

# User Manual

## *Defibstart Automated External Defibrillator*



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## **FOREWORD**

Congratulations on your purchase of US DEFIB MEDICAL TECHNOLOGIES LLC Equipment!

This product incorporates state of the art technology. We are certain you will be satisfied with the AED DefibStart.

READ ALL INSTRUCTIONS CONTAINED IN THIS MANUAL BEFORE operating the AED DefibStart.

This User's Manual contains all the information required for a complete interaction with the equipment, from information about the operation to the required care for better conservation of the AED DefibStart. The AED should only be used by trained professionals (physicians or trained rescuers) to provide basic and / or advanced life support.

When you finish reading the User Manual, keep it in a protected location so that you can refer to it anytime. New users may require a further reference. The ongoing consultation of this manual is a prerequisite to obtain a better performance of the equipment, proper operation, and to provide greater safety for both the operator and for the patient.

This manual also contains information related to technical assistance.

Carefully read the warnings contained on pages 5 and 6 of this manual.

**SUMMARY**

|         |  |    |
|---------|--|----|
| 1.      | WARNINGS.....  | 5  |
| 2.      | CLASSIFICATION AND SYMBOLS .....   | 7  |
| 3.      | MEASUREMENT UNITS .....  | 8  |
| 4.      | ACRONYMS USED IN THIS USER MANUAL.....   | 8  |
| 5.      | DISCARDING THE EQUIPMENT .....   | 8  |
| 6.      | AED DEFIBSTART DESCRIPTION AND ITS COMPONENTS.....                                     | 9  |
| 6.1     | Introduction.....  | 9  |
| 6.2     | Overview .....   | 10 |
| 6.3     | Identifications of Parts and Commands.....   | 11 |
| 6.4     | AED DefibStart List of Parts and Accessories.....                                      | 11 |
| 6.4.1   | Accessories Accompanying the Equipment.....  | 11 |
| 6.4.2   | Optional Accessories .....   | 12 |
| 6.4.3   | Accessories Pictures .....   | 12 |
| 6.4.3.1 | Important Notes.....   | 13 |
| 6.5     | Cable Connections and Accessories .....  | 13 |
| 7.      | AED DEFIBSTART FEATURES.....   | 14 |
| 7.1     | Patient Analysis System - AED .....  | 15 |
| 7.2     | Entry for External Power Supply in Ambulances and Aircrafts (optional accessory) ..... | 15 |
| 7.3     | Entry for Compact Flash Card (Optional).....   | 15 |
| 7.4     | Installing the AED Backup Software.....  | 15 |
| 8.      | INSTALLING THE AED DEFIBSTART .....  | 17 |
| 8.1     | Unpacking and Accommodating the Equipment.....   | 17 |
| 8.1.1   | Notes .....  | 17 |
| 9.      | POWER SUPPLY / BATTERY .....   | 18 |
| 10.     | ISOLATING THE PATIENT, THE OPERATOR AND THE EQUIPMENT .....                            | 19 |
| 10.1    | Safety and Protection .....  | 19 |
| 11.     | GUIDELINES 2010 - AMERICAN HEART ASSOCIATION .....                                     | 19 |
| 11.1    | References .....   | 22 |
| 12.     | HANDLING CABLES AND ACCESSORIES.....   | 22 |
| 13.     | USE INSTRUCTIONS .....   | 23 |
| 13.1    | Semi-Automatic Mode – Model DEFIBSTART.....  | 23 |
| 13.2    | Medical Mode – Model DEFIBSTART .....  | 27 |
| 14.     | APPLIED TECHNOLOGY .....   | 30 |
| 14.1    | Heart Rate Detector .....  | 30 |
| 14.1.1  | Recording Methods.....   | 30 |
| 14.1.2  | Rate (Pace) Source .....   | 30 |
| 14.1.3  | Pace Selection Criteria .....  | 30 |
| 14.1.4  | Annotation Methods .....   | 30 |
| 14.1.5  | Detector Performance Results.....  | 30 |
| 14.2    | Truncated Exponential Biphasic Waveform.....   | 31 |
| 14.2.1  | Variations According to the Patient Thoracic Impedance.....                            | 31 |
| 15.     | SELF-TEST.....   | 33 |
| 16.     | PRECAUTIONS AND SPECIAL CARE .....   | 33 |
| 17.     | EQUIPMENT AND ACCESSORIES CLEANING AND DESINFECTION .....                              | 33 |
| 18.     | STORAGE AND TRANSPORTATION.....  | 34 |
| 19.     | TROUBLESHOOTING .....  | 34 |
| 20.     | MAINTENANCE AND INSPECTION .....   | 35 |
| 20.1    | Maintenance .....  | 35 |
| 20.1.1  | Calibration .....  | 35 |
| 20.1.2  | Preventive Inspections and Cleaning .....  | 35 |
| 20.1.3  | Preventive Inspections.....  | 36 |
| 21.     | REPLACING THE NON-RECHARGEABLE BATTERY.....  | 36 |
| 21.1    | How to Replace the Battery .....   | 37 |

|   |    |
|---|----|
| 22. ADVERSE EFFECTS.....  | 37 |
| 23. GENERAL TECHNICAL SPECIFICATIONS .....  | 38 |
| 24. AED DEFIBSTART TECHNICAL SPECIFICATIONS.....  | 40 |
| 24.1 Terms Definition .....   | 40 |
| 25. TECHNICAL SPECIFICATIONS AED MODE.....  | 41 |
| 26. BATTERY IMPORTANT NOTE .....  | 41 |
| 27. APPENDIX THE – MANUFACTURER GUIDELINES AND DECLARATION - ELECTROMAGNETIC EMISSIONS..... | 42 |
| 28. TECHNICAL ASSISTANCE.....   | 46 |
| Customers Registration Form .....   | 47 |
| 29. FOR FURTHER INFORMATION .....   | 47 |
| 30. VERSION CONTROL .....   | 48 |

## 1. WARNINGS

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### ATTENTION!

The AED DefibStart must be used by properly trained personnel in basic or advanced life support, or by personnel authorized by physicians to treat emergency defibrillation in patients with cardiac arrest.



### ATTENTION!

The operator should examine the equipment and accessories conditions (regular trials) the correct functioning prior to use.



### ATTENTION!

The operator must have the knowledge and awareness of all side effects caused while using the defibrillator.



### ATTENTION!

When installing the equipment, make sure that it is in a location that has enough space for ventilation so that it is placed away from heat radiation.



### ATTENTION!

The AED DefibStart was developed for applications in defibrillation procedures enabling the application of electrical stimulation to the heart. It can be used in any hospital or outside hospital environment, including air or ground rescue units, providing advanced life support.



### ATTENTION!

Do not touch the patient, the bed (stretcher), the equipment or any accessory attached to the patient during the defibrillation.



### ATTENTION!

Keep the patient away from conductive and / or wet surfaces and dry his / her chest if necessary, before using the AED DefibStart.



### ATTENTION!

In order to prevent fire or undue shock risk, avoid operating the defibrillator close to water source and / or flammable products; do not allow any liquid to get in touch with the cabinet.



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In order to prevent fire or undue shock risk, avoid operating the defibrillator close to water source and / or flammable products; do not allow any liquid to get in touch with the cabinet.



**ATTENTION!**

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



**ATTENTION!**

There is risk of electric shock if the equipment cabinet is open. Every type of service or future updates of this equipment and its parts may only be performed by properly trained personnel and authorized by the US Defib Medical Technologies LLC.



**ATTENTION!**

Avoid using mobile phones or any devices that captures radio frequency near the equipment. The high level of electromagnetic radiation emitted by these appliances can result in a great interference, impairing the normal functioning of the defibrillator, jeopardizing patient safety.



**ATTENTION!**

The disposable materials should not be reused even after being subjected to a process of cleaning and sterilization. They should be disposed in appropriate locations according to the special procedures for hospital waste.



**ATTENTION!**

If any part of the equipment needs to be replaced, except the disposable material, you should contact the manufacturer or authorized network to provide the material and perform its replacement when necessary. If accessories from suppliers other than those indicated by the US Defib Medical Technologies LLC are used, the company will not be responsible for equipment operation and may have your warranty voided.



**ATTENTION!**

Generally, the parts of the EQUIPMENT and ACCESSORIES of the Automatic External Defibrillator Monitor - AED, intended to come into contact with biological tissues, cells and body fluids are tested and analyzed according to the guidelines and principles of ISO 10993-1, which deals exclusively with biocompatibility testing of the applied parts.



**ATTENTION!**

There is a risk of polluting the environment associated with the use of accessories and consumables at the end of their lifespan. The accessories and consumables should be disposed in hospital waste according to environmental law. The batteries should be returned to the manufacturer after replacing due to defect or end of lifespan.

## 2. CLASSIFICATION AND SYMBOLS



Hazardous Electricity Voltage



Continuous Electrical Current



ATTENTION! Consult accompanying documents.



Defibrillation Proof CF Type Applied Part.



Defibrillation Proof BF 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 that the package should be kept on a dry location.



Number 5: indicates stacking up to five units overlapped.



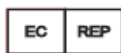
Minimum and Maximum Temperature.



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



Manufacturer.



Representative in the European Community.



Mark of compliance with the European Community.



Indicates to be comprised of raw recyclable material.



Electrical and Electronic Equipment Waste - Discard it separately from other objects

### 3. MEASUREMENT UNITS

| Symbols                          | Unit        | Description  |
|----------------------------------|-------------|--|
| m, cm, mm                        | Length      | Meter, centimeter, millimeter  |
| h, m, s, ms                      | Time        | Hour, minute, second, millisecond  |
| Kg, g                            | Weight      | Kilogram, gram   |
| °F, °C                           | Temperature | Fahrenheit Degrees, Celsius Degrees  |
| mmHg, hpa                        | Pressure    | Mercury Millimeters, hectopascal   |
| 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              | Velocity    | Meter per second, millimeter per second, beats per second, liters per minute |
| Ω                                | Impedance   | Ohms   |
| J                                | Energy      | Joules   |
| m <sup>3</sup> , mm <sup>3</sup> | Volume      | Cubic meters, cubic millimeters  |

*Table 1 – MEASUREMENT UNITS*

### 4. ACRONYMS USED IN THIS USER MANUAL

- ❖ **ACLS:** Advanced Cardiologic Life Support;
- ❖ **AHA:** American Heart Association;
- ❖ **BLS:** Basic Life Support;
- ❖ **ICDM:** Implantable Cardioverter-Defibrillator Monitor;
- ❖ **AED:** External Automated Defibrillator Monitor;
- ❖ **ECG:** Electrocardiogram;
- ❖ **VF:** Ventricular Fibrillation;
- ❖ **INCOR:** Heart Institute;
- ❖ **LCD:** Liquid Crystal Display;
- ❖ **CPA:** Cardiopulmonary Arrest;
- ❖ **CPR:** Cardiopulmonary Resuscitation;
- ❖ **BSC:** Brazilian Society of Cardiology;
- ❖ **VT:** Ventricular Tachycardia;
- ❖ **ICU:** Intensive Care Unit;
- ❖ **PPM:** Pulse per Minute.

### 5. DISCARDING THE EQUIPMENT

In order to avoid contamination of the environment, people or other equipment, make sure you have properly disinfected and decontaminated the equipment before disposing of it, according to national laws for equipment with electrical content and electronic parts. In order to discard parts and accessories, follow the local regulations regarding hospital waste





Electrical and Electronic Equipment Waste. Discard them separately from other objects from the establishment. Consult the local regulation for waste / garbage (consult the European Policy 2002/96/CE).

## **AED DEFIBSTART DESCRIPTION AND ITS COMPONENTS**

### **5.1 Introduction**

The Automated External Defibrillator AED DefibStart is a portable equipment, biphasic and designed for application in defibrillation procedures enabling the application of electric stimulation to the heart. The Biphasic Technology enables its use in any environment, such as: stadiums and gymnasiums, bus and railway stations, malls and commercial centers, ports and airports, hotels, temples, trains, subways, airplanes and boats, ambulances and air or ground rescue vehicles of the police and fire departments, venues for events of any kind, in addition to hospital, allowing basic and advanced life support. This revolutionary defibrillation technology requires less than half of the energy required by the conventional monophasic defibrillator monitors.

The AED DefibStart offers the possibility to be used by laypersons after training and/or under medical supervision. It features simple operation, with the capability of recording in Memory via Date Card of 256MB that corresponds to over 100 hours of continuous recording (Optional) and event memory that includes the ECG pace (rhythm) recording and identification of the treatment stage. It presents high sensitivity and specificity in the diagnosis of shockable arrhythmias. Optionally includes the recording of ambient sounds. It is possible to integrate to the equipment the function of measurement of blood oxygen saturation (optional). The use of the AED DefibStart increases the possibility of survival to a cardiopulmonary arrest (CPA).

The AED DefibStart features a liquid crystal display or colored in several sizes and resolutions (optional) for visualization of the procedures in emergency care and for the cardiac monitoring. It features a microprocessor for the analysis of the cardiac activity, which time for analysis is lower than 12 seconds. It is a waterproof equipment, resistant to dust, impact and height.

The AED DefibStart can be applied in adult patients and, optionally, in pediatric patients who are in Cardiopulmonary Arrest. It features voice and text command to instruct the rescuer during the CPR sequence, memorization (Compact Flash) and ambient sound recording (optional) and ECG analysis to identify shockable arrhythmias (VT – Ventricular Tachycardia, VF – Ventricular Fibrillation).

The AED DefibStart can be set according to the need and be supplied in the following setting:

- ❖ AED DefibStart

Automated External Defibrillator AED with voice and text command.

NOTE: it is possible to include:

- ❖ Rechargeable battery – Includes US DEFIB MEDICAL TECHNOLOGIES LLC battery charger;
- ❖ Medical Mode – Software where it is possible to change the setting for the evaluation control and determination of shock treatment. When enabled the decision whether the treatment will be performed or not is made exclusively by the medical rescuer;

Any option can be set up, at criterion of the specifics needs of each client; it doesn't alter the characteristics of the product purpose.

## 5.2 Overview



**Figure 1 - Overview of the AED DefibStart**

### 5.3 Identifications of Parts and Commands



**Figure 2 - General Identification of the AED DefibStart**

1. On and Off Key;
2. Treatment Button, used for triggering the shock. When flashing, confirms that the shock is ready to be applied to the patient;
3. Display (exhibits the treatment time, ECG trace, text command for the user according to the voice command);
4. Shock paddles connector (electrodes);
5. Low Battery Indicator;
6. Transportation Handle;

*\*The pictures contained herein are illustrative only.*

### 5.4 AED DefibStart List of Parts and Accessories

#### 5.4.1 Accessories Accompanying the Equipment

- ❖ 01 Lithium-Polymer Battery;
- ❖ 01 Pair of Disposable External Electrodes – Models: F7959W for adult patients and F7959P for child / pediatric patients;
- ❖ 01 DVD with User Manual and date card reading software;
- ❖ Transportation Bag intended to accommodate for transport and also safer storage of the equipment;

- ❖ Warranty Certificate.

#### **5.4.2 Optional Accessories**

- ❖ Cardiopulmonary Arrest Mobile Cart;
- ❖ Emergency Cabin to hold the equipment up on walls in places easily accessible;
- ❖ Interconnect cable for external power supply;
- ❖ BLS Rescue Bag – Contains Support, First Aid, Temporary Immobilization, Burn and Ventilation Kits;
- ❖ Battery charger (if the equipment has a rechargeable battery);
- ❖ Cleaning Kit;
- ❖ Compact Flash – 256MB Memory Card.  
Permanent Material Replacement
- ❖ Lithium-Polymer Battery Charger;
- ❖ Lithium-Polymer Battery.

#### Consumables

- ❖ Disposable External Electrodes – Models: F7959W for adult patients and F7959P for child / pediatric patients;

#### **5.4.3 Accessories Pictures**



**Figure 3 - External Adhesive Transthoracic Electrodes used for defibrillation – model F7959W - Adult (disposable material).**



**Figure 4 - External Adhesive Transthoracic Electrodes used for defibrillation – model F7959P - Child / Pediatric (disposable material).**



*Figure 5 - Battery Charger (non-disposable accessory).*



*Figure 6 - Interconnection cable with the external battery (permanent use accessory-Exclusive)*



*Figure 7 - Compact Flash Card - optional accessory.*

### **5.4.3.1 Important Notes**

- ❖ All of the accessories should be stored on a well-ventilated and humidity and dust free location;
- ❖ The user should be aware to place a new pair of adhesive transthoracic electrodes after its use, so that the equipment is always ready for another emergency;
- ❖ You should verify the expiry date of the electrodes to perform a prompt and fast treatment. If the electrodes are expired, they should be replaced immediately.

## **5.5 Cable Connections and Accessories**



**Figure 6 - Connection of the cables and accessories of the AED DefibStart**

1. Connection of the external adhesive transthoracic electrodes used for defibrillation;
2. Connection of the battery charger (optional);
3. Connection for ambulance entry (optional accessory);
4. Connection for software update (optional).

## **6. AED DEFIBSTART FEATURES**

- ❖ Defibrillation on the Truncated Exponential Biphasic Waveform, with the charge of 150J Joules in adult mode and 50 Joules in pediatric mode;
- ❖ It features Intelligent Safety System that limits the charge for pediatric use;

- ❖ Automatic internal discharge after 30 seconds if there is no the trigger;
- ❖ Capability to perform up to 140 discharges in maximum load (new battery fully charged);
- ❖ Electroluminescent Liquid Crystal Display, that displays the ECG trace / waveform;

### **6.1 Patient Analysis System - AED**

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

### **6.2 Entry for External Power Supply in Ambulances and Aircrafts (optional accessory)**

- ❖ It is possible to use the AED DefibStart utilizing the ambulance or any vehicle or aircraft 12 VDC input, the equipment operates continuously, without the use of the AED's internal battery. For that, just connect it through the linking cable with the external battery (figure14).



Only use linking cables with external battery supplied by US DEFIB MEDICAL TECHNOLOGIES LLC. Other cables may damage the equipment.

### **6.3 Entry for Compact Flash Card (Optional)**

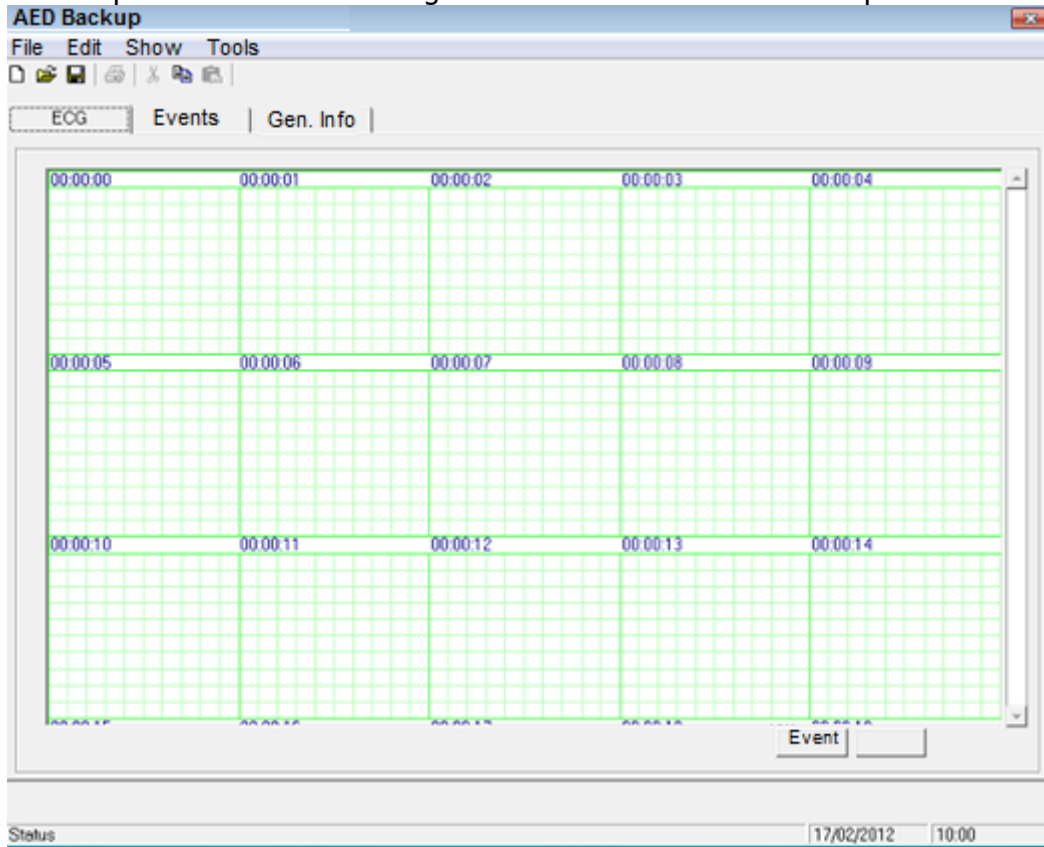
It is possible to record the traces, date and hour of the events occurring during the use of the AED DefibStart, for that just connect the memory card where indicated (figure 2). The input connector only allows the card to be connected on the correct side, so it is not necessary to indicate the fitting side. Each time the equipment is initialized the information (approximately up to 100 hours of continuous recording) will be registered.

- ❖ In order to view the information recorded on the card just disconnect it from the equipment through the handle (figure 15) and connect it to the card entry of the computer or if that is not possible just use and compact flash / USB adaptor to unload the data on the AED Rescue (Backup) Software.

NOTE: The Compact Flash Memory Card (256MB) is supplied by US DeFib Medical Technologies LLC. In the event of use of another card other than the one supplied by the manufacturer, the card reader will have its warranty voided.

### **6.4 Installing the AED Backup Software**

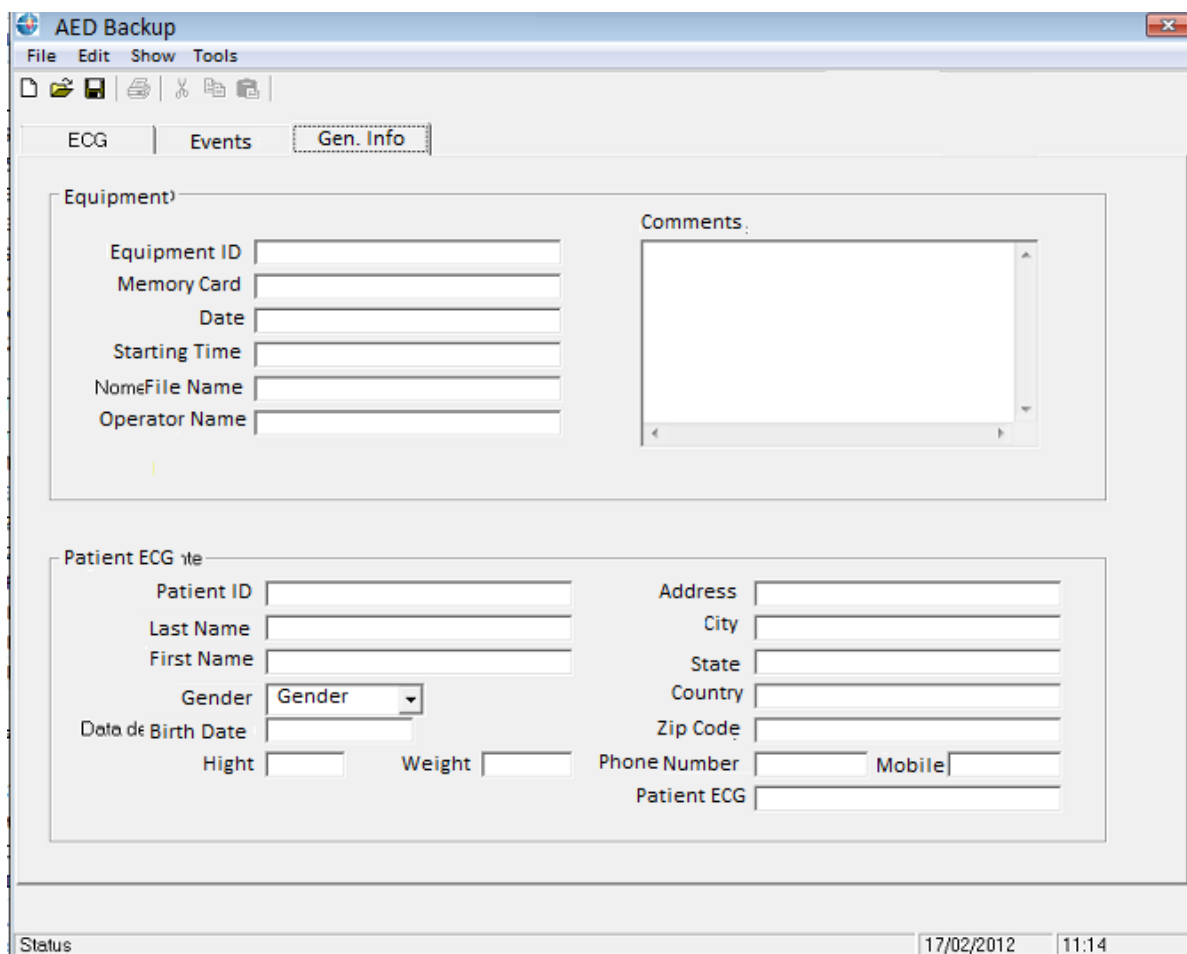
- ❖ Insert the software CD on the CD / DVD-ROM drive;
- ❖ If the installer does not automatically start, locate the "Setup.exe" file on the CD software and double-click;
- ❖ Follow the instructions displayed on the screen;
- ❖ After the installation is complete, click on the software icon that will be displayed on the computer start menu. The figure below shows the AED Backup Screen.



**Figure 7 - AED Software Main Screen**

- ❖ In order to view the information contained in the memory card, just connect it to the computer, click on the menu File – Import. The information will be displayed on the screen with the event ECG Trace, Date and Hour;
- ❖ At the Event tab all of the occurred events will be displayed, with date and hour;
- ❖ At the General Information tab (figure below). The equipment data will be displayed automatically and it is possible to insert comments. The patient information should be filled by the rescuer, or professional who is operating the software;
- ❖ To print the information, just click on the print icon on the screen.





**Figure 8 - AED Software General Information Screen**

## **7. INSTALLING THE AED DEFIBSTART**

### **7.1 Unpacking and Accommodating the Equipment**

- ❖ Remove the equipment from the packing box;
- ❖ Settle it in an appropriate and easy access location;
- ❖ Install it away from other equipment that generates strong magnetic fields, such as radiologic device, air conditioning system and others.
- ❖ Make sure that the installation location has an appropriate ventilation and that it is within the pressure and temperature ranges indicated in this manual (item 17).

#### **7.1.1 Notes**

- ❖ Always keep the AED DefibStart stored in its transportation bag or on the Emergency Cabin, thus preventing damage;
- ❖ This equipment was designed to operate in environments non-constituents of Anesthetic and Flammable Cleaning Agents. Do not operate it in the presence of flammable gases.

## **8. POWER SUPPLY / BATTERY**

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The AED DefibStart features two options of battery:

- ❖ Non-rechargeable battery – 11.1V 2200mA;
- ❖ Rechargeable battery – 11.1V 2200mA. The battery charger is supplied with the equipment.
- ❖ Lithium-Polymer Battery Pack (non-rechargeable), lifespan of 5 years in standby (new and unused battery), capacity of more than 5 hours of monitoring or up to 140 shocks of 150J (adult mode).
- ❖ Lithium-Polymer Battery - rechargeable (specific manageable charger accompanying the equipment) with lifespan of approximately of 5 years in standby with capacity of 5 hours of monitoring or up to 140 shocks in 150J (adult mode). In order to obtain the time of monitoring or the number of charges described it is necessary the battery to be fully charged (new battery fully charged).
  - a. It is important to observe that the battery (LI-PO) requires a special attention, that is described below:



### **ATTENTION!**

- ❖ Do not use another battery charger, other than the one recommended by US DEFIB MEDICAL TECHNOLOGIES LLC;
- ❖ The equipment will not operate for treatment while connected to the battery charger. This equipment is ready to operate only with the battery power supply;
- ❖ Do not short-circuit the battery;
- ❖ Charge it in a ventilated location;
- ❖ Do not completely discharge the battery;
- ❖ Do not compress or disassemble it;
- ❖ Battery operating temperature: 0° to 60°C;
- ❖ Risk of burn, fire and explosion;
- ❖ When you use charges with the pediatric electrode (50 Joules) the amount of shocks will be proportionally higher;
- ❖ Optional: Intelligent battery charger, with time of maximum (complete) charge in up to 2 hours for Lithium-Polymer Batteries- LI-PO – rechargeable.

## **9. ISOLATING THE PATIENT, THE OPERATOR AND THE EQUIPMENT**

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- ❖ Do not use the equipment inside puddles of water, nor use it near flammable agents and flammable anesthetic gases. Always move away from the patient when performing the treatment;
- ❖ Do not touch the contact surface of the adhesive paddles, on the patient or in any conductive material that is in contact with the patient during the ECG analysis or defibrillation;
- ❖ If the patient's chest is wet it is recommended that the rescuer dries it before connecting the electrodes.

### **9.1 Safety and Protection**

#### 1 – Patient

- ❖ The capacitor is charged shortly before the triggering and the charge voltage is linked to the electrodes only at the moment of the shock.

#### 2 – Operator

- ❖ The equipment only operates with internal battery (lithium-polymer).

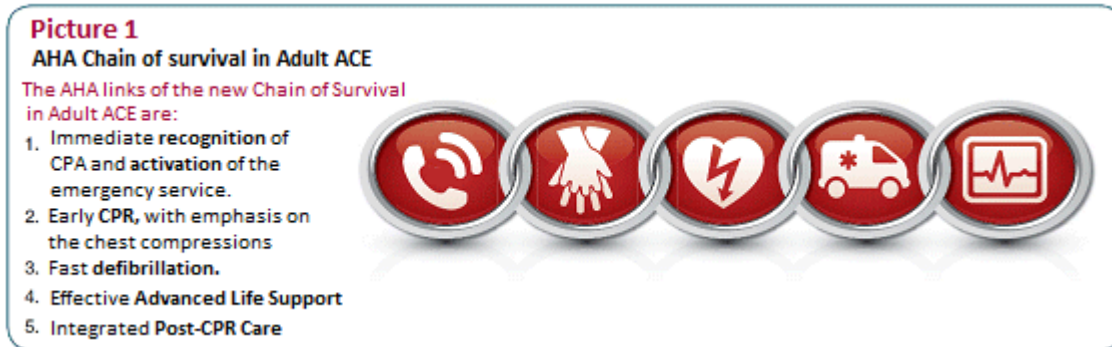
#### 3 – Aircraft

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

## **10. GUIDELINES 2010 - AMERICAN HEART ASSOCIATION**

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1. The importance of the Chain of Survival for the Emergency Cardiovascular Care (ECC) proposed by the American Heart Association (AHA) was enhanced in the new guidelines. Besides the emphasis on the high quality CPR, the chain acquired another link – Post-cardiopulmonary arrest (CPA) care. The first link of the chain still is the immediate recognition of the emergency situation, which includes CPA and calling the Emergency Medical Service.



**Figure 9 – Reproduced from American Heart Association: Highlights of the 2010 American Heart Association Guidelines for CPR and ACE. [Translated from the Portuguese version].**

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

3. The breathing assessment "See, Listen and Feel" was removed from the SBV algorithm. These steps are shown to be inconsistent, as well as the time consuming.

4. The recommended treatment sequence for a rescuer that acts alone was modified. Now the recommendation is that he / she starts the chest compressions before the rescue ventilation. The old sequence A-G-C (Airway - Good ventilation – Chest Compression) agora is C-A-G. The sequence A-G-C remains for the neonatal care, therefore almost always the cause of CPA in newborns is asphyxia.

5. There was no change on the recommendation regarding the compression-ventilation ratio of 30:2 for a single rescuer of adults, children and babies (except newborns).

6. The greater emphasis of the 2010 Guideline is the need of a high quality CPR:

- ❖ Frequency of minimum compression of 100/minute (instead of "approximately" 100/minute, the it was before);
- ❖ Minimum compression depth of 5 cm in adults;
- ❖ Full return of the chest after each compression;
- ❖ Minimization of the interruption on the chest compressions;
- ❖ Avoid excessive ventilation.

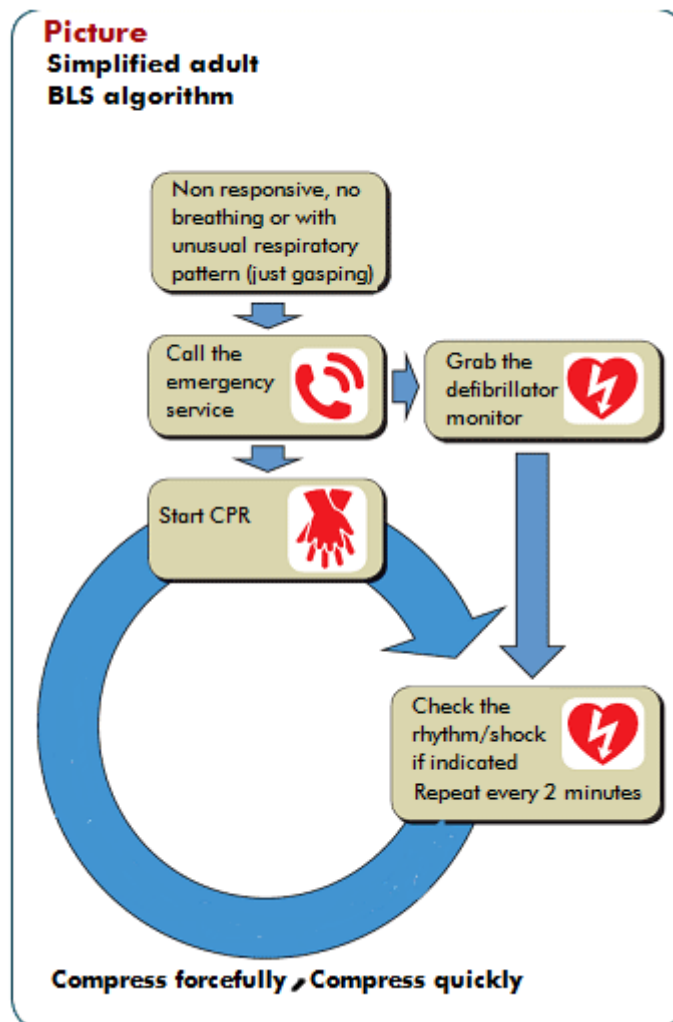
7. The new guidelines minimize the importance of checking the pulse by the trained health professionals. The pulse detection can be difficult even for experienced providers, especially when the arterial pressure is too low. When executed, the pulse checking cannot take more than 10 seconds.

8. The previous recommendation to use the External Automated Defibrillator Monitor (AED) is in as soon as possible, category, in case of witnessing an extra-hospital CPA, was reinforced. When the CPA is not witnessed, the EMS team should initiate CPR (if it hasn't

already been started by the layperson) while the AED checks the rhythm. In these cases, you may consider 1 to 3 minutes of CPR, before of the first defibrillation shock.

9. The implementation programs which set accessible AED in public places were encouraged where there is a relatively high probability of witnessed CPA. The AHA recommends these programs to be followed by planning, training and integration with the EMS for improved efficiency.

10. The post-CPA care include: cardiopulmonary function and infusion of the vital organs, optimization after the return of spontaneous circulation, transportation to a suitable hospital or ICU that features means for post-CPA treatment, including capacity of intervention in cases of acute coronary syndromes, temperature control to improve the neurological prognosis, and treatment and prevention of multiple organ dysfunction.



*Figure 10 - Reproduced from American Heart Association: Highlights of the 2010 American Heart Association Guidelines for CPR and ACE. [Translated from the Portuguese Version].*

## 10.1 References

This text was based on the new AHA guidelines for CPR, American Heart Association. Highlights of the 2010 American Heart Association Guidelines for CPR and ACE. [Translated from the Portuguese Version]. Available on:

[http://www.heart.org/idc/groups/heart-public/@wcm/@ecc/documents/downloadable/ucm\\_317343.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@ecc/documents/downloadable/ucm_317343.pdf)

## 11. HANDLING CABLES AND ACCESSORIES

- ❖ Before placing the equipment in contact with the patient, the operator should regularly check if it is in good operating conditions. Check the expiry date and the transthoracic electrodes package integrity regularly;
- ❖ Only use the accessories, consumables and others listed in this manual. The US DEFIB MEDICAL TECHNOLOGIES LLC does not guarantee the correct operation of the equipment with the use of unknown accessories, besides, the company will not take any responsibility for operating failures of the equipment or possible damage caused by them.



### **ATTENTION!**

- ❖ Generally, the EQUIPMENT Parts and Accessories of the External Automated Defibrillator Monitor – AED, designed to be in contact with biological tissues, cells or body fluids are tested and analyzed according to the ISO 10993-1 guidelines and principles, which deals exclusively with biocompatibility test of the applied parts;
- ❖ The US Defib Medical Technologies LLC ensures that all of the permanent and disposable material in contact with the patient does not cause any type of damage or harmful physiological effect, as long as: the procedures described in this manual are followed; it is installed in an appropriate medical location; it is used with the correct accessories; it is operated by trained personnel and all of the precautions described in this User Manual are followed;
- ❖ The disposable electrodes are Single-Use, therefore should not be re-sterilized;
- ❖ Do not use the disposable electrodes if the package is damaged;
- ❖ Risk of burn on the patient skin when applying the defibrillation;
- ❖ Refer to the operation instructions and the other accompanying documents.

## **12. USE INSTRUCTIONS**

The DefibStart Defibrillator features 02 clinical modes:

- ❖ Semi-Automatic Mode;
- ❖ Medical Mode;

According to the 2010 AHA Guideline. "The settings of shock with biphasic waveform (trace) differ depending on the manufacturer, none of which were directly compared in humans concerning relative efficiency. Due to these differences on the waveform settings, the professionals should use energy charge recommended by the manufacturer (120 a 200J) for the respective waveform. If the charge recommended by the manufacturer is not known, consider the defibrillation the maximum permissible charge".

The DEFIBSTART Defibrillators are configured with the sequence of shocks on the manufacture standard:

- ❖ ADULT – 150 – 150 – 150 joules
- ❖ PEDIATRIC – 50 – 50 – 50 joules

Optional of available Settings according to the user needs: it features the following options for shock sequence:

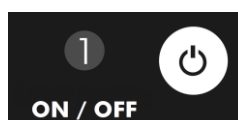
- ❖ 1ª: 90J – 130J – 150J
- ❖ 2ª: 150J – 150J – 200J
- ❖ 3ª: 150J – 200J – 200J
- ❖ 4ª: 150J – 200J – 360J
- ❖ 5ª: Other settings may be supplied.

**Note:** In case of pediatric use, the equipment automatically selects the appropriate sequence, as soon as the pediatric paddles are connected.

### **12.1 Semi-Automatic Mode – Model DEFIBSTART**

Utilization: When using this mode, with voice command and indicator lights the rescuer will be guided to a work of defibrillation procedures and/or CPR – cardiopulmonary resuscitation.

**1º - Turn the equipment On:** Press the on/off key.



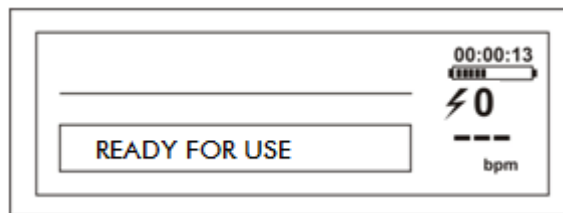
After completing the initialization, the information below will be displayed on the screen:

- Beats per minute (bpm) and the ECG trace of the patient;
- Battery and timer indicator icons. As soon as the equipment is turned on the timer is automatically triggered. This information is displayed through the icon -

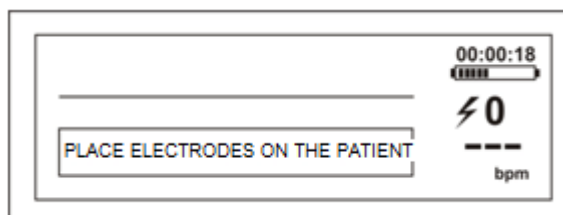


- Number of triggered shocks – indicates how many shocks were triggered on the patient. This information is displayed through the icon - ⚡ 0

**2° - Visual and Sound Instructions:** After turning the equipment on, it runs an internal SELF-TEST, and starts a sequence of voice command and instructions on the display. Wait for the first voice command and the following message will be displayed:



**3° - Connect the electrodes on the equipment (blue and white connector) and fix the paddles on the patient:** The next voice command and the message on the display request the rescuer to place the electrodes on the patient's chest:



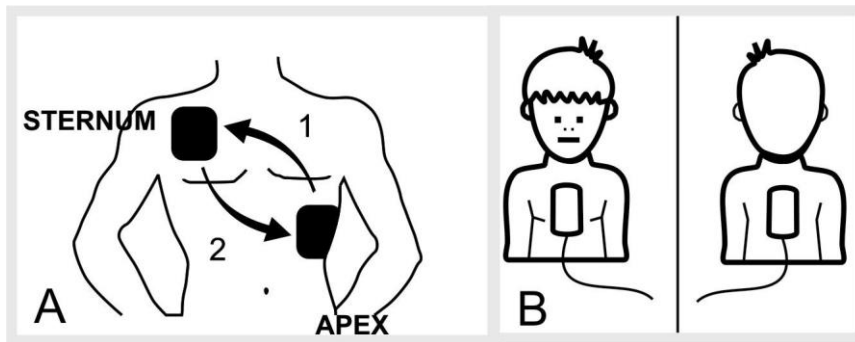
You should open the transportation bag or the Emergency Cabin of the DefibStart, remove the electrodes and open its package.

**Important Note:** The rescuer should open the patient's shirt for quick access to the chest, check if it is dry and if it has a great amount of hair, it requires trichotomy (hair shaving) for better contact of the electrodes with the patient's chest, and fix the electrodes on the chest and on the AED.

Optionally, the electrodes may already be pre-connected to the device.

Pay attention to the anterolateral position of the electrodes, as shown in the handling instructions on the Transportation Bag internal lid of the DefibStart, the figure bellow. They can, according to the 2010 AHA Guidelines, be used in other positions (front-back, front-left subscapular and front-right subscapular with the same efficiency:

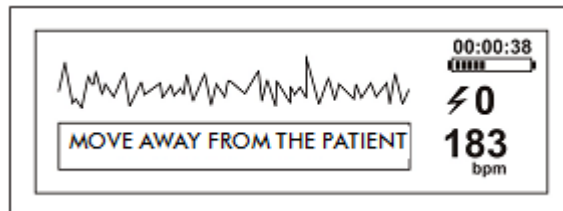




**Figure 11 - Where to fix the Electrodes on the patient's chest (A – In adults and children older than 08 years of age; B – In children who are between 01 and 08 years old)**

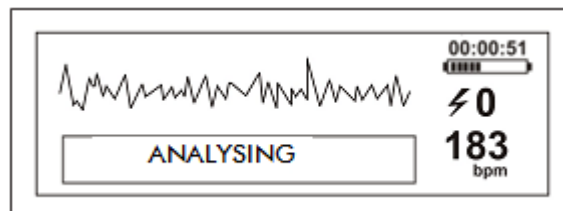
At this moment, the ECG trace will be displayed on the screen, the timer reporting the treatment period, and the patient beats per minute, and the analysis will be initiated.

**4° Clear:** After fixing the electrodes, the voice command and the following message will be displayed:



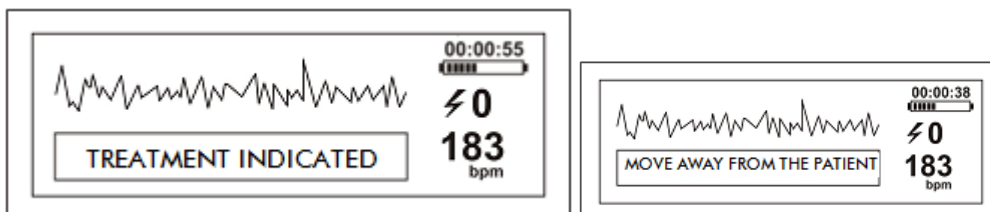
**Important Note:** Make sure that the patient is totally still to avoid readings errors.

**5° Analysis:** Wait for the voice command and the message that will be displayed:



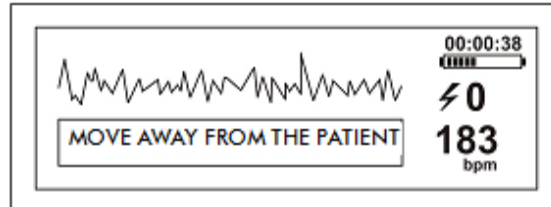
**Important Note:** The equipment will be analyzing the patient conditions and checking whether the shock is necessary or not. There are two possibilities, indication or non-indication for the treatment.

**6° Treatment Indicated:** If the **TREATMENT IS INDICATED**, the following information will be provided through the voice command and the display:

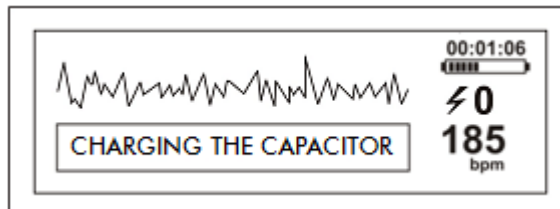


After the INDICATION OF THE TREATMENT, the following sequence of commands and voice instructions will occur:

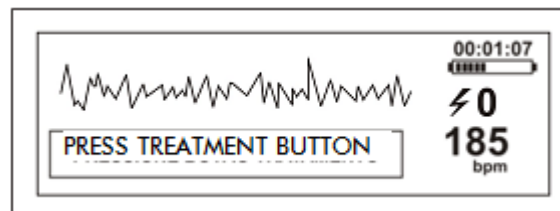
**1 - CLEAR;**



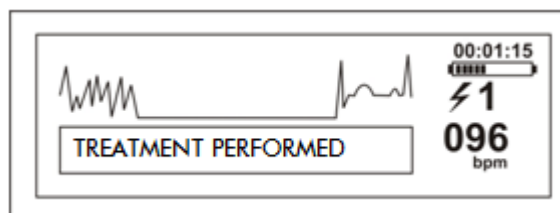
**2 - AUDIBLE SOUND (Charging the Capacitor);**



**3 - PRESS THE TREATMENT BUTTON (Press the Button);**

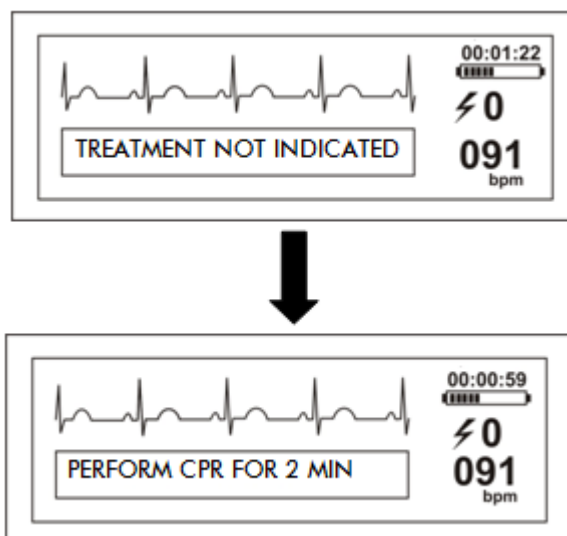


**4 - TREATMENT PERFORMED.**



**Important:** If there is no triggering (Treatment Button) in 30 seconds, an automatic internal discharge will occur and the AED will proceed with the analysis automatically.

**7° Non-Indicated Treatment:** When the AED displays the message "NON-INDICATED TREATMENT" and the patient does not breath normally the rescuer should **perform the basic procedure of CPR according to the 2010 AHA Guidelines.**



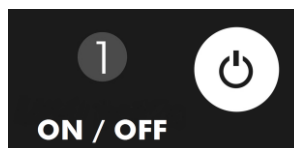
**NOTE:** The timer with the time of CPR will be displayed on the screen. After 2 minutes, the AED automatically restarts the additional analysis of the rhythm of ECG and guides the rescuer if the **TREATMENT IS INDICATED** or **NON-INDICATED**, or if it will require performing CPR for 02 minutes.

❖ Uncertainty of the timer is on the order of 1.5 ms / min.

**FOR MORE INFORMATION AND CLARIFICATIONS IT IS RECOMMENDED TO FOLLOW THE PROTOCOL preconized by the American Heart Association (AHA) – Guideline 2010.**


### 12.2 Medical Mode – Model DEFIBSTART

Utilization: When using this mode, it issues voice commands and indicator lights, but the assessment control and determination of shock treatment is exclusive of the medical rescuer.

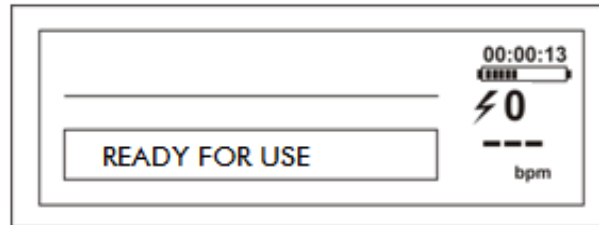


**1º - Turn the equipment On:** Press the on/off key.

After completing the initialization, the following information will be displayed:

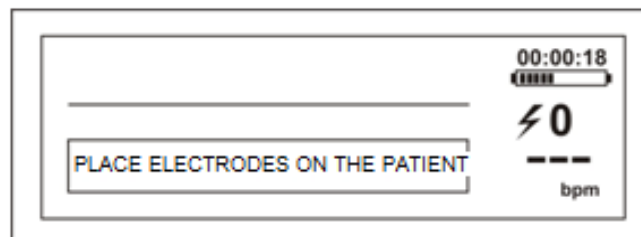
- Beats per minute (bpm) and the ECG trace of the patient;
- Battery and timer indicator icon. As soon as the equipment is turned on the timer is triggered automatically. This information is displayed through the icon -  
**00:00:13**  

- Number of triggered shocks – indicates how many shocks were triggered on the patient. This information is displayed through of the icon - **⚡ 0**

**2° - Visual and Sound Instructions:** After turning the equipment on, it runs an internal self-test, and starts the sequence of voice command and instructions on the display. Wait for the first voice command and the message that will be displayed:



**3° - Change of USE INSTRUCTIONS - The Rescuer should press the TREATMENT key, for 3 seconds in order to enable the Medical Mode, the identification of this status will be presented on the equipment display with the message "MEDICAL USE".**

**4° - Connect the electrodes on the equipment (blue and white connector) and fix the paddles on the patient:** The next voice command and the message on the display request the rescuer to place the electrodes on the patient's chest:

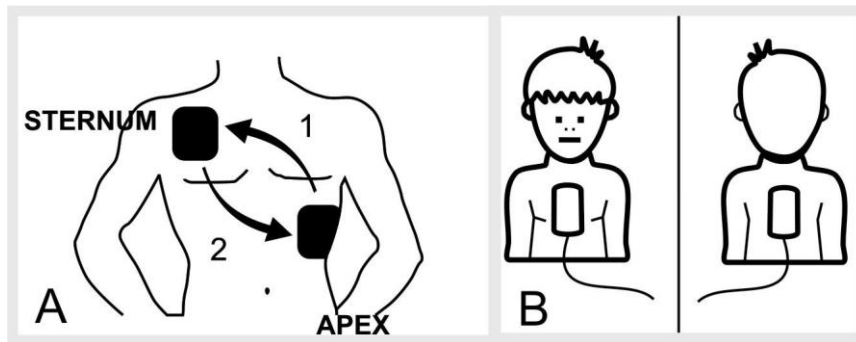


You should open the transportation bag or the Emergency Cabin of the DefibStart, remove the electrodes and open its package.

**Important Note:** The rescuer should open the patient's shirt for quick access to the chest, check if it is dry and if it has a great amount of hair, it requires trichotomy (hair shaving) for better contact of the electrodes with the patient's chest, and fix the electrodes on the chest and on the AED.

Optionally, the electrodes may already be pre-connected to the device.

Pay attention to the anterolateral position of the electrodes, as shown in the handling instructions on the Transportation Bag internal lid of the DefibStart, the figure bellow, according to the 2010 AHA Guidelines, it can be used in other positions (front-back, front-left subscapular and front-right subscapular with the same efficiency):



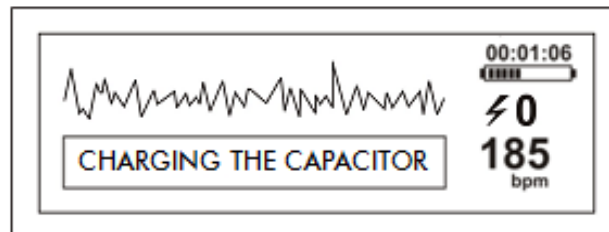
**Figure 12 - Where to fix the Electrodes on the patient's chest (A- In adults and children older than 08 years of age; B - In children who are between 01 and 08 years old)**

**5° Assessment:** After fixing the electrodes on the patient, the equipment will start providing a ECG rhythm reading, that will be evaluated by the rescuer, who will determine whether the therapy will be used or not.

**Important Note:** Make sure that the patient is totally still to avoid readings errors.

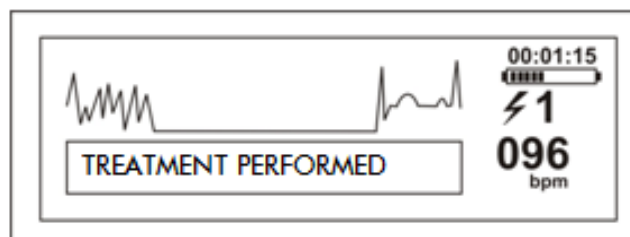
**After the ECG signals assessment by the rescuer and if performing the treatment is chosen, the sequence below should be followed:**

- 1 – REQUEST THAT EVERYONE CLEAR FROM THE PATIENT;**
- 2 – THE RESCUER SHOULD PRESS THE TREATMENT KEY TO CHARGE THE CAPACITOR - AUDIBLE SOUND (Charging the Capacitor);**



- 3 – AFTER THE CAPACITOR CHARGES, THE TREATMENT KEY WILL KEEP BLINKING UNTILL IT IS PRESSED BY THE RESCUER SO THAT THE THERAPY IS PERFORMED (Press the Button);**

- 4 - TREATMENT PERFORMED.**



- 5 – A NEW CYCLE OF NOTES IS STARTED.**

**Important:** If there is no triggering (Treatment Button) in 30 seconds, an automatic internal discharge will occur and the AED begins a new cycle of information for analysis.

**Important:** The Medical Mode will be active until the equipment is turned back on, and starts to operate in Semi-Automatic Mode.

**FOR MORE INFORMATION AND CLARIFICATIONS IT IS RECOMMENDED TO FOLLOW THE PROTOCOL preconized by the American Heart Association (AHA) – 2010 Guideline.**

## **13. APPLIED TECHNOLOGY**

### **13.1 Heart Rate Detector**

The AED DefibStart is prepared to recognize and indicate defibrillation to cardiac rhythms of ventricular tachycardia (VT) of several frequencies and widths of QRS and ventricular fibrillation (VF) of several amplitudes, AUTOMATICALLY, leaving to the operator to connect the paddles on the patient’s chest and to follow its voice and text commands.

#### **13.1.1 Recording Methods**

The arrhythmias subject to defibrillation (VT and VF) are pre-programmed on the equipment, eliminating the need of setup by the operator, resulting in significant gain on the time of treatment.

#### **13.1.2 Rate (Pace) Source**

Through the equipment *Defibrillator Analyzer*, model QA-40M, manufactured by METRON, the heart rates (rhythm) subject to defibrillation are simulated, such as VT and VF, the natural rhythm, in several amplitudes and frequencies.

#### **13.1.3 Pace Selection Criteria**

The selected rhythms are those notoriously known as classic indication for a defibrillation, these being: ventricular fibrillation and ventricular tachycardia.

#### **13.1.4 Annotation Methods**

The AED DefibStart is equipped with a electroluminescent liquid crystal display, or colored in several resolutions (optional), where the procedures of emergency care and the ECG trace are plotted, allowing the graphic register of the heart rates.

#### **13.1.5 Detector Performance Results**

| <b>Rhythm</b>            | <b>Classification</b> |
|--------------------------|-----------------------|
| Ventricular Tachycardia  | A/(A+B)               |
| Ventricular Fibrillation | A/(A+B)               |

Table 2

**True Positive (A):** Accurate classification of rhythm subject to defibrillation.

**True Negative (B):** Organized rhythm or in infusion or asystole that was incorrectly classified as a rhythm subject to defibrillation.

**False positive (C):** It is a VT or VF associated with a cardiac arrest that was incorrectly classified as non-subject to defibrillation.

**False negative (D):** Accurate classification of all of the rhythm in which a shock is not indicated.

### 13.2 Truncated Exponential Biphasic Waveform

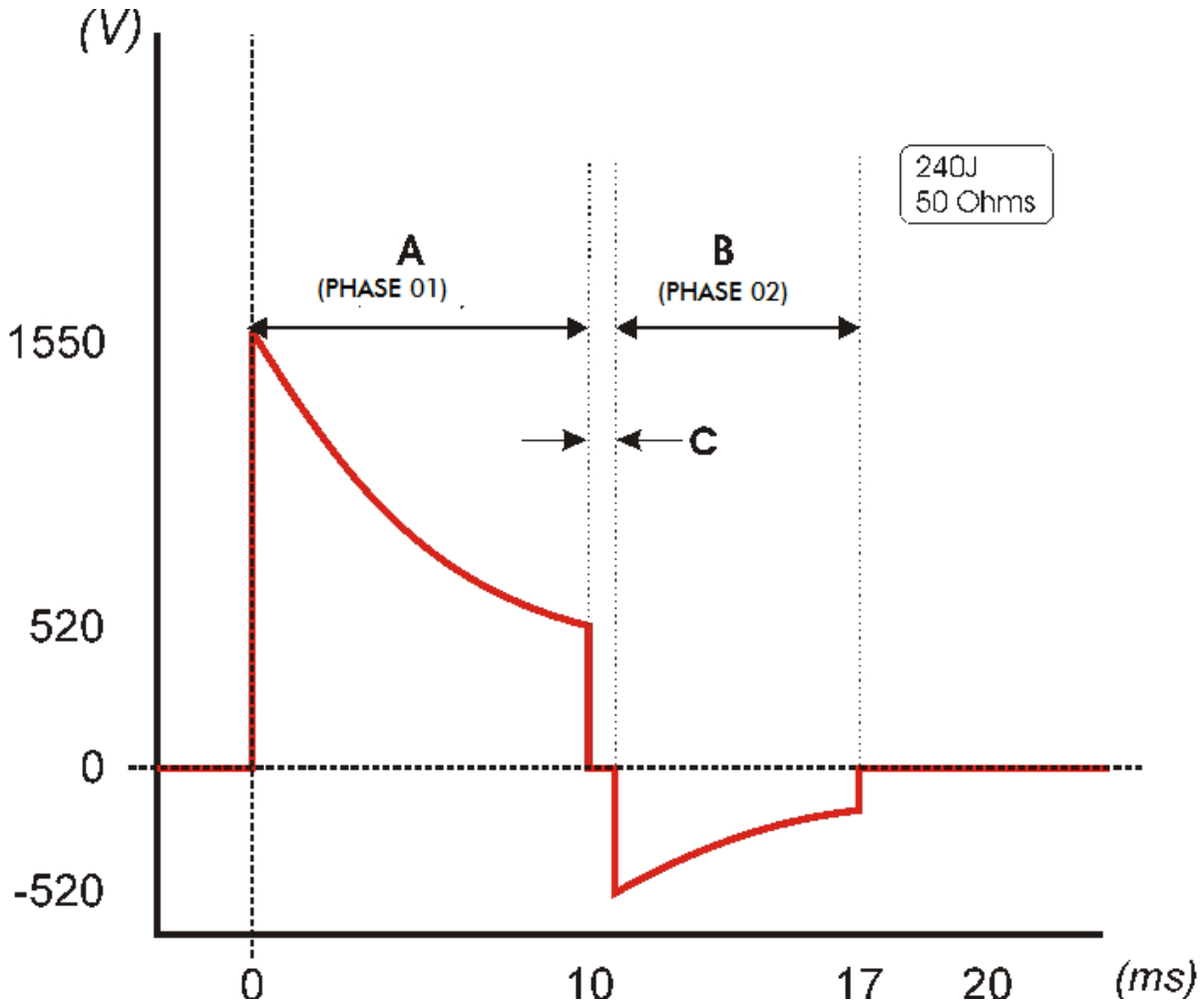


Figure 13 – Truncated Biphasic Waveform

#### 13.2.1 Variations According to the Patient Thoracic Impedance

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

Table 3 - Variations According to the Patient Thoracic Impedance

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

Maximum Width (A+B): 20 ms  
Dead-time (C): 0,5 ms

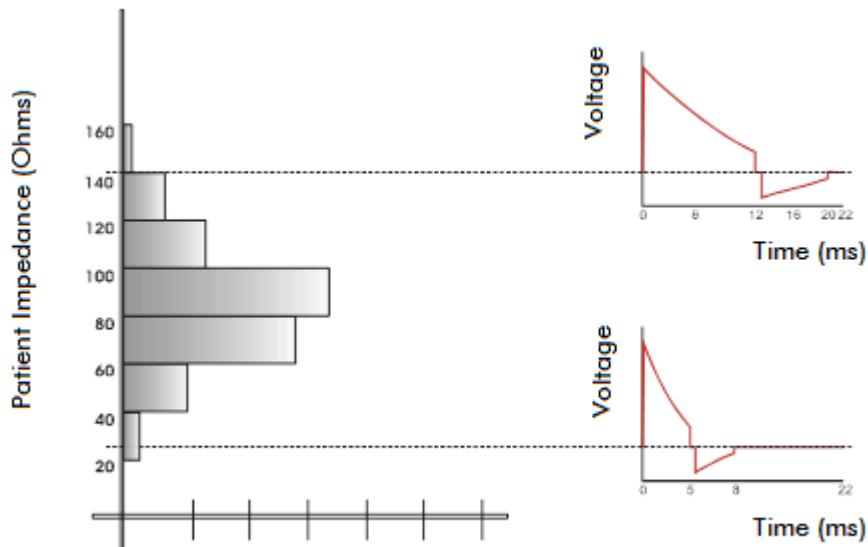


Figure 14 – Waveform Variation According to the Patient Impedance

| Capacitor Charge 1237 Volts (150 Joules) |                   |                   |            |           |                                  |
|--|-------------------|-------------------|------------|-----------|----------------------------------|
| Impedance<br>Ω                           | Phase 1 – A<br>ms | Phase 2 – B<br>ms | A+ B<br>ms | %A – %B   | Delivered<br>Energy in<br>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<br>Ω                           | Phase 1 – A<br>ms | Phase 2 – B<br>ms | The + B<br>ms | %A – %B   | Delivered<br>Energy in<br>Joules |
| 25                                       | 5,0               | 3,3               | 8,3           | 60% – 40% | 199,94                           |
| 50                                       | 10,0              | 6,7               | 16,7          | 60% – 40% | 196,62                           |
| 75                                       | 12,0              | 8,0               | 20,0          | 60% – 40% | 186,84                           |
| 100                                      | 12,0              | 8,0               | 20,0          | 60% – 40% | 174,02                           |
| 125                                      | 12,0              | 8,0               | 20,0          | 60% – 40% | 160,92                           |
| 150                                      | 12,0              | 8,0               | 20,0          | 60% – 40% | 148,70                           |
| 175                                      | 12,0              | 8,0               | 20,0          | 60% – 40% | 137,69                           |

Table 4 - Variation of the delivered energy and of the duration of the defibrillation phases performed with Truncated Biphasic Wave



## **14. SELF-TEST**

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The AED DefibStart, when turned off, performs a SELF-TEST periodically for monitoring its battery charge. This monitoring has the purpose of automatically inform the AED status for the user. Each 4 hours the AED DefibStart automatically turns on and checks its status. When detected that the battery only has 50% of its capacity the equipment will trigger the battery alarms by emitting a luminous and sound signal (beep) of the alarm. The frequency in which the SELF-TEST is performed is altered according to the battery capacity.

The frequency of the SELF-TEST increases insofar as the battery gradually loses charge, in other words, insofar as the battery level decreases the alarms become more frequent indicating that the battery needs to be replaced or charged (if it is rechargeable).

| <b>Frequency of SELF-TEST</b> | <b>Battery Capacity</b> | <b>Alarm</b>                            |
|-------------------------------|-------------------------|---|
| Each 4 hours                  | Over 50% of the charge  | There is no alarm                       |
| Each 2,5 minutes              | Below 50% of the charge | Sound and Visual Alarm each 2,5 minutes |
| Each 2 minutes                | Below 40% of the charge | Sound and Visual Alarm each 2 minutes   |
| Each 1 minute                 | Below 10% of the charge | Sound and Visual Alarm each 1 minute    |
| Each 30 seconds               | Below 5% of the charge  | Sound and Visual Alarm each 30 seconds. |

- ❖ Below 2% of the battery charge it is not possible to turn the equipment on.

**NOTE:**

- ❖ Even with the low battery alarm, the equipment is still able to perform shocks.
- ❖ If the battery is not rechargeable, from the moment in which the equipment starts to emit the low battery alarm it is advisable to get in contact with US DEFIB MEDICAL TECHNOLOGIES LLC to acquire a new battery.
- ❖ If the battery is rechargeable, just connect the charger to the equipment to charge it again. Charging time with the battery fully discharged is of approximately 2 hours.

## **15. PRECAICUONS AND SPECIAL CARE**

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It is recommended to keep a few auxiliary materials such as surgical scissors, disposable razor blade for the removal of the chest hair and disposable gloves, in case its use is necessary when there is an accident.

## **16. EQUIPMENT AND ACCESSORIES CLEANING AND DESINFECTION**

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It is recommended a cleaning to be performed (every other three months) on the AED DefibStart and accessories, following the instructions below:

- ❖ Do not spill any type of liquid and/or place needles and objects in general on the equipment and/or accessory;
- ❖ Do not immerge the equipment and accessories in any type of liquid to clean it;
- ❖ The cabinet cleaning and disinfection should be performed with a slightly moistened cloth in demineralized water and neutral liquid soap and another slightly soft and moistened cloth in demineralized water with 2% of hypochlorite. Do not use Cleaning agents with abrasives, organic solvents, chlorine, alcohol or hydrocarbon solvent. In order to prevent scratches on the panel display screen (display), carefully wipe with dry flannel in case of dirt, slightly moistened cloth in water, and remove the dust or dirt particles;
- ❖ The tags present on the equipment are important, and for that should not be removed when cleaning it;
- ❖ After the use of the *disposable electrodes* and *accessories*, they should be *disposed in appropriate locations* according to the special procedures for hospital waste.

## **17. STORAGE AND TRANSPORTATION**

---

- ❖ As soon as you acquire the equipment, make sure that it does not have any sign of damage. Store all of the packing materials, because they can be useful in case of posterior transportation.
- ❖ Whenever you transport the AED DefibStart, use the original packaging which has the necessary protection and parts indication that should stay on top. It should be kept on a dry location and stacked in a maximum of five boxes respecting the limits of the following environmental conditions:
  - Range of Room Temperature of 0° to 50° C
  - Range of Relative Humidity of 10% to 95% (without condensation)
  - Range of Atmospheric Pressure of 700 hPa to 1060 hPa (525mmHg to 795mmHg)

Note: The US DEFIB MEDICAL TECHNOLOGIES LLC, does not guarantee and does not take any responsibility for any damage that occurs to the equipment that is transported or stored in other package – should only be transported in its original packaging.

## **18. TROUBLESHOOTING**

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The User should always be checking the equipment conditions. Among the items that should be observed are:

- ❖ The cabinet conditions (if it is intact or presents cracks, dirt);
- ❖ The battery conditions (if it is charged or not);

- ❖ Presents all of the accessories required for its use? (Adult and/or pediatric electrodes).

| <b>Problem</b>   | <b>Recommended Action</b>  |
|--|--|
| The AED does not turn on.  | Check the Battery conditions, if it is discharged or installed incorrectly.  |
| The AED turns on, but keeps repeating the message "Place the Electrodes on the Patient's Chest". | Check the electrodes connection to the AED or if the Patient has a lot of chest hair, it will be necessary to perform a Trichotomy (hair shaving) and/or change such electrodes. |
| The AED emits a "beep" frequently.   | This is the SELF-TEST, sign that the battery is low and, therefore, should be recharged or replaced.   |

**Table 7**

\***NOTE:** If the recommended actions are not enough to correct the problem, contact the TECHNICAL ASSISTANCE Authorized by US Defib Medical Technologies LLC.

## **19. MAINTENANCE AND INSPECTION**

### **19.1 Maintenance**

The corrective and/or preventive maintenance of the AED DefibStart should be performed exclusively by US DEFIB MEDICAL TECHNOLOGIES LLC or with some representative, where is at the client discretion the periodicity to execute this maintenance according to the table below:

| <b>Maintenance Frequency</b> | <b>Indication</b> |
|------------------------------|-------------------|
| Quarterly                    | Advisable         |
| Semiannually                 | Recommended       |
| Annually                     | Mandatory         |

Table 5

The lithium-polymer battery, the disposable external transthoracic electrodes should be acquired EXCLUSIVELY through the US DEFIB MEDICAL TECHNOLOGIES LLC for a low cost, being replaced by the user, because there are differences on the connectivity amongst manufacturers.

#### **19.1.1 Calibration**

It is not necessary to perform the periodic Calibration of the AED DefibStart, because it is calibrated in the factory according to the parameters of the 2010 AHA – American Heart Association Guide, so new calibration is not necessary.

#### **19.1.2 Preventive Inspections and Cleaning**

For increased durability of the AED DefibStart and its accessories we recommend that the Preventive Inspections and Cleaning are performed periodically following the table below.

|                        |             |
|------------------------|-------------|
| Applied Verification   | Periodicity |
| Preventive Inspections | Semiannual  |
| Cleaning               | Quarterly   |

Table 6

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

The tags /labels on the equipment should not be removed when cleaning it.

This process should be performed following the criteria described on the item 18 of this manual.

### 19.1.3 Preventive Inspections

We recommend an inspection to be performed on the AED DefibStart and its accessories semiannually, regardless if the equipment was used or not, following the instructions below:

- ❖ Check the expiry date of the accessories (shock paddles and battery), if some of these accessories are close to expire or already have expired, we request that you acquire a new material only by the manufacturer US DEFIB MEDICAL TECHNOLOGIES LLC or in some representative;
- ❖ Check the conservation of the equipment and its accessories, if there is any irregularity on the equipment it should be shipped to the manufacturer for maintenance, and in case of the accessories, a new material should be acquired only from the manufacturer;
- ❖ Perform the SELF-TEST on the equipment, following the instructions already described on the manual, if there is any irregularity; contact an authorized TECHNICAL ASSISTANCE or directly the US DEFIB MEDICAL TECHNOLOGIES LLC.



ATTENTION!

- ❖ The AED DefibStart contains no parts serviceable by the user. Opening the equipment will void all warranties.

## 20. REPLACING THE NON-RECHARGEABLE BATTERY

The REPLACEMENT OF THE NON-RECHARGEABLE BATTERY should be performed when the equipment emits a visual and sound signal (beep) of low battery.

- ❖ For more information about the alarm frequency of the status indicator, consult the section SELF-TEST of this manual.

NOTE: The user should request from US DEFIB MEDICAL TECHNOLOGIES LLC the supply of a new battery due to replacement at the end of the lifespan or in case of defect.

## 20.1 How to Replace the Battery

- 1) There is a compartment that contains a Philips Screwdriver at the bottom of the equipment, unscrew the 04 screws and remove the battery support, remove the old battery and introduce the new battery and carefully plug in the connectors.
- 2) After placing the battery, press the on/off key of the equipment and check the voice and text message: "READY TO USE".

**IMPORTANT:** The defibrillator batteries should be returned to US DEFIB MEDICAL TECHNOLOGIES LLC after the replacement because of defect or end of the lifespan. Do not disassemble or discard in fire, there is also the risk of explosion.

### **Rechargeable Battery**

In order to recharge the equipment battery, just connect it to the battery charger.

When connecting the battery charger to the power grid, the green led (connected to the power grid) lights up, indicating that the charger is connected to the power grid. When connecting it to the equipment, the red led (charging) lights up, indicating that the battery is being charged. When completing the charge, the red led (charging) turns off and the green led (connected to the power grid) will remain lit.



#### **ATTENTION!**

The AED - when it uses data card, it is equipped with internal batteries – model CR 2032 – that may be replaced between 4 to 5 years. This replacement should be performed on the factory or at the authorized TECHNICAL ASSISTANCE.

## **21. ADVERSE EFFECTS**

The US DEFIB MEDICAL TECHNOLOGIES LLC, as the manufacturer of medical and hospital equipment, asks the users to report possible defects or the occurrence of any undesirable event, to ensure the quality of the equipment. Therefore, if there is any failure or malfunction, contact the closest Authorized TECHNICAL ASSISTANCE or directly with the sales consultant on the phone or website below:

US DEFIB MEDICAL TECHNOLOGIES LLC  
Phone: +1 305 887 7552  
Fax: + 1 305 887 7541  
[www.usdefib.com](http://www.usdefib.com)

### **IMPORTANT NOTE:**

- ❖ Do not shock with short-circuited paddles, because the triggering gadget may be damaged;
- ❖ Always transport the equipment with the paddles inside its transportation bag;

- ❖ It is required to keep the patient totally still during the ECG analysis, to avoid readings errors.

NOTE: The pictures contained herein are illustrative only and are subject to minor modifications without prior notice.

## **22. GENERAL TECHNICAL SPECIFICATIONS**

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- ❖ Truncated Exponential Biphasic Waveform;
- ❖ High Impact Cabinet, electrically isolated;
- ❖ Defibrillator with degree of protection against electric shock Defibrillation Proof CF Type Applied Part.
- ❖ Automatic system for triggering in 150, 200 and 200 J on the Adult Mode (according to the setting) and 50 J fix on the Child / Pediatric Mode (according to the setting);
- ❖ The AED (PEDIATRIC MODE), for pediatric use, the charge is automatically limited to  $\frac{1}{4}$  of the energy for adult. When the PEDIATRIC PADDLE is inserted, the system automatically limits the energy in proportion to the sequence of the 1<sup>o</sup>, 2<sup>o</sup> and subsequent shocks respectively;
- ❖ Suitable for any patient;
- ❖ Patient thoracic impedance analysis, adjusting the time duration, the level of electric current of the shock, increasing the efficiency on the defibrillation and decreasing the risk of damage caused to the heart;
- ❖ Time of charge until 150J lower than 5 seconds;
- ❖ High Speed Electronic Commutation System for biphasic energy delivery;
- ❖ Timer (seconds counter);
- ❖ Utilization of adhesive disposable paddles;
- ❖ SELF-TEST;
- ❖ Possibility to use a rechargeable or non-rechargeable battery;
- ❖ Intelligent Charger for Lithium-Polymer rechargeable battery (optional);
- ❖ Indicator of battery charge;
- ❖ Low Battery Alarm– sound and visual;
- ❖ Battery Status;

- ❖ Electroluminescent Monochromatic Liquid Crystal Display, or colored in several resolutions (optional), that displays ECG trace in real time;
- ❖ Cardiac Frequency: Any frequency reading of 10 to 300 bpm with Numerical Introduction;
- ❖ Only enables shock if the patient is fibrillating or the patient has ventricular tachycardia;
- ❖ Allows programming alteration of the shock protocols without the need of any complementary accessory. (Optional);
- ❖ Possibility of charge of up to 360 joules (optional);
- ❖ Weight: approximately 1,9 Kg with battery of lithium-polymer;
- ❖ Approximated Dimensions: 295 x 225 x 155 [mm];
- ❖ Shipped Firmware: AED\_100\_A001;
- ❖ Operating Temperature: 10°C a 40°C;
- ❖ Operating Humidity: 30% a 75%;
- ❖ Storage Temperature: 0° a 50°C;
- ❖ Shipping and Transportation Temperature: 0° a 50°C;
- ❖ Relative Humidity: 10% a 95% (without condensation);
- ❖ Operating Atmospheric Pressure: 700 hPa to 1060 hPa (525 mmHg to 795 mmHg)
- ❖ Allows the register in memory of continuous ECG and critical events (optional);
- ❖ Internal Event Memory including curve, date and hour (optional) of approximately 256MB, that corresponds to over 100 hours of continuous recording;
- ❖ Allows through the connection or other mean, communication with microcomputer, for memory data visualization;
- ❖ Allows a reading posterior of the ECG trace through of hardware and/or software;
- ❖ Text and voice messages;
- ❖ Language: Portuguese, English, Spanish, German and others (Possibility of language switch through of the software);
- ❖ ECG with beep;
- ❖ The ECG is monitored by the paddles, during and after the shock;
- ❖ System of patient analysis;

- ❖ Automatic ECG evaluation system that detects QRS complexes and automatically identifies malignant arrhythmias, VT / VF that require defibrillation;
- ❖ Impedance measurement for adjust of the phase 1 and 2 of the biphasic wave (mentioned on the pages 28 and 29), not allowing triggering in patients with low impedance, impedance, with open paddles or in short-circuit (20 200 Ohms);
- ❖ Event Memory until 72 (seventy and two) hours;

## **23. AED DEFIBSTART TECHNICAL SPECIFICATIONS**

|   |  |
|---|--|
| <b>According to the Harmonized Technical Regulations</b>                            | NBR IEC 60601-1-1:2004, NBR IEC 60601-1-2:2010, NBR IEC 60601-1-4:2004, NBR IEC 60601-2-4:2005, NBR IEC 60601-2-27:1997, NBR IEC 60601-2-49:2003, MDD 93/42/EEC:2007, EN ISO 14971:2007, EN ISO 13485:2003, and other. |
| <b>Relevant Certifications</b>  | Product Certification - INMETRO  |
| <b>Degree of protection against electric shock</b>                                  | AED – Defibrillation Proof CF Type Applied Part  |
| <b>Protection against hazardous penetration of water</b>                            | IP54   |
| <b>Safety degree of utilization in the presence of flammable anesthetic mixture</b> | Equipment not suitable for use in the presence of flammable mixture with air, O2 and N2O.  |
| <b>Defibrillator Output Specifications</b>  | 1,5KV Max.<br>50A Max.   |
| <b>Operation Mode</b>   | Continuous with intermittent charge<br><br>Minimum Interval between triggering – 30 seconds  |
| <b>Powering</b>   | Internally Energized Equipment   |
| <b>Operating Temperature</b>  | 10°C to 40°C   |
| <b>Operating Humidity</b>   | 30% to 75%   |
| <b>Dimension</b>  | 295 x 225 x 155 mm   |
| <b>Weight</b>   | Approximately 2,8Kg  |
| <b>Operating Atmospheric Pressure</b>   | 700 hPa to 1060 hPa (525 mmHg to 795 mmHg)   |

### **23.1 Terms Definition**

**BF Type:** Equipment which provides a special degree of protection against electric shock, especially in relation to admissible leakage currents and reliability of the grounding connections for protection.

**CF Type:** Equipment which provides a superior degree of protection to the BF Type applied part, against electric shock especially in relation to admissible leakage currents.



Internally Energized Equipment: It is capable of operating receiving energy from an internal electrical power supply.

IP54: Closed equipment with protection against splashes of water and protection against dust.

## **24. TECHNICAL SPECIFICATIONS AED MODE**

|  |  |
|--|--|
| <b>Entry Impedance</b>   | > 10 Mohms   |
| <b>Frequency Response</b>  | 0.05 to 100 Hz   |
| <b>Filters</b>   | Notch: 60 - 50 Hz<br>Muscular: pass-low 35 Hz  |
| <b>Gains</b>   | 5 - 10 - 20 mm/mV  |
| <b>Range of Beats Reading</b>  | 10 to 300 BPM  |
| <b>Tolerance</b>   | ± 3 %  |
| <b>Output</b>  | Analogic ECG Signal 1V/mVpp  |
| <b>Sign of Calibration</b>   | 1mVpp ±3%  |
| <b>Shock Application</b>   | Through multifunctional adhesive paddles .   |
| <b>Scales for Defibrillation</b>   | Adult – 150J<br>Child / Pediatric - 50J  |
| <b>Selection Adult/Child / Pediatric</b>   | Automatic by the type of paddles.  |
| <b>Degree of protection against electric shock</b>   | CF type applied part defibrillator proof.  |
| <b>Defibrillator Output Specifications</b>   | 1,5KV Max.<br>50A Max.   |
| <b>Maximum Time since the beginning of the defibrillator operation to the discharge ready on the maximum energy:</b> | 31seconds  |
| <b>AED MODE - Waveform</b>   | Exponential truncated biphasic. Waveform parameters adjusted according to the patient impedance. |
| <b>Discharge Time</b>  | < 240 ms   |

## **25. BATTERY IMPORTANT NOTE**

- ❖ The AED DefibStart battery charger alternates the type of recharge automatically, it can stay connected to the power grid 24 hours per day, there is no need to turn the AED of the battery charger off;
- ❖ When performing the testes, check the battery charge through the bargraff located on the inferior right corner of the display;

- ❖ There is loss of battery charge when performing the AUTOTESTs (decreasing the battery lifespan);
- ❖ It is recommended to replace the battery when there is an intervention for monitoring and discharges;

Preventive Maintenance:

- ❖ Perform the operating test every other 2 months

**IMPORTANT:**

- ❖ The AED can be connected to the charger indefinitely, but when its use is necessary it should be disconnected from the charger, because the equipment DOES NOT operate connected to the power grid, ONLY with the internal battery power supply. The equipment features an interlocking system, where it is not possible to turn it on while connected to the battery charger.

**26. APPENDIX THE – MANUFACTURER GUIDELINES AND DECLARATION - ELECTROMAGNETIC EMISSIONS**

| <p><b>The AED DefibStart was designed to operate in any environment presented below.<br/>The client or AED DefibStart user should ensure its operation in one of these environments.</b></p> |                   |  |
|--|-------------------|--|
| <b>RF EMISSION MEASUREMENT</b>   | <b>ACCORDANCE</b> | <b>ELECTROMAGNETIC ENVIRONMENT - GUIDANCE</b>  |
| <b>RTCA/DO-160D:1997, section 21, category M</b>   | According         | THE AED DEFIBSTART is suitable for utilization in environmental conditions and test procedures for Aero transported Equipment  |
| <b>RF Emissions According to ABNT NBR IEC CISPR 11</b>   | Group 1           | THE AED DEFIBSTART uses RF energy exclusively for its internal functions. So, its RF emission is too low and it is not likely to cause any interference in electronic equipment nearby.        |
| <b>RF Emissions According to ABNT NBR IEC CISPR 11</b>   | Class A           | The AED DefibStart is suitable for utilization in all of the home establishments and those directly connected to the public power grid of low voltage that supplies buildings for domestic use |
| <b>Harmonic Emissions IEC 61000-3-2</b>  | Class A           |  |
| <b>Emissions due to</b>  | According         |  |

|  |  |  |
|--|--|--|
| <b>voltage / scintillation fluctuation IEC 61000-3-3</b> |  |  |
|--|--|--|

Table 7

**THE AED DEFIBSTART was designed to operate in any environment presented below.**


**The client or user of the AED DefibStart should ensure its operation in where of these environments.**


| <b>Resistance Test to interference</b>  | <b>Assay Level of ABNT NBR IEC 60601</b>   | <b>Accordance Level</b> | <b>Electromagnetic Environment - Guidance</b>  |
|---|--|-------------------------|--|
| <b>Discharge of Static Electricity (DSE) according to com a IEC 61000-4-2</b>                               | ± 6kV per contact<br>± 8 kV by the air   | According               | Floors should be made of wood or cement, and should have ceramic tiles. If the floor is made of synthetic material, the relative humidity should be of at least 30%  |
| <b>Disorders / triggering electrical fast transients according to the IEC 61000-4-4</b>                     | ±2 kV on the power supply lines<br>±1 kV on input / output lines   | According               | Quality of the power supply should correspond to the voltage supplied in a typical commercial or hospital environment.   |
| <b>Overvoltages according to the IEC 61000-4-5</b>  | ± 1 kV differential mode<br>± 2 kV common mode   | According               |  |
| <b>Voltage drop, Short interruption and fluctuation on the supplied voltage according to IEC 61000-4-11</b> | < 5% Ut<br><br>(> 95% of voltage drop in Ut) for 0,5 cycle.<br><br>40% Ut<br><br>(60% of voltage drop in Ut) for 5 cycles.<br><br>70% Ut<br><br>(30% of voltage drop in Ut) for 25 cycles. | According               | The supplied voltage quality should correspond to the voltage supplied in a typical commercial or hospital environment.<br><br>If the AED DefibStart user requires the continuous operation even when there is interruption on the power supply, the AED DEFIBSTART should receive energy without interruption or with a battery |

|   |  |           |   |
|---|--|-----------|---|
|   | <5% Ut<br><br>(> 95% of voltage drop in Ut) for 5 seconds. |           |   |
| <b>Magnetic field on the power supply frequency (50/60 Hz) according to the IEC 61000-4-8</b> | 3 A/m  | According | Magnetic field on the power supply frequency should be at characteristic levels of a typical location in a hospital or commercial typical |
| <i>Note Ut is the voltage of A.C. power supply before the application of the assay level.</i> |  |           |   |

**Table 8**

**THE AED DEFIBSTART was designed to operate in any environment presented below.  
The client or AED DefibStart user should ensure its operation in one of these environments.**

| <b>Resistance Test to interference</b><br> | <b>Assay Level of ABNT NBR IEC 60601</b>                      | <b>Accordance Level</b>                         | <b>Electromagnetic Environment - Guidance</b>  |
|--|---|---|--|
| <b>Conducted RF IEC 61000-4-6</b><br><br><b>Radiated RF IEC 61000-4-3</b>  | 3 Vrms<br>150 kHz to 80 Mhz<br><br>3 V/m<br>80 Mhz to 2,5 Ghz | [V1]V<br>According<br><br>[E1] V/m<br>According | Equipment of communication of portable and mobile RF should not be used near any part of the AED DefibStart, including cables, with separating distance shorter than the recommended; this safe distance will be calculated from the equation applicable to the transmitter frequency.<br>Recommended Separating Distance:<br>$d = [3,5 / V1] \sqrt{P}$<br>$d = [3,5 / E1] \sqrt{P}$ 80 MHz to 800Mhz<br>$d = [7/E1] \sqrt{P}$ 800 MHz to 2,5 Ghz<br><br>where $P$ is the maximum nominal potency of the transmitter output in watts (w), according to the transmitter manufacturer, and $d$ is distance of the recommended separation in meters (m)<br><br>It is recommended that the field intensity established by the RF transmitter, as determined through an electromagnetic inspection on the |

|  |  |  |  |
|--|--|--|--|
|  |  |  | <p>location,<sup>a</sup> is lower than the level of accordance in each range of frequency.<sup>b</sup></p> <p>An interference may occur to the surroundings of the equipment marked with the following symbol:</p>  |
|--|--|--|--|

Note 1 *In 80 MHz and 800 MHz, the higher frequency range is applied.*

Note 2 *These guidelines may not be applicable in all of the situations. The electromagnetic propagation is affected by the absorption and reflexing of structures, objects and persons.*

<sup>a</sup> *The field intensities established by the fixed transmitters, such as radio base stations, phone (wireless phones) and mobile terrestrial radios, amateur radio, AM and FM radio transmission and VT transmission cannot be theoretically predicted with precision. In order to evaluate the electromagnetic environment due to transmitters of fixed RF's, an electromagnetic inspection is recommended on the location. If the measure of the field intensity on the location in which the AED DefibStart is used exceeds the level of accordance used above, the AED DefibStart should be observed to check if the operation is Normal. If an abnormal performance is observed, additional procedures may be required, such as the reorientation or repositioning of the AED DefibStart.*

<sup>b</sup> *Above the frequency range of 150 kHz to 80 MHz, the intensity of the field should be lower than [V1] V/m.*

**Table 9**

## **27. TECHNICAL ASSISTANCE**

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### **Permanent TECHNICAL ASSISTANCE**

**Mr. Owner,**

The US Defib Medical Technologies LLC has a list of representatives and TECHNICAL ASSISTANCE.

In order to provide you a personalized service, please send us the registration form. This aims to update our database for the best direction of the Authorized TECHNICAL ASSISTANCE services for each region, training and others.

For complaints, questions, suggestions, and TECHNICAL ASSISTANCE, contact the Customer Assistance Service below:



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



OBELIS S.A  
AV. DE TERVUEREN 34, BTE 44,  
BRUSSELS CITY – BELGIUM



In special cases, if deemed necessary, the US Defib MEDICAL TECHNOLOGIES LLC maintains available, upon agreement, all the technical material, such as circuit diagrams, list of materials, technical information, lists of components, instructions for Calibration and gauging or whatever is necessary so that the qualified personnel by the user, may proceed repairs on the parts designated repairable by the manufacturer. The authorization for maintenance should be formally expressed by the US Defib MEDICAL TECHNOLOGIES LLC.

**Customers Registration Form**



|  |                       |
|--|-----------------------|
| <b>Equipment Description</b>                           | <b>Serial Number:</b> |
| <b>Automated External Defibrillator AED Defibstart</b> |                       |

|               |             |
|---------------|-------------|
| Client Name:  |             |
| Address:      |             |
| City:         | State:      |
| Phone Number: | Fax Number: |

|   |
|---|
| <b>TECHNICAL ASSISTANCE:</b>  |
| <p><b>ATTENTION</b></p> <p style="text-align: center;">Mr. Owner,</p> <p>Please, complete the gaps above, with your data and send us via FAX so that we can register them in our system, in order to maintain our contacts for questionings and TECHNICAL ASSISTANCE.</p> |



**28. FOR FURTHER INFORMATION**

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For additional information, please call:  
 Phone: +1 305 8877552 / +1 305 8877541 or write to Address: 7831 NW 72nd AVENUE,  
 MEDLEY, FL 33166 – USA; or send an e-mail for: [info@usdefib.com](mailto:info@usdefib.com)

Service Hours:  
 From Monday to Friday, 09:00am to 05:00pm

## **29. VERSION CONTROL**

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### **USER MANUAL**

**PROJECT NAME: Automated External Defibrillator AED - DefibStart**  
**CODENAME ENG<sup>a</sup>: AED200**

### **VERSION CONTROL**

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| <b>Rev</b> | <b>Date</b> | <b>Author</b> | <b>Description</b> |
|------------|-------------|---------------|--------------------|
| 1.0        | Nov/05/2012 | Luara Delfin  | First Issue        |