

9. Input of Battery Charger;
10. Ambulance connector;
11. USB input;

9 - Ambulance connector: It is possible to use the Defibrillator DEFIBSTART - AED using the input to 12 VDC of its own ambulance or any vehicle and aircrafts; the equipment operates continuously, without using the internal battery of AED. To do this, simply connect it via interconnection cable to the external battery.

⚠**Use only interconnection cables with external battery provided by USDEFIB. Other cables might damage the equipment.**

10 - USB input: It is possible to record curves, date and time of events occurred during the use of Defibrillator DEFIBSTART in the internal memory (2GB). Each time the equipment starts up, the information is recorded and may be drawn to the computer by connecting the USB extension cable. The data can be viewed through the Phoenix software.
The USB input is also designed for software updates of the equipment. These updates can be made by authorized personnel of USDEFIB only.

DISPLAY

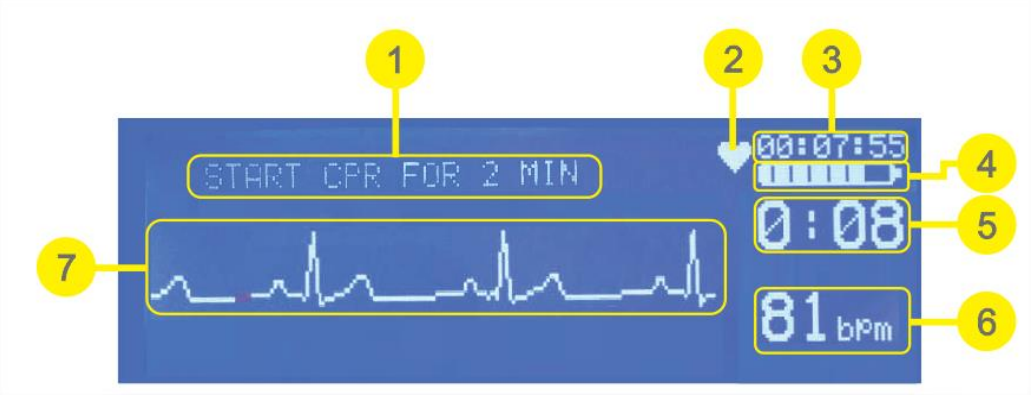


Figure 3 - Information of AED Display

1 - Display of text commands;
2 - Heart beat indicator on the equipment display.
3 - Chronometer - Indicates the time the equipment is in use;
4 - Battery charge level indicator;
5 - 2min CPR Timer - decreasing counter of CPR time for guidance of rescuer;
6 - BPM - Indication of beats per minute of the patient
7 - ECG curve.

BATTERY CHARGE

Figure 4 – Charge information's

1 - Connection to the mains.
2 - Connection to AED.
3 - Led indicator of battery charge:
Blue LED - Battery charging;
Green LED - Battery full
4 - Label of battery charger with technical information of the charger.

SWITCHING ON THE EQUIPMENT

1. Disconnect the battery charger;
2. Press the on/off button located on the front panel of the equipment;

Figure 5 - On/off button

3. Follow the AED instructions (voice and text command);

Throughout the procedure, keep the AED away from the patient and operator as shown below.
The operator must remain at the patient side, near to the chest, to check the vital signs.
AED must remain at a minimum distance of 20 cm from the operator and patient.

To turn off the equipment
After completion of the procedure:

1. Turn off the AED through the on/off button;
2. Disconnect the connector of paddles of the equipment;
3. Disconnect the patient oximetry sensor (if used);
4. Make cleaning of AED and the oximetry sensor as cleaning procedure described in this manual;
5. Reconnect the battery charger to the AED and keep it always connected;
6. Connect a new adhesive shock paddle to the AED to streamline the next service.

11. SUPPLY / BATTERY

The Defibrillator DEFIBSTART – AED uses two options of battery:

- Non-rechargeable battery - 11.1V 2200mA - Pack of lithium-polymer batteries with life cycle of 5 years in standby (never used and new battery), capacity greater than 5 hours of monitoring or up to 140 shocks of 150J (adult mode).
- Rechargeable Battery - 11.1V 2200mA. - Lithium-polymer battery - rechargeable (The battery charger is supplied with the equipment), life cycle of approx. 5 years in standby and capacity for 5 hours of monitoring or up to 140 shocks at 150J (adult mode). To obtain the monitoring time or the number of charges described is necessary that the battery is fully charged (new battery fully charged).

CONNECTING THE CHARGER TO THE RECHARGEABLE BATTERY PACK

This battery charger is intended for use in exclusive set of the Defibrillator DEFIBSTART.

1. Connect the battery charger of AED in the rear panel of AED as the image below;

Figure 6 - Connection of Battery Charger

Figure 7 - Minimum Distance for connection/disconnection of the Battery Charger

The battery charger has a bicolor LED to indicate the charge status:

- Blue LED on - Battery charging;
- Green LED on - Battery full

Keep the rear part of the equipment at a minimum distance of 20cm from any other device or wall, so to ensure there is no risk of the battery charger plug to be pressed or disconnected from the equipment, and it is possible to easily disconnect the battery charger plug of the equipment.

⚠**The operator and/or patient must remain at a minimum distance of 40 cm from the battery charger.**

⚠**Do not connect the battery charger to MULTIPLE SOCKETS close to the ground, to prevent liquid penetration in the supply contacts and prevent electrical and mechanical damages.**

⚠**The battery charger of the Defibrillator DEFIBSTART switches the type of recharge automatically and can stay connected to the mains for 24 hours, with no need to turn off the AED of the battery charger;**

⚠**If the equipment is stored for a period exceeding 40 days without any possibility of connection to the same mains, it is recommended that the battery be removed from the equipment so there is no risk of leakage and damage to the equipment.**

⚠**Do not use another battery charger if not provided by the USDEFIB.**

⚠**The equipment will not operate for treatment while connected to the battery charger. This equipment is ready to run on battery power only. Disconnect the AED battery charger to start the use. By connecting the equipment with the connected charger, a message will appear on the screen: *"TO USE, DISCONNECT THE EQUIPMENT FROM THE CHARGER!"***

⚠**There is loss of battery charge for carrying out the self-test (decreasing the battery life cycle);**

⚠**The replacement of the battery is recommended every 2 years when in constant use, or when the operating time is less than 1 hour.**

⚠**If the equipment presents a performance loss, with low battery life, contact USDEFIB for a customer service assistance.**

⚠The equipment is not powered by the mains; the battery charger is not able to energize the AED for use in cases where the battery is discharged;

⚠Do not short-circuit the battery;

⚠Do not discharge the battery completely;

⚠Do not crush or disassemble;

⚠Battery Operating Temperature: 0° to 60°C;

⚠Risk of burns, fire and explosion;

⚠When using loads with infant electrode (50 Joules), the amount of shocks will be proportionately greater;

⚠The AED - has internal battery - model CR 2032 - 3V - to be replaced from 4 to 5 years. This change should be performed at the manufactory.

12. SELF-TEST

The Defibrillator DEFIBSTART - AED, when switched off, periodically performs a self-test to monitor the battery charge. This monitoring is intended to inform the AED status to the user. Every 4 hours, the equipment automatically turns on and checks its status.
When it is detected that the battery is only 50% full, the equipment will beep and show an alert light. The frequency with which the self-test is performed will be changed according to the battery level, increasing as the charge goes down, i.e., as the battery level goes down, the alerts are more frequent, indicating that the battery needs to be replaced or charged (if rechargeable).

Frequency of Self-Test	Battery Capacity	Alert
Every 4 hours	Above 50% charge	No alert
Every 2,5 minutes	Below 50% charge	Audible and visual alert every 2.5 minutes
Every 2 minutes	Below 40% charge	Audible and visual alert every 2 minutes
Every 1 minute	Below 10% charge	Audible and visual alert every 1 minute
Every 30 seconds	Below 5% charge	Audible and visual alert every 30 seconds

⚠**If below 2% of charge on the battery, it is no possible to power on the equipment.**

⚠**Even with low battery alert, the equipment is still able to perform shocks.**
A high current of the battery is required to charge the capacitor, this can lead the battery to reach the shutdown voltage level of the equipment with no low battery warning.

⚠**If the battery is disposable, from the moment the equipment starts the low battery alert, contact USDEFIB to purchase a new battery.**

13. TREATMENT - DEFIBRILLATION

CARE WHEN DEFIBRILLATING

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

⚠**Do not apply the shock with the short-circuited paddles, because the triggering device may be damaged.**

ABOUT DEFIBRILLATION

The heart has a system that produces and transmits impulses throughout the heart muscle which, in turn, is responsible for contraction and pumping of blood throughout the body. These pulses can be measured on the body surface, creating an electrocardiogram (ECG).
The analysis of an ECG signal allows detection of electrical and mechanical heart problems. Cardiac arrhythmias may reflect disturbances in the initiation or conduction of impulses that, in severe cases, may occur as a Sudden Cardiac Arrest (SCA). During a SCA, there is a lack of appropriate blood flow in the body and brain, a situation that may quickly lead to AEDth, if not reversed. As a SCA rarely reverses spontaneously, the use of a defibrillator to treat it may be indicated. In this context, the application of a defibrillating shock aims to restore the normal heart rate.
The most common arrhythmias that lead to Sudden Cardiac Arrest are Ventricular Fibrillation (VF) and Ventricular tachycardia (VT). An Automatic External Defibrillator (AED) is able to analyze the ECG of a patient and recognize the presence or absence of VF and VT in order to indicate whether a shock should or should not be administered in the patient. It is important to mention that, according to the European Resuscitation Council (ERC), in its latest Guide to Resuscitation [1], the use of a AED is only indicated for patients with Sudden Cardiac Arrest (SCA) that are unconscious and not breathing normally - so, AED should be used only if the patient presents such conditions.

ANALYZER OF HEART RATE

The Defibrillator DEFIBSTART is able to analyze the patient's ECG and automatically identify the presence or not of Ventricular Fibrillation (VF) and Ventricular tachycardia (VT). According to the American Heart Association (AHA) [2] [3], the FV and TV are arrhythmias that should be treated with shock (shockable) by AED. Thus, if the Rhythm Class to assess the patient's ECG in PCS identify the occurrence of a FV or a TV, the equipment will

produce sound and visual signals of appropriate treatment, signaling that a shock should be administered to the patient.
During analysis of the patient's ECG, the equipment shall produce a "Analyzing" audible and visual signal. During this period, for proper operation of the analyzer, one should not touch the patient, ensuring that the patient is immobile. When one finishes the analysis, AED will indicate or not the treatment (shock) through sound and visual messages on the display.
If a treatment is indicated, move away from the patient before pressing the treatment button. If AED does not indicate the treatment, return to the CPR.

VALIDATION

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

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

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

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

Performance tests resulted in a sensitivity Se = 93.83% and specificity Sp = 95.01% for the assessment group RO230704. The algorithm analysis time is about 14 seconds.
The transthoracic impedance of the patient is measured through the defibrillation electrodes. If the baseline impedance is higher than the maximum limit value, the system will determine if the electrodes do not have proper contact with the patient or are not properly connected. Consequently, the ECG analysis and the release of defibrillation shocks will be prevented. The voice and text message in the display will inform the user to *place the electrodes on the patient's chest* if the contact of the electrodes is not enough.
Optionally, the AED for pediatric use limits the charge on 1/4 of power to adult in an automatic form. When entering the PEDIATRIC PADDLE, the system automatically limits the power in proportion to the sequence of the 1st, 2nd and other shocks, respectively.

14. HOW TO USE

The DEFIBSTART, presents 02 clinical modes:

- ❖ Semi-Automatic mode;
- ❖ Medical Mode.

According to the Guidelines of AHA 2015. “Shock configurations with biphasic waveform differ according to the manufacturer, none of which directly compared in humans on the relative effectiveness. Due to these differences in the configuration of the waveform, professionals must use the power load recommended by the manufacturer (120 to 200 J) for its waveform. If the load recommended by the manufacturer is not known, consider the maximum load defibrillation".
The AED is configured with the shock sequence in the manufactory standard:

- ❖ ADULT - 150 - 150 - 150 joules
- ❖ INFANT - 50 - 50 - 50 joules

Optionally, it is possible to set other sequences of power for shocks:

- ❖ 1ª: 90J - 130J - 150J
- ❖ 2ª: 150J - 150J - 200J
- ❖ 3ª: 150J - 200J - 200J
- ❖ 4ª: 150J - 200J - 360J
- ❖ 5ª: Other settings may be provided.

In cases of pediatric use, the equipment automatically selects the appropriate power as soon as the pediatric paddles are connected.

At every attendances, it is necessary to perform the following procedures:
1 Check if the patient is unconscious;
2 Open the patient's shirt;
3 If there is hair on the patient's chest, it is necessary to make the hair removal with the aid of a razor blade before connecting the paddles.

OPERATION SEQUENCE

Defibrillator DEFIBSTART has a pre-defined operation sequence, as illustrated below.

Sequence for indicated treatment

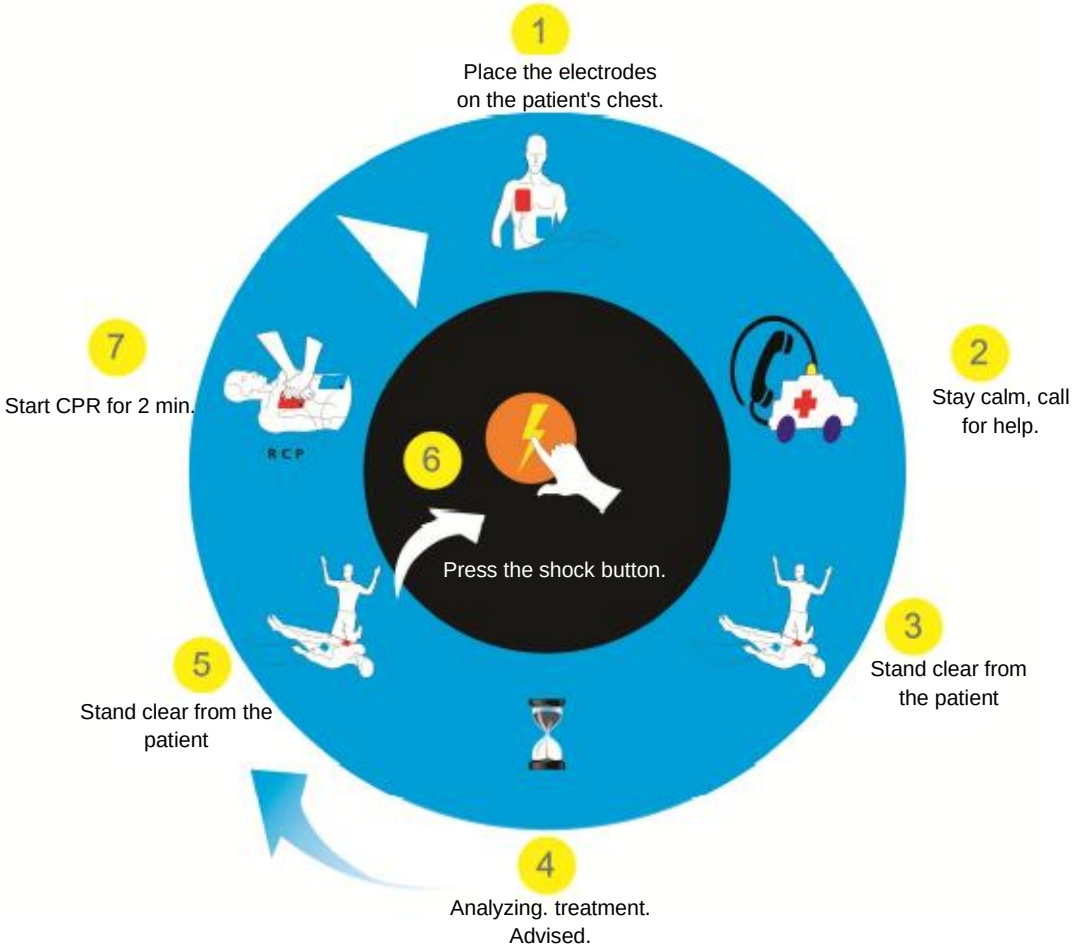


Figure 8 - Resuscitation procedure in cases of indicated treatment

Sequence for not indicated treatment

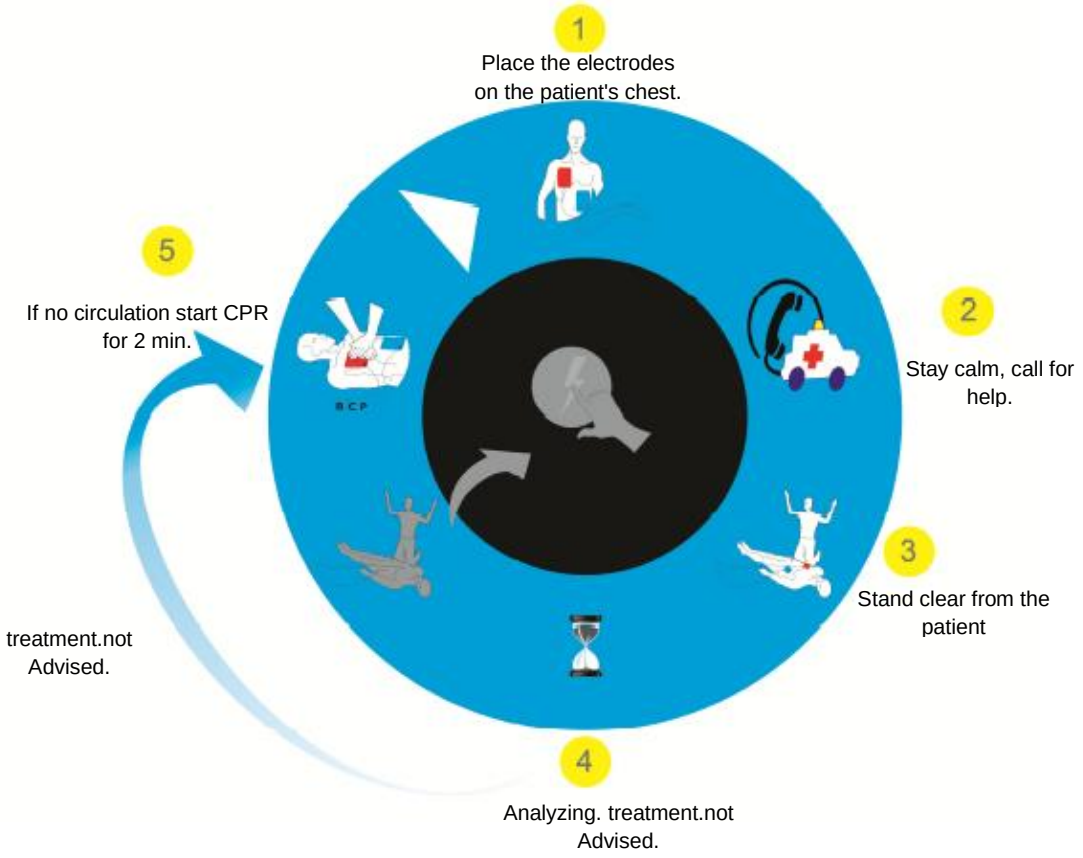


Figure 9 - Resuscitation procedure in cases of not indicated treatment

1 2 Place the electrodes on the patient's chest.
Stay calm, call for help.

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

To connect the electrodes on the patient's chest, the rescuer shall:

1. Check the expiry date of paddles;
2. Open the package and remove the electrodes;
3. Connect the electrodes to the equipment, as the following figure;

Figure 10 - Connecting the electrodes to the AED

4. Open the patient's shirt for quick access to the chest;
5. Check if the skin is dry;
6. If there is a large amount of hair, perform the hair removal (shaving of hair) for better contact of the electrodes to the patient's chest;
7. Attach the electrodes on the patient's chest according to the indication of paddles (next figure);

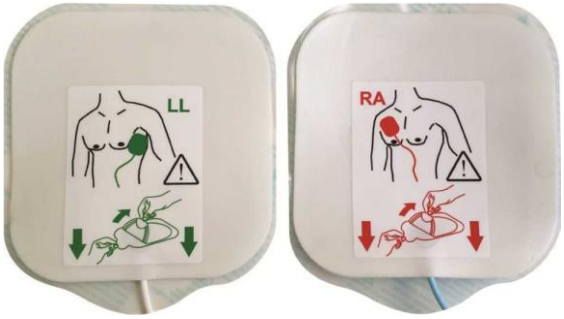


Figure 11 - Indication of the electrodes' positioning on the patient's chest

According to the AHA Guidelines 2015, the electrodes may be placed in the anteroposterior position, left anterior infrascapular and right anterior infrascapular with the same efficiency.

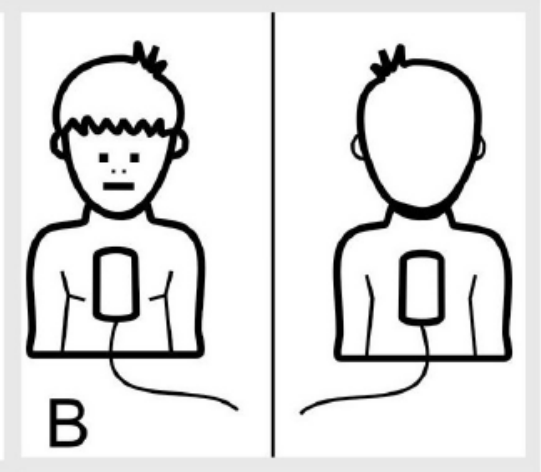


Figure 12 - Positioning of electrodes in infants

⚠The user must be careful to reset a new pair of transthoracic adhesive electrodes after use, so the equipment is always ready for another emergency;

⚠It is necessary to check the expiry date of electrodes in order to ensure compliance with promptness and speed. If the electrodes are expired, replace them immediately.

⚠The disposable electrodes are single use only, so, they must not be re-sterilized;

⚠Do not use disposable electrodes if the packaging is damaged;

⚠Do not use the electrodes have been removed from the bag for more than 24 hours. The electrodes should be used within 30 minutes after being taken from the protective coating.

⚠The shock paddles (intended to contact the patient's skin) should not be connected under the skin to have any injury where contact with body fluids is possible.

⚠Considering water is a conductor of electricity and the Defibrillator will transfer a high energy to the patient, the skin should be dry for the energy penetrate in the body, through the shock paddles, until the heart.

⚠To improve the contact with the skin, the shock paddles has a conductive gel to guarantee the good contact and the correct energy transfer. If the patient is wet energy will not penetrate the skin and will be dissipate the body surface, which can even cause burns.

⚠ **If patient uses an internal pacemaker and receive the treatment shock, the internal pacemaker can be damage by electrical discharge.**

3 **Stand clear from the patient.**

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

4 **Analyzing.**

The AED will analyze the ECG signal in accordance with preprogrammed algorithms and shall determine if the treatment is indicated (VT/VF) or not.

For indicated treatment:

5 **Stand clear from the patient.**

Everyone should get away from the patient for shock application.
At this time, the shock capacitor will be charged. There is no risk of electric shock, since the equipment has protective relays that only enable the power delivery when the rescuer presses the treatment button.

6 **Press the Shock button.**

When pressing the treatment button, the power is delivered to the patient.

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

⚠ **Keep the patient off conductive and/or wet surfaces and dry the chest, if necessary, before using the Defibrillator DEFIBSTART.**

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

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

After triggering, the icon  will be shown in the display with the number of shocks triggered in the patient during the treatment.

Start CPR for 2 minutes.

The countdown chronometer shall be exhibited on the screen with the CPR time and the equipment will beep for guidance of compressions (100 compressions per minute).

After 2 minutes, the AED automatically restarts the analysis of the ECG rate.

- Uncertainty of chronometer is 1.5ms/min order.

For not indicated treatment:

If no circulation, start CPR for 2 minutes.

In cases of not indicated treatment, it is necessary that the rescuer check again if there is a movement and, only if no movement is detected, it is necessary to perform CPR for 2 minutes.

MEDICAL MODE (OPTIONAL)

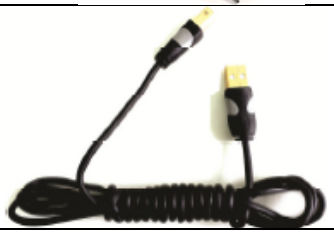
In the use of this mode, the control of assessment and determination of shock treatment is exclusive to the medical rescuer. The AED will thereafter operate as a Cardioverter and will not make the analysis of the ECG signal.
To enter the medical mode, simply turn the AED on and press the treatment button for four seconds. The "medical mode" message will appear on the screen.

If the rescuer decides to apply the shock, the treatment button must be pressed once to charge the capacitor and, when charging is finished, the LED will flash indicating that the equipment is ready for shock.

To exit the medical mode, simply turn the equipment off and on.

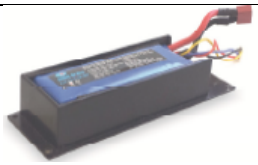
15. ACCESSORIES' DESCRIPTION

Basic Accessories Accompanying the Equipment

Description	Code / Reference	Supplier	Image
DISPOSABLE ADHESIVE SHOCK PADDLES- ADULT	F7959W/CM	USDEFIB /FIAB	
BATTERY CHARGER	MLT25508	Exclusive of USDEFIB	
Professional Bag BLS for basic life support for AED.	33940	Exclusive of USDEFIB	
USB EXTENDER CABLE A/B - PROTECTED FOR DATA TRANSFER.	35375	USDEFIB / Computer Shops	
PHOENIX SOFTWARE IN CD.	35369	Exclusive of USDEFIB	
User Manual printed	12486	Exclusive of USDEFIB	
Equipment Warranty Certificate.	33778	Exclusive of USDEFIB	

Optional Accessories

Parameter	Description	Code / Reference	Manufacturer	Image
DISPOSABLE ADHESIVE SHOCK PADDLES	DISPOSABLE ADHESIVE SHOCK PADDLES - INFANT	F7959P/CM	USDEFIB /FIAB	

EXTERNAL CABLE FOR MOBILE ICU	EXTERNAL SUPPLY CABLE	33324	Exclusive of USDEFIB	
USB CABLE				
PHOENIX SOFTWARE				
Extra battery	Extra Lithium-Polymer battery	LT655	Exclusive of USDEFIB	

⚠ **All accessories should be stored in a ventilated area and free from moisture and dust;**

⚠ **Before putting the equipment in contact with the patient, the operator should regularly check if it is in proper working conditions;**

⚠ **Use only accessories, consumables and others listed in this manual. The USDEFIB does not guarantee the proper functioning of equipment with the use of unknown accessories, and assume no liability for malfunction of the equipment or possible damage caused by them;**

⚠ **Overall, the EQUIPMENT and ACCESSORIES Parts of the Automatic External Defibrillator - AED, intended to come in contact with biological tissues, cells or body fluids are tested and analyzed in accordance with the guidelines and principles of ISO 10993-1, which AEDs exclusively with biocompatibility test of the parts applied;**

⚠ **USDEFIB ensures that all permanent and disposable materials in contact with the patient do not cause any kind of damage or harmful physiological effect, provided that: the procedures in this manual are respected; that they are installed in the appropriate medical site; that they are used with the right accessories; they are operated by trained personnel and follow all precautions described in this User Manual.**

16. CLEANING OF THE EQUIPMENT, ACCESSORIES AND BATTERY CHARGER

It is necessary to perform the cleaning of the AED and its NON-DISPOSABLE ACCESSORIES at every use, or if not used, the cleaning is quarterly recommended, following the instructions below:

- ❖ The cleaning and disinfection of the cabinet and the charger battery should be made with a slightly damp cloth in water and mild liquid soap, and another cloth dampened with 70% ethyl alcohol. Do not use abrasive cleaning agents, organic solvents, chlorine, alcohol or hydrocarbon solvents. In order to prevent scratches on the display screen panel, carefully pass a dry cloth or, in case of dirt, a cloth lightly dampened with water, and remove dust and dirt particles;
- ❖ The labels present in all items (AED, Accessories and Battery Charger) are important, and therefore, should not be removed and must not be damaged when performing cleaning;
- ❖ For disposable electrodes and accessories, after use, they should be disposed in the appropriate locations as special procedures for medical waste.

⚠**Do not pour any liquid and/or put needles and objects in general on the equipment and/or accessories;**

⚠**Do not immerse the equipment and accessories in any liquid to perform the cleaning.**

17. DATA MANAGEMENT

With the Phoenix software, you can view all events occurred during the use of products of USDEFIB.
The data transfer will be possible through the memory card or UBS cable for the Phoenix software and detailed analysis of recorded events while using the AED.

INSTALLING PHOENIX SOFTWARE

- Insert the program CD into the CD/DVD ROM drive;
- The installation will start automatically;
- Follow the instructions that appear on the screen;
- At the end of installation of Phoenix software, an installation window of Java virtual machine will appear and it must also be installed;

After installation is complete, a shortcut will be created on the user's desktop; just click in the shortcut to open the program.

Transferring AED data to the Phoenix software

1 - Start the Phoenix software;
2 - Connect the USB cable to the AED and the computer;

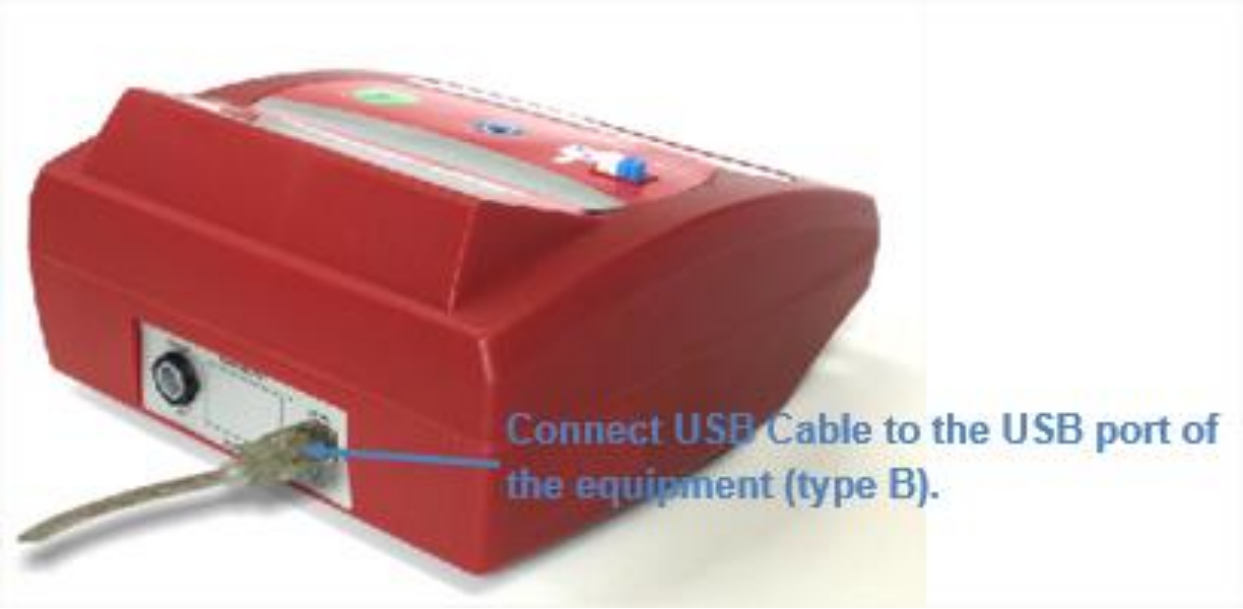


Figure 13 - Connecting the USB cable to the AED

VIEW OF DATA STORED

To view the stored data, enter in the "File" menu, click "Open" or click directly on the "open" icon of the toolbar, and select the desired file.

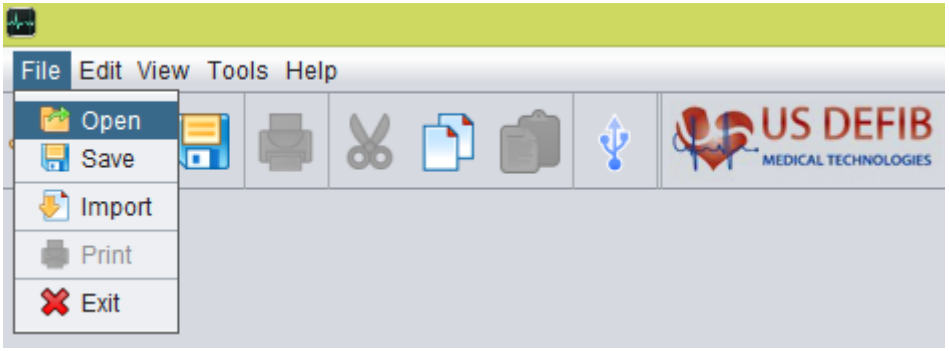


Figure 14 - Opening data files.

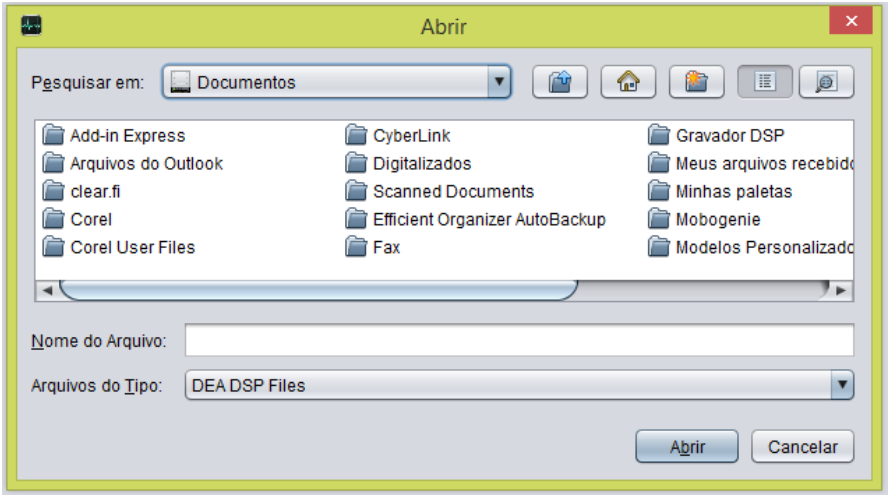


Figure 15 - By clicking "Open", a window for file selection will open.

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

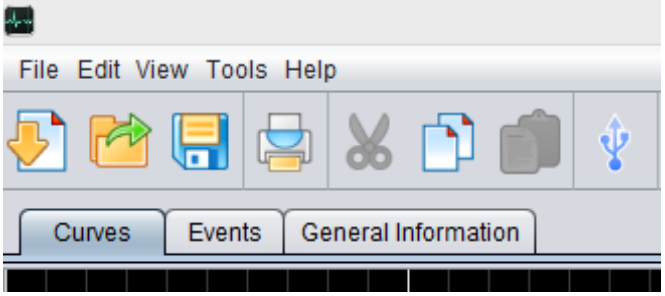


Figure 16 - Data display tabs.

SAVE IMAGE OF ECG

To save the image, you must click in the "Save" icon, or go to the "File" menu and click in “Save”.

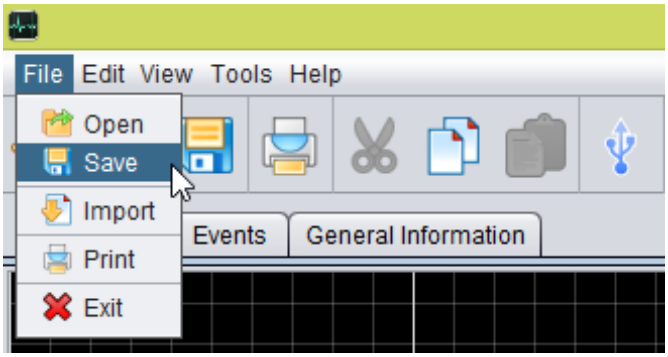


Figure 17 - Saving the file.

A screen to select the folder and file name will appear. After selecting the folder and the file name, the user must click in "Save".

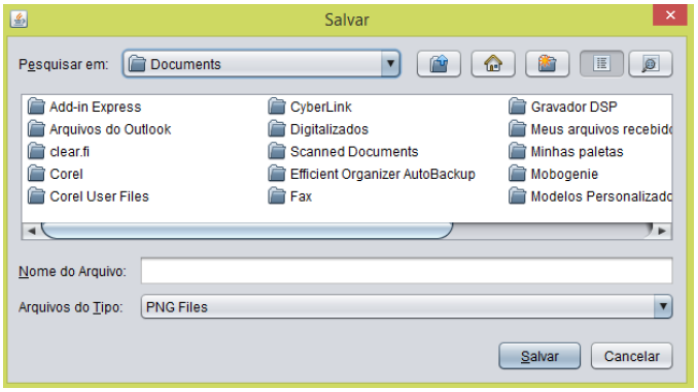


Figure 18 - Window for selection of the file to be saved.

PRINT FILE

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

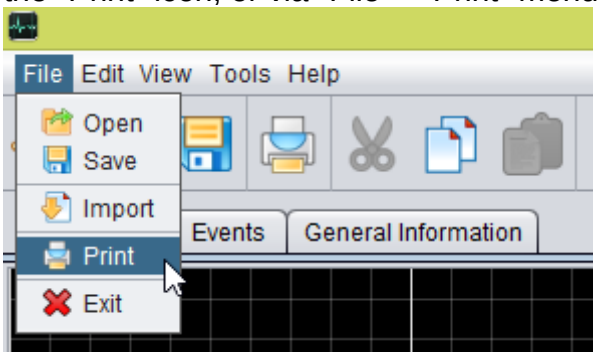


Figure 19 - Printing file through the "File" - "Print" menu.

A window for selection of the document to be printed will appear.
Although you can select more than one document for printing, the printing will be individual.

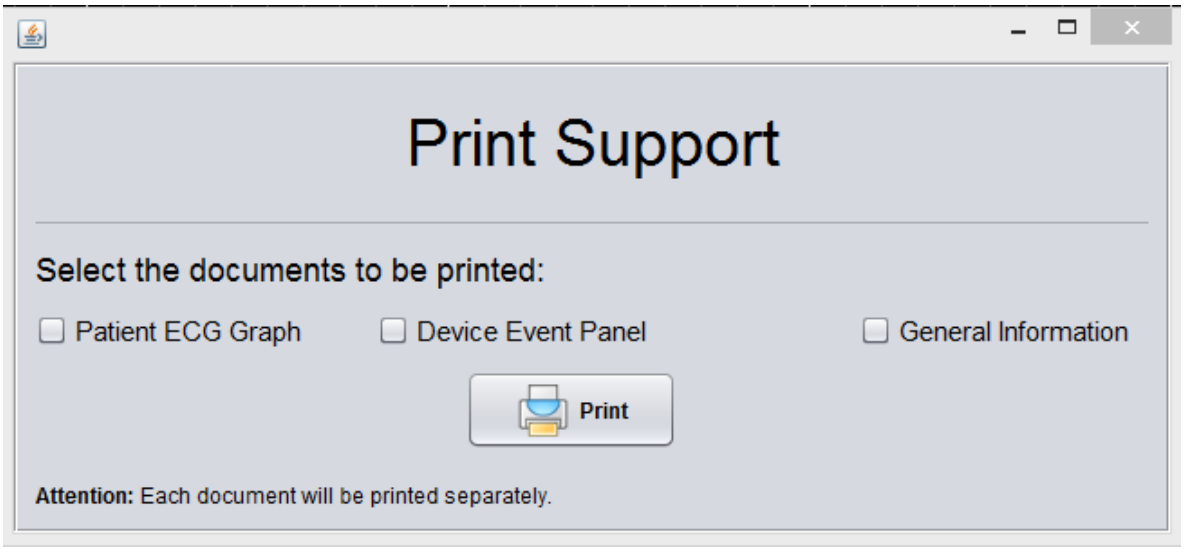


Figure 20 - Window for selection of the file to be printed.

COPY PROGRAM CONTENT

The "Copy" function will hold a copy of the tab displayed on the screen, as follows:

- ECG Tab - will copy an image to the clipboard.
- Events tab - will copy the text in the selected table cell.
- General Information tab - will copy the text in the selected area.

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

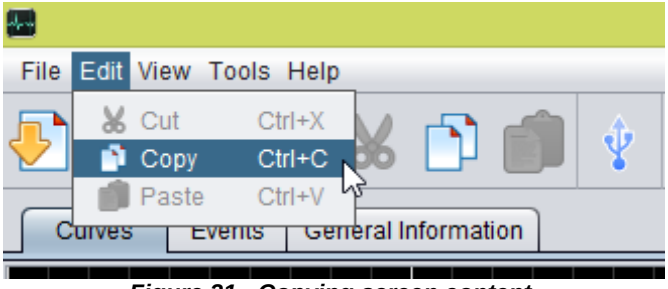


Figure 21 - Copying screen content.

CHANGE LANGUAGE

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

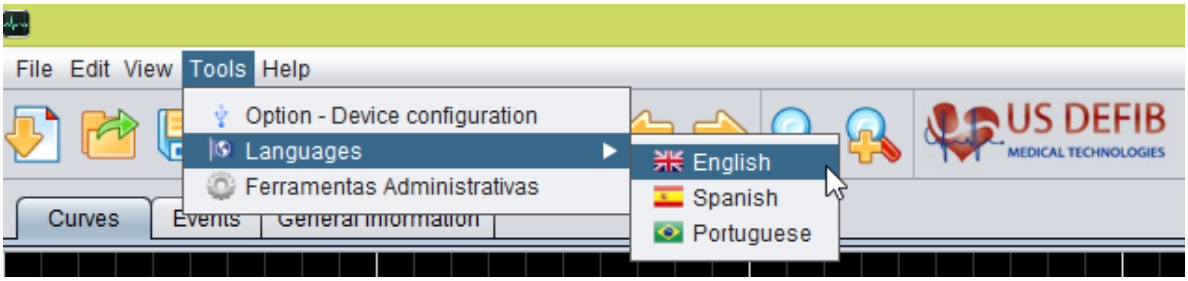


Figure 22 - Language selection.

CHANGE PAGE

On the toolbar, Click in the yellow arrow to the right. The pages will be changed in the chronological sequence in which they were recorded.
Right arrow moves to the next page. To return to the previous page, just click in the left arrow.

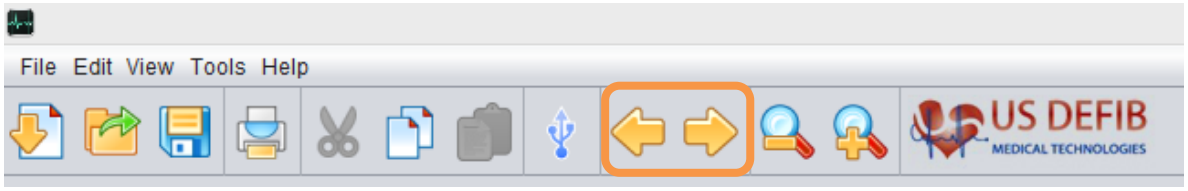


Figure 23 - Next Page - (arrow to the right).

VIEW EVENTS

Click with the right button on the screen curves and select events. Event messages appear on the ECG curve.

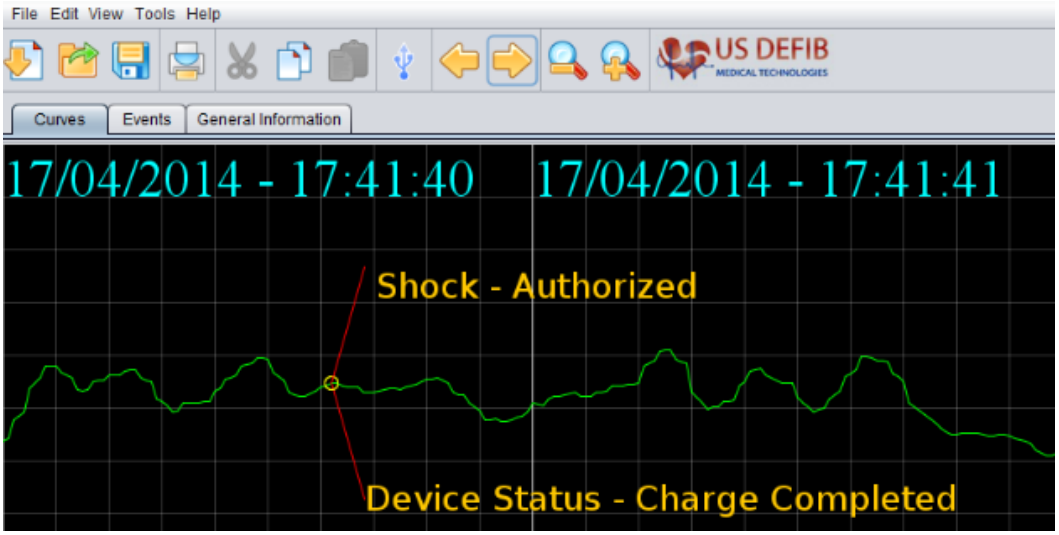
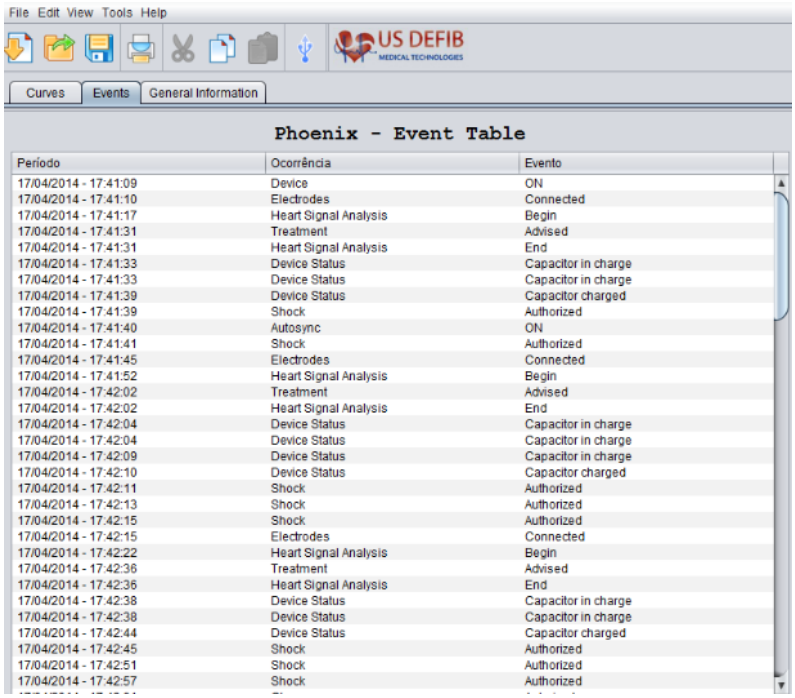


Figure 24 - Description of events occurred.

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



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

Figure 25 - Teb of events

ZOOM

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

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

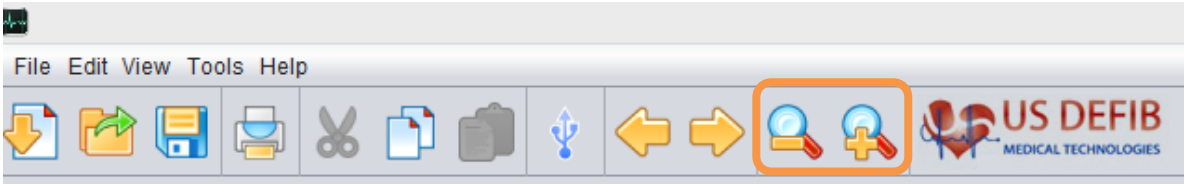


Figure 26 - Zoom of screen.

GENERAL INFORMATION

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

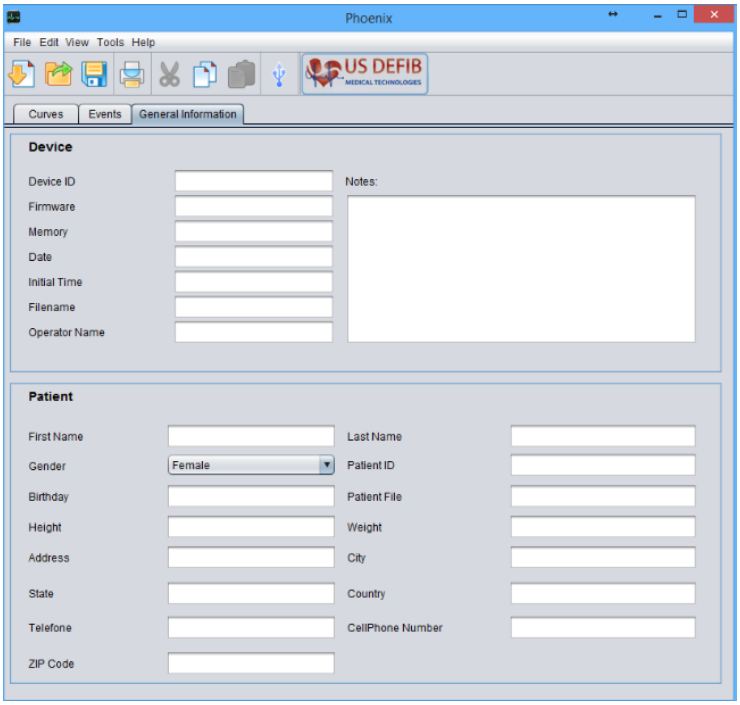


Figure 27 - General Information Tab

HELP

Click "Help" - "About".

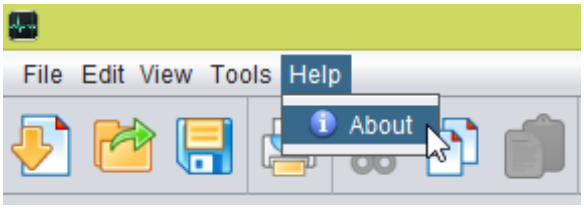


Figure 28 - Help Menu.

A window will open with the software version information and contact for support if any question arise.

EXIT PROGRAM

Click in the "File" - "Exit" menu. The software implementation should be closed.

18. SIDE EFFECTS

USDEFIB, as a manufacturer of medical equipment, requests to users a report of possible defects or occurrence of any undesirable event, in order to ensure the quality of the equipment, accessories and battery charger. Therefore, in case of any failure or malfunction, contact the nearest sales consultant directly on the phone or website below:

www.usdefib.com
Phone: +1 305 887 7552

19. SAFETY INFORMATION

The Defibrillator DEFIBSTART - AED and its basic and optional accessories will promote safety, if used for the right purpose and in accordance with the instructions described in this manual.
All those who need or wish to make use of the AED defibrillator should be trained in basic life support, and this course shall be provided by companies accredited and/or medical professionals accredited. Guidance on the fundamentals of defibrillation and indications and contraindications are essential for attendance of a victim of cardiopulmonary arrest. The reading of the instruction manual and the compliance of safety standards and warnings contained therein are mandatory.

THE MANUAL READINGS DO NOT OVERLAP, IN NO EVENT, THE TRAINING ITSELF.

Do not use the defibrillator DEFIBSTART - AED in areas where there is danger of explosion. In the event of improper use of the equipment, the user, patient and/or others will be subject to the risk of electric shock due to high voltage generated by the equipment, and if the electrodes are wrongly positioned, it may result in burns.

RESPECT THE RULES AND GUIDELINES DESCRIBED BELOW

GENERAL

⚠**Only trained and authorized personnel should perform the maintenance of DEFIBSTART;**

⚠**Use the equipment in only one patient at a time;**

⚠**Use the charger supplied by USDEFIB only;**

⚠**Do not operate the equipment at places with water;**

⚠**In places surrounded by agents and flammable anesthetic gases, avoid the use of the Defibrillator DEFIBSTART due to risk of explosion;**

⚠**Do not use the defibrillator DEFIBSTART near other equipment, neither stack it. If this is necessary, check if the operation works as usual;**

⚠**Always move away from the patient to apply the treatment;**

⚠**Do not connect multiple devices to the patient at once;**

⚠**Do not touch in the contact surface of the adhesive paddles, the patient or any conductive material that is in contact with the patient during the ECG analysis or defibrillation, since the results may be affected and the security may be reduced;**

⚠**If the patient's chest is wet, it is recommended that the rescuer dry it before attaching the electrodes;**

⚠**It is recommended to keep some auxiliary materials such as surgical scissors, disposable razor blade, for removal of hair in the chest, and disposable gloves, if there is an accident during use.**

DEFIBRILLATION

⚠Prevent the adhesive paddles to touch each other, in ECG electrodes, bandages or any other metallic object, due to the patient's risk of suffering skin burns during defibrillation and the current to be diverted from the heart;

⚠During defibrillation, burns on the patient's skin may also occur if there is any air pocket between the skin and the adhesive paddles. To prevent this from happening, check the paddles, so they are fully adhered to the skin. Always use new paddles and only once, immediately after withdrawing them from their packaging;

⚠Do not touch the patient, bed (litter), equipment or any accessory connected to the patient during the defibrillation.

⚠The patient shall not have contact with metallic objects and/or conductive fluids, as this may cause not intentional currents through accessible routes;

BATTERY

⚠The recycling or disposal of batteries expired must occur in accordance with local regulations;

⚠The batteries are designed for temperatures up to 60°C.

⚠Keep the battery pack away from fire and other heat sources;

⚠Do not put the batteries around metallic objects that could cause a short circuit;

⚠Never disassemble, puncture, crush, or open the battery. Respect the safety circuit;

SAFETY AND PROTECTION

To the Patient:

- **The capacitor is charged just before the triggering and the charge voltage is connected to the electrodes only at the time of shock.**

To the Operator:

- **The equipment works with internal battery (lithium-polymer) only.**

In Aircrafts:

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

20. PROCEDURE FOR DISPOSAL AT THE END OF THE PRODUCT SHELF-LIFE

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

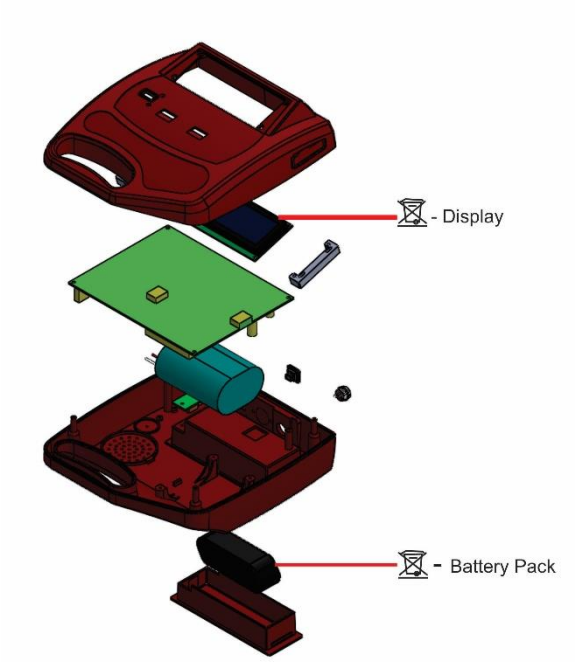


Figure 29 – Special attention to dispose the Display and Battery

For disposal of accessories, follow local regulations related to medical waste.

Waste of electrical and electronic equipment. Discard separately from other objects of the establishment. Please check local regulations for disposal (see European Directive 2002/96/EC). Accessories' Description

21. MAINTENANCE AND INSPECTION

CORRECTIVE AND PREVENTIVE MAINTENANCE

Precautions and Special Care

- Do not place any kind of material on the equipment;
- Do not reuse disposable materials; after use, they should be disposed in the appropriate locations as special procedures for medical waste;
- We recommend to keep some auxiliary materials such as surgical scissors, disposable razor blade, for removal of hair in the chest, and disposable gloves, if necessary.

Preventive Inspection & Cleaning
For durability of the DEFIBRILLATOR DEFIBSTART and its accessories, we recommend that the Preventive Inspections & Cleaning be performed periodically, following the table below.

Checking Applied	Periodicity
Preventive Inspections	Semester
Cleaning	Weekly

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

This process should be performed following the criteria below:

Preventive Inspections

We recommend that an inspection be performed every six months in the DEFIBRILLATOR DEFIBSTART and its accessories, independently if the equipment was used or not, following the instructions below:

- Check the validity/expiry date of (disposable shock paddles) and functional status of accessories. If some of these accessories are close to the expiry date, or are already due, or in bad conditions, we request that a new material be purchased from the USDEFIB manufacturer only, or from any authorized representative;
- Check the preservation of the equipment and its accessories; if there is any irregularity in the equipment, it must be sent to the manufacturer for maintenance and, regarding the accessories, a new material must be purchased from the manufacturer only.

Preventive maintenance

Maintenance and conduction of periodic tests on the equipment and its accessories are preventive measures that help to prevent and detect possible electrical and mechanical failures. During the maintenance schedule recommended by USDEFIB, if the test reveals a possible discrepancy with the AED, accessories and sensors, discontinue use immediately and contact the qualified technical area.

Schedule and maintenance tests

The tables below shall be used in conjunction with the hospital internal quality control program or any location where the AED is used. The list below, called Checklist, will help the operator to verify the corrective recommended post problem action.
The electrical safety, performance and calibration tests of AED should be performed by qualified service and personnel authorized by USDEFIB. These tables should stay with the equipment for personnel checking related to the equipment.

Scheduling	**Before use**	**After use**	**If necessary**	**Daily**	**Weekly**	**3 months**	**6 months**	**12 months**
Check the expiration date of the adhesive shock paddles.	x							
Inspect the equipment (visual and mechanical)	x	x						
AED Cleaning		x	x					
Accessories' cleaning		x	x					
Check if all necessary materials and accessories are complete				x				
Function Checking:								
Check the message on the screen and the voice command						x		
Electrical safety test								x
Electrical safety test after technical intervention	x							
Test with the defibrillator analyzer in the first and second year								x
Test with the defibrillator analyzer in the third year onwards							x	
Check the battery charge level		x	x					

Check List									
Defibrillator DEFIBSTART									
Unit Serial Number:									
Location:									
Purpose:									
We recommend that this unit be inspected and tested daily.									
We authorize the reproduction of this Check List form.									
Instruction		Corrective Action Recommended		Date Initials					
				Enter a V in the box after performing each statement in full					
1 - Inspect the physical conditions to check for:									
Foreign substances		Clean the equipment							
Damage or cracks		Contact the qualified technical area							
2 - Inspect the battery charger to check for:									
Charger connected to the unit and mains; the LED is not flashing		Check the connections on the device and in the outlet; if the LED remains off, contact US DEFIB service center.							
3- Check the disposable adhesive shock paddles.									
Expiry date		Replace if expired							
Spare electrodes available		Replace the electrodes							
4 - Check the cables to see if there are		Replace the damaged or broken							

cracks, damages, broken or bent parts and pins, and the surfaces of paddles to know if there are damages		parts							
5 - Disconnect the battery of the charger unit, press the ON button, and check for:									
Battery charge level		If low, plug the charger until the charge is full. Repeat the procedure; if the charge still remains low, contact US DEFIB.							

CAUTION!
Possibility of damage to the equipment.
Do not clean any part of this device or its accessories with bleach, bleach dilution or chemical compounds with phenol base. Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this device or any of its accessories.
Possibility of damage to the paddles and burns in the patient.

Every 12 months, the equipment must be sent to US DEFIB service center so the preventive maintenance is performed. This procedure ensures that all product features are in full working condition.

It is not necessary to calibrate the Defibrillator DEFIBSTART, because it is calibrated in the manufactory according to technical specifications, requiring no new calibrations.

SOFTWARE VERSION

To check the equipment software version, use the recording software (GravaDSP - Software USDEFIB); turn the AED on and connect the recording cable. The software version installed in the equipment will appear on the program screen. This procedure should be performed by USDEFIB.

DISPOSABLE BATTERY REPLACEMENT

The replacement of non-rechargeable battery must be performed when the equipment emits a beep and a visual warning of low battery.
For more information about the frequency of the alert
, see the self-test section of this manual.

NOTE: The user must request the supply of a new battery pack to USDEFIB for proper replacement when the life cycle is over of due to damage.

REPLACING THE BATTERY

1) The battery pack compartment is at the bottom of the equipment. To remove it, simply pull the latch as the following figure.
2) After opening the compartment, simply unplug the cables and replace the battery.

3) After replacing the battery pack, press on/off in the equipment and check the voice and text message: "READY TO USE".

⚠The defibrillator batteries must be returned to USDEFIB after replacement due to defect or end of life cycle thereof.

⚠Do not disassemble or dispose in fire, since there is a risk of explosion.

INTERNAL FUSE

The Defibrillator DEFIBSTART has a fuse on its main board located in the F1A position of the plate. To replace it, it is necessary to open the equipment.
Fuse specification: SMD 1206 (3216) 32V 5A - delayed action.
Only USDEFIB can exchange the fuse.
Opening of the equipment will result in loss of the warranty.

22. TROUBLESHOOTING

The User shall always check the conditions of the equipment. Among the items to be observed, there are:

- ❖ Integrity of cabinet;
- ❖ Battery charge level;
- ❖ Does it have the necessary accessories for use? (Adult and/or pediatric electrodes)

Problem	Action Recommended
AED does not turn on.	Check the battery condition, if empty or incorrectly installed.
AED turns on, but keeps repeating the message "Place the electrodes on the patient's chest".	Check the connection of electrodes with AED, or if the patient presents hair on the chest you must perform hair removal (hair shaving) and/or exchange such electrodes.
AED "beeps" often.	This is the self-test, a sign that the battery is low and, therefore, it must be recharged or replaced.

Table 5

***NOTE:** If the recommended actions are not sufficient to correct the problem, contact US DEFIB Service Center.

23. PARTS APPLIED OF THE DEFIBRILLATOR DEFIBSTART

Part applied - part that comes into physical contact with the patient so the equipment performs its function.
The part applied of the Defibrillator DEFIBSTART:

Part Applied	Protection Grade
Disposable Shock paddles AED Mode	Defibrillation-proof CF

24. TECHNICAL SPECIFICATIONS OF THE DEFIBRILLATOR DEFIBSTART

According to the applicable harmonized technical standards	EN 60601-1:2006/A1:2013; EN 60601-1-2:2007/ AC:2010; EN 60601-2-4:2003; EN 60601-1-6:2010; EN62366:2008; EN ISO 10993-1:2009; ISO 109935:2009; IEC 60529:1989+A1:1999+A2:2013; EN980:2008; EN 62304:2006/AC:2008; EN ISO14971:2012; EN ISO14155:2011; EN ISO13485:2012; EN 1041:2008; EN 15986:2011
Protection against electric shock	AED - Part applied of Type CF defibrillation-proof.
Protection against harmful penetration of water and particles	IP56 IP5X – (solid particles - dust) Protected against dust depression: 200 mm of water column. IPX6 – (water) Protected against powerful water jets 12.5 l/min - 30 kN/m²
Security degree of use in the presence of flammable anesthetic mixture	Equipment not suitable for use in the presence of flammable mixture with air, O2 and N2O.
Operation mode	Not-continuous operation mode: Operation cycle: ON max. - Charge capacitor: 6 seconds OFF Min. interval between triggers: 30 seconds.
Battery Charger	Input: 100 - 240 VAC/ 50 - 60 Hz Output: 12,6VDC - 800mA Charger combination with the equipment composes a system.
Internal power supply	Type: Rechargeable Lithium-Polymer (Li-Po), 11.1 VDC,

(internal battery)	2200mAh, battery Full-charge time (fully discharged): 4 hours Temperature + 10°C to + 60°C
Mean used for equipment separation from the mains	Network plug
Maximum Cumulative Time of Exposure of operator/patient to the equipment.	Maximum exposure time: approx. 6 hours (battery duration).
Protection against electric shock	Internally powered when in operation and class II when the battery is under charge.
Data recording on Internal Memory (2GB).	Data recording capability throughout the life cycle of the equipment without the necessity of transfer.
Operation temperature	10ºC to 40ºC
Operation Humidity	30% to 75%
Atmospheric pressure of Operation	700 hPa to 1060 hPa (525 mmHg 795 mmHg) 61
Storage temperature	0 to 50 °C.
Storage humidity	10 to 95%, no condensation
Transportation Conditions	Environment temperature range from 0° to + 50°C; Relative humidity range from 10% to 95%; Atmospheric pressure range from 700 hPa to 1060hPa (525mmHg to 795mmHg). Maximum stacking of 5 boxes. Transport in the original equipment box. USDEFIB does not guarantee and is not responsible for any damage that might occur to the equipment transported or stored in another packaging.
Dimension	295 x 225 x 155 mm
Weight	Approximately 1.9 kg

TECHNICAL SPECIFICATIONS AED

Input impedance	> 10 Mohms
Frequency response	0.05 - 100 Hz
Filters	Notch: 60 - 50 Hz Muscular: 35 Hz low-pass
Gains	5 - 10 - 20 mm/mV
Range of beat reading	10 - 300 BPM
Tolerance	+/-3J or 15% whichever is greater
Output	Analog ECG signal 1V/mVpp
Calibration signal	1 mVpp ±3%
Shock application	Through multifunctional adhesive paddles.
Defibrillation scales	Adult - 150J/200J/ 360J (optional) Infant - 50J
Adult/Infant Selection	Automatic per type of paddles.
Protection level against	Part Applied of Type CF defibrillation-proof .

electric shock	
Output features of defibrillator	1,5KV Máx. 50A Max.
Maximum time since the beginning of the defibrillator operation up to readiness for discharge at full power (200J)	30 seconds
Maximum time to charge the battery (completely discharged) with the voltage of the power network in 90% to be able to deliver 6 shocks in 200J.	20 minutes.
AED MODE – Waveform	Biphasic truncated exponential. Waveform parameters adjusted according to patient impedance.
Internal Pacemaker Pulse	Detects the pacemaker pulse and rejects the pulse.
Synchronism	Does not synchronism the shock with QRS. In accordance with the Algorithm arrhythmias, this product indicate treatment only in arrhythmias where the QRS was not identified. Shockable Arrthymias: VFIB VTACH CVF MVT_140 MVT_160 PVT_140 PVT_160
	DefibStart does not display on the screen synchronism detection indicators;
Discharge time	< 240 ms
Disposable Electrodes	
Q.ty of tolerable discharges x power max	Adult – 50 x 360 J Pediatric – 50 x 100 J
Indications for use (patient body weight)	Adult - > 25kg Pediatric - < 25kg
Width adhesive ring	Adult – 1,3 cm Pediatric – 1,6 cm
Total surface (for each electrode)	Adult – 148 cm^2 Pediatric – 75 cm^2
Active area (for each electrode)	Adult – 95 cm^2 Pediatric – 40 cm^2
Conductive material	Metal sheet
Electro-conductive gel	Low impedance conductive adhesive gel

TECHNICAL SPECIFICATIONS OF BATTERY CHARGER

According to the harmonized technical standards	FCC CE(EN55024,EN6100) C-TICK UL1310, EN55014
Relevant certifications	CE,RoHS,UL
Type of protection against electric shock	Class II
Operation mode	Continuous
Brand / Model	USDEFIB / MLT25508 11,1-800
Maximum output voltage	12.6Vdc
Output current	800mA
Powering	100 - 240 VAC - Automatic - 50/60 Hz
Maximum input current	1A
Mean used for equipment separation from the mains	Network plug, AC UE and 5.5x2.10mm
Cabinet	Plastic ABS+PA
Operation temperature	10°C to + 40°C
Operation Humidity	30% to 75%
Storage temperature	0 to 50 °C
Storage humidity	10 to 95%, no condensation
Dimension	Approximately 74x28x42 mm
Weight	Approximately 60g including all accessories
Atmospheric pressure of Operation	700 to 1060 Pa (525 mmHg 795 mmHg)

25. TECHNOLOGY APPLIED

DETECTOR OF HEART RATE

The Defibrillator DEFIBSTART - AED is prepared to recognize and indicate defibrillation to cardiac rates of ventricular tachycardia (VT) of several frequencies and width of QRS and ventricular fibrillation (VF) of several amplitudes, AUTOMATICALLY, so the operator can connect the paddles in the patient's chest and follow its voice and text commands.

RECORDING METHODS

Arrhythmias subject to defibrillation (VT and VF) are pre-programmed in the equipment, eliminating the need of setting by the operator, resulting in a significant gain of treatment time.

RATE SOURCE

Through the Desfibrillator Analyzer equipment, QA-40M model of the company METRON, the heart rates subject to defibrillation as VT and VF, the natural rates in several amplitudes and frequencies are simulated.

RATE SELECTION CRITERIA

Selected rates are those notoriously known as classical indication for defibrillation, namely: ventricular fibrillation and ventricular tachycardia.

NOTE METHODS

The Defibrillator DEFIBSTART - AED is equipped with a liquid crystal display electroluminescent or colored in several resolutions (optional), where the urgent care procedures and ECG traces are plotted, allowing the graphic recording of heart rates.

RESULTS OF THE DETECTOR PERFORMANCE

Rate	Rating
Ventricular Tachycardia	A/(A+B)
Ventricular Fibrillation	A/(A+B)

Table 2

True Positive (A): Correct rating of rate subject to defibrillation.
True Negative (B): Organized or in perfusion rate or asystole that was incorrectly classified as a rate subject to defibrillation.
False positive (C): A VT or VF associated with a cardiac arrest that was incorrectly classified as not subject to defibrillation.
False negative (D): Correct rating of all rates in which a shock is not indicated.

BIPHASIC TRUNCATED EXPONENTIAL WAVEFORM

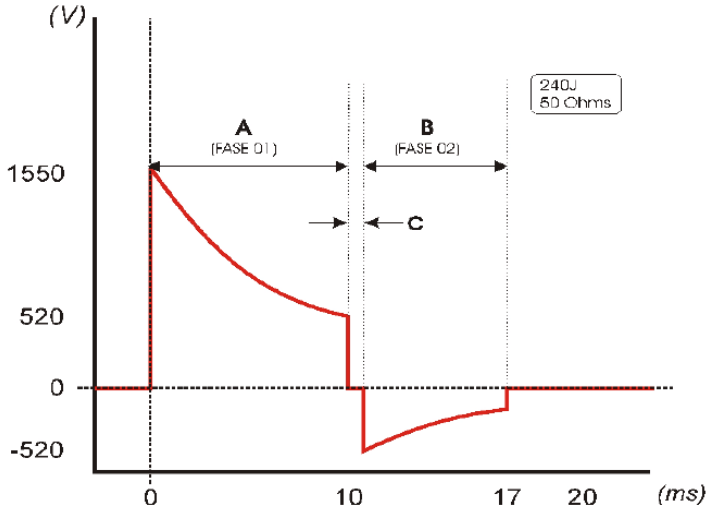


Figure 30 - Biphasic Truncated Waveform

Legend:
A - Phase 01
B – Phase 02

VARIATIONS ACCORDING TO CHEST IMPEDANCE OF THE PATIENT

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

Table 3 - Variations according to chest impedance of the patient

The Phase B corresponds to 2/3 of Phase A

Maximum width (A+B): 20 ms
AEDd-time (C): 0,5 ms

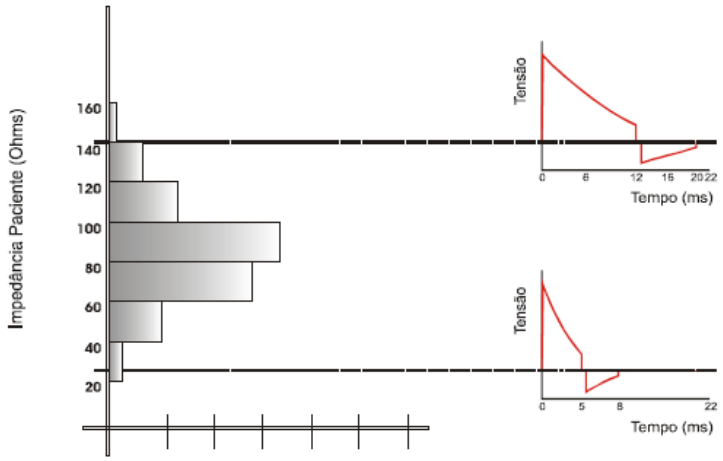


Figure 31 - Variation of waveform according to the patient's impedance

Legend: Patient's Impedance (Ohms)
Voltage
Time (ms)

Energy (Joules)	***Impedance (ohms)***						
	25	***50***	***75***	***100***	***125***	***150***	***175***
50	47.1	47.7	47.9	44.7	48.7	45.4	47.1
150	145.8	148.9	147.1	147.5	142.5	138.1	131.8
200	182.6	187.5	191.1	180.8	197.5	183.8	199.7
	Delivered Energy						

Figure 32 – Variation of energy delivered x Impedance

26. APPENDIX A - GUIDELINES AND STATEMENT OF THE MANUFACTURER - ELECTROMAGNETIC EMISSIONS

The Defibrillator DEFIBSTART - AED was designed for operation in any environment presented below.
The customer or user of the DEFIBRILLATOR DEFIBSTART - AED should ensure its operation in one of these environments.

MEASURES OF RF EMISSIONS	ACCORDANCE	ELECTROMAGNETIC ENVIRONMENT - GUIDANCE
RTCA/DO-160D:1997, section 21, category M	In accordance	The DEFIBRILLATOR DEFIBSTART - AED is suitable for use in environmental conditions and test procedures for Airborne Equipment.
RF emissions according to ABNTNBR IEC CISPR 11	Group 1	The DEFIBRILLATOR DEFIBSTART - AED uses RF power for its internal functions only. Thus, the RF emission of it is very low and is not likely to cause any interference in electronic equipment nearby.
RF emissions according to ABNTNBR IEC CISPR 11	Class B	The Defibrillator DEFIBSTART - AED is suitable for use in all residential establishments and for those directly connected to the public network of low voltage electricity distribution, which supplies buildings for domestic use
Emissions of Harmonics IEC 61000-3-2	Class A	
Emissions due to voltage fluctuation / scintillation IEC 61000-3-3	In accordance	

The Defibrillator DEFIBSTART - AED was designed for operation in any environment presented below.
The customer or user of the DEFIBRILLATOR DEFIBSTART - AED should ensure its operation in one of these environments.

Resistance test to interference	**Test level of ABNT NBR IEC 60601**	**Accordance level**	**Electromagnetic Environment - Guidance**
Static electricity discharge (ESD) according to IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	In accordance	Floors should be made of wood or cement, and should have ceramic tile. If the floor is made of synthetic material, the relative humidity should be at least 30%
Disorders / fast transient electrical triggering according to IEC 61000-4-4	± 2 kV in lines of supply ± 1 kV in lines of input/output	In accordance	Quality of power supply must correspond to the voltage provided in a typical hospital or commercial environment.
Surges according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	In accordance	
Voltage drop, short interruptions and fluctuations in the supply voltage according to IEC 61000-4-11	< 5% Ut (> 95% voltage drop in Ut) for 0.5 cycle. 40% Ut (60% voltage drop in Ut) for 5 cycles. 70% Ut (30% voltage drop in Ut) for 25 cycles. <5% Ut (> 95% voltage drop in Ut) for 5 seconds.	In accordance	The quality of the supplied voltage must correspond to the supplied voltage in a hospital or typical commercial environment. If the user of the DEFIBRILLATOR DEFIBSTART - AED requires continuous operation even when there are interruptions in the power supply, the DEFIBRILLATOR DEFIBSTART - AED should receive power without interruptions or with a battery.
Magnetic field in the supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	In accordance	Magnetic fields in the frequency of the supply should be at levels from a typical location in a hospital or typical commercial

			environment.

Note: Ut is the supply voltage a.c. before application of the test level.

The Defibrillator DEFIBSTART - AED was designed for operation in any environment presented below.

The customer or user of the DEFIBRILLATOR DEFIBSTART - AED should ensure its operation in one of these environments.

Resistance test to interference	**Level of Test of ABNT NBR IEC 60601**	**Level of Accordance**	**Electromagnetic environment - Guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz - 80 Mhz	[V1]V In accordance	Portable and mobile RF communication equipment should not be used near any part of the DEFIBRILLATOR DEFIBSTART - AED, including cables, with a separation distance lower than the recommended, This safe distance will be calculated from the equation applicable to the transmitter frequency. Separation Distance Recommended: d= [3,5 / V1] P d= [3,5 / E1] P 80 MHz - 800Mhz d= [7/E1] P 800 MHz - 2,5 Ghz where P is the maximum output power of the transmitter in watts (w), according to the transmitter manufacturer, and d is the separation distance recommended in meters (m) It is recommended that the Field intensity established
Radiated RF IEC 61000-4-3	3 V/m 80 Mhz - 2,5 Ghz	[E1] V/m In accordance	

			by the RF transmitter, as determined by an electromagnetic inspection at the site [a], should be less than the compliance level in each frequency range.[b] Interference may occur around the equipment marked with the following symbol: 

Note 1 At 80 MHz and 800 MHz, the highest frequency range is applied.
Note 2 These guidelines may not apply in all situations. The electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
[a] Field intensity established by fixed transmitters, such as base radio stations, telephone (wireless cell phone) and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be theoretically predicted with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site inspection is recommended. If the measured field intensity in the location where the DEFIBRILLATOR DEFIBSTART - AED is used exceeds the compliance level used above, the DEFIBRILLATOR DEFIBSTART - AED should be observed to verify if the operation is normal.
If an abnormal performance is observed, additional procedures may be necessary, such as new guidance or replacement of the DEFIBRILLATOR DEFIBSTART - AED.
[b] Over the frequency range of 150 kHz to 80 MHz, the field intensity should be less than [V1] V / m.

27. FORM OF CUSTOMER REGISTRATION

EQUIPMENT DESCRIPTION	SERIAL NUMBER
DESFIBRILADOR DEFIBSTART - AED	

CUSTOMER NAME	
ADDRESS:	
CITY:	STATE:
Telephone:	FAX:

Warning
Mr. Owner,

Please fill the fields above with your data and send us via FAX so we can register you in our system, in order to keep our contacts for questions and technical support.

28. WARRANTY CERTIFICATE

US DEFIB WARRANTY CERTIFICATE

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

1. The term beginning of the warranty period occurs from the date of issue of the bill of sale related to the equipment purchased by the consumer with mandatory identification of the model, serial number and features of the equipment.
2- The term duration of warranty is twelve (12) months from the date corresponding to the item above.
3. US DEFIB MEDICAL TECHNOLOGIES LLC does not grant any form or any kind of warranty for the equipment without the bill of sale to the consumer.

Prescribed conditions of this warranty

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

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

- Sensors, cables in general and accessories required for the proper operation of the product are guaranteed against manufacturing defects for the legal period of ninety (90) days, beginning from the date of product purchase prescribed in the bill.
- Accessories marked as disposable and consumable (non-durable) will have its warranty in accordance with the Art. 26, item I of the Consumer Protection Code.

The warranty will be terminated when:

1- There is a removal or changing of the serial number of the equipment purchased by the consumer.
2- The equipment is installed or used differently from the provided in the USER MANUAL.
3 - The equipment is used with cables, sensors, accessories or consumables not recognized by US DEFIB or out of normal conditions of use, as expiry date or period or use.
4- The consumer will lose the right to the warranty for twelve (12) months in the event that the equipment:
a - receives maintenance or repair by professional not accredited by the manufacturer.
b - is used differently from the use described in the operation instructions,
c - is damaged by accidents or natural phenomena.
5- The manufacturer is not liable for expenses with facilities, products or accessories damaged due to traffic accident, handling, scratches, dents, non operation or failure due to problems in the supply of electricity.
In locations where there is no authorized service of US DEFIB MEDICAL, the transport costs of the device or of the authorized technician to the location where the equipment is will be payable by the Consumer requesting the service.

Serial Number:

29. REFERENCES AED MODE

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