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USER MANUAL

Rescue LIFE

EXTERNAL BIPHASIC
DEFIBRILLATOR and MONITOR

CE 0068

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GENERAL AND SAFETY INFORMATION

Thank you for choosing the RESCUE LIFE.

The RESCUE LIFE monitor/defibrillator is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols.

RESCUE LIFE is designed to monitor the patient ECG signals and to deliver defibrillation shocks in MANUAL, ADVISORY or AED mode. This Operator's Manual contains all the information that a user needs to operate the RESCUE LIFE properly.

ELPRO S.r.l. reserves the right to make changes on the device specifications contained in this manual at any time without prior notice or obligation to customer.

If you have any problems regarding the operation of the device, please do not hesitate to contact the manufacturer.

These operating instructions include information and procedures related to all features and options of the RESCUE LIFE monitor / defibrillator.

Your RESCUE LIFE monitor/defibrillator may not have all of these features or optional.

Please read this Operator's Manual carefully and thoroughly before using the RESCUE LIFE. This Manual contains instructions on how to operate and maintain the RESCUE LIFE.

It is very important that you fully understand all the necessary instructions discussed in this manual so as to act quickly in an emergency.

ELPRO S.r.l. designs and manufactures all of its products in accordance with international standards (93/42/EEC) and subsequent amendments. This ensures that ELPRO S.r.l. provides products of high quality and reliability.

In this regard:

> **ONLY PERSONS AUTHORIZED BY ELPRO S.R.L. SHOULD DO THE SERVICING OF THE DEVICE. THERE ARE NO USER SERVICEABLE PARTS IN THIS DEVICE.**

You should operate this device in accordance with the instructions specified in this manual.

> **TO ENSURE SAFETY AND RELIABILITY, USE ONLY PARTS AND ACCESSORIES RECOMMENDED BY ELPRO S.R.L.**

SAFETY INSTRUCTIONS

The following conditions are used either in this User Manual or on the RESCUE LIFE defibrillator/monitor:

DANGER IMMEDIATE HAZARDS THAT WILL RESULT IN SERIOUS PERSONAL INJURY OR DEATH.
WARNING HAZARDS OR UNSAFE PRACTICES THAT MAY RESULT IN SERIOUS PERSONAL INJURY OR DEATH.

CAUTION HAZARDS OR UNSAFE PRACTICES THAT MAY RESULT IN MINOR PERSONAL INJURY, PRODUCT DAMAGE, OR PROPERTY DAMAGE.

RESPONSIBILITY FOR INFORMATION

It is the obligation of our customers to ensure that the appropriate person(s) within their organization have access to this information, including general safety information which are given in this manual.

GENERAL

Assure yourself prior and after the use of the RESCUE LIFE that the unit is in safe and usable condition (cables integrity, pads, battery status).

Assure that the battery charge, ECG trace, selected energy value, SYNC mode and status battery are well functioning.

RESCUE LIFE is not intended for use in areas of highly inflammable anesthetics or other inflammable substances, especially in high concentration of oxygen areas.

RESCUE LIFE does not have to be put or used nearby a nuclear spin tomography plant, which is turned on.

CAUTIONS

- ***MANUAL MODE*** DEFIBRILLATION MUST BE PERFORMED ONLY BY HIGHLY TRAINED MEDICAL PERSONNEL.
- **NEVER** PUT IN CONTACT THE **SHOCK PADDLES** (SHORT CIRCUIT).
- BE SURE THAT BOTH SURFACES OF THE **SHOCK PADDLES** ARE COMPLETELY MOISTENED WITH GEL.
- THE **SHOCK PADDLES** MUST BE HELD AT DISTANCE FROM OTHER ELECTRODES AND ANY METAL PARTS IN CONTACT WITH THE PATIENT. THIS CONTACT CAN CAUSE ELECTRICAL ARCING AND PATIENT SKIN BURNS DURING DEFIBRILLATION AND MAY DIVERT DEFIBRILLATING ENERGY AWAY FROM THE HEART MUSCLE
- THE **SHOCK PADDLES** INCLUDING HANDLES SHOULD ALWAYS BE CLEANED THOROUGHLY AFTER USE.
- IN ORDER TO PREVENT ACCIDENTALLY CREATING CURRENT PATH FOR THE DEFIBRILLATION IMPULSE, THE PARTS OF THE **PATIENT BODY**, SUCH AS THE HEAD OR LIMBS MUST NOT BE IN TOUCH WITH METAL PARTS, BED FRAMES OR STRETCHERS. THE PATIENT MUST NOT BE TOUCHED DURING DEFIBRILLATION.
- DURING DEFIBRILLATION WITH CONNECTED **ECG CABLE** ENSURE THAT ALL BINDING CLIPS ARE CONNECTED WITH THE PATIENT.
- WHEN DEFIBRILLATING **CHILDREN** (UNDER THE AGE OF 8 YEARS AND WEIGHING LESS THAN 25 KG) DO NOT EXCEED 4J/KG AND DO NOT USE THE ADVISORY OR AED MODE.
- DISCONNECT FROM THE PATIENT **EVERY DEVICE THAT IS NOT EQUIPPED** WITH APPLICATED PART PROTECTED BY DEFIBRILLATION.
- THE **PATIENT CABLE** PROVIDED BY ELPRO S.R.L. IS DEFIBRILLATION PROTECTED AND IT CAN BE CONNECTED.
- **DO NOT** REUSE **DISPOSABLE DEFIBRILLATION PADS**. CHECK THAT THE CASE IS IN GOOD CONDITION AND THAT THE DISPOSABLE PADS HAVE NOT YET REACHED THEIR EXPIRATION DATE.

SHOCK OR FIRE HAZARDS

The defibrillator delivers up to 230 joules of electrical energy.

Unless properly used as described in these operating instructions, this electrical energy may cause serious injury or death.

Do not attempt to operate this device unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.

Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.

DO NOT IMMERSE ANY PORTION OF THIS DEFIBRILLATOR IN **WATER** OR **OTHER FLUIDS**. AVOID SPILLING ANY FLUIDS ON DEFIBRILLATOR OR ACCESSORIES. SPILLED LIQUIDS MAY CAUSE THE DEFIBRILLATOR AND ACCESSORIES TO PERFORM INACCURATELY OR FAIL.

DO NOT CLEAN WITH KETONES OR OTHER **FLAMMABLE AGENTS**.

DO NOT AUTOCLAVE OR **STERILIZE** THIS DEFIBRILLATOR OR ACCESSORIES UNLESS OTHERWISE SPECIFIED.

USE CARE WHEN OPERATING THIS DEVICE CLOSE TO OXYGEN SOURCES (SUCH AS BAG-VALVE-MASK DEVICES OR VENTILATOR TUBING). TURN OFF GAS SOURCE OR MOVE SOURCE AWAY FROM PATIENT DURING DEFIBRILLATION.

POSSIBLE ELECTRICAL INTERFERENCE

Using cables, electrodes, or accessories not specified for use with this defibrillator may result in increased emissions or immunity from electromagnetic or radio frequency interference (RFI) which could affect the performance of this defibrillator or of equipment in close proximity. Use only parts and accessories specified in these operating instructions. This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity.

Verify the effects of defibrillator discharge on other equipment prior to using the defibrillator in an emergency, if possible.

POSSIBLE IMPROPER DEVICE PERFORMANCE

Using other manufacturers' cables, electrodes, or batteries may cause the device to perform improperly and may invalidate the safety agency certifications. Use only the accessories that are specified in these operating instructions.

POSSIBLE DEVICE SHUTDOWN OR NOT SWITCHING ON

Always check that the battery is fully charged.

WHEN OPERATING ON BATTERY POWER, THE LARGE CURRENT DRAW REQUIRED FOR DEFIBRILLATOR CHANGING MAY CAUSE THE DEFIBRILLATOR TO REACH SHUTDOWN VOLTAGE LEVELS WITH NO LOW BATTERY WARNING. IF THE DEFIBRILLATOR SHUTS DOWN WITHOUT WARNING, OR IF A BATTERY LOW MESSAGE APPEARS ON THE MONITOR SCREEN, THE OPERATOR HAS TO CONNECT IMMEDIATELY THE AC POWER CORD TO AN OUTLET.

ELECTRICAL SAFETY GUIDELINES

Use only the original power cord during recharging. The right value for the AC power supply is: 100V to 240V, 50 / 60 Hz AC.

During recharging, do not place the device where the environmental conditions exceed the storage conditions specified.

DURING OPERATION, THE DEVICE SHOULD BE PLACED AWAY FROM SOURCES OF ELECTROMAGNETIC INTERFERENCE SUCH AS MOTORS, GENERATORS, X-RAY EQUIPMENT, RADIO TRANSMITTERS, CELLULAR MOBILE TELEPHONES AND OTHERS, AS THESE MIGHT INTERFERE WITH THE SIGNALS BEING ACQUIRED.

The RESCUE LIFE is classified as follows:

Class II equipment, applied parts **BF** for pads, SpO2 and NIBP connector and **CF** for ECG cable (EN 60601-1).

The Electromagnetic compatibility level is **Class A group 1** according to the EN 60601-1-2 (Electromagnetic Compatibility Requirements).

SYMBOLS USED

The symbols below may be found in this manual or in rear sticker or accessories of *Rescue LIFE* defibrillator.

Symbol	Description of symbol
	Identification of device
	Serial Number of device
	Manufacturer identification
	Date of production
	Defibrillation-proof BF type
	Defibrillation-proof CF type
	Alternated
	Class II
	Danger of an electrical shock
	The user must to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Indicates the need for the user to consult the instructions for use.
	Do not use AED mode on NEWBORN

	Follow local regulations on battery disposal or recycling
CE 0068	CE Mark & Notified Body identification
	Fragile content, handle with care (on the package)
	To keep dry and to not exposure to weathering (on the package)
	To keep up (on the package)

INTRODUCTION

UNPACKING AND INSPECTING

Be sure that you have all the required supplies and accessories including cables and ECG paper, when you remove the RESCUE LIFE defibrillator/monitor from the container used for the shipment. Verify the defibrillator and all accessories for any sign of damage that may have occurred during shipping. If possible, save the shipping container and foam inserts in case you must ship the defibrillator in the future.

DEVICE OPERATION AND STORAGE GUIDELINES

Do not operate or store the device in conditions that are beyond the following specified limits.

- **Operating Conditions**

Temperature -5 °C to 46 °C
Humidity 10 % to 95 % (non-condensing)

- **Storage Conditions (without disposable defibrillation electrodes)**

Temperature -20 °C to 50 °C
Humidity 10 % to 95 % (non-condensing)

- **Storage Conditions (with disposable defibrillation electrodes)**

Temperature 5 °C to 35 °C
Humidity 20 % to 80 % (non-condensing)

DO NOT STORE THE DEVICE IN AREAS WITH HIGHLY FLUCTUATING TEMPERATURES

DO NOT OPERATE OR STORE THE DEVICE IN ENVIRONMENTS WITH HIGH CONCENTRATION OF FLAMMABLE GAS OR ANESTHETICS.

CLEANING AND MAINTENANCE

After each use, clean the defibrillator and the reusable pads using a soft, damp cloth moistened with any of the following solvents:

- Water and soap.
- Clorexina and water mixture (30 ml clorexina/liter of water).
- Ammonia.
- Hydrogen peroxide.

If necessary, sterilize just the defibrillation pad part touching the patient skin only with liquid CIDEX.

DO NOT IMMERSE ANY PART OF THE DEFIBRILLATOR IN FLUIDS.
DO NOT LET ANY FLUID ENTER THE CASE OF THE DEVICE DO NOT USE ABRASIVE MATERIALS IN CLEANING THE UNIT, ESPECIALLY ON THE LCD DISPLAY.
DO NOT STERILIZE THE DEVICE.
DO NOT REUSE THE DISPOSABLE PADS.

POSSIBLE EQUIPMENT DAMAGE.
DO NOT CLEAN ANY PART OF THIS DEVICE OR ACCESSORIES WITH BLEACH, BLEACH DILUTION, OR PHENOLIC COMPOUNDS. DO NOT USE ABRASIVE OR FLAMMABLE CLEANING AGENTS. **DO NOT** ATTEMPT TO STERILIZE THIS DEVICE OR ANY ACCESSORIES UNLESS OTHERWISE SPECIFIED IN ACCESSORY OPERATING INSTRUCTIONS.

The operator has to do daily maintenance checks that will help ensure that the device stays in perfect operational condition.

Check the case of the device for any apparent damage.

Check the ports (defibrillator lead port, patient cable port, AC plug and cable, paddles).

Check the accessories, especially the defibrillation pads and cables, to see that they are in good condition.

Check the battery status and if the level is low attach the power cord to the AC line. The internal nickel-metal hydride battery is rechargeable and intended to be used for standby operation. The defibrillator automatically switches to battery power when the power cord is disconnected from an AC outlet or from the defibrillator.

CONNECTING TO POWER

The RESCUE LIFE defibrillator/monitor operates on AC (line) power or with internal rechargeable Lithium-Ion battery.
You can switch from battery to AC power or AC power to battery while the device is on and in use by plugging in or unplugging the AC power cord.

AC Operation

The AC Mains LED illuminates, when the RESCUE LIFE defibrillator/monitor operates on AC power. When the defibrillator is not in use, maintain better the battery charge connecting the power cord to an AC outlet and turn off the defibrillator.

Battery Operation

The defibrillator automatically switches to battery power when the power cord is disconnected from an AC outlet or from the defibrillator. The internal Lithium-Ion battery is rechargeable and intended to be used for standby operation.

A new, completely charged battery provides approximately 150 shocks at 230 J discharges, 250 minutes of pacing, or approximately 330 minutes of continuous monitoring before the defibrillator turns off.
Connect instantly the power cord into an AC outlet to continue use and start recharging the battery, when the LOW BATTERY message appears on the screen.

If low battery messages often appear, the battery may need to be replaced.

Please contact ELPRO S.r.l. or qualified service personnel for assistance.

In order to improve the monitoring performance we suggest to connect the defibrillator to AC power after each use to recharge the battery.
Normally, new fully depleted batteries recharge for 3 hours to regain full capacity.

BATTERY CHARGE

When the message of the battery status displays a value under 25%, batteries should be charged. Insert the power supply cord in the RESCUE LIFE socket (located on the back side) and connect to the AC line. The battery status led will switch on.
When the charge finished the led will switch off. To see the battery charge status switch on the device with pads connector not attached.

When the battery value is under 10% a message appears on display: "CHARGE BATTERY OR SYSTEM WILL SHUT OFF". Insert the power supply cord in RESCUE LIFE socket, otherwise system will shout down automatically in 2 minutes.

During this time defibrillation functions are disabled.

WHEN THE DEVICE IS OFF, DO NOT LEAVE THE AC CHARGER CONNECTED MORE THAN 3 HOURS. IF AFTER THIS TIME THE CHARGING LIGHT DOES NOT GO OFF, PLEASE CONTACT THE SERVICE CENTER FOR CHANGING THE BATTERIES.

WARRANTY

Every device that goes out of the assembly line passes through a full reliability tests. In case of problems, our maintenance and exchange policies are in accordance with the relevant consumer protection laws and regulations in the particular country where the device is sold.
The warranty period of this device is one year after the date of purchase. Other warranty period may be agreed with the users.
When the device malfunctions during the warranty period it will be repaired free of charge by our service centers.

When you submit the device for maintenance, please specify the details as listed below:

- Product name.

- Product serial number.

- Date of purchase.

- Name of sales representative.

- Information of customer and a brief description of the problems encountered.

All of the service works for the product must be undertaken only by the producer or its authorized agents.
If unauthorized personnel render repairing service during the warranty period, this warranty becomes null and void.

ELPRO S.r.l. has no information regarding the performance or effectiveness of its RESCUE LIFE defibrillators if they are used with defibrillation electrodes or other parts and supplies from other sources. Using defibrillation electrodes, adapter devices, or other parts and accessories from other sources than ELPRO S.r.l. is not recommended. If device failure is attributable to defibrillation electrodes or other parts or supplies not manufactured by ELPRO S.r.l., this may void the warranty.

SERVICE

We remind that only ELPRO S.r.l. or its authorized representatives should service the device. If unauthorized personnel service the device during the warranty period, the warranty will become null and void.

Regularly maintenance and testing of the RESCUE LIFE defibrillator/monitor and accessories will help to detect and prevent possible electrical and mechanical discrepancies.

When the device is not functioning properly, it has to be submitted for maintenance immediately.

When any abnormalities are found in the device or when a danger to bodily harm exists, the device has to be repaired fast and adequately by authorized personnel.

When the need for maintenance arises please contact ELPRO S.r.l. or its authorized representatives immediately. Prepare a summary of the problems. Also include the name of model, product serial number, date of purchase, name of sales representative, customer information.

OPERATIONAL

PRODUCT DESCRIPTION

RESCUE LIFE is an external defibrillator and monitor for acute cardiac care response used by authorized healthcare providers in hospital and clinic settings.
The RESCUE LIFE defibrillator and monitor is available only with the biphasic defibrillation waveform. The delivered energy is adjusted to the patient impedance to obtain the best result. It is a battery powered, lightweight and portable device designed to deliver defibrillation shocks during rescue operations.
In manual mode the user has to do the analysis of the ECG trace of the patient and set the energy level of the shock to be delivered. The energy range is from 1 to 230 Joules.

During synchronized cardio-version, the defibrillating shock is delivered in less than 50 milliseconds of the occurrence of the ECG 'R' peak.
The RESCUE LIFE in the basic configuration has only the manual mode available and the ECG monitoring can be done by defibrillation pads (1 trace) or by 5 wire ECG monitoring cable assembly from ELPRO S.r.l.
The RESCUE LIFE can be supplied with (optional) 10 wire ECG cable.
Optional module: RESCUE LIFE can be ordered with ADVISORY/AED mode, Pacemaker, SpO_2 as well as NIBP. On the AED version RESCUE LIFE includes a mass storage memory for recording the ECG trace and events.
Integrated thermal printer allows the hardcopy of the ECG traces.
The RESCUE LIFE may be equipped with disposable defibrillation pads. Through these pads, the electrical signal from the patient's heart is acquired. The defibrillation shock is delivered also through the same defibrillation pads.

IN CHILDREN UNDER THE AGE OF 8 YEARS OR WEIGHING LESS THAN 25 KG DO NOT EXCEED 4 JOULE/KG. **DO NOT** USE **AED** MODE IN **NEWBORN**.

IF BATTERIES ARE NOT FULLY CHARGED AFTER A 3 HOURS CHARGING PERIOD, PLEASE CONTACT THE ELPRO S.R.L. OR ITS AUTHORIZED REPRESENTATIVES

INTENDED USE (PATIENTS GROUP AND MEDICAL CONDITIONS)

In manual mode the RESCUE LIFE is intended for use by health care professionals and emergency rescue personnel who have been trained in advanced cardiac life support. The user must know how to interpret ECG's, decide the energy level required and when the defibrillation is necessary.

RESCUE LIFE is designed for any group of patients to treat:

- Ventricular Fibrillation (VF)
- Fine Ventricular Fibrillation (FVF)
- Ventricular Tachycardia (VT) with a rate higher than 150 bpm (beats per minute)

RESCUE LIFE is designed for to be used on pediatric patients, adult patients and on "special patients" (e.g. pregnancy women) according to the *ECR Guidelines* 2015 - Section 4 "*Cardiac arrest in special circumstances*" par. C - SPECIAL PATIENTS.

Moreover it is designed to treat, by means of Synchronous defibrillation (cardioversion), patients with ECG's that show the presence of Atrial Fibrillation. It is designed to monitor patient ECG by means of the multiple signal acquisition electrodes.

The pacing option is indicated for treating patients with symptomatic bradycardia.

When used in AED mode, the RESCUE LIFE is a semiautomatic defibrillator that provides a prompted treatment protocol and ECG analysis using special analysis algorithm. This software algorithm analyzes the patient's electrocardiographic (ECG) rhythm and indicates whether or not a shockable rhythm is detected.

AED mode requires operator interaction in order to defibrillate the patient.

AED MODE ON RESCUE LIFE IS RECOMMENDED FOR USE BY PERSONNEL WHO ARE AUTHORIZED BY A PHYSICIAN OR MEDICAL DIRECTOR AND HAVE, AT A MINIMUM, THE FOLLOWING SKILLS AND TRAINING:

- CPR TRAINING
- AED TRAINING EQUIVALENT TO THAT RECOMMENDED BY THE *AMERICAN HEART ASSOCIATION* (AHA) OR THE *EUROPEAN RESUSCITATION COUNCIL* (ERC)
- TRAINING IN THE USE OF THE RESCUE LIFE DEFIBRILLATOR IN AED MODE

INDICATIONS

Asynchronous defibrillation – the shock delivery is not synchronized with the ECG 'R' peak.

In **asynchronous defibrillation**, the RESCUE LIFE is indicated for use on patients with the following symptoms:

- Unconsciousness
- Absence of normal breathing and
- Lack of detectable pulse.
- Rhythms need a shock.

Synchronous defibrillation – the shock delivery is synchronized with the 'R' peak of the patient's ECG.

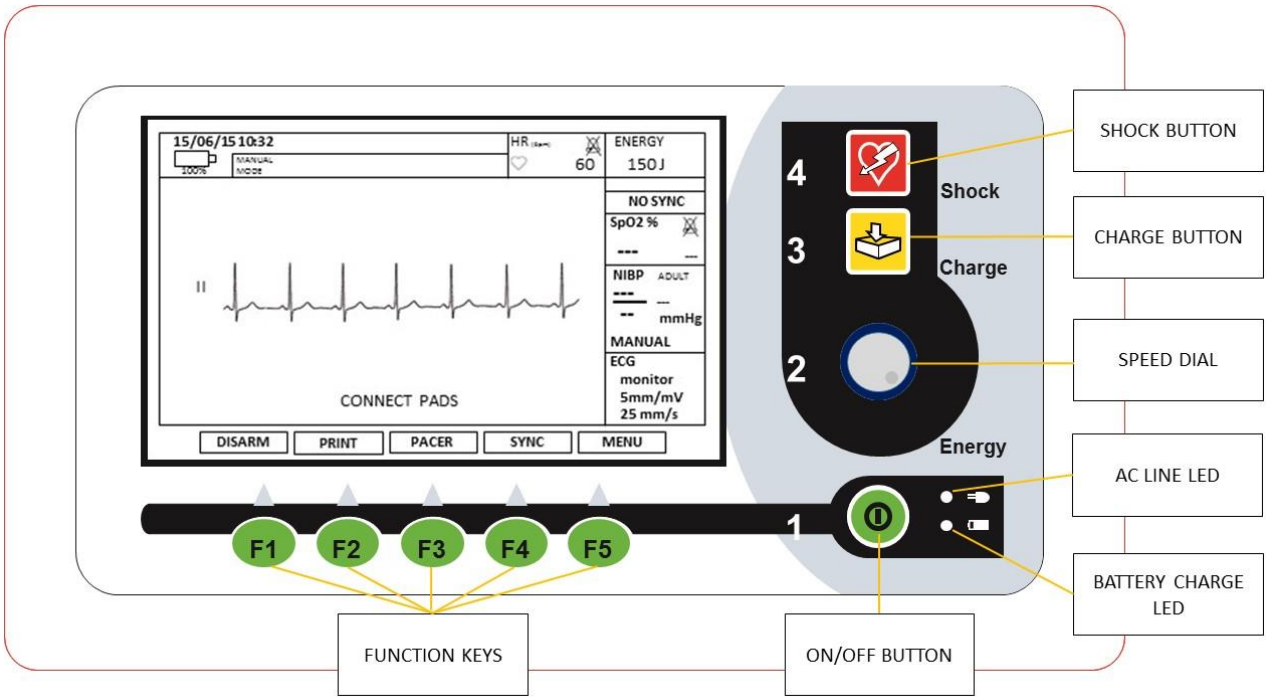
In **synchronous defibrillation**, the RESCUE LIFE is indicated for use on patients with ECG's that show the presence of Atrial Fibrillation.

CONTRAINDICATIONS

The RESCUE LIFE should not be used in defibrillation mode on patients that:

- Are conscious
- Are breathing normally
- Have detectable pulse.

FRONT PANEL DESCRIPTION



FRONT PANEL KEYS

Keys on the right part are used to manage main defibrillation function.

ON/OFF BUTTON 	Power On-Off push button of RESCUE LIFE. At switch on, if the paddles are disconnected, the battery status and clock set-up screen will appear. In this case to start ECG monitoring press F1 key. To access the DATA BASE (only on the AED models) press F2 key (MEMORY). To switch off the RESCUE LIFE press once the ON/OFF button. To power-off the device press the On-Off key only once.
SPEED DIAL 	Used to select energy and modify the settings on MENU screen or in other sub-menus. When pressed, menu screen will appear on the display.

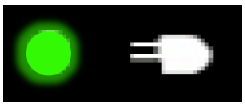
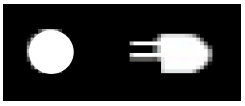
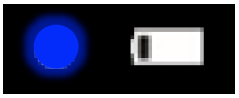
CHARGE BUTTON 	This key start the charge for the shock. (This key is active only when disposable pads are used). To start the charge with the standard pads press both push buttons on the pads handles.
SHOCK BUTTON 	When the red light inside this key is on it means that RESCUE LIFE is ready to defibrillate. Pressing this key will release the defibrillation shock. (This key is active only when disposable pads are used). To release the shock with the standard pads press both push buttons on the pads handles.

FUNCTION KEYS (F1-F5)

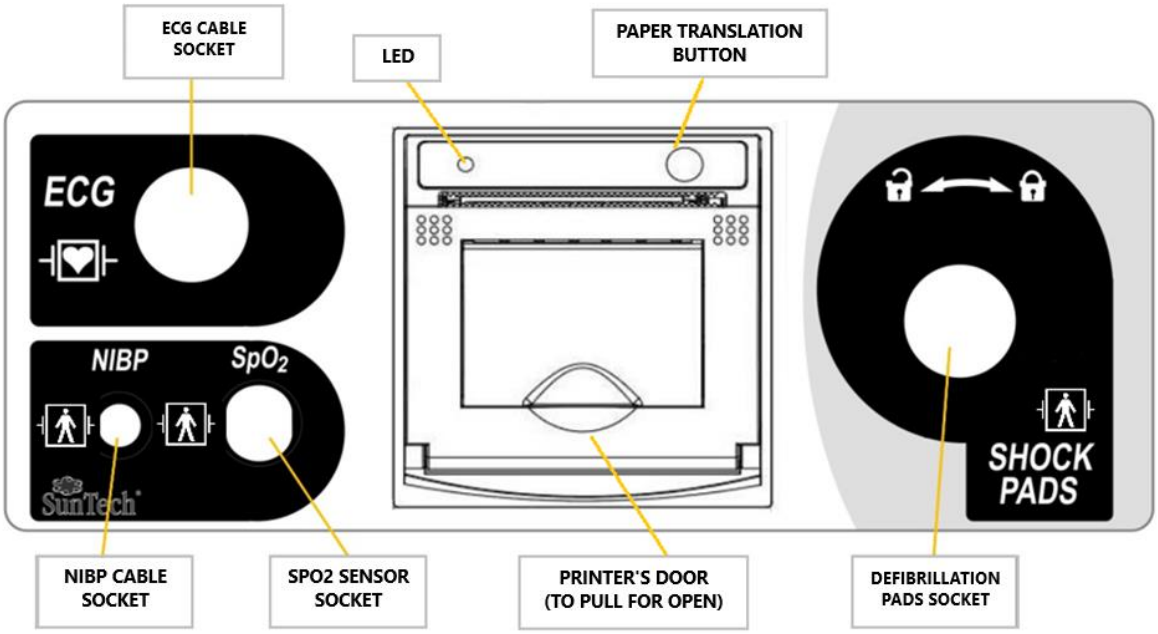
These keys are used for different functions, according to the screen where they are used.

KEY	INITIAL SCREEN	OPERATIONAL SCREEN	PACEMAKER SCREEN
F1	**START OPERATION**	**DISARM –** Internal discharge	Select the pace maker rhythm. To set the requested rhythm use the Speed dial.
F2	**MEMORY DATABASE**	**PRINT –** Start/stop printing	Select pace maker current. Set the current intensity using the Speed Dial.
F3	**AUTOTEST**	**PACER –** Enable Pacemaker	Set the pace maker mode: manual or on demand
F4	**SET CLOCK**	**SYNC –** enable Sync or No Sync Mode	Switch on/off the pace maker
F5		**MENU –** default parameters setup	Exit the pace maker mode

LIGHT INDICATORS

Indicator (LED) **CONNECTION TO AC LINE** **CASE A**  **CASE B** 	**CASE A** When the LED indicator is green lighted it informs that connection to AC line is carried. **CASE B** When the connection to AC line is removed the LED will switch off.
Indicator (LED) **BATTERY CHARGE** **CASE A**  **CASE B** 	**CASE A** When the LED indicator is blue lighted it informs that battery are in charging (by connection to AC line) **CASE B** When the battery charge is finished the LED will switch off.

CONNECTIONS

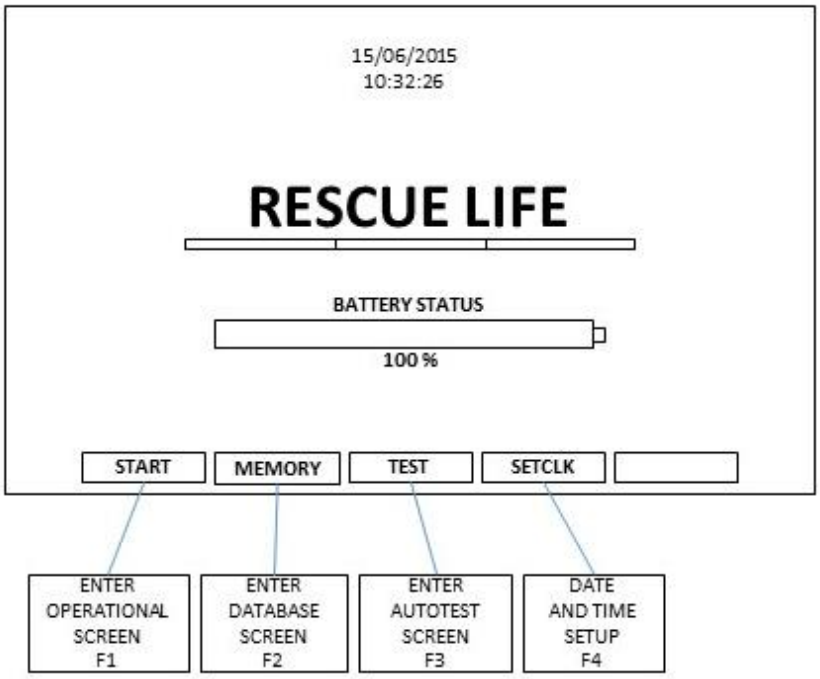


DEFIBRILLATION PADS INPUT	It connects the defibrillation pads lead (APEX, STERNUM) to RESCUE LIFE. For connecting the lead, push in the connector and turn it right. For disconnecting the lead, pull the lead lever and turn left the connector.
ECG PATIENT CABLE	ECG patient cable input. RESCUE LIFE displays 3, 6 or 12 traces
SpO_2 INPUT (optional)	When the SpO_2 sensor is connected, saturation values and heart rate are displayed.
NIBP CONNECTOR (optional)	When NIBP tube and cuff are connected the NIBP function can be used.
AC POWER SUPPLY INPUT (back side)	RESCUE LIFE AC power supply and battery charger. USE ONLY THE ORIGINAL AC POWER CORD!

START SCREEN INTERFACE

The start screen will be displayed when RESCUE LIFE is switched on with the defibrillation paddles disconnected.

Battery status and clock are shown.



Using function keys it is possible to enter in different screens.

START – F1: to enter in Operational screen

MEMORY – F2: to enter in Database screen

TEST – F3: to enter in Auto Test screen

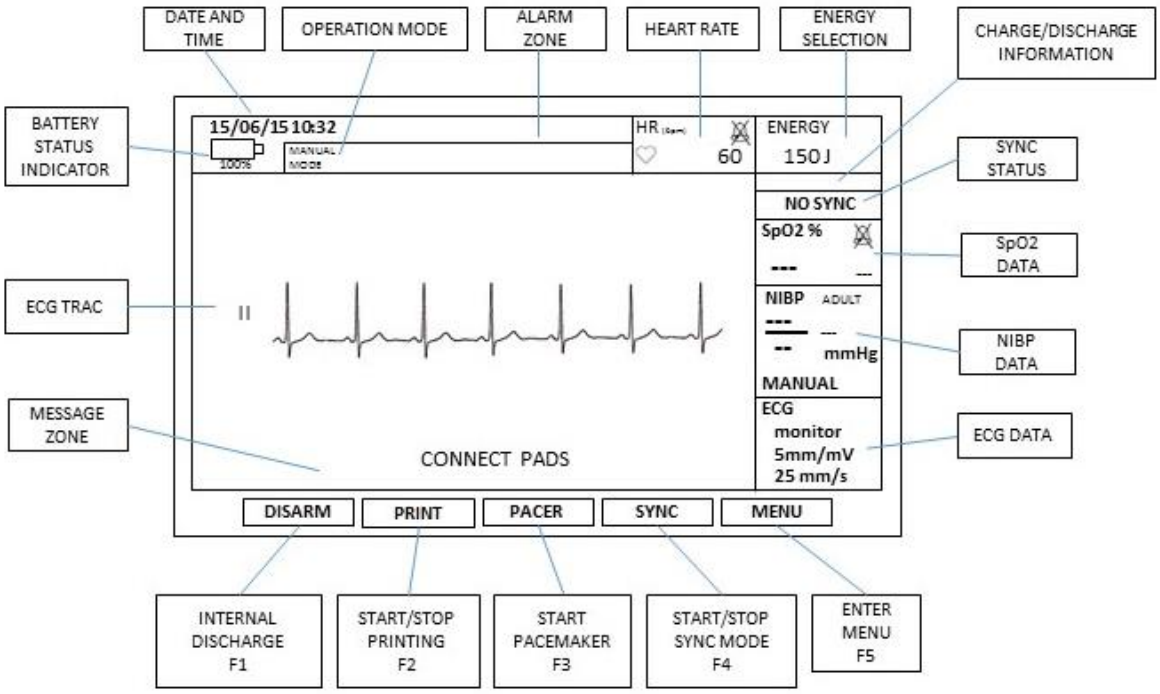
SETCLK – F4: to set date and time

To switch off RESCUE LIFE press once On/Off button.

OPERATIONAL SCREEN

At power ON, if the paddles are connected the RESCUE LIFE will start the operation.

If the paddles are not connected the start screen will be displayed. Press START – F1 key to enter in operational screen.



OPERATIONAL SCREEN FEATURES

In the Operational screen are shown all vital parameter and message as well as function button and some setting.

MESSAGGE ZONE: area where messages are shown.

ECG TRACE: area where ECG trace is shown. In menu it is possible to choose traces to display, signal gain and speed.

BATTERY STATUS INDICATOR: battery status is shown. If charge value is under 40 % indicator is yellow and if value is under 10 % indicator is red. Connecting power cord indicator becomes green.

When the battery value is under 10% a message appears on display. Insert the power supply cord in RESCUE LIFE socket, otherwise system will shout down automatically in 2 minutes. During this time defibrillation functions are disabled.

DATE AND TIME: date and time are shown.

OPERATION MODE: operation mode selected is shown. It is possible to select MANUAL, ADVISORY (ADV) and SEMIATUMATIC (AED) mode.

ALARMI ZONE: area where alarm are shown.

HEART RATE: heart rate is shown. It is possible to activate or deactivate acoustic beep of heartbeat.

ENERGY SELECTION: energy set is shown. To set energy turn knob clockwise to increase energy and counterclockwise to decrease energy.

CHARGE/DISCHARGE INFORMATION: when charging starts the status bar indicates the progress of the charge.

It also indicates when discharge is done and the amount of discharge when the charge level of the battery is under 15 %.

SYNC STATUS: it is shown if the sync mode is active or not.

SPO_2 DATA (optional): when the SpO_2 sensor is connected, it indicates the oxygen saturation and the heart rate acquired.

NIBP DATA (optional): when the NIBP cuff is connected, it indicates the non-invasive blood pressure.

ECG DATA: it shown signal gain and speed and the operating mode (MONITOR - DIAGNOSTIC).

Using functional keys it is possible to manage some function.

DISARM – F1: It allows to discharge the capacitor internally once it has been charged.

PRINT – F2: it allows to start and stop printing.

PACER – F3: it allows to enter in Pacemaker screen (optional).

SYNC – F4: it allows to activate and deactivate sync mode.

MENU – F5: it allows to open menu.

SET-UP MENU

The START-UP menu is accessible pressing the F5 key (MENU) or the Speed Dial on the operational screen and all the values can be changed using the Speed Dial.

Pressing the Speed Dial will select the field to change and rotating the Speed Dial will change the field value.

The entered values can be stored (when the 'SAVE SETUP') is selected and will be used as default values when RESCUE LIFE is switched on.

If the user needs to change the values only for the actual session then after changing the desired values should exit the start-up menu pressing the F5 key (MENU).

When menu screen is open the only keys to be active are F5 and Speed Dial.

SET-UP MENU FIELDS:

DEF MODE: select the function mode: manual (MANUAL), advisory (ADV) or semiautomatic (AED).

ECG TRACE: select ECG traces that the user choose to display or print. When the patient cable is connected, users can select which groups of traces to display. When the patient cable is disconnected, the ECG trace is acquired by defibrillation pads (lead II).

ECG MODE: it refers to the bandwidth of the signal. In MONITOR mode bandwidth in 0,6 Hz to 40 Hz, in DIAGNOSTIC mode bandwidth is 0,05 Hz to 120 Hz. Notch filter is always active. If the ECG trace is acquired by defibrillation pads active mode is MONITOR.

ECG SETUP: select the speed of ECG traces (display and printer) and the ECG gain.

ALARMS: to set alarms.

HR MAX: set the maximum heart rate alarm.

HR MIN: set the minimum heart rate alarm.

SpO_2 MIN: set the SpO_2 minimum alarm.

SOUND: enable/disable all the alarms

HR BEEP: Enable/disable the heart rate beep.

PRINT MODE: Set the print mode automatic or manual.

NIBP SETUP: set NiBP parameters.

SAVE: Save the actual settings as default and exit the menu.

EXIT: exit the menu.

The HR BEEP is not stored and when the machine is switched on, will be active (heart rate beep on). For patient safety reason, it can be set to off only for the actual working session.

DEVICE AND PATIENT PREPARATION

PRODUCT CHECK

Check carefully the content of the packing for any damage that might have been occured during shipping.

Check carefully all the accessories to ensure that the unit comes with the complete accessories necessary for a proper use of the device.

HOW TO TEST THE DEFIBRILLATOR

It is possible to charge without attaching the pads to the patient and discharge internally from the standard paddles only for the defibrillator testing and only selecting 1 joule.

If the defibrillator is charged using this mode the standard impedance of 50 ohm is assumed.

ELPRO S.r.l. recommended to make one functional check, preventive maintenance and electrical safety test at least once a year.

WHEN THE RESCUE LIFE IS CHARGED WITH THE PADDLES NOT ATTACHED TO THE PATIENT AND THE ENERGY IS SET TO A VALUE HIGHER THAN 150 J THE CHARGED ENERGY WILL BE LIMITED TO 150 J.
IN THIS CASE THE MESSAGE "ENERGY LIMIT" WILL BE DISPLAYED.
TO OBTAIN THE BEST SHOCK RESULT IT IS STRONGLY RECOMMENDED TO CHARGE THE ENERGY WITH THE PADDLES ATTACHED TO THE PATIENT.
NEVER CHARGE THE DEFIBRILLATOR WITH THE PADDLES IN CONTACT BETWEEN THEM.

MAKE SURE THAT THE CONTACT GEL IS SPREAD ONLY ON THE PADDLES AND NOT ALL OVER PATIENT CHEST.
IF THIS INDICATION IS NOT FOLLOWED BURNS TO PATIENT CHEST AND DEFIBRILLATOR FAULTS MAY OCCUR.

PROVIDE AN INTERVAL OF AT LEAST 60 SECONDS BETWEEN THE CYCLE OF CHARGE / DISCHARGE WHEN THE ELECTRODES ARE NOT CONNECTED TO THE PATIENT.

HOW TO USE THE ECG PATIENT CABLE CONNECTION AND ELECTRODES PLACEMENT

The ECG (electrocardiogram) is a recording of the electrical activity of the heart. The ECG is obtained by placing either electrodes or paddles on the patient and allows the heart's electrical activity to be monitored and recorded. ECG monitoring allows to identify and interpret the cardiac rhythms or dysrhythmias and calculation of heart rate.

ECG Electrode Requirements

Electrode quality is critical for obtaining an undistorted ECG signal. Always check the date code on electrode packages for the Use By date before applying the electrodes to a patient. Do not use electrodes with expired Use By date codes. Disposable electrodes are intended for a single use.

For best ECG monitoring results, use silver/silver chloride (Ag/AgCl) electrodes.

Other types of electrodes will display the post-defibrillation ECG in less time than expected.

Possible misinterpretation of ECG data.

The frequency response of the monitor screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for diagnostic and ST segment interpretation. For diagnostic or ST segment interpretation, or to enhance internal pacemaker pulse visibility, attach the ECG cable and then print the ECG rhythm.

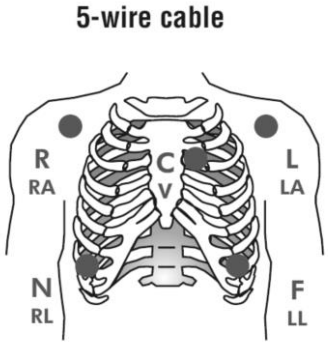
ECG CONNECTION

Connect the patient cable in its proper port **'ECG',** placed on the frontal panel of the device.

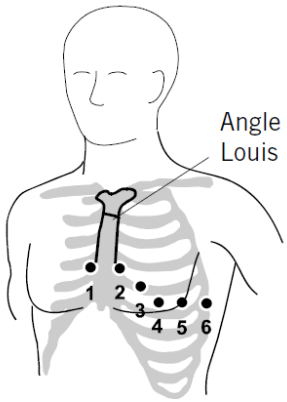
The 5 wires and 10 wires (optional) ECG cable can be used.

Follow the drawings below for the electrodes connection.

Limb lead electrodes placement:



Precordial lead electrodes sites for the 10 wires ECG cable:



LEAD		LOCATION
V1	C1	Fourth intercostal space to the right of the sternum
V2	C2	Fourth intercostal space to the left of the sternum
V3	C3	Directly between leads V2/C2 and V4/C4
V4	C4	Fifth intercostal space at midclavicular line
V5	C5	Level with V4/C4 at left anterior axillary line
V6	C6	Level with V5/C5 at left midaxillary line

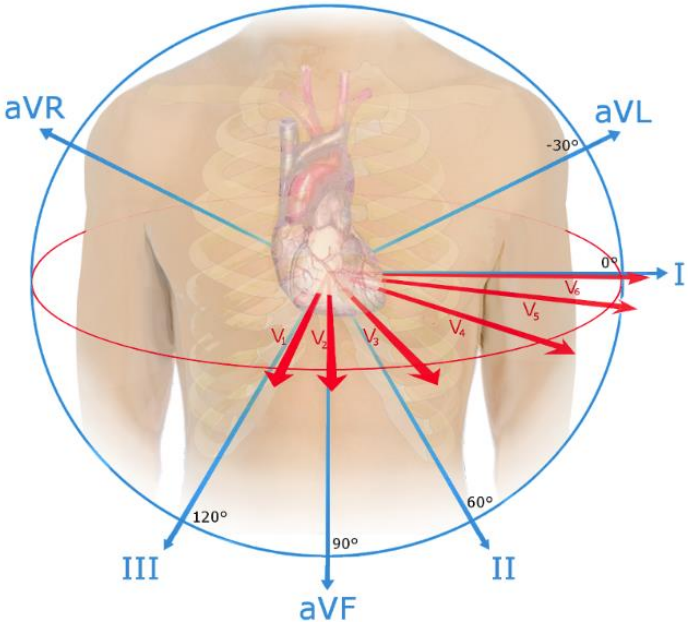


Figure. I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 derivations on frontal and orizzontal planes.

DEFIBRILLATION THERAPY

GENERAL INFORMATION FOR PROFESSIONAL USER

Defibrillation is only one aspect of the medical care required to resuscitate a patient with a shockable.

A direct current defibrillator applies a brief, intense pulse of electricity to the heart muscle. The RESCUE LIFE defibrillator/monitor delivers this energy through disposable pads, standard paddles or internal paddles applied to the patient's chest.

Successful resuscitation is associated to the length of time between the onset of a heart rhythm that does not circulate blood (ventricular fibrillation, pulseless ventricular tachycardia) and defibrillation. The American Heart Association has identified the following as critical links in the chain of survival from cardiac arrest:

Early access
Early CPR by first responders or bystanders
Early defibrillation
Early advanced life support

ECG rhythm. Depending on the situation, other supportive measures may include:
Cardiopulmonary resuscitation (CPR)
Administration of supplemental oxygen
Drug therapy

The physical state of the patient may affect the likelihood of successful defibrillation. Thus, failure to resuscitate a patient is not a reliable indicator of defibrillator performance. Patients will often exhibit a muscular reaction (like a jump or a twitch) during an energy transfer. The absence of such a response is not a reliable indicator of actual energy delivery or device performance. For further information, refer to the booklet, Defibrillation: What You Should Know.

Indications

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias, like a ventricular fibrillation and symptomatic ventricular tachycardia. Delivery of this energy in the synchronized way is a method for treating atrial fibrillation, atrial flutter, paroxysmal supraventricular tachycardia, and, in relatively stable patients, ventricular tachycardia.

The biphasic defibrillation waveform used in this device has only been clinically tested on adults; it has not been tested on pediatric patients.

Contraindications

Defibrillation is contraindicated in the treatment of Pulseless Electrical Activity (PEA) such as idioventricular or ventricular escape rhythms, and in the treatment of asystole.

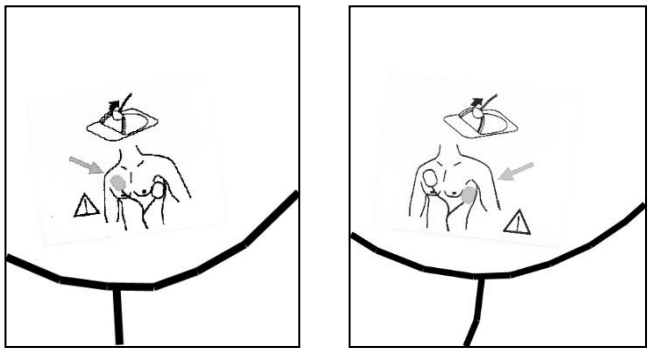
HOW TO PREPARE THE PATIENT

Evaluate the patient condition; he must exhibit the symptoms for which the defibrillation is indicated and these symptoms are:

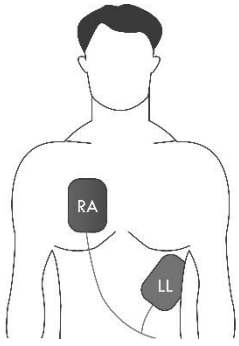
Unconsciousness
Absence of normal breathing
Lack of detectable pulse.

If the patient exhibits the above symptoms, do the following:
Remove clothing from the patient's chest. Dry the area, and clip or shave excessive chest hair. Then apply the pads.

In the case of use of disposable plates, open the package by tearing along the dotted line near the top of the package. Remove the pads from the package and follow the directions and diagram showing proper defibrillation pad placement located on the defibrillation pad package. The correct placement of pads is indispensable for effective analysis of the patient's cardiac rhythm and subsequent shock delivery (if required). Peel off the protective backing from each pad before placing it as shown on the picture on the pad. Peel the backing off only when the pad is ready to be placed. Place the pads with the sticky side of the pad on the patient's skin. Place the pads as shown in the left side diagram.
On the right side of the diagram are indicated each pad position marking printed on.



Pads position marking



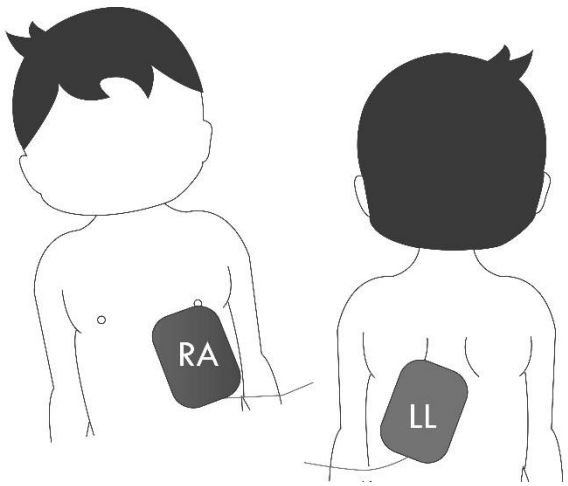
Pads placement

HOW TO PREPARE THE PEDIATRIC PATIENT

Apply the pads as shown in the picture. In the case of use of disposable plates. Open the package by tearing along the dotted line near the end of the pack. Remove the pads from the package and follow the directions and the schema for the correct placement of defibrillation electrodes placed on the packaging of the defibrillation electrodes and on the electrodes. Remove the protective coating from each electrode before placing them. Remove the coating only when the electrode is ready to be applied. Put the electrodes with the adhesive side of the patient's skin. Place the electrodes as shown in the diagram. The placement of pediatric electrodes in children under the age of 8 years is different from that of adults or children older than 8 years.

The device must be used with the attenuated defibrillation electrodes for children, if the patient is an infant or a child under the age of 8 years or weight less than 25kg (55 lbs). Do not delay the procedure to define the exact weight or age.

Follow the instructions in the figure shown here:



Children under 8 years old: Place one pad in the center of the chest and one pad on the back as shown.

DEFIBRILLATION MODE

With RESCUE LIFE users can choose between three operating modes: manual, advisory and semiautomatic.

In MANUAL mode users have to analyze heart rhythm and decide time and energy value to use for the defibrillation while in other modes RESCUE LIFE automatically analyze heart rhythm.

In ADVISORY mode (ADV) RESCUE LIFE only analyzes and suggest if patient needs defibrillation, after that users have to choose energy value, charge defibrillator and deliver the shock.

In SEMIAUTOMATIC mode (AED) RESCUE LIFE analyzes heart rhythm and helps operators with visible and audible prompts. If patient needs a defibrillation RESCUE LIFE automatically charge with energy value of 200 Joule.

Operators only should to deliver shock and perform CPR when indicated.

DEFIBRILLATOR PROCEDURE IN MANUAL MODE

1. Switch on the device pressing the **ON/OFF** button. Connect and lock the paddles plug to start the operation. The ECG signal will be displayed and by default the energy is set to **150 J.**
2. Place the paddles (set in adult or in pediatric version) on the patient chest and analyze the ECG trace in order to decide if defibrillation is necessary.
3. Select the energy level required using the Speed Dial.
4. If you are using the standard paddles press both push buttons on the handles to start charging.
5. If you are using disposable pads press the **CHARGE** button on the device panel to start charging.
6. On the screen the charge status bar indicates that the charging procedure is on; at the same time the ascending sound will start.
7. When the charge ends the red light on the **SHOCK** button will turn on indicating that **RESCUE LIFE** is ready for defibrillation.
8. **To release the defibrillation shock, press both push buttons on the standard paddles. If using disposable pads press the SHOCK key in the front panel to release the defibrillation shock.**
9. The shock has to be released within 25 sec from the charge completed; after 25 sec the RESCUE LIFE will discharge internally.
10. If the defibrillation is not required, press the **DISARM (F1)** key to discharge internally.
11. If the SYNC function is on, SYNCHRONIZED CARDIOVERSION can be done.

DO NOT TOUCH THE PATIENT DURING DEFIBRILLATION.

WHEN THE MESSAGE "**ATTACH PADS"** IS DISPLAYED ON THE SCREEN AND THE CHARGE IS STARTED, THE DEVICE ASSUMES A STANDARD IMPEDANCE OF 50 OHM. IF THE MESSAGE **"ATTACH PADS"** PERSISTS WHEN THE SHOCK HAS TO BE DELIVERED, THE DEVICE WILL DISCHARGE INTERNALLY

THE MESSAGE **"ATTACH PADS"** CAN BE DISPLAYED ALSO IN PRESENCE OF A NO SUFFICIENT ELECTRIC CONTACT BETWEEN THE PADS AND THE PATIENT SKIN; IN THIS CASE ADD CONDUCTIVE GEL AND PRESS STRONGLY THE DEFIBRILLATION PADS ON THE PATIENT SKIN. DURING ***SYNC MODE***, THE SHOCK WILL NOT BE RELEASED IF THE ECG TRACE IS NOT STABLE AND THE QRS COMPLEX IS NOT VALID.

WHEN USING ***SYNC MODE*** MAKE SURE THAT THE ECG TRACE HAS A STABLE BASE LINE AND THE HEART RATE IS STABLE. DEFIBRILLATING IN ***SYNC MODE*** WITH A DISTURBED ECG SIGNAL IS DANGEROUS BECAUSE THE MACHINE WILL NOT BE ABLE TO IDENTIFY CORRECTLY THE 'R' PEAK TO SYNCHRONIZE TO.

THE MACHINE CAN DELIVER A SYNC SHOCK USING AS INPUT THE ECG CABLE OR THE PADS, BUT IT IS RECOMMENDED TO USE THE PADS INPUT FOR THE BEST RESULT.

DEFIBRILLATOR PROCEDURE IN ADVISORY MODE (ADV)

1. Switch on the device pressing the **ON/OFF** button. Connect and lock the paddles plug to start the operation. The ECG signal will be displayed and by default the energy is set to **150 J.** To set advisory mode open menu and select advisory in DEF MODE.
2. Place the paddles on the patient chest and let RESCUE LIFE analyze the ECG trace in order to decide if defibrillation is necessary.
3. If RESCUE LIFE recognizes a patient needs defibrillation select the energy level required using the Speed Dial.
4. If you are using the standard paddles press both push buttons on the handles to start charging.
5. If you are using disposable pads press the **CHARGE** button on the device panel to start charging.
6. On the screen the charge status bar indicates that the charging procedure is on; at the same time the ascending sound will start.
7. When the charge ends the red light on the **SHOCK** button will turn on indicating that RESCUE LIFE is ready for defibrillation.
8. **To release the defibrillation shock, press both push buttons on the standard paddles. If using disposable pads press the SHOCK key in the front panel to release the defibrillation shock.**
9. The shock has to be released within 25 sec from the charge completed; after 25 sec the RESCUE LIFE will discharge internally.
10. If the defibrillation is not required, press the **DISARM (F1)** key to discharge internally.

DO NOT TOUCH THE PATIENT DURING HEART RHYTHM ANALYSIS.

DO NOT TOUCH THE PATIENT DURING DEFIBRILLATION.

AUTOMATED EXTERNAL DEFIBRILLATION (AED)

When RESCUE LIFE is set on advisory or semiautomatic mode, after applying the defibrillation pads to the patient's chest, it will automatically analyze the patient's electrocardiogram (ECG) and advises the operator if the rhythm is shockable or not.
In advisory mode the user should select the energy, charge and deliver the shock.
In the semiautomatic mode RESCUE LIFE guides the operator through the rescue procedure using visible and audio prompts and will charge automatically at a fixed energy of 200J when a shockable rhythm is detected. The operator should only deliver the shock and perform CPR when indicated.

INDICATIONS FOR USE

The RESCUE LIFE with the semiautomatic option is intended to be used by personnel who have been trained in its operation. The operator should be qualified by training in basic life support, CPR/AED. The device is indicated for emergency treatment of victims exhibiting the following symptoms of a sudden cardiac arrest:
un-consciousness, absence of normal breathing and lack of detectable pulse. If the victim is breathing post-resuscitation, the RESCUE LIFE should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy.

MAKE SURE THAT ALL ELECTRONIC DEVICES WHICH MAY DISTURB THE ECG SIGNAL MUST BE SWITCHED OFF OR PLACED AT A SAFE DISTANCE FROM RESCUE LIFE BEFORE DEFIBRILLATION.

PLEASE MAKE SURE NOBODY TOUCHES THE PATIENT DURING THE DEFIBRILLATION.

DO NOT USE THE AED MODE IN NEWBORN.

DO NOT CREATE A SHORT CIRCUIT BETWEEN THE DEFIBRILLATION PADS.
DO NOT PLACE THE PADS TOO CLOSE BETWEEN THEM. MAKE SURE THAT THE PADS ARE NOT TOUCHING THE ECG CABLE LEADS OR OTHER METALLIC PARTS THAT CAN CAUSE PATIENT SKIN BURNS.

ENSURE A GOOD CONNECTION BETWEEN PADS AND PATIENT SKIN TO PROVIDE AN EFFECTIVE DEFIBRILLATION.

ECG ANALYSIS ALGORITHM

The features available with the AED include the following:

- Ventricular Fibrillation (VF) and Fine Ventricular Fibrillation (FVF).
- Ventricular Tachycardia with a rater higher than 150 bpm (beats per minute).
- Asystole threshold less than 0.15 mV.
- Non-Committed shock, when the rhythm changes from shockable to non shockable.

CPR PROTOCOL

The CPR protocol is consistent with the guidelines recommended by the European Resuscitation Council (ERC)[1].

[1] "European Resuscitation Council (ERC) Guidelines for cardiopulmonary resuscitation (CPR)", European Resuscitation Council, vol. 81/2010.

Upon detecting a shockable cardiac rhythm, the RESCUE LIFE charges automatically at a 200J energy level and advises the operator to press the SHOCK button to deliver a shock; then advises the operator to check the patient pulse and start CPR for 120 seconds with a chest compression. If the shock is not released within 25 sec from the indication, the defibrillator will discharge internally.

During CPR the ECG analysis is interrupted and the CPR time will be displayed (120 seconds).

SELECTING THE AED OPERATION MODE

To enter the AED operation mode (semiautomatic) enter in menu and select semiautomatic in DEF MODE after connecting pads.

THE AED OPERATION MODE CAN BE SET ENTERING ONLY THE DISPOSABLE PADS OR ENTERING THE 2ND DERIVATION. THE DEFIBRILLATOR RESCUE LIFE TURN ON ALWAYS ON THE 2ND DERIVATION.

IF A PATIENT IS MONITORED WITH OTHER DERIVATIONS, REMEMBER TO SELECT THE 2ND ONE THROUGH SPEED DIAL FOR CHANGING TO THE AED OPERATION MODE. USING THE DISPOSABLE PADS, PLEASE SELECT THE PADS DERIVATION.

At switch on the defibrillator, by default, is set to the MANUAL mode.

DEFIBRILLATOR PROCEDURE IN SEMIAUTOMATIC MODE (AED)

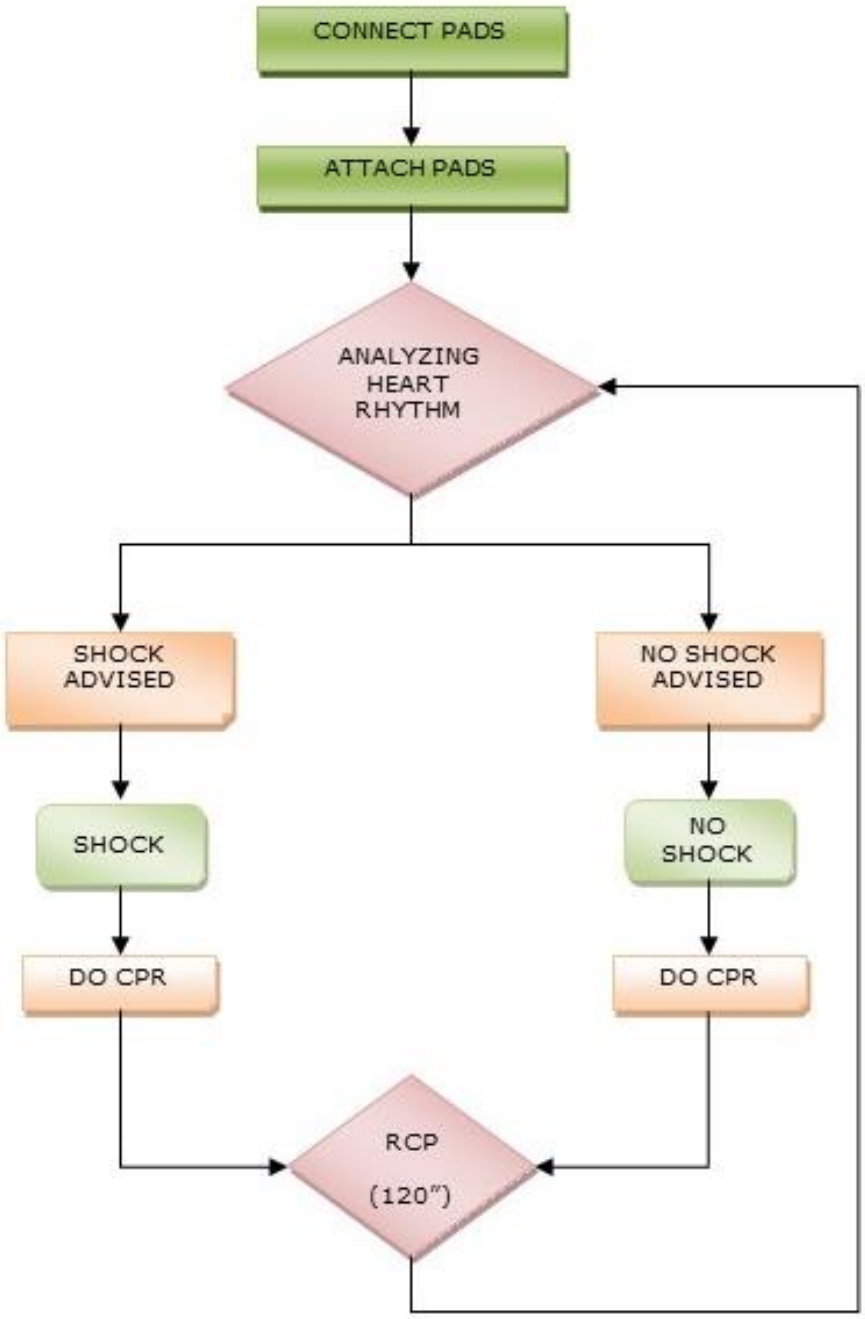
1. Switch on the device pressing the **ON/OFF** button. Connect and lock the disposable pads plug to start the operation.
2. Place the disposable pads on the patient chest then open menu and select AED in DEF MODE. When RESCUE LIFE recognizes pads are connected hearth rhythm analysis starts. At the same time "REC" message will appear on the display, below status battery indicator. It means that device will record for 1 minute the ECG trace on the USB FLASH STORAGE.
3. If RESCUE LIFE recognizes a shockable rhythm it automatically will charge energy to a value of 200 Joule. On the screen the charge status bar indicates that the charging procedure is on; at the same time the ascending sound will start.
4. When the charge ends the red light on the **SHOCK** button will turn on indicating that RESCUE LIFE is ready for defibrillation. At the same time an audio alert will notify that RESCUE LIFE is ready to deliver the shock.
5. **To release the defibrillation shock, press the SHOCK key in the front panel.** The shock has to be released within 25 sec from the charge completed; after 25 sec the RESCUE LIFE will discharge internally.
6. If the defibrillation is not required, press the **DISARM (F1)** key to discharge internally.
7. When discharge has been delivered CPR phase starts. During this phase RESCUE LIFE guides operator by enunciating the time of 120 s.
8. At the end of CPR RESCUE LIFE analyzes heart rhythm again. If it recognizes a shockable rhythm it automatically will charge energy to a value of 200 Joule (point 3 of this paragraph) otherwise CPR phase starts again.

DO NOT TOUCH THE PATIENT DURING HEART RHYTHM ANALYSIS.

DO NOT TOUCH THE PATIENT DURING DEFIBRILLATION.

TURNING OFF THE DEFIBRILLATOR BEFORE RECORDING IS FINISHED IT WILL PRODUCE LOSS OF DATA IN THE MEMORY.

SEMIAUTOMATIC (AED) MODE FLOW CHART



AUDIO AND TEXT PROMPTS

PROMPTS	MEANING
CONNECT PADS	Indicates that you have to connect the pads to the defibrillator.
ATTACH PADS	Indicates that the user have to attach the defibrillator electrode pads to the bare chest of the patient
ANALYZING HEART RHYTHM	Indicates that the device is doing an analysis of the patient's ECG
SHOCK ADVISED	Indicates that the patient has a shockable ECG rhythm.
PRESS THE RED BUTTON NOW	Indicates that the user have to press the SHOCK button for the delivery of a defibrillation shock. At this time, the SHOCK button light is on (red).
SHOCK DELIVERED	Indicates on the display that the device has delivered a defibrillation shock.
NO SHOCK ADVISED	Indicates that the patient has a non-shockable ECG rhythm.
BEGIN CPR NOW	The user should perform CPR for 120 seconds.

PACEMAKER (OPTIONAL)

ABOUT NON INVASIVE PACEMAKER

A non-invasive pacemaker is a device that delivers an electrical stimulus to the heart, causing cardiac depolarization and myocardial contraction. The energy is delivered through large adhesive disposable electrodes placed on the chest. In addition to noninvasive pacing, other supportive measures may be necessary.

Among other factors, it is recognized that successful pacing of a patient depends to the length of time between the onset of a dysrhythmia and the initiation of pacing. Rapid pacing and prompt follow-up care are essential. The physiologic state of the patient may affect the probability of successful pacing or of skeletal muscle activity. The failure to successfully pace a patient is not a reliable indicator of pacemaker performance. In the same way, the patient's muscular response to pacing is not a reliable indicator of energy delivered.

Indications

Non-invasive pacing is indicated for symptomatic bradycardia in patients with a pulse.

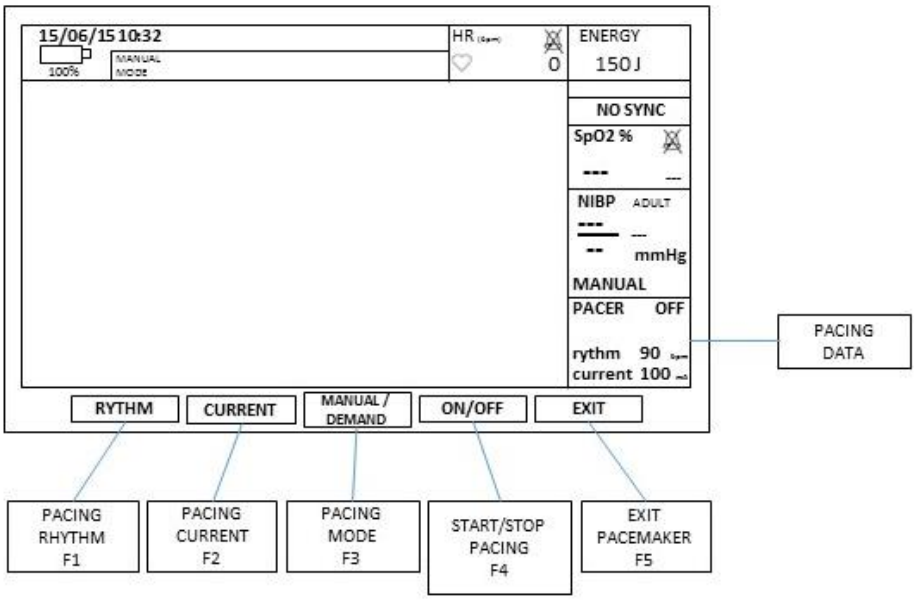
Contraindications

Non-invasive pacing is contraindicated for the treatment of ventricular fibrillation and asystole.

On the operational screen, pressing the F3 key (PACER) the RESCUE LIFE will open the pacemaker mode and will display the pacemaker menu.

IF THE PADDLES ARE NOT ATTACHED TO THE PATIENT THE MACHINE WILL NOT ENTER THE PACEMAKER MODE.
THE ECG TRACE WILL BE DISPLAYED AND THE DEMAND MODE IS AVAILABLE ONLY IF THE PATIENT CABLE IS CONNECTED (THE PADDLES ARE USED FOR PACING SO THEY CANNOT ACQUIRE THE ECG TRACE).

PACEMAKER SCREEN



In the PACING DATA area you can see pacing rhythm and current values and if pacing is activate or deactivate.

Using function keys it is possible to set pacing parameter.

KEY	FUNCTION
RYTHM – F1	Press key and use the Speed Dial to change the value to set the pacing rhythm.
CURRENT – F2	Press key and use the Speed Dial to change the value to set the pacing current.
MANUAL / DEMAND - F3	Press key to change the pace maker operation mode.
ON / OFF - F4	Press key to start and stop the pacer.
EXIT – F5	Press key to exit.

Pressing EXIT key you will return to the operational screen.

HOW TO PREPARE THE PATIENT

The connection of the electrodes is possible in two ways, depending on what you want:

- ANTERIOR-POSTERIOR Connection (only pacing).
  Front pad positioned on the left part of the chest, halfway between the xiphoid apophysis and the left nipple at the sites V2-V3.
  Back pad positioned immediately below the left shoulder blade side of the spine at the same level than the front.

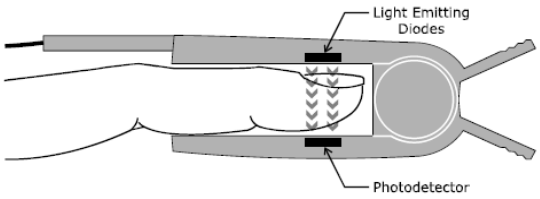
- ANTERIOR-ANTERIOR connection - (for defibrillation and pacing).
  Front pad positioned below the right clavicle.
  Lateral plate positioned on the middle axillary line at the height of his left nipple, position V6.

PACING PROCEDURE

1. Switch on the device pressing the **ON/OFF** button. Connect and lock the disposable pads plug to start the operation.
2. Place the disposable pads on the patient then press PACER – F3 key.
3. Press F1 then use the Speed Dial to set the value of the pacing rhythm, then press F1 key again.
4. Press F2 then use the Speed Dial to set the value of the pacing current, then press F2 key again.
5. Press F3 to select pacing mode (default mode is fixed).
6. Press F4 key to start pacing, then press F4 key again to stop pacing.
7. Press F5 key to exit and return to operational screen.

SpO_2 MONITORING

The SPO_2 Module measures functional oxygen saturation in the blood. The measurement determines the oxygenated hemoglobin as a percentage of the hemoglobin that can transport oxygen.



Pulse oximetry works by having light emitting diodes pass red and infra-red light into arteriolar vascular beds such as a finger or a toe and having the light detected by a photo detector afterwards.

Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during the pulsations. The ratio of light absorbed is translated into a measurement of functional oxygen saturation (SpO_2).

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). A pulse oximeter determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry sensor serve as light sources; a photo diode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The pulse oximeter bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of non pulsatile absorbers such as tissue, bone, and venous blood.

PULSE OXIMETRY SENSORS

The RESCUE LIFE is equipped with a SpO_2 sensor that is designed to be used with a finger of the patient.

Other sensors from the manufacturer could also be used with the RESCUE LIFE.

The following table shows all available sensors that may be used with the RESCUE LIFE.

Choose the sensors to suit the weight of the patient.

RLFS-004.1	Adult SpO_2 digital finger sensor
RLFS-004.2	Pediatric SpO_2 digital finger sensor

Reusable sensors may be reused on different patients after cleaning and disinfecting.

Do not use other sensors aside from the ones recommended.

Before using, carefully read the sensor directions for use, including all warnings, CAUTIONS AND INSTRUCTIONS.

SETTING THE ALARM

The SpO_2 alarm can be set to warn you if the SpO_2 value goes outside of the defined lower limit.

The alarm can be set by accessing in "ALARMS" in the Menu screen.

If the SPO_2 value falls below the specified limits, an alarm tone alerts you.

NIBP (NON-INVASIVE BLOOD PRESSURE)

INTRODUCTION

The **RESCUE LIFE NIBP** option is based on the ***Advantage* A+** module platform available in the series of oscillometric OEM NIBP technologies from *SunTech Medical*®. The *Advantage* series of OEM NIBP technologies provides the simplicity of the oscillometric technique of acquiring blood pressure with the most reliable, flexible and clinically accurate modules in the industry.

Advantage OEM NIBP technologies have been integrated in many different medical devices throughout the world including general multi-parameter patient monitors, cardiac output monitors, dialysis machines, defibrillators, 24-hour ABPM devices, anesthetic delivery devices as well as several niche market devices.

The *Advantage* A+ module provides the highest NIBP performance in the smallest complete package available. SunTech Medical designed the *Advantage* A+ to meet the needs of the most challenging clinical application with internal automatic modes, low voltage communication protocols, the lowest power consumption in the industry and readily equipped to integrate the *Advantage* RMT technology option for the highest level of motion tolerant performance.

OPERATIONAL OVERVIEW

For pediatric and adult patient populations, blood pressure measurements made with the *Advantage* series of OEM NIBP technologies are equivalent to those obtained by trained observers using the cuff/stethoscope auscultatory method within the limits prescribed by ANSI/AAMI SP10: 2002 (mean error difference of ± 5 mmHg or less, standard deviation of 8 mmHg or less) as well as EN1060-4:2004.

For neonatal patient populations, blood pressure measurements made with the *Advantage* series of OEM NIBP technologies are equivalent to those obtained by intra-arterial blood pressure devices within the limits prescribed by ANSI/AAMI SP10: 2002 (mean error difference of ± 5 mmHg or less, standard deviation of 8 mmHg or less) as well as EN1060-4:2004.

TERMINOLOGY FOR NIBP

Oscillometry

The oscillometric method of blood pressure measurement is a non-invasive method that monitors the amplitude of cuff pressure changes during cuff deflation to determine arterial blood pressure. The cuff pressure is first elevated above the patient systolic blood pressure level and the cuff begins to deflate at a certain rate. The initial rise in amplitude of these pressure fluctuations during cuff deflation corresponds closely to the systolic blood pressure. As the cuff is further deflated, these pressure fluctuations increase in amplitude until a peak is reached which is usually referred to as the mean arterial pressure (MAP). As cuff deflation continues, the diastolic pressure can be determined based upon the rapidly diminishing amplitude of the pressure fluctuations. Thus systolic, MAP and diastolic blood pressures can be accurately obtained by supervising the pressure fluctuations while controlling the cuff deflation rate.

mmHg

Millimeters of Mercury, which is the most common unit of measure for pressure in non-invasive blood pressure.

NIBP

Non-invasive blood pressure.

bpm

Beats per minute, which is the most common unit of measure for pulse rate.

Advantage OEM NIBP Technology Series

Term encompassing all of the *Advantage* OEM NIBP technologies and module platforms.

Patient Populations

There are three major patient groups which are formally defined as neonate (up to 28 days), pediatric (29 days to 12 years) and adult (13 years and older).

WARNINGS & PRECAUTIONS DURING THE NIBP MESURAMENT

This device should not be used when oscillometric pulses may be altered by other devices or techniques such as External Counterpulsation (ECP) or Intra Aortic Balloon Pump Counterpulsation.

DO NOT USE THE **NIBP MODULE** FOR ANY PURPOSE OTHER THAN SPECIFIED IN THIS MANUAL WITHOUT WRITTEN CONSENT AND APPROVAL FROM ELPRO S.R.L.

DO NOT USE IN THE **PRESENCE OF FLAMMABLE GASEOUS ANESTHESIA AGENTS** BECAUSE OF FLAME HAZARD.

DO NOT ATTACH THE CUFF TO A LIMB BEING USED FOR IV INFUSIONS AS THE CUFF INFLATION CAN BLOCK THE INFUSION, POTENTIALLY CAUSING HARM TO THE PATIENT.

SUBSTITUTION OF A COMPONENT DIFFERENT FROM THAT SUPPLIED MAY RESULT IN MEASUREMENT ERROR. REPAIRS SHOULD BE UNDERTAKEN ONLY BY PERSONNEL TRAINED OR AUTHORIZED BY ELPRO S.R.L.

Accuracy of any blood pressure measurement may be affected by the position of the subject, his or her physical condition and use outside of the operating instructions detailed in this manual. Interpretation of blood pressure measurements should be made only by a physician or trained medical staff.

The RESCUE LIFE NIBP module is designed to work with SunTech® cuffs and hoses. The use of cuffs and hoses not supplied by SunTech® may compromise performance and accuracy.

If the blood pressure cuff is on the same limb as a pulse oximeter probe, the oxygen saturation results will be altered when the cuff occludes the brachial artery.

To obtain accurate blood pressure readings, the cuff must be the correct size, and also be correctly fitted to the patient. ***Incorrect size or incorrect fitting may result in incorrect readings.***

When a cuff is going to be positioned on a patient for an extended length of time, be sure to occasionally check the limb for proper circulation. The module may not operate

correctly if used or stored outside the relevant temperature or humidity ranges described in the Performance specifications.

Adverse Reactions

Allergic exanthema (symptomatic eruption) in the area of the cuff may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff.

Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple petechia) on the forearm following the application of the cuff, which may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

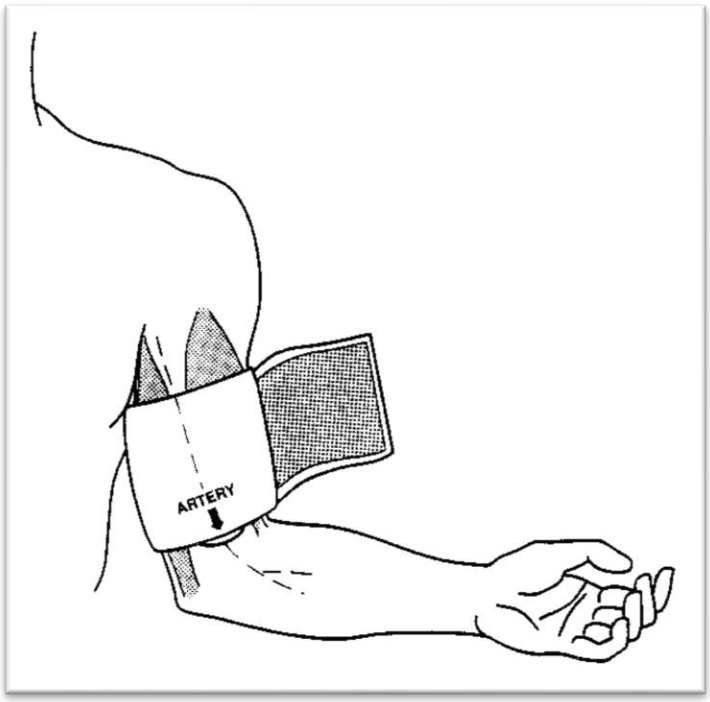
User Responsibility

This module is designed to perform in conformity with the description thereof contained in this operation manual when operated, maintained and repaired in accordance with the instructions provided.

CUFF SELECTION & PLACEMENT

It is important to select the cuff size that is appropriate to the diameter of the patient's upper arm. Use the *Range Lines* on the inside of the cuff to determine the correct size cuff to use.

Wrap the cuff around the arm making sure that the *Artery Marker* is aligned over the brachial artery as shown in Figure. If possible, do not wrap the cuff over the patient's clothing. The cuff should fit snug to the patient's arm for maximum oscillometric signal quality. An appropriate sized cuff should be placed on the non-dominate arm where the lower edge of the cuff is located 2cm above the antecubital fossa (interior bend of the elbow).



Ensure that the air hose from the monitor to the cuff is not compressed, crimped or damaged.

The midpoint of the subject upper arm should be supported at heart level for proper measurement accuracy. When the cuff is below heart level, measurement results may be higher and when the cuff is above heart level, measurement results may be lower than comparative results obtained at heart level.

USING A CUFF THAT IS THE WRONG SIZE MAY GIVE FALSE AND MISLEADING RESULTS.

THE NIBP MODULE IS DESIGNED TO WORK WITH SUNTECH CUFFS AND HOSES. THE USE OF CUFFS AND HOSES NOT SUPPLIED BY SUNTECH MAY COMPROMISE PERFORMANCE AND ACCURACY.

DO NOT ATTACH THE **CUFF TO A LIMB** BEING USED FOR IV INFUSIONS AS THE CUFF INFLATION CAN BLOCK THE INFUSION, POTENTIALLY CAUSING HARM TO THE PATIENT.

If the blood pressure cuff is on the same limb as a pulse oximeter probe, the oxygen saturation results will be altered when the cuff occludes the brachial artery.

Intra-arm differences vary between people. Do not assume that measurements from both arms are same.

When a cuff is going to be positioned on a patient for an extended length of time, be sure to occasionally check the limb for proper circulation.

ACTIVATION AND OPERATION OF THE NIBP MODE

To activate the NIBP mode, press the 'MENU' (F5) key form the operational Rescue Life screen.

On the menu select NIBP than ON using the jog.

WHEN IN NIBP MODE, IT IS POSSIBLE TO SELECT ENERGY AND DEFIBRILLATE. IF THE DEFIBRILLATOR IS MEASURING THE PRESSURE WHEN ENERGY IS CHARGED PRESSURE MEASURING WILL BE STOPPED
TO RETURN TO THE DEFIBRILLATOR FUNCTIONS AND SETUPS PRESS 'EXIT' (F5) KEY.

On the right side of the graphic screen the following NIBP values are displayed:

Patient type:	'ADULT' (default), 'PEDIATRIC' or 'NEONATAL'
Systolic pressure:	'SYS'
Diastolic pressure:	'DIA'
Mean arterial pressure:	'MEAN'
Cuff pressure:	'PRESS'
Operation mode:	'MANUAL' (default), 'AUTO'

On the bottom side of the screen the function keys (F1…F5) are the commands for the NIBP:

START/STOP – F1: to start or abort the NIBP measurement in manual or automatic mode.

PRINT – F2: to print the last NIBP measurement in manual mode or paper feed. If the last measurement was already printed it will only perform paper feed. In automatic operation mode will perform only paper feed as the last measurement is automatically printed.

CLEAR – F3: to clear the last measurement values (SYS,DIA,MEAN).

SET – F4: to enter the NIBP set up menu.

EXIT – F5: to exit the NIBP and return to the defibrillator functions.

NIBP SET-UP MENU

Pressing the **SET – F4** key the NIBP set-up menu is displayed.
To modify the values press the selection jog to choose the field then rotate the selection jog to change the value assigned to the field.
To exit the set-up menu press the **SET – F4** key.

PATIENT: select the patient type: ADULT, PEDIATRIC or NEONATAL.

MODE: select the measurement mode: MANUAL or AUTOMATIC.

AUTO INTERVAL: select the automatic measurement interval: 1,2,3,4,5,10,15,30,60 or 90min.

PRINT MODE: select manual or automatic hardcopy only for MANUAL measurement mode. In automatic measurement mode the printing is always automatic.

By default when entering the NIBP mode the set-up is:

PATIENT:	ADULT
MODE:	MANUAL
AUTO INTERVAL:	5 min
PRINT MODE:	AUTO

OPERATION SEQUENCE

Before any measurement please select the right patient type (set-up menu).
For a manual NIBP measurement, place the cuff according with paragraph "cuff selection & placement" and press the **START - F1** key.
At the end of the measurement the values for 'SYS', 'DIA' and 'MEAN' pressure will be displayed and printed (if the automatic print mode is active). In manual print mode press the **PRINT - F2** key to get the hardcopy of the measurement.

For an automatic measurement enter the set menu, select the automatic mode and the time interval then press the **START - F1** key.
At each selected time interval the measurement will be taken automatically and printed.

In both modes if the **STOP - F1** key is pressed while measuring, the process will be aborted and the pressure will be released.

If an error was found during the measurement it will be reported on the display with a code number and on the hardcopy with a brief description. Please see the remedies in the errors **Appendix 1**.

Appendix 1
Error Code List & Definitions

If more than one error occurs during a single measurement, the higher numbered error code will be displayed.

EC 1 Weak or no oscillometric signal

Corrective Action: Check that the cuff is in the correct position.
Check the patient.
Check that the cuff is properly tightened.
Check that there is no excessive clothing between the arm and the cuff.
Check that the correct size cuff is being applied.

EC 2 Artifact / erratic oscillometric signal

Corrective Action: The patient may have been moving too much.
Check that the cuff is in the correct position.
Check that the correct size cuff is being applied.

EC 4 Exceeded measurement time limit

Corrective Action: The patient may have been moving too much.
Check that the cuff is properly tightened.
Check that the cuff is in the correct position.
Check that the correct size cuff is being applied.
Check that there is no excessive clothing between the arm and the cuff.

EC 85 Pneumatic Blockage

Corrective Action: Check that the hose has no sharp bends or is pinched.
Check that the patient is not lying on the cuff.
Check that the cuff is in the correct position.

EC 86 BP reading terminated by user

Corrective Action: Check the patient.
Take another BP measurement.

EC 87 Inflate Timeout, Air Leak or Loose Cuff

Corrective Action: Check that the hose is connected to the system and the cuff.
Check that the cuff is properly tightened.
Check that the cuff is in the correct position.
Check that the correct size cuff is being applied.
Check that the cuff is not leaking air.
Check that the hose connections are not damaged or loose.

EC 88 Safety Timeout

Corrective Action: Check the patient.
Check that the cuff is in the correct position.
The patient may have been moving too much.
Take another BP measurement.

EC 89 Cuff Overpressure

Corrective Action: Check that the correct size cuff is being applied.
Check that the hose has no sharp bends or is pinched.
Check that the cuff is in the correct position.
Check that the patient is not lying on the cuff.

EC HIGHER THEN 89 System error

Corrective Action: Service may be required. Call ELPRO S.r.l. representative.

Appendix 2
Accessories

Part #	Description
RLFS-0010.1	NIBP Cuff, Adult
RLFS-0010.2	NIBP Cuff, Pediatric
RLFS-011	NIBP Cable

Appendix 3
Specifications

- Method of Measurement:
  Oscillometric. Diastolic values correspond to Phase 5 Korotkoff sounds.

- Blood Pressure Range:
  Systolic:

ADULT	40 – 260 mmHg
PEDIATRIC	40 – 160 mmHg
NEONATE	40 – 130 mmHg

  MAP:

ADULT	26 – 220 mmHg
PEDIATRIC	26 – 133 mmHg
NEONATE	26 – 110 mmHg

  Diastolic:

ADULT	20 – 200 mmHg
PEDIATRIC	20 – 120 mmHg
NEONATE	20 – 100 mmHg

- Pulse Rate Range:
  30 to 220 BPM

- Pulse Rate Accuracy: ± 2% or ± 3 BPM, whichever is greater

- Cuff Deflate Rate:
  Deflation step size varies with heart rate, cuff pressure and cuff volume.

- Initial Inflation Pressure:

ADULT	160 mmHg (default)
PEDIATRIC	120 mmHg (default)
NEONATE	90 mmHg (default)

- Subsequent Inflation Pressure:

ADULT	Previous Systolic + 30 mmHg
PEDIATRIC	Previous Systolic + 30 mmHg
NEONATE	Previous Systolic + 20 mmHg

- Clinical Accuracy:
  Meets accuracy requirements of ANSI/AAMI SP10:2002 and EN1060-4:2004.

- Pressure Transducer Accuracy:
  3 mmHg between 0 mmHg and 300 mmHg for operating conditions between - 5° C and 46° C.

- Operating Conditions:
  - 5° C to 46° C, 10% to 95% non-condensing humidity

- Storage Conditions:
  -20° C to 50° C, 15% to 95% non-condensing humidity (without Disposable multifunction electrodes for defibrillator);

- Altitude:
  Measurement accuracy is not affected by altitude

- Auto Interval Periods: 1, 2, 3, 4, 5, 10, 15, 30, 60 and 90 minutes

- Patient Safety:

  Internal operating software ensures that:

  Maximum cuff inflation time is limited to 75 seconds

  Duration of blood pressure reading is limited to:

  130 seconds (Adult mode)

  120 seconds (Adult Motion Tolerant mode)

  90 seconds (Pediatric mode)

  75 seconds (Neonate mode)

  Additional redundant safety circuitry oversees normal operation and will override to abort a BP measurement if:

  cuff pressure exceeds 300 mmHg (Adult & Pediatric modes) or 150 mmHg (Neonate mode) at any time the cuff has been inflated for 180 seconds above 15 mmHg (Adult & Pediatric modes) or 90 seconds above 5 mmHg (Neonate mode).

- Regulatory Standards:

  The Module meets all relevant parts of the following Safety/Regulatory Standards:

  IEC 60601-1

  IEC/EN 60601-2-30

  AAMI SP10

  OIML R 16-2

  EN1060-1

  EN1060-3

  EN1060-4

DATA BASE

DESCRIPTION

The memory is based on a flash disk. The machine will register 30 events and after that it will replace the oldest events.

The data base is composed of *Files* and *Records.*

Each time the machine is switched on, automatically a *File* with the current date will be created.

In each *File* RESCUE LIFE can store up to 30 *Records* of 1 minute length.

Each *Record* holds the actual ECG trace data (acquired from lead II of pads or the ECG patient cable) and the initial recording time stamp.

RECORDING

The recording is available only in AED mode.

The recording will start automatically each time the ANALISYS starts.

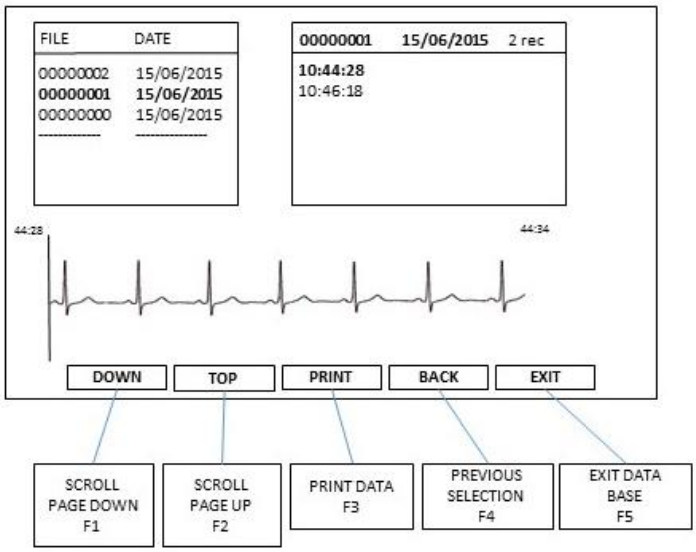
When RESCUE LIFE is recording, on the top side of the display, below battery status indicator a "**REC**" is shown. Recording duration is 1 minute which is the *Record* length.

NEVER SWITCH OFF THE MACHINE UNTIL THE RECODING STOPS.

IF THE MACHINE IS SWITCHED OFF DURING THE RECORDING THE DATA MAY BE LOST.

MAKE SURE THAT THE CLOCK IS UPDATED SO THE FILES RECORDED DATE AND TIME WILL BE CORRECT.

DATA BASE SCREEN



With function keys users can manage Data Base.

KEY	FUNCTION

DOWN – F1	To scroll next 10 record.
TOP – F2	To scroll previous 10 record.
PRINT - F3	To print data.
BACK - F4	To move to previous selection.
EXIT – F5	To exit Data Base.

DATA RETRIEVAL

The Memory consultation is a very accurate analysis phase of the ECG Trace. For this reason, we recommend to do it in a not-emergency situation.

The access to the data base management and data view/print is done from the initial screen. Just disconnect the paddles connector and switch on the machine.

In the initial screen the data base can be accessed pressing the **MEMORY – F2** key when the label has the white color.

On the data base screen the left window shows the files list with the corresponding opening date while the right window shows records.

The list starts with the most recent file. Pressing the **DOWN – F1** key the next 10 files will be shown. Pressing the **TOP –F2** key the previous 10 file will be shown.

Pressing the Speed Dial will select a file from the list and rotating Speed Dial will move the selection within the list.

After the file selection pressing again the Speed Dial will show on the top right window the selected file the number of records in the file and a list of the starting time of each record.

Rotating the Speed Dial is possible to select the desired record and pressing the Speed Dial will show on the bottom side of the screen the ECG graph of the selected record.

Rotating the Speed Dial is possible to scroll the view within the record in multiples of 6 seconds. Once decided the desired view pressing the **PRINT - F3** key a hardcopy will start and will stop at the end of the record or if the PRINT key is pressed again.

The **BACK - F4** key is used to come back to previous selection.

The **EXIT - F5** key is used to exit Data Base and return to initial screen.

Switch off defibrillator by pressing On/Off key.

On the graphic hardcopy if a defibrillation shock was recorded the graph will show the base line for about 1 second (shock event).

DATE AND TIME SETUP

To set-up the real time clock, switch on the RESCUE LIFE with paddles connector disconnected.

On the screen will be displayed the battery status, the date and time. The **SETCLK**-**F4** key enables the clock set-up. With the Speed Dial select the value to change and rotating it the value can be modified. Press the Speed Dial once the value has been changed.

To exit the clock set-up press again the **SETCLK - F4** key.

PRINTING AND PAPER CHANGE

The printing can be done in manual mode or automatic mode.

To select print mode enter the menu and select MANUAL or AUTOMTIC mode from PRINT MODE.

MANUAL MODE

To start printing press the **PRINT - F2** key. The hardcopy will start with the set-up parameters and with the ECG trace. The hardcopy will keep the LCD display set-up (amount of the traces, group, speed the gain)

To stop the printing, press again the **PRINT – F2** key.

If SpO_2 sensor is connected (optional) in hardcopy user will found value of oxygen saturation.

AUTOMATIC MODE

RESCUE LIFE will print an ECG frame of 6 seconds when the charge starts.

When the shock is released the energy delivered, as well as the time stamp will be printed together with a 6 seconds after shock ECG frame.

The manual printing (using F2 key, "PRINT") is operational independently of the printing mode.

Do not leave the device without supervise during printing. The thermal printer can be damage by a prolonged use.

When the paper is finished the green light on the printer cover button will switch on.

To replace the paper, push the green button and open the printer cover. Insert a new paper roll with the thermo-sensible side up and then close the cover. Push the **FEED** key (on the printer panel) until the paper comes out straight.

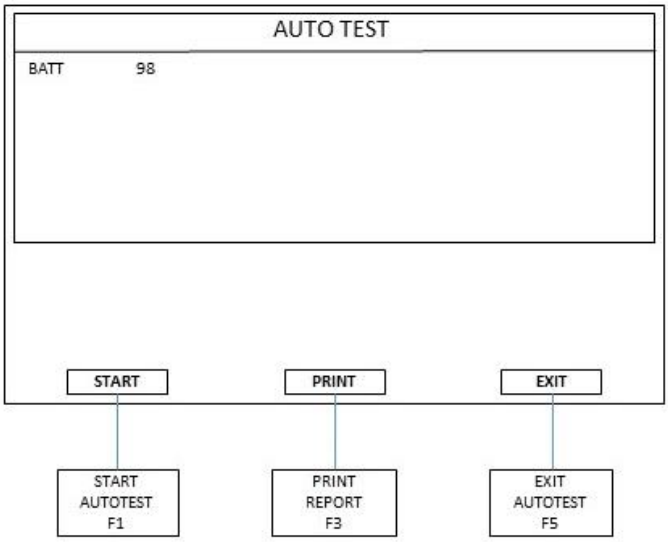
To print all the traces of ECG signal start printing after selecting the leads I, II, III. While print is in progress enter the menu and select the successive derivations, aVR, aVL, aVF. Repeat until you have printed all leads. Then stop printing.

AUTO TEST

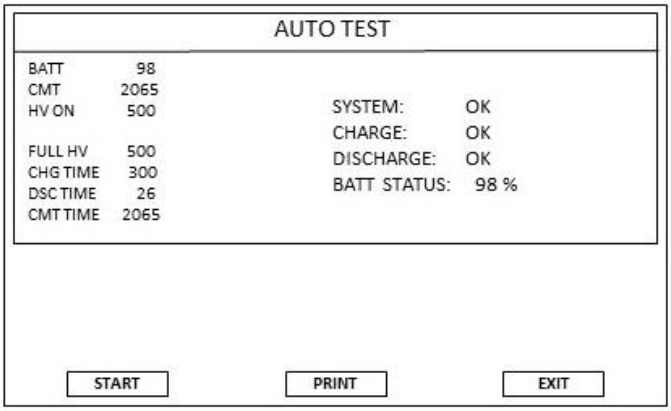
RESCUE LIFE is equipped with internal auto test that checks the correct functioning of the device.

It is advisable to do the test at least once a week. It 'also possible to print the report.

On the initial screen, press the function key **TEST - F3** to access the test screen.



Press **START – F1** key to start auto test. RESCUE LIFE will do internal tests and will show results.



If during the check the RESCUE LIFE founds some fault, the system will indicate it. Note the error code and communicate it to the authorized technical service. Pressing the **PRINT - F3** you can print the test report.

EVERY REPORT HARDCOPY REFERS TO THE LAST TEST. IF YOU NEED A SECOND HARDCOPY DO AUTO TEST AND PRINT THE REPORT AGAIN.

RESCUE LIFE CHECKLIST

ELPRO Srl recommend using the following checklist to monitor the status of RESCUE LIFE. It includes all the tests for checking the functionality and the safety.

Operator should test the defibrillator at least once a week.

It is possible to do a discharge test by connecting the test load (optional) using the cable adapter for disposable pads.

CONDITION		
Check integrity of the enclosure and the keys and make sure the unit is clean.	OK	KO
ACCESSORIES		
Check and clean the accessories. Check the integrity of the power, ECG and SpO_2 (optional) cable. Check expiration date of disposable pads and ECG electrodes.	OK	KO
AUTO TEST		
Perform auto test as explained in the section (page 65)	OK	KO
PADDLES		
Check the integrity of the paddles, the connector and the cable. Make sure the paddles are clean and free of traces of gel. To test the paddles switch on defibrillator, set an energy of 1 Joule, charge the capacitor by pressing the buttons on the paddles and release the discharge into the air, taking care not to touch the paddles together.	OK	KO
VOICE		
Switch on defibrillator, select ADVISORY mode from the menu and verify that voices are audible.	OK	KO
AED		
If you have the test load (optional) it is possible to simulate a condition of asystole, and verify that the AED module works properly, recognizing that condition and recording data. Turn on the defibrillator, connect the load test and select semi automatic (AED) by the menu. Wait for the defibrillator recognizes asystole and the recording coming to an end. Switch off defibrillator then check in Data Base if record was recorded properly.	OK	KO
PRINT		
Switch on the defibrillator and press PRINT key. Print will start. Press PRINT key again to stop print. Check the quality of the printed report.	OK	KO

APPENDIX A

CLINICAL INFORMATION

Sudden cardiac arrest (**SCA**) associated with ventricular fibrillation (**VF**) remains a leading cause of unexpected death in the Western world. It has been estimated that chances for survival from SCA decrease approximately 7% to 10% with each passing minute and that survival rates after 12 minutes are only 2% to 5%.

The most common cause of **SCA** is ventricular fibrillation (**VF**), a lethal heart rhythm, and survival depends on the rapid treatment called *de*-fibrillation, an electrical shock sent to the heart to resume normal and healthy heart rhythm.

So early defibrillation is the sole definitive determinant of survival and is the key factor in cardiopulmonary resuscitation. Currently, fewer than 5% of the 250,000 persons who experience out-of-hospital cardiac arrest each year survive to hospital discharge.

HOW DOES BIPHASIC WAVEFORM DEFIBRILLATE?

For defibrillation to be successful, a sufficient amount of electrical current must be delivered to the heart muscle. How to deliver the electrical current to the heart muscle is the core technique to defibrillate the heart.

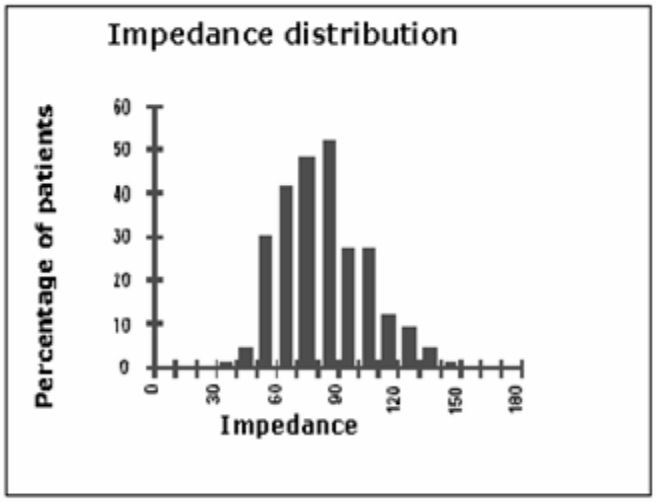
Successful defibrillation would be done when the cell membranes of the heart are "coated" with positive ions on one side and negative ions on the other side, enough to depolarize nearly 100 percent of the cardiac cells at the same instant. Optimal current is determined with the pressure (this means electric Voltage) that controls what an amount of current can be pushed and the duration of time the current flows. This defibrillation current is commonly described in joules of energy. Energy is a measure of the amount of current, voltage, and duration of time the current flows.

$$\text{Energy(joules)} = \text{Current(amps)} \times \text{Voltage(volts)} \times \text{Time(sec)}$$

When the Defibrillation shock is delivered, current flow is affected by transthoracic impedance, the body's resistance from electrode to heart. Impedance is dependent on the anatomy of the chest, skin surface, air in the chest, hair, fat and bone, as well as the size and location of the defibrillation electrodes.

$$\text{Current(amps)} = \frac{\text{Voltage(volts)}}{\text{Resistance(ohms)}}$$

Research has shown that chest resistance can vary significantly from patient to patient. Patients with low impedance are generally easier to defibrillate because the flow of current meets little resistance. Those with higher impedance may be more difficult to defibrillate. According to the International Guidelines 2000 by the American Heart Association (AHA) in collaboration with the International Liaison Committee On Resuscitation (ILCOR), average adult impedance is 70-80 ohms. Defibrillation energy should be designed to optimize the delivery of current over a wide range of patient impedances. Too much current to the myocardial cells can cause damage to the cells and result in an unsuccessful defibrillation. Too little current to the myocardial tissue cells will not depolarize the cells and result in an unsuccessful defibrillation.



The waveform biphasic technology:

1) Makes it easy to compensate the shock waveform to match the patient impedance,
2) Is more efficient than monophasic technology,
3) Delivers enough energy for restoring heart rhythm.

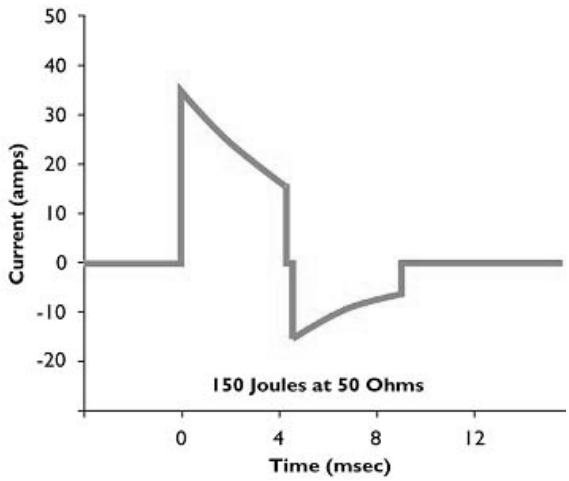
EASE IN COMPENSATION OF PATIENT IMPEDANCE

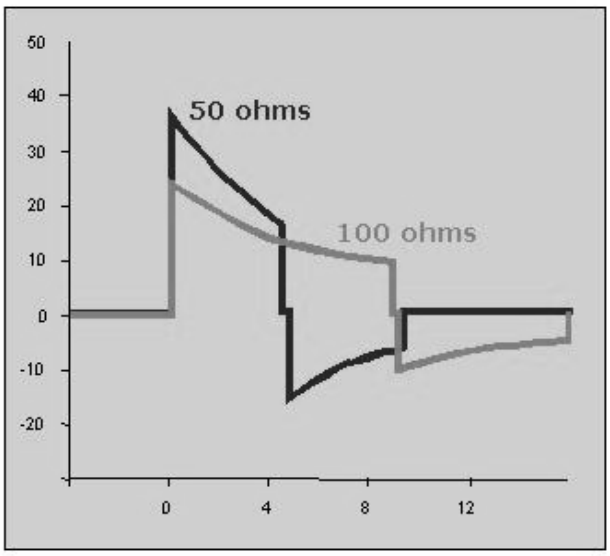
Through Biphasic technology, defibrillation shock delivery is controlled while taking into consideration the patient's impedance. The patient's impedance is measured through the defibrillator electrodes. According to the measured patient's impedance, e-cube Biphasic technology adjusts the duration of current flow to optimize the effectiveness of the shock delivery. E-cube Biphasic technology is based on 3 core technologies. 1 The technology for measuring the patient's impedance. 2 The technology for controlling the voltage level to be delivered. 3 The technology for controlling the duration of current flow.

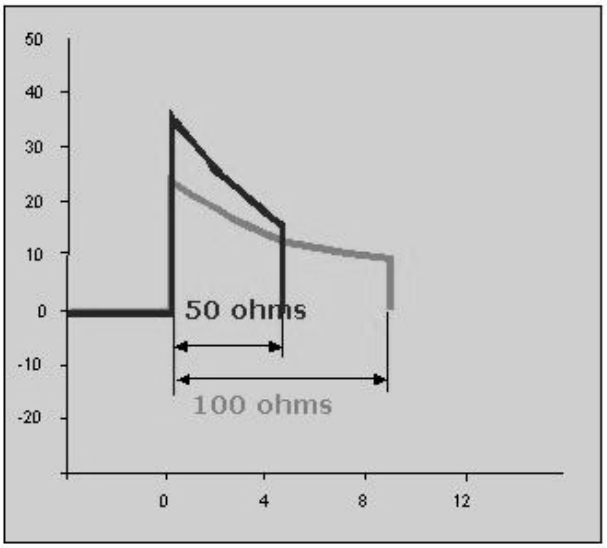
These technologies can adjust the parameters of the shock waveform to match the transthoracic impedance of the patient. Biphasic technology increases the duration of current flow for patients with high impedance. When escalating energy, for example 150J to 180J, it delivers the electrical energy with higher voltage level if the patient's impedance does not vary.

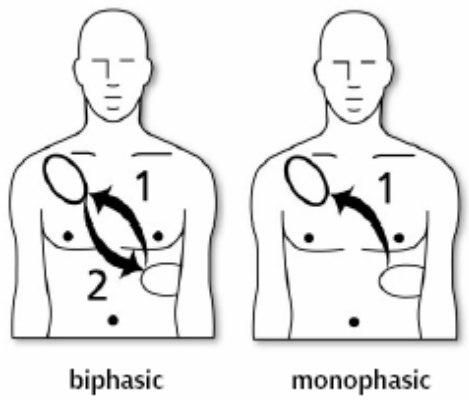
MORE EFFICIENT THAN MONOPHASIC WAVEFORM

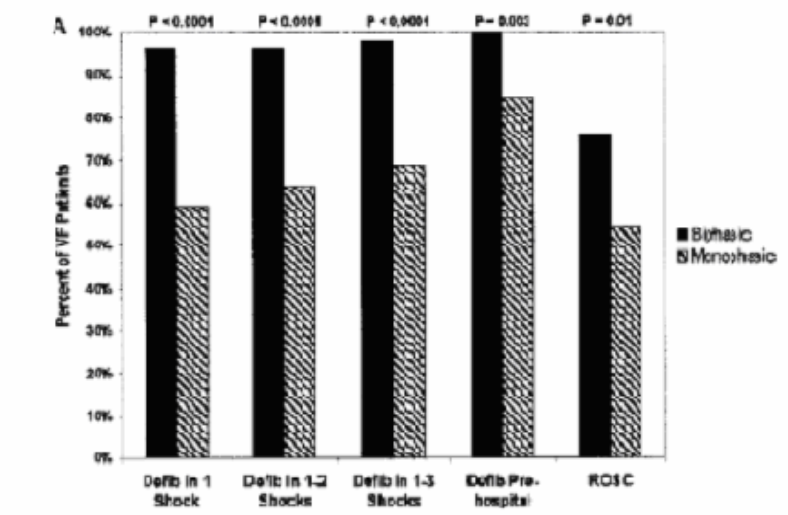
The electrical therapy delivered by transthoracic cardiac defibrillators has changed little since the introduction of direct-current defibrillation more than 30 years ago. Throughout this time, the industry-standard shock waveform for external defibrillators has been a monophasic damped sine (MDS) waveform, in which current flows in one direction throughout the shock. Many well-organized emergency medical systems, using monophasic devices for early defibrillation, have documented better than 20% survival to hospital discharge for cardiac arrest patients found in ventricular fibrillation (VF). Attempts to improve this survival rate have adapted proposals to change the waveform and energy level of defibrillation shocks [6].





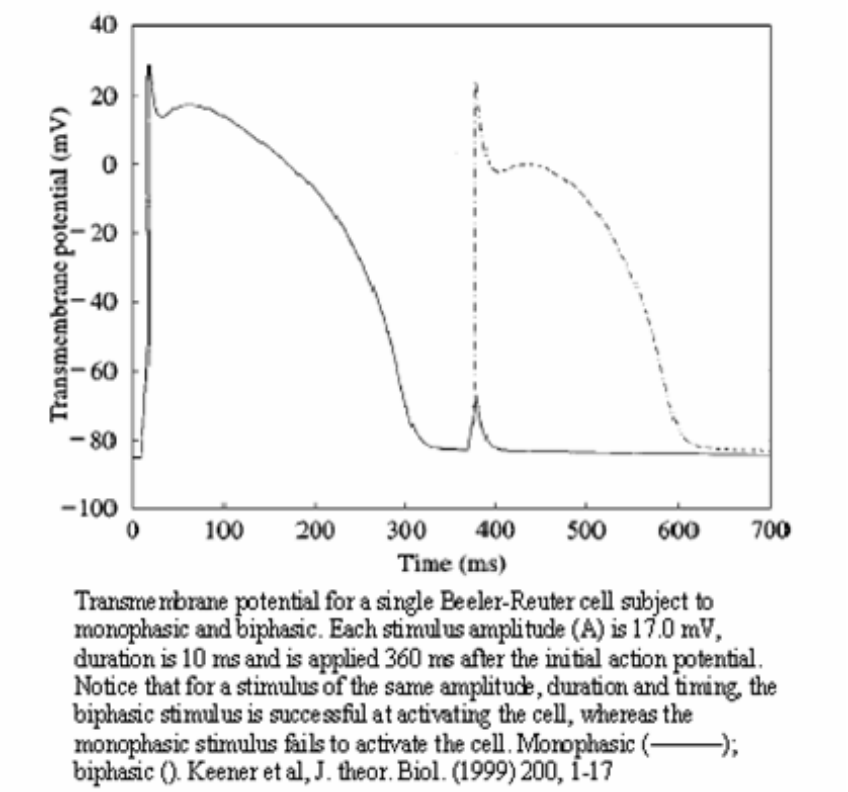






Prehospital defibrillation and resuscitation efficacy for 115 patients who presented with VF
Schneider et al. Circulation. 2000;102:1780-1787

Extensive animal and human data with implanted devices demonstrate that biphasic waveforms offer substantial reductions in defibrillation thresholds and produce less myocardial dysfunction than monophasic waveforms [1], [2], [3], [4].
The defibrillation efficacy of the 150-J biphasic waveform was superior to that of the 200-J to 360-J conventional escalating-energy monophasic waveforms for 115 patients who presented with VF [5].

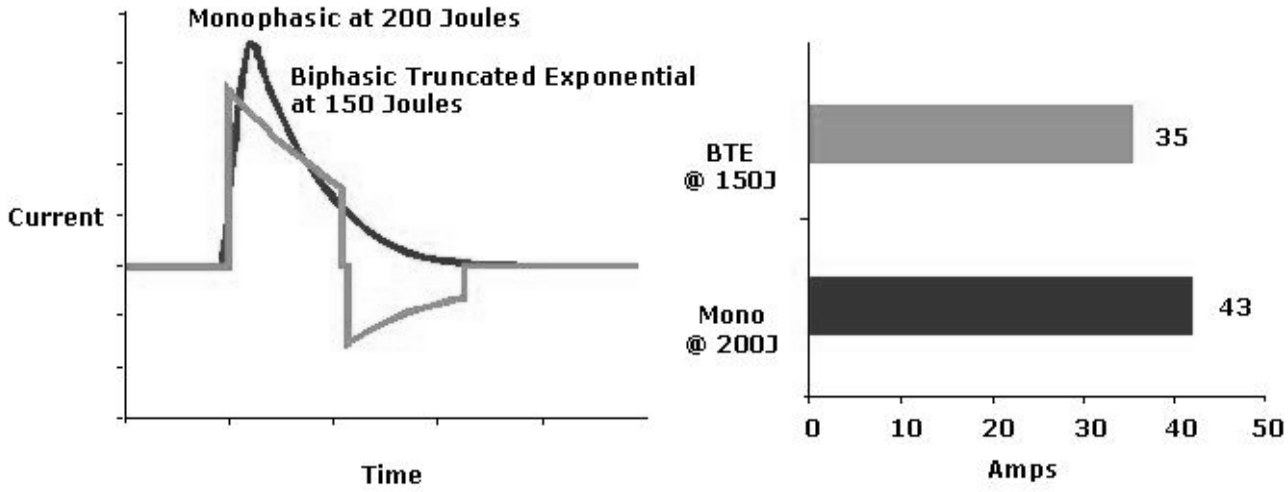


Transmembrane potential for a single Beeler-Reuter cell subject to monophasic and biphasic. Each stimulus amplitude (A) is 17.0 mV, duration is 10 ms and is applied 360 ms after the initial action potential. Notice that for a stimulus of the same amplitude, duration and timing, the biphasic stimulus is successful at activating the cell, whereas the monophasic stimulus fails to activate the cell. Monophasic (———); biphasic (). Keener et al, J. theor. Biol. (1999) 200, 1-17

The difference between monophasic and biphasic waveform is qualitatively similar but varies quantitatively for different parameter values. The fundamental difference is that first phase of the biphasic pulse acts as a pre-pulse to remove inactivation from the heart cell, accelerating its recovery, and thereby lowering the activation threshold for defibrillation prior to second phase of biphasic pulse which is reversed current flow.

ENOUGH ENERGY FOR RESTORING HEART RHYTHM

The Biphasic Truncated Exponential waveform uses lower energy than the Monophasic waveform. But the lower energy of biphasic shock is more efficient than high energy of the monophasic shock for defibrillation to restore heart rhythm.



In a multicenter, randomized, controlled trial of 150J biphasic waveform compared with 200J and 360J monophasic waveforms done in humans, Schneider et al [5] showed that "the 150-J biphasic waveform defibrillated at higher rates, resulting in more patients who achieved a return of spontaneous circulation. Although survival rates to hospital admission and discharge did not differ, discharged patients who had been resuscitated with biphasic shocks were more likely to have good cerebral performance."

Positive evidence for safety and clinical effectiveness of biphasic truncated exponential waveforms for internal and external use was ascertained by the AHA ECC committee [8], [9].

REFERENCES

[1] Chapman PD, Vetter JW, Souza JJ, Wetherbee JN, Troup PJ. Comparison of monophasic with single and dual capacitor biphasic waveforms for nonthoracotomy canine internal defibrillation. J Am Coll Cardiol. 1989;14:242.5.
[2] Kavanagh KM, Tang ASL, Rollins DL, Smith WM, Ideker RE. Comparison of the internal defibrillation thresholds for monophasic and double and single capacitor biphasic waveforms. J Am Coll Cardiol. 1989;14:1343.9.
[3] Winkle RA, Mead RH, Ruder MA, et al. Improved low energy defibrillation efficacy in man with the use of a biphasic truncated exponential waveform. Am Heart J. 1989;117:122.7.
[4] Ruppel R, Siebels J, Schneider MA, Kuck KH. The single endocardial lead configuration for ICD implantation: biphasic versus monophasic waveform [abstract]. J Am Coll Cardiol. 1993;21:128A.
[5] T. Schneider, et al. Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared With 200- to 360-J Monophasic Shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims. *Circulation*. 2000;102:1780-1787.)
[6] Steven L. Higgins, et al. A comparison of biphasic and monophasic shocks for external defibrillation. *Prehospital Emergency Care* 2000;4:305.313
[7] J. P. KEENER , T. J. LEWIS. The Biphasic Mystery: Why a Biphasic Shock is More Effective than a Monophasic Shock for De5brillation. *J*. *theor*. *Biol*. (1999) 200, 1-17
[8] AHA, Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: an international consensus on science. *Circulation* 2000;102 (Suppl 1).
[9]. U. Achleitner, et al. Waveform analysis of biphasic external defibrillators, *Resuscitation* 50 (2001) 61–70

[10] *European Resuscitation Council* Guidelines for Resuscitation 2015 Section 2. Adult basic life support and automated external defibrillation
[11] *European Resuscitation Council* Guidelines for Resuscitation 2015 Section 3. Adult advanced life support
[12] *European Resuscitation Council* Guidelines for Resuscitation 2015 Section 4. Cardiac arrest in special circumstances
[13] *European Resuscitation Council* Guidelines for Resuscitation 2015 Section 5. Guidelines for post-resuscitation care of the European Resuscitation Council Guidelines for Resuscitation 2015
[14] *European Resuscitation Council* Guidelines for Resuscitation 2015 Section 6. Paediatric life support

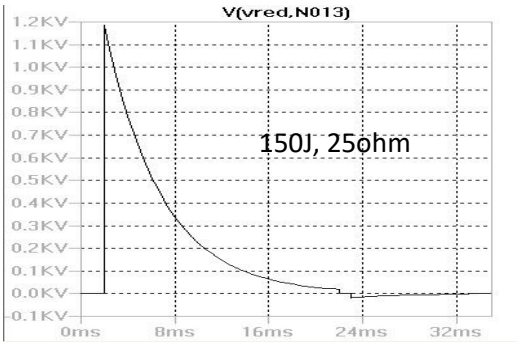
APPENDIX B
ACCESSORIES AND MODULES

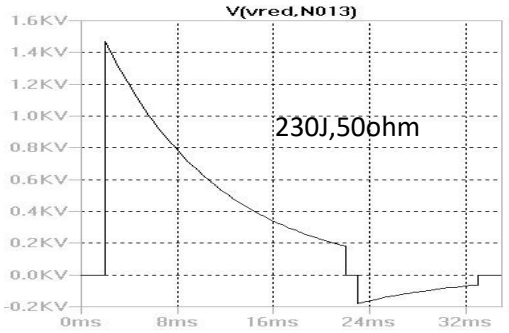
Part #	Description
RLFS-001	Standard Electrodes for defibrillation
RLFS-002.1	5-leads ECG cable
RLFS-002.2	10-leads ECG cable
RLFS-004.1	Adult SpO2 sensor
RLFS-004.2	Pediatric SpO2 sensor
RLFS-005	AC Adapter
RLFS-006	Disposable electrodes cable
RLFS-007.1	Adult disposable electrodes for defibrillation
RLFS-007.2	Pediatric disposable electrodes for defibrillation
RLFS-008	Travel bag
RLFS-009	Paper roll
RLFS-0010.1	NIBP Cuff, Adult
RLFS-0010.2	NIBP Cuff, Pediatric
RLFS-011	NIBP Cable
RLFS-012	User Manual

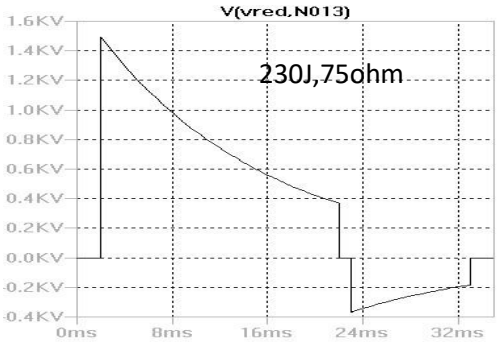
APPENDIX C
TECHNICAL SPECIFICATIONS

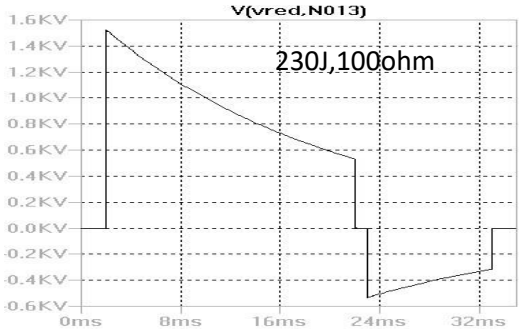
Waveform time-impedance

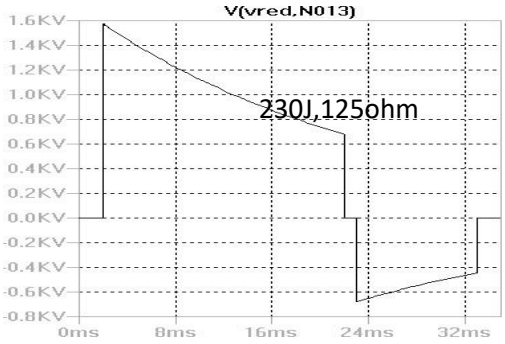
Following flow-charts show typical defibrillation impulses considering the impedance between the defibrillation electrodes for a maximum of 230 Joule:

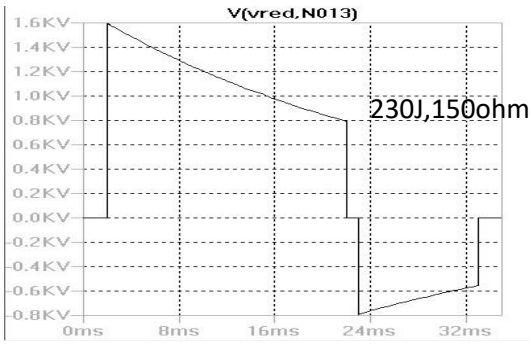


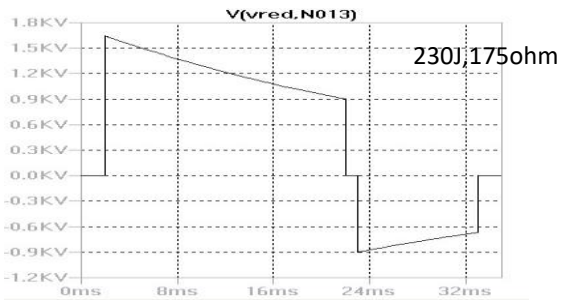












For impedance value of 40ohm or less the maximum energy is 150J. If the energy is set to a value higher then 150J the machine will set automatically the energy to 150J. For impedance values different from 50 ohm the accuracy of the released energy is +/- 15%. For impedance of 50 ohm the accuracy is +/- 10%.

IMPENDANCE LIMITS

RESCUE LIFE does not release the shock if the patient impedance is less than 25 ohm or over 200 ohm.

SYNC/NO SYNC MODE

When the **RESCUE LIFE** is on it is automatically set on no-sync mode.

Only the operator can set the sync/no-sync mode which is clearly displayed on the screen. The device can not automatically set the sync mode.

In the sync mode the device releases the defibrillation shock only when the 'R' peak in the 'QRS' complex is detected.

The maximum response time between the "R" peak and the defibrillation shock is less than 60ms.

CHARGING TIME TO ACHIEVE THE MAXIMUM ENERGY (230 JOULE)

When the device is connected to the AC supply (nominal AC voltage) and batteries are 100% charged :< 8 sec.

When the device is connected to the AC supply (AC voltage 90%) after 15 shocks :< 10 sec.

APPENDIX D
TECHNICAL FEATURES

ECG Monitoring

- Patient connection:

  Defibrillation pads and 5 or 10 wire ECG cable.

- Bandwidth:

  0.6 to 40 Hz (-3 dB) in monitor mode.

  0.05 to 120 Hz (-3 dB) in diagnostic mode.

- ECG trace parameters:

  Velocity : 5,10,25, 50 mm/sec.

  Gain: 2,5, 5, 10, 20, 40 mm/mV with patient cable. AUTO with pads.

  Alarm: HR max settable 250 bpm and HR min 20 bpm.

  Filters: 50/60 Hz, EMG filter, base line.

  Traces: 3+3+1 (I,II,III – aVR,aVF,aVL, V) with 5 wires patient cable.

  Traces: 3+3+6 (I,II,III – aVR,aVF,aVL – V1 to V6) with 10 wires patient cable.

- Heart rate:

  Digital readout on the display from 20 a 300 bpm (± 5% or ±3 bpm, on higher value).

Defibrillator

- Operation mode:

  Manual, Advisory, Semiautomatic AED.

- Defibrillabile impedance:

  Compensated from 25 ohm to 200 ohm.

- Energy charging time:

  < 8 sec (with batteries fully charged).

- Manual Mode:

  Syncro/Asyncro.

- Defibrillation pads:

  Standard or disposable, adult and pediatric.

- Waveform:

  Biphasic Truncated Esponential (BTE) with impedance compensation.

  HiCAP Technology (Large Storage Capacitor).

Display

- LCD Display color TFT.
- LCD Dimensions: high contrast 7 inches 800X600 pixels.

Device Dimensions

- Dimensions: 369 x 240 x 340 mm (L x W x H).
- Weight 5.5 kg approximately.

AC charger power supply

- Input: 100 ~ 240 V AC 50/60 Hz max - inverter 12 V car adapter (optional).

Battery pack

- 15.0 V – 3.2 Ah Lithium-Ion battery (internal rechargeable).
- charging time maximum 3 hours.
- capacity: 150 shocks at 230 J (battery fully charged).

Manual mode

- Energy range:

  1 – 230 J (from 1 – 10 J in 1 J steps; from 10 – 230 J in 10 J steps).

- Commands:

  Multifunction Trim Knob. Charge and shock button directly in the front panel for hands free defibrillation.

- Paddles:

  Reusable adult & pediatric defibrillator paddles with charge/shock command.

  Disposable defibrillator pads.

- Operating mode:

  ECG « R » wave synchro or asynchro mode.

- Indicators:

  Battery and main led indicators.

  Clear and visible backlight color buttons.

AED mode

- Energy:

  Fixed energy at 200 J.

- Protocol:

  ERC 2010 CPR Guidelines with voice and text prompts.

- Shockable rhythms:

  VF with amplitude >0.15 mV and VT with rhythm >150 bpm.

- Sensitivity:

  Shockable rhythm VF > 95%.

  Shockable rhythm VT > 75%.

- Specificity:

  Normal sinusoidal rhythm > 99%.

  Asystole and other non-shockable rhythms > 95%.

SpO_2 (optional)

- SpO_2 range:

  0 – 100%.

- HR range:

  30 – 250 bpm.

- Accuracy:

  70 – 100 % ~ 2% for adults with finger clip sensor.

- Alarm:

  Adjustable min 50 %.

NIBP (optional)

- Technique:
  oscillometric.
- NIBP Accuracy:
  Meets ANSI/AAMI SP10-2002, EN 1060-4.
- Patient Application:
  Adult/Paediatric/Neonatal.
- Systolic Range:
  Adult: 40-260mmHG, Pediatric: 40-160 mmHG, Neonatal: 40-130 mmHG.
- Range MAP:
  Adult: 26-220 mmHG, Paediatric: 26-133mmHG, Neonatal: 26-110 mmHG.
- Diastolic Range:
  Adult: 20-200 mmHG, Paediatric: 20-120 mmHG, Neonatal: 20-100 mmHG.
- PR RANGE:
  30-220 BPM.
- PR Accuracy:
  +/-2% or +/3 bpm.
- Transducer Accuracy:
  +/- 3 mmHg over full range in operating conditions.
- Operating Modes:
  Manual, Long Term Automatic, Stat, Service.
- Auto Interval Periods:
  1,2,3,4,5,10,15,30,60 and 90 minutes.
- Safety & Regulatory Standards:
  IEC60601-1, IEC/EN60601-2-30, AAMI SP10, OIML R 16-2.

  EN1060-1, EN1060-3, EN1060-4.

External pacemaker (optional)

- Type: rectangular wave.
- Operating mode: Fixed, on demand.
- Pulse rate: 30 bpm to 250 bpm, adjustable in steps of 5 bpm.
- Impulse duration: 22.5 ms.
- Pulse current: 0 to 150 mA, adjustable in steps of 5 mA.
- Amplitude: max 150 V.

Printer

- Type**:**

  Integrated thermal printer 200 dpi for ECG traces and events documentation hardcopy including HR/SpO_2 values.

- Paper Speed:

  5, 10, 25, 50 mm/sec.

- Paper width:

  58 mm.

- Operating model:

  Manual, automatic (10” pre and post shock recording).

Environmental

- Temperature (without Disposable Multifunction Electrodes for defibrillator):

  Operational -5° - 46° C.

  Storage -20° - 50° C.

  Relative humidity 10 - 95%.

Temperature (without Disposable Multifunction Electrodes for defibrillator):

  Operational -5° - 46° C.

  Storage 5° - 35° C.

  Relative humidity 20 - 80%.

- Isolation:

  ECG connector type CF - Pads, NIBP and SpO2 connector type BF.

- Water proof:

  Class IPX4.

Standards & Safety

- Standard:

  EN 60601-2-4; EN 60601-1; EN 60601-1-2; Class II, type BF/CF.

- EC Mark 93/42/EEC :

  Medical device, Class IIb.

APPENDIX E – INSTRUCTION FOR USE FOR DISPOSABLE MULTIFUNCTION ELECTRODES FOR DEFIBRILLATOR

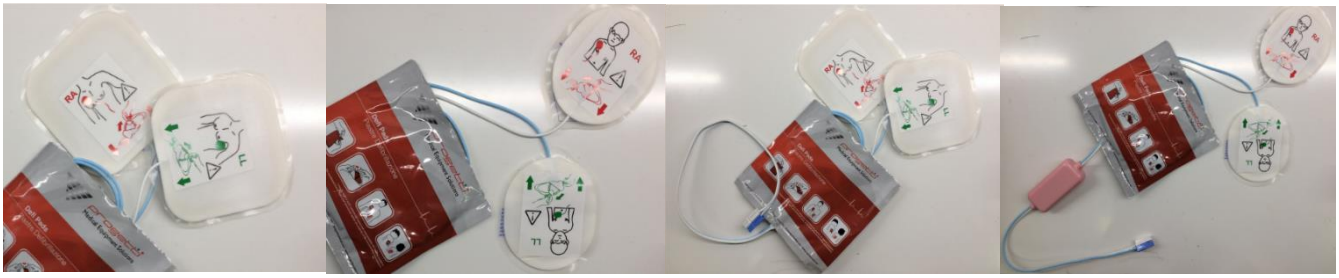
Disposable Multifunctional

Electrodes for Defibrillator

(defibrillation, synchronized stimulation, transcutaneous cardiac stimulation, ECG monitoring)

DFB**AD**01**STD** / DFB**AD**01**PRC** (Adult)

DFB**PED**01**STD** / DFB**PED**01**PRC** (Pediatric)



CE 0068

Progetti S.r.l.
Strada del Rondello, 5
10028 Trofarello (TO), Italy

V2.0
Rev. 2018/02

References

[1] Ian Jacobs, Kjetil Sunde, et al. “Part 6: Defibrillation. 2010 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science With Treatment Recommendations” Circulation 2010;122:S325-S337

[2] Jerry Nolan et al. “European Resuscitation Council Guidelines for Resuscitation 2010” Resuscitation Vol. 81, 2010, Editor Jerry Nolan, Bath, UK

[3] A. Luciano et al., "BODY-MASS INDEX REFERENCE CURVES FOR CHILDREN AGED 3-19 YEARS FROM VERONA, ITALY", European journal of clinical nutrition, 51(1), 1997, pp. 6-10

[4] Edward J. Sondik, et al. “2000 CDC Growth Charts for the United States: Methods and Development” Vital and Health Statistics. Series 11, Number 246: May 2002

[5] John M. Field et al. “2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care” Circulation 2010, 122:S640-S946 Journal of the American Heart Association Editor Mary Fran Hazinski, RN, MSN

[6] Luis A. Pagan-Carlo, Kirk T. Spencer, et al. “Transthoracic defibrillation: importance of avoiding electrode placement directly on the female breast” Journal of American College of Cardiology 1996;27:449-452

[7] Edward A. Panacek, Mark A. Munger et al. “Report of nitropatch explosions complicating defibrillation” American Journal of Emergency Medidicine 1992;10:128-9

[8] Keith Wrenn “The hazards of defibrillation through nitroglicerin patches” Annals of Emergency Medicine 1990;19:1327-8

[9] Johannes C. Manegold, Carsten W. Israel et al. “External cardioversion of atrial fibrillation in patients with implanted pacemaker or cardioverter-defibrillator sistems: a randomized comparison of monophasic and biphasic shock energy application” European Heart Journal 2007;28:1731-8

DISPOSABLE MULTIFUNCTION ELECTRODES
OPERATING INSTRUCTION

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a physician.

IMPORTANT

The product is intended for use in non-sterile environment by authorized personnel only. Before using the product, the user should deeply understand these instructions.

DESCRIPTION

The disposable multifunction electrodes *PROGETTI* are constituted by a pair of adhesive pads provided with gels and direct connection to cables and defibrillators which may be used in place of the manuals reusable paddles [1].

PACKAGING

Each pair of *PROGETTI* disposable multifunction electrodes is packaged in sealed envelopes of opaque material suitable to protect the gel from light and moisture. Envelopes are included in the carton sales package along with a copy of the operating instructions.

INDICATIONS

The disposable multifunction electrodes *PROGETTI* are indicated for:

- Transthoracic external defibrillation.
- Transthoracic synchronized cardioversion.
- Transthoracic ECG Monitoring.
- Temporary transthoracic cardiac pacing (non-invasive).

PROGETTI disposable multifunction electrodes allow the user to effectively operate in the treatment of rhythm disorders related to the above-mentioned applications, without the risk of accidental electrocution related to the use of normally available reusable paddles.

CONTRAINDICATIONS

- *PROGETTI* disposable multifunction electrodes for adults are generally contraindicated in patients younger than 8 years old [2] (weighing less than 25kg [3][4])), but can be used if the size of the chest allow it, taking care that one pad do not come in contact with the other one. Follow the operating instructions of the defibrillator for energy to be delivered.
- The use of *PROGETTI* disposable multifunction electrodes in versions for adult or adult/paediatric is generally contraindicated in patients aged less than 12 months (weighing less than 10kg).
- The use of *PROGETTI* pediatric disposable multifunction electrodes is generally contraindicated in patients older than 8 years old [2] (weighing more than 25kg [3][4]);
- Do not apply on skin that shows signs of irritation or injury.

MODE OF USE

External Defibrillation and synchronized cardioversion: the disposable multifunction electrodes are able to transfer to the patient the electrical energy supplied by the defibrillator up to a maximum value of 360J in the adult version and of 100J in the paediatric version [5].

The depolarization of the critical mass of the myocardium, which is essential for the success of the therapy, is only possible if it is crossed by a current of appropriate intensity: the active surface of the electrodes is optimized for this purpose. It is therefore appropriate, in addition to a targeted selection of the positioning sites, to apply the adhesive pads in such a way that their contact surface with the skin is maximum. The choice of power to supply is at the discretion of the operator.

In paediatric applications the Guidelines for cardiopulmonary resuscitation recommend a supply of energy of 2-4J / kg; the recommended starting level is of 2 J / kg and it is preferable not to exceed 100J in order to avoid burns [5].

ATTENTION *PROGETTI* disposable multifunction electrodes can withstand up to 50 defibrillation shocks.

ATTENTION Do not supply a shock with manual metal paddle above the disposable electrode pads or ECG electrodes.

Non-invasive transthoracic pacing: *PROGETTI* disposable multifunction electrodes can be used for non-invasive transthoracic pacing. To minimize the threshold of pacing it is appropriate to apply the adhesive plates in the manner described above. It is also necessary to have a good understanding of the equipment you want to use and follow the manufacturer's instructions.

ATTENTION It is good practice to replace *PROGETTI* disposable multifunction electrodes after 8 hours, checking, in case of prolonged pacing (greater than 30 minutes), the skin of the patient for signs of irritation.

ATTENTION Replace *PROGETTI* disposable multifunction electrodes after 30 minutes if the supplied pulses are monophasic and longer than 20ms.

ECG monitoring: *PROGETTI* disposable multifunction electrodes can also be used for ECG monitoring.

ATTENTION If the tracing is not sufficiently clear, use an ECG patient cable, if it is present, and a separate set of ECG electrodes.

MODE OF APPLICATION

- The multifunction electrodes can be applied to the patient even in the mere suspicion that a severe arrhythmic disease may develop.
- The points where it is possible to apply the adhesive electrodes are listed in “PLACEMENT AND POLARITY”.
- Uncover the chest and prepare the skin. Remove excessive hair [1]. Slightly abrade the skin surface to reduce the contact impedance. Avoid applying the adhesive pad on the nipple or breast tissue [6].
- Remove any debris (dirty, greasy and debris), using non-flammable cleaners. Finally, make sure the application sites are clean and dry.
- Open the package and remove multifunction electrodes.
- Gently remove the protective liner, starting from the tab to expose the adhesive and conduction areas.
- In case of multifunctional electrodes with clips remove the protective support.
- Apply the adhesive pads one-to-one starting with one side and pressing progressively over the entire surface to avoid the formation of air bubbles and ensure complete adhesion to the skin. Keep the adhesive pads well separated one from the other and be careful not to overlap them with other objects (ECG electrodes, cables, transdermal patches, clothing etc.) [7][8].
- Do not replace the adhesive pads once applied. If the position must be changed, remove and replace with new multifunction electrodes.
- To remove the adhesive plate without irritating the patient's skin, lift an edge and gently pull back. Hold at the same time the skin with the other hand.
- For multifunctional electrodes without clip: connect the electrodes to the defibrillator or the adapter cable by following the instructions for use of the defibrillator.
- For multifunctional electrodes with clips: connect the clip to the cable of the defibrillator for the correct polarity, observing the instructions for use of the defibrillator.
- For on demand pacing, separately connect ECG monitoring electrodes.

POSITIONING AND POLARITY

The international guidelines indicate various placements as equally effective for the treatment of atrial or ventricular arrhythmias [5].

The following figures show the application sites commonly used and recommended by most manufacturers of defibrillators. Choose the most appropriate points of application of the therapy according to manufacturer's instructions for use of the defibrillator to be used.

For ease of placement and for training purposes, the anterior-lateral side (Fig.1) is preferred for arrhythmias defibrillation and cardioversion; the anterior-posterior side (Fig.2) is more common in hemodynamics and in transthoracic pacing and recommended in case of use of electrodes for adults on pediatric patients.

Fig.1

- Defibrillation
- Cardioversion
- Pacing
- Monitoring (it provides a track Lead II)

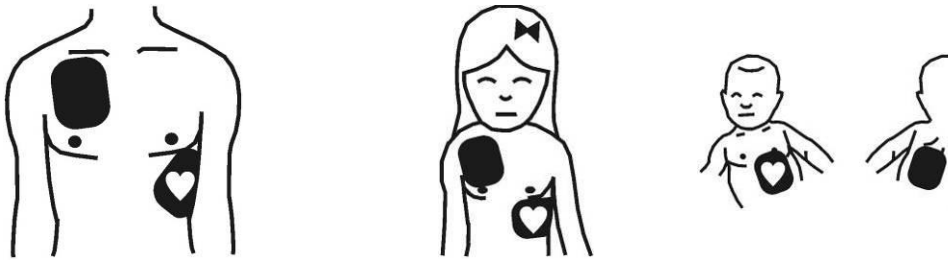
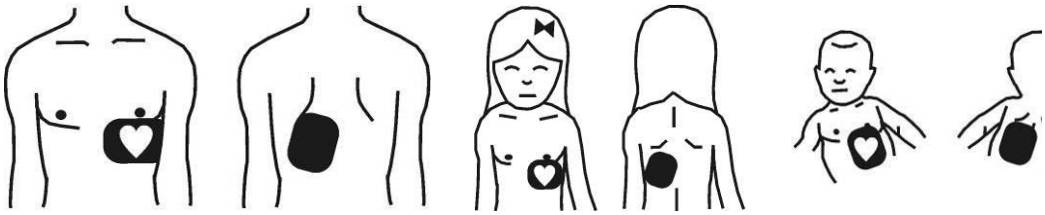


Fig.2

- Pacing
- Monitoring
- Defibrillation
- Cardioversion



To maintain the proper signal polarity, apply the electrode pads in the indicated positions (the apex is identified by the symbol of the heart). However note that for the purpose of the therapy, it is not relevant which electrode pad (apex / sternum) is placed in one of the two positions [2].

Regarding the polarity of the electrodes in unique version adult/pediatric, follow the directions on the labels of the electrode pad (according to the instructions of the manufacturer of the defibrillator to be used).

SIDE EFFECTS

- Plate adhesive may cause light cutaneous irritation.
- The prolonged transthoracic stimulation or the repeated administration of defibrillation shock may cause more or less noticeable skin reddenings according to the supplied energy.
- A lack in adhesion and/or air presence under the electrode may cause burnings.

PRECAUTIONS AND WARNINGS

- Use the product only on defibrillators brands indicated on the labels.
- Check that the product is compatible with the specific model of defibrillator intended to be used.
- Read the instructions for use of the defibrillator, with particular attention on the placement of multifunction electrodes, their polarity and the power to be supplied.
- In paediatrics and for some models of automatic defibrillators the use of specific reducing power devices or the adoption of special precautions may be required. Always pay a special attention to energy levels set on the defibrillator and that can be delivered to the paediatric patient (see section "MODE OF USE").

ATTENTION

Paediatric multifunction electrodes marked with the symbol shown beside are indicated for use with automatic defibrillators.

- The electrode choice should be based on the evaluation of chest size and weight of the patient. Paediatric electrodes used beyond the specified energy limit may cause also major skin burns; on the contrary the extended active surface of adult electrodes may jeopardize the therapy when used for pediatric treatment.
- After an extended period of transthoracic pacing the ability to detect the evoked ECG signal can be reduced. In this case it is necessary to provide for the collection of the evoked signal by a separate set of ECG electrodes.
- Replace the multifunction electrodes after 24 hours from their application on the patient's skin.
- Check the expiration date on the package. Do not use after this date.
- Do not use multifunction electrodes if removed from the envelope for more than 24 hours. The adhesive pads are to be applied within 30 minutes after removal of the protective coating.
- Check that the packaging is intact: do not use the product otherwise.
- Do not use the multifunction electrodes if the gel is removed from the support or if it is ripped, torn or dry. Any discoloration localized on gel or on conductive foil does not affect the functionality of the product.
- Do not use the multifunction electrodes if during removal of the protective coating the product is damaged (eg. the insulating coating of the contact has detached or there are tears in the foam support and/or in the electrode).
- Do not bend, do not cut and do not squash the adhesive pads.
- Do not use the multifunction electrodes if the connector, the cable or the clips appear to be damaged.
- Check on the operating instructions of the defibrillator at which safety distances the devices (surgeon's electric knife, RF ablators, diathermy equipment, mobile phones, etc.) that emit strong electromagnetic interferences must be placed.
- To prevent accidental damage from electric shock, ensure that during discharge operators are not in contact with the electrode pads, with the patient, or with conductive parts close to the patient.
- When defibrillators are used near oxygen sources or other flammable gases, use extreme care to avoid risk of fire or explosion.
- The product neither is sterile nor can be sterilized.
- The product is disposable. For use on a single patient. Discard after use.

POTENTIAL COMPLICATIONS

There are no complications related to the use of multifunction electrodes.

ATTENTION: The defibrillator discharge may cause irregularities in the operation of an implanted pacemaker/defibrillator [1]; apply the multifunction electrodes at a distance of at least 8cm [9]. After defibrillator discharge check its operation.

ATTENTION: If the chosen energy level is insufficient the success of therapy may be jeopardizing. On the contrary, higher levels may modify the enzyme structure without actual evidence of myocardial damage.

PRODUCT LIFE AND STORAGE

Check the expiration date printed on the package.
The product should be stored in its original packaging in rooms with environment conditions of temperature (5-35°C) and relative humidity (20-80%), specified on the label. The storage at extreme temperatures must be limited to short periods (24 hours at -30°C or +65°C). Prolonged storage at extreme temperatures can shorten the life of the product.

ATTENTION: The overlap of weights on the packaging could damage the product.

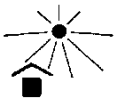
DISPOSAL

Refuses deriving from health structures must be disposed in according to the regulation in force.

WARRANTY AND LIMITATIONS

PROGETTI S.r.l. guarantees that the product complies with Directive 93/42/EEC. No responsibility may be ascribed to the producer who shall not be held liable for medical costs, director indirect damage due to lacking function or malfunction of the above product, when used differently from the instruction for use. We recommend to report opportunely any malfunction or defect of the product to ELPRO S.r.l. or PROGETTI S.r.l.

DESCRIPTION OF USED SYMBOLS

								
EC Mark & Notified Body Identification	Manufacturer information	Manufacture date	Catalogue Number	Batch number	Pcs. per box/pack	Use before of the date	Temperature range for storage	Operating body temperature range
								
Humidity range for storage	Keep away from humidity	Keep away from sun light	Warning: read the enclosed documentation	Consult instructions for use	Do not reuse	Latex free	Disposable multifunction electrodes are not sterile	Paediatric disposable multifunction electrodes indicated for use with automatic defibrillators

Declaration of EC conformity

to council
Directive 93/42/EEC of 14 June 1993 and subsequent amendments
concerning medical devices

MANUFACTURER:	**ELPRO S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) ITALY
PRODUCT:	Defibrillator
MODEL:	**Rescue LIFE**
GMDN Code:	**17882**
CLASS:	**II b**
STANDARDs REFERENCES:	**EN ISO 13485:2016** **EN 60601-1:2006+A1:2013+A12:2014, EN 60601-1-2:2015, EN 60601-2-4:2011, EN 60601-2-27:2014, EN 60601-2-31:2008+A1:2011, EN 62353:2014, EN 62366-1:2015, EN 60601-1-6:2010, EN 62304:2006, EN ISO 14971:2012, EN ISO 15223-1:2012, MEDDEV 2.7/1 Rev.4, MEDDEV 2.12-1 Rev.8, MEDDEV 2.12/2 Rev.2**
SERIAL NUMBER**:**	*

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL **DIRECTIVE 93/42/EEC** OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES, ACCORDING TO ESSENTIAL REQUIREMENTS AND SUBSEQUENT AMENDMENTS.
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.
ALSO, THE **DEFIBRILLATOR** IS MANUFACTURED BASED ON: **DIRECTIVE 2011/65/EEC** AND ITS SUBSEQUENT AMENDMENTS (***ROHS***). THE PRODUCT CONCERNED HAS BEEN MANUFACTURED UNDER A QUALITY MANAGEMENT SYSTEM ACCORDING TO **ANNEX II OF DIRECTIVE 93/42/EEC.**

NOTIFIED BODY:	MTIC InterCert S.r.l. (N.0068) Via Moscova, 11 20017 Rho - MI, ITALY
EC MARKING:	CE **0068**
EC CERTIFICATE N°:	**0068/QCO – DM/031-2009**
EXPIRE DATE:	**2021, May 19th**
FIRST ISSUE:	2009, May 20th
PLACE, DATE :	TROFARELLO (TO) – **2019, 01st March**
SIGNATURE:	Dr. CESARE MANGONE MANAGEMENT REPRESENTAIVE

*IF YOU WANT RECEIVE DEDICATED DECLARATION OF CONFORMITY FOR YOUR DEVICE SERIAL NUMBER AND/OR UPDATED ONE, PLEASE CONTACT ELPRO S.R.L. OFFICE TO THE EMAIL info@elpromedical.com

APPENDIX E

WARRANTY CERTIFICATE

WARRANTY CONDITIONS

This device is warranted against defects in materials and workmanship.

The warranty does not apply if the product has not been properly used as suggested in the user manual, has been damaged by accident or misuse, has been damaged as the result of service or modification by an entity other than ELPRO S.r.l..

This warranty does not cover any accessories.

ELPRO S.r.l. will replace damaged parts and components, according to its option.

ELPRO S.r.l. will replace cost free those parts and components under guarantee in its laboratory.

CLIENT:

_____

_____

_____

DEVICE: Biphasic Defibrillator/Monitor

Model: RESCUE LIFE SN _____

VALIDITY starting from : ___/___/_____

Delivery date:_____

Invoice N°_____dated_____

Distributed by

ELPRO S.r.l.
Strada del Rondello, 5
10028 Trofarello (TO)
ITALY

www.elpromedical.com