INSTRUCTION FOR USE

Defibrillator

Rescue Life 9

ENG

Doc.N. TF-RescueLife9-0.0/3.1ENG-0.2

CE 0068

ELPRO S.r.l.
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Disclaimer of Liability

ELPRO S.r.l., as Manufacturer of the medical device Rescue Life[9] and of its accessories, is responsible of the safety and performances within expected lifetime (10 years). If the customer cannot demonstrate compliance to the use, maintenance and storage provisions of the present user manual, ELPRO S.r.l. will be not responsible of Rescue Life[9]'s safety and performances.

ELPRO S.r.l. disclaims any responsibility for any accidental damage caused to the Rescue Life[9] and its accessories during transport to the customer or during use.

ELPRO S.r.l. is available to the customer for any further information.

⚠ ELPRO S.r.l. recommends to subject the Rescue Life[9] to an annual preventive maintenance program (functional check and electrical safety check) and to check during the service period of the medical device:

- the integrity of the main unit casing and its accessories;
- the integrity of the packaging of the multifunction disposable electrodes and their cable as well as the validity of the same (see expiry date on the labeling);
- the legibility of the labeling.

For more information, please contact the technical assistance service at the email address **service@progettimedical.com** or at the telephone number **+39.011.644.738**

The information contained in this document may be subject to change without notice.

Limited Warranty

The "Limited Warranty" shipped with ELPRO products is the one and only with regard to the product.

Useful contacts

- COMPANY - **info@elpromedical.com**
- SERVICE - **service@progettimedical.com**
- QUALITY & REGULATORY AFFAIRS - **quality@progettimedical.com**

For the purpose of continuous improvement, the Manufacturer is pleased to welcome and manage the customer's opinion on the device and / or on this user manual. Therefore write to the Quality & Regulatory department of ELPRO S.r.l. (quality@progettimedical.com) for any suggestions or explanations.

Please report any serious accident occurring in relation to the medical device by sending an email to the addresses info@elpromedical.com and quality@progettimedical.com

1 INTRODUCTION

1 - INTRODUCTION

1.1 INTENDED USE (PATIENTS GROUP AND MEDICAL CONDITIONS)

The RESCUE LIFE 9 is a NON-INVASIVE ACTIVE MEDICAL DEVICE intended for treatment of cardiac arrhythmias such as a) Ventricular Fibrillation (VF), b) Fast Ventricular Tachycardia (FVT). In this field is possible the acquisition of biomedical parameters like ECG.

The RESCUE LIFE 9 can be applied to the following classes of patients:

- Adult patients (including pregnant women, as no significant clinical data is available in the literature to demonstrate unacceptable adversities, relating to the intended use, on the patient and her fetus);
- Pediatric patients (age <8 years or weight <25 kg).

Neonatal patients (<1 year of age) are not intended for treatment.

The manufacturer recommends to not use RESCUE LIFE [9] in the following environments:

- Places where high oxygen concentration is present;
- Places where inflammable substances are present.

In **manual mode** the RESCUE LIFE 9 is intended to be used by health care professionals and emergency rescue personnel who have been trained in Advanced Life Support (ALS) protocol. The user must know how to interpret ECG's, decide the energy level required and when the defibrillation is necessary.

RESCUE LIFE 9 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)

Used in **MANUAL MODE**, RESCUE LIFE 9 is designed to be used on **pediatric patients**[1], **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.

Used in **AUTOMATED MODE (AED)**, RESCUE LIFE 9 is designed to be used on **adult patients** (by use of DISPOSABLE MULTINFUNCTIONAL ELECTRODES – ADULT PATIENTS), on **pediatric patients** (by use of DISPOSABLE MULTINFUNCTIONAL ELECTRODES – PEDIATRIC PATIENTS) and **special patients** (e.g. pregnant women) according to the *ECR Guidelines* 2015 - Section 4 "*Cardiac arrest in special circumstances*" par. C - SPECIAL PATIENTS.

[1] Pediatric patient: a person of age under 8 years and weighing less than 25 Kg.

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When used in AED mode, the RESCUE LIFE 9 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 9 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)

1 - INTRODUCTION

1.2 MEDICAL DEVICE DESCRIPTION

RESCUE LIFE 9 is an external defibrillator and monitor for acute cardiac care response used by authorized healthcare providers in hospital and clinic settings.

The RESCUE LIFE 9 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 rechargeable 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 ECG acquisition can take place through the STANDARD DEFIBRILLATION ELECTRODES or DISPOSABLE ELECTRODES MULTIFUNCTION (1 lead) or through the ECG CABLE and its leads.

Optional modules are: Pacemaker, SpO_2, NIBP, $EtCO_2$ and Temperature modules.

Integrated thermal printer allows the hardcopy of some parameters as ECG, SpO2, etc.

RESCUE LIFE 9 can be equipped with DISPOSABLE MULTIFUNCTION ELECTRODES through which the patient's myocardial electrical signal is acquired and the defibrillation shock is delivered.

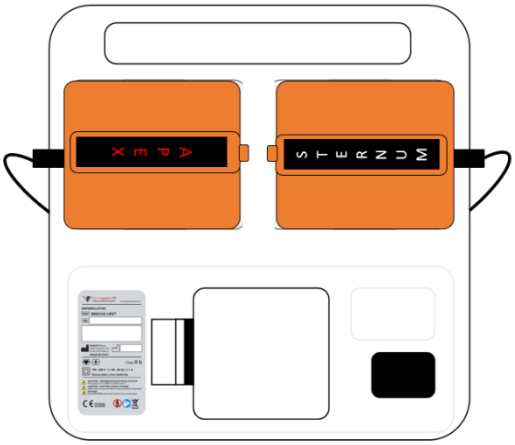
IN **PEDIATRIC PATIENT** (AGE UNDER OF 8 YEARS OR WEIGHING LESS THAN 25 KG) **DO NOT** EXCEED 4 J/KG.
IN **NEONATAL PATENT** (AGE UNDER 1 YEAR) **DO NOT** USE AED MODE.

IF BATTERIES ARE NOT FULLY CHARGED AFTER A 3 HOURS CHARGING PERIOD, PLEASE CONTACT THE MANUFACTURER OR ITS AUTHORIZED REPRESENTATIVES, OR OPEN A SERVICE PROCESS.

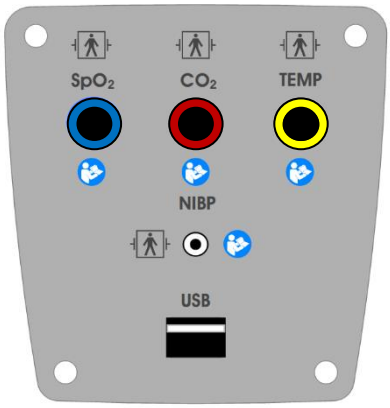
1.2.1 MAIN UNIT

FRONT VIEW

REAR VIEW



LEFT VIEW (full optional case)



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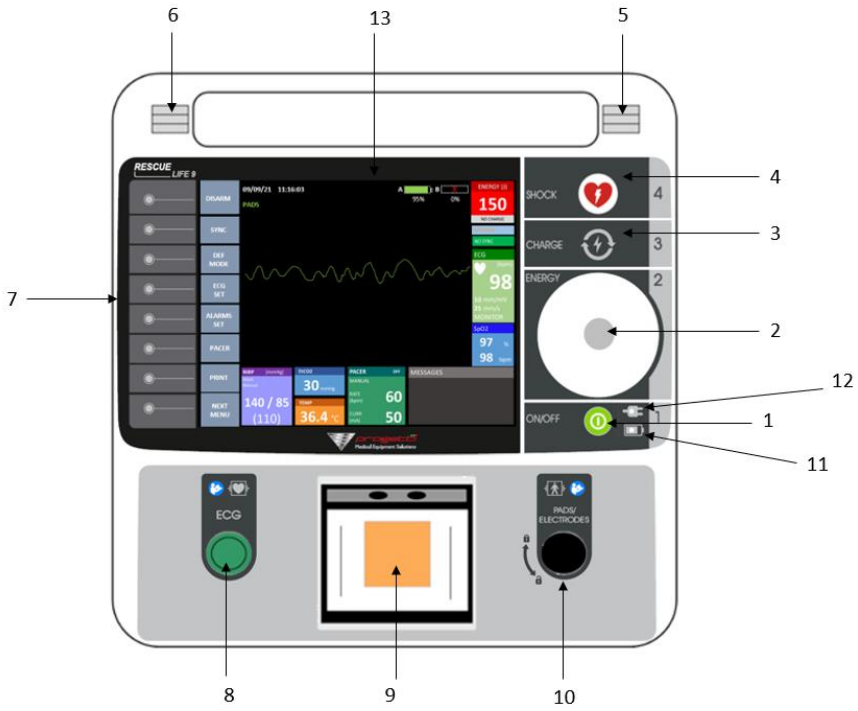
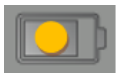
1.2.1.1 FRONT PARTS



#	PART IDENTIFICATION	ICON	PURPOSE
1	ON/OFF BUTTON		To power ON/OFF
2	KNOB	N.A.	To select a field displayed or to increase/decrease defibrillation energy
3	CHARGE BUTTON		To enable the charging of defibrillation energy
4	SHOCK BUTTON		To deliver the shock when the red light is ON and the disposable multifunction electrodes are used
5	SPEAKER	N.A.	For audio prompts
6	BUZZER	N.A.	For energy charge status
7	MENU BUTTON		To select the specific menu function
8	ECG PORT	N.A.	For ECG cable connection
9	PRINTER	N.A.	To print ECG and some other parameters
10	DEFIBRILLATION PORT	N.A.	For therapy Defibrillation Electrodes connection
11	BATTERY LED		To inform the user that battery is charging
12	AC POWER LED		To inform the user that the connection to AC line is doing
13	DISPLAY	N.A.	To show signals and parameters

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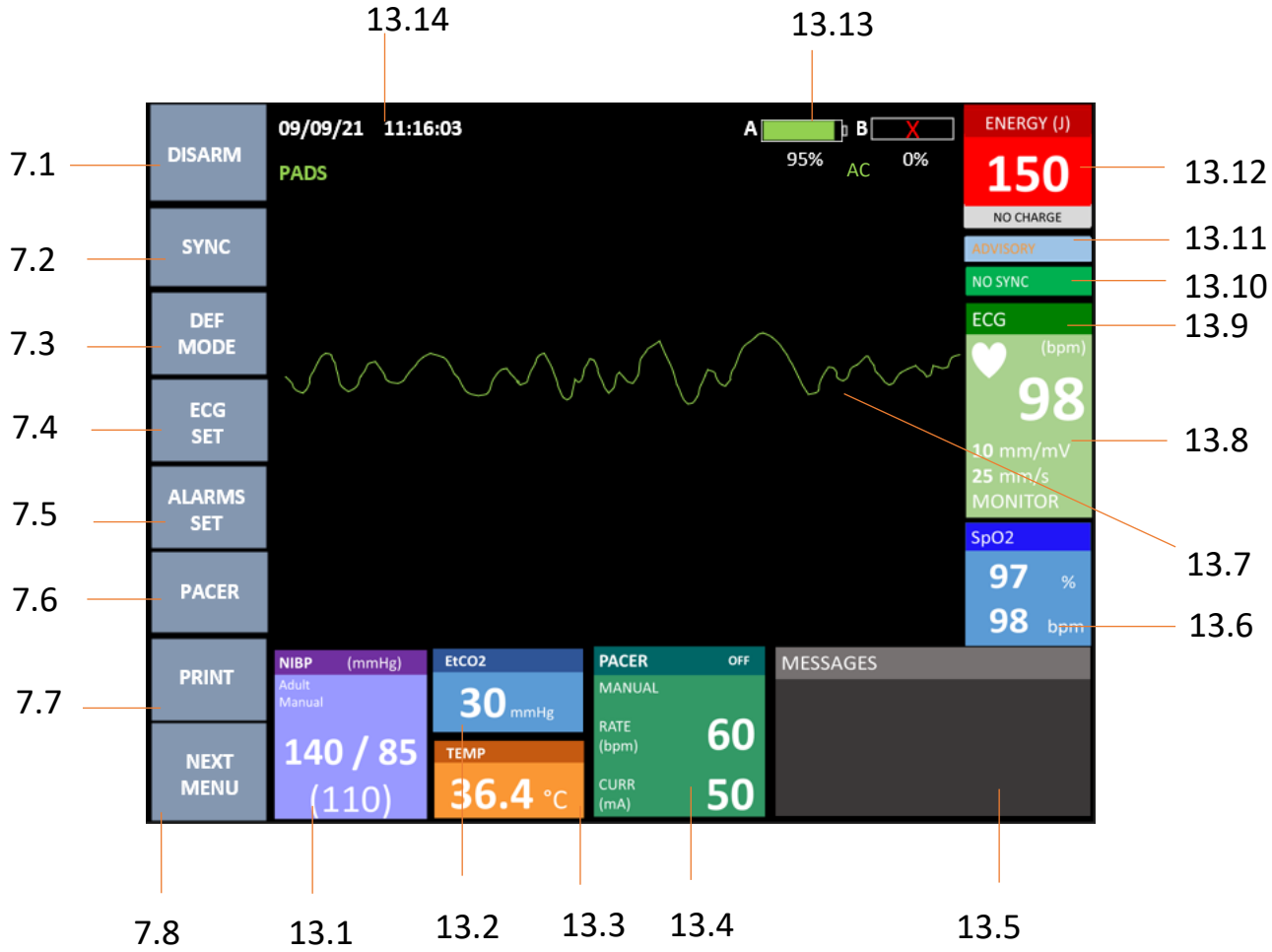
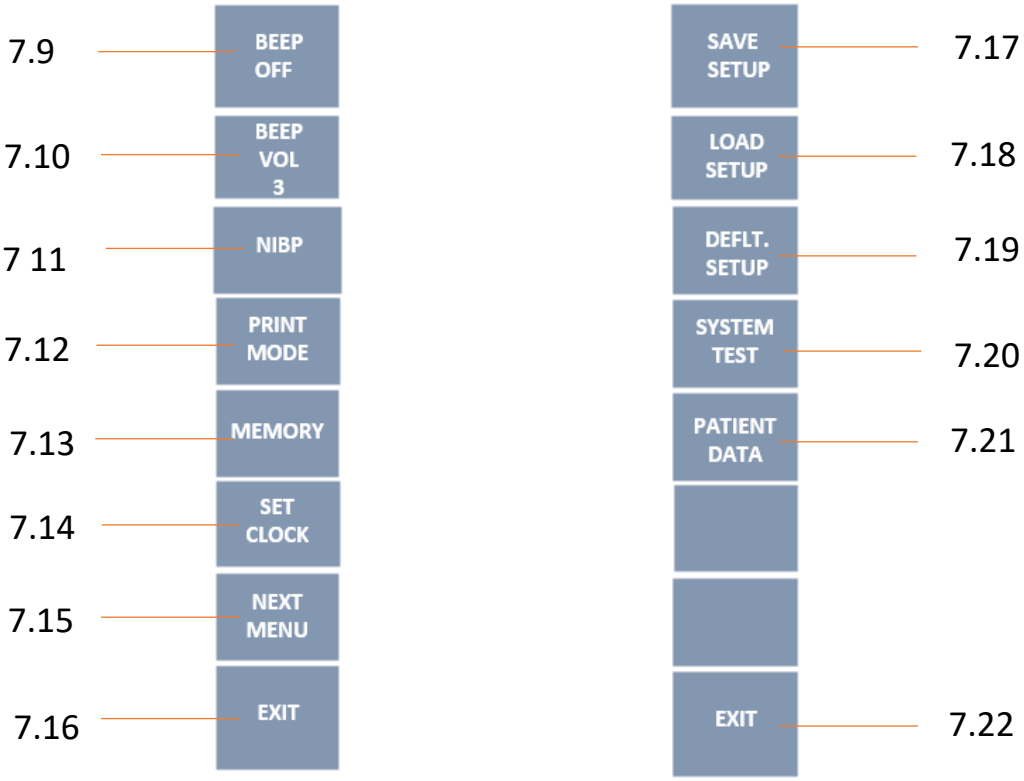
1.2.1.2 GRAPHIC INTERFACE





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#	IDENTIFICATION	PURPOSE
7.1		to perform **INTERNAL DISCHARGE**
7.2		to enable/disable **SYNC MODE.**
7.3		to open **DEFIBRILLATION MODES** window ("Manual", "AED", "Advisory" mode are available).
7.4		to set **ECG PARAMETERS** The following items are available: PADS: • (1) I • (1) II • (1) III LEADS: • (3) I, II, III • (3) aVR, aVL, aVF • (3) V1, V2, V3 • (3) V4, V5, V6 • (6) I, …, aVF • (6) V1, …, V6 • (12) I, …, V6 • GAIN: 2.5 to 40 mm/mV; • SPEED: 5 to 50 mm/s; • FILTER: it refers to the bandwidth of the signal. In MONITOR mode bandwidth is 0,6 Hz - 40 Hz (3dB), in DIAGNOSTIC mode bandwidth is 0,05 Hz - 120 Hz (3dB).

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7.5		to set **ALARMS PARAMETERS**. The following items are available: • ECG HR alarm: set the maximum and minimum heart rate alarm; • SpO_2 alarm: set the SpO_2 minimum alarm; • $ETCO_2$ alarm: set the $EtCO_2$ maximum alarm; • TEMP alarm: set the maximum and minimum temperature alarm; • ALL OFF: disable all alarms;
7.6		to enable/disable **PACEMAKER** The follow items are available: • (7.6.1) - RATE: 0 to 170 bpm; • (7.6.2) - INTENSITY: 0 to 200 mA; • (7.6.3) - MODE: Manual or Demand; • (7.6.4) - ON/OFF; • (7.6.5) - PULSE: 20, 30 or 40 ms.
7.7		to start/stop the **PRINTING**
7.8		to go **OTHER FUNCTIONS**: • (7.9) BEEP ON / OFF • (7.10) BEEP VOL • (7.11) NIBP • (7.12) PRINT MODE • (7.13) MEMORY • (7.14) SET CLOCK
7.9		to enable/disable sound **BEEP**
7.10		to set sound **BEEP VOLUME** level (4 levels are available)

7.11		to open **NIBP FUNCTIONS** (violet "NIBP MODE" is shown on the top of display): • (7.11.1) **START MEAS** – to start measurement; • (7.11.2) **STOP MEAS** – to stop measurement; • (7.11.3) **CLEAR LAST** – to clear measures on NIBP field (13.1); • (7.11.4) **SET PARAM** – to set type of patient ("ADULT", "PEDIATRIC", "NEONATAL"), to set interval of measurement (from 1 min to 90 min is available); • (7.11.5) **PRINT MEAS** – to print measures • (7.11.6) **PMODE** – to set automatic printing ("AUTO") or manual printing ("MAN") • (7.11.7) **OPR MODE** – to set automatic NIBP measurement ("AUTO") or manual NIBP measurement ("MAN")
7.12		to set **PRINT MODE** in manual printing "MAN" or automatic printing "AUTO"
7.13		To open **MEMORY** functions: • (7.13.1) **COPY FILES** – to copy selected file copy to the USB pen • (7.13.2) **COPY ALL** – to copy all files to the USB PEN • (7.12.3**) CHECK USB PEN** – to check the presence of the USB PEN • (7.12.4) **STOP COPY**
7.14		to set **DATE** and **TIME**
7.15		to go **OTHER FUNCTIONS**: • (7.17) SAVE SETUP • (7.18) LOAD SETUP • (7.19) DEFLT. SETUP • (7.20) SYSTEM TEST • (7.21) PATIENT DATA
7.16		to go back to **HOME VIEW**

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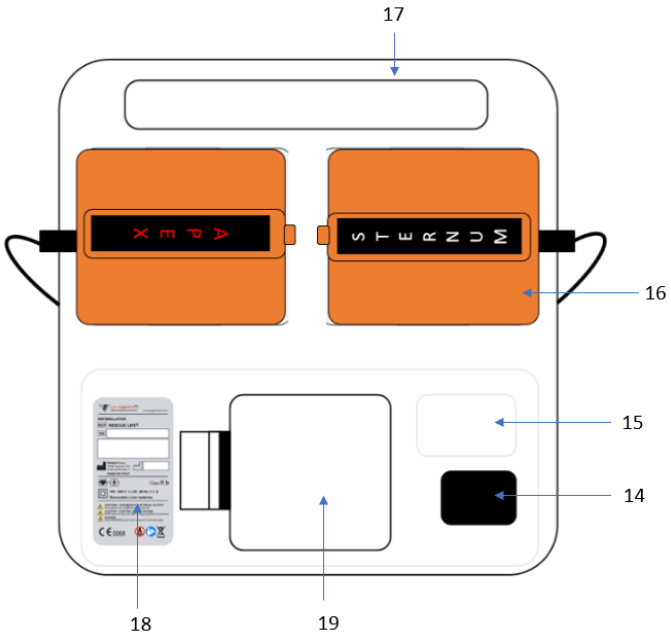
7.17		to **SAVE** the parameters settings: • ECG SPEED • ECG GAIN • ECG FILTER • ALARM HR MIN • ALAR HR MAX • ALARM SPO2 MIN • ALARM ETCO2 MAX • ALARM TEMP MIN • ALARM TEMP MAX • PACER CURRENT • PACER RATE • PRINT MODE
7.18		to **LOAD** the saved parameters settings: • ECG SPEED • ECG GAIN • ECG FILTER • ALARM HR MIN • ALAR HR MAX • ALARM SPO2 MIN • ALARM ETCO2 MAX • ALARM TEMP MIN • ALARM TEMP MAX • PACER CURRENT • PACER RATE • PRINT MODE
7.19		to **LOAD** the default parameters settings
7.20		to perform **TESTING** on device: • AUTO TEST • SHOCK TEST • PRINT RESULT
7.21		To insert **INFORMATION** about the **PATIENT**: • PATIENT ID • AGE • SEX • DOCTOR • HOSPITAL • COMMENTS
7.22		to go back to **HOME VIEW**

13.1	**NIBP field**	(if available) to show **NIBP SETUP AND MEASUREMENT** The following values are possible: • NIBP ALARM enabled /disabled • ADULT / PEDIATRIC • MANUAL / ON DEMAND • SISTOLIC, DIASTOLIC, MEAN PRESSURE measure [mmHg]
13.2	**$EtCO_2$ field**	(if available) to show **$ETCO_2$ LEVEL** [mmHg]
13.3	**TEMPERATURE field**	(if available) to show **SKIN TEMPERATURE VALUE** [°C]
13.4	**PACEMAKER field**	(if available) to show **PACEMAKER SETUP.** The following values are possible: • ON / OFF • MANUAL / ON DEMAND • RATE [BPM] • CURRENT [mA]
13.5	**MESSAGES field**	to show **MESSAGES** (e.g. “warning”)
13.6	**SpO_2 field**	(if available) to show **SPO_2 MEASURES**: • SpO_2 [%], • HEART FREQUENCY [BPM]
13.7	**ECG signal**	to show **ELECTRICAL CARDIAC ACTIVITY**
13.8	**ECG field**	to show **ECG SETUP AND MEASUREMENT**: • ECG ALARM enable/disabled • HEART FREQUENCY [BPM] • GAIN [mm/mV] • SPEED [mm/s] • MONITORING MODE (monitor, diagnostic)
13.9	**SYNC field**	to show **SYNC SETUP** (enabled/disabled)

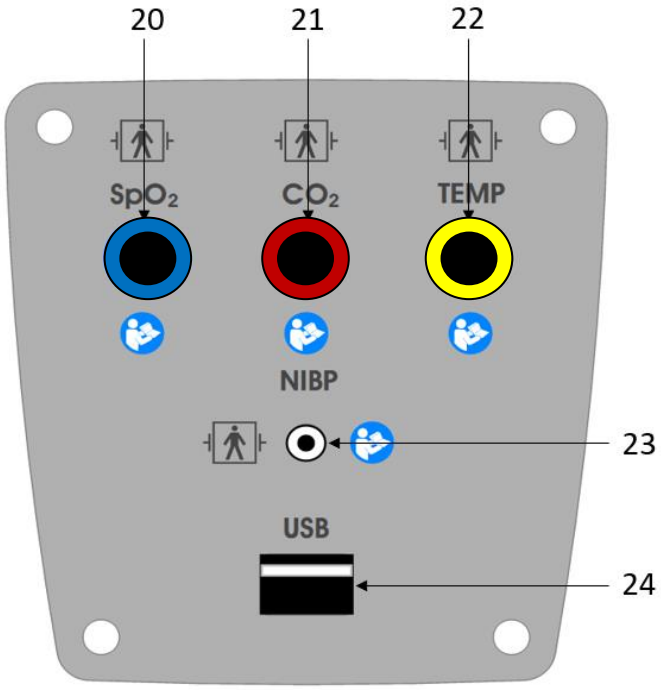
13.10	**DEF MODE field**	to show the actual **SET DEFIBRILLATION MODE** (manual, AED, ADV)
13.11	**CHARGE status**	to show **ENERGY CHARGING STATUS** (CHARGING / NO CHARGE)
13.12	**ENERGY field**	To show **SELECTED ENERGY VALUE** [J]
13.13	**BATTERY field**	To show **BATTERIES CHARGE STATUS** [%]
13.14	**DATE & HOUR field**	To show **DATE** and **HOUR**

1.2.1.3 REAR PARTS



#	PART IDENTIFICATION	PURPOSE
14	AC POWER PORT	To connection AC line
15	LABEL A	To inform user
16	STANDARD DEFIBRILLATION ELECTRODE PLACING WHEN NOT IN USE OR DURING TEST	Storage of standard defibrillation electrodes when not in use
17	HANDLE	For transport
18	NAMEPLATE LABEL	Device labelling
19	BATTERIES COVER	For accessing the batteries

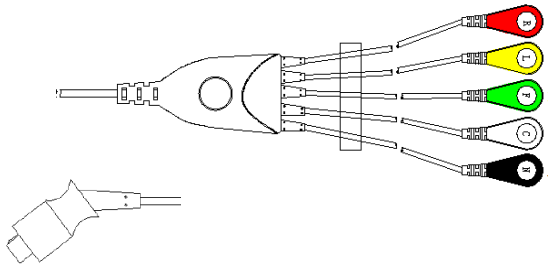
1.2.1.4 LEFT PANEL CONNECTIONS (full optional version)



#	PART IDENTIFICATION	PURPOSE
20	SpO_2 PORT (if available)	SpO_2 sensor connection
21	$EtCO_2$ PORT (if available)	$EtCO_2$ sensor connection
22	TEMPERATURE PORT (if available)	TEMPERATURE connection
23	NIBP PORT (if available)	NIBP extension cable connection
24	USB PORT (if available)	USB pen connection

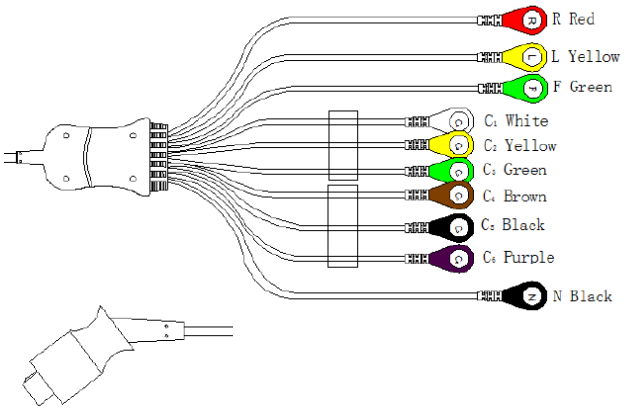
1.2.2 ACCESSORIES VIEW

1.2.2.1 Standard Accessories

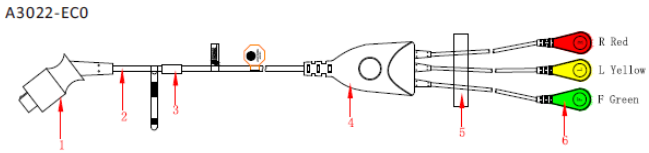
Standard Defibrillation Electrodes (qty:1) REF: **RLF9-STDEFEL** 	Disposable Multifunction Electrodes for Defibrillator - adult patient (qty:1) REF: **DFBAD01STD** 
Extension cable for disposable electrodes (qty:1) **REF: RLF9-DISPEXCAB** 	ECG cable - 5 wires (qty:1) **REF: A5022-EC0** 
Paper roll (qty:1) **REF: RLF9-PAPE** 	AC power cable (qty:1) **REF: RLF9-ACCORD** 
Lithium battery (qty:2) REF: **RRC-2054** 	

1.2.2.2 Optional Accessories

ECG cable - 10 wires
REF: **A1022-EE0**



ECG cable – 3 wires
REF: **A3022-EC0**



SpO_2 sensor - adult patient
REF: **S136AL**

SpO_2 sensor (for pediatric patient)
REF: **S136CL**

SpO_2 wrap sensor
REF: **S136EL**

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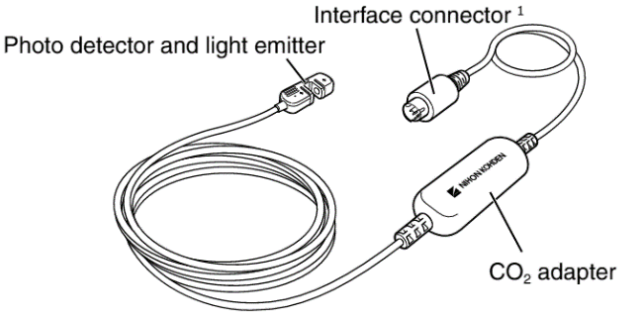
$EtCO_2$ kit sensor
REF: **TG-981T**



NIBP cuff (Adult Version - small)
REF: **98-0095-04**

NIBP cuff (Adult Version - standard)
REF: **98-0097-04**

NIBP cuff (Pediatric Version)
REF: **98-0093-03**

NIBP cuff (Infant Version)
REF: **98-0092-02**

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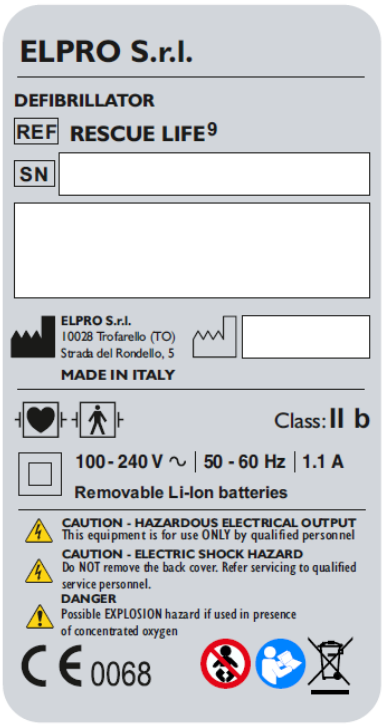
NIBP extension cable REF: **91-0028-69** 	Skin Temperature sensor (YSI400 Compatible) REF: **ATP-03** 
Disposable Multifunction Electrodes for Defibrillator (pediatric version) REF: **DFB01PEDPRC** 	Bag **REF: RLF9-BAG** 

1.2.3 LABELLING VIEW

The symbols are present in the below rear sticker or in the package of *Rescue Life 9* defibrillator.



SYMBOL	DESCRIPTION OF SYMBOL
REF	Identification of device
SN	Serial Number of device
	Manufacturer identification
	Date of production
	Defibrillation-proof type BF applied part (ref. IEC 60417-5334)
	Defibrillation-proof type CF applied part (ref. IEC 60417-5336)
	Alternated current (ref. IEC 60417-5032)
	Class II equipment (ref. IEC 60417-5172)

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	Caution: dangerous voltage (ref. IEC 60878)
	Signal of general warning (ref. ISO 7010-W001) 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.
	Follow the Instructions for Use (ref. ISO 7010-M002)
	Do not use AED mode on NEWBORN
	Follow local regulations for 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)

1.3 INDICATIONS

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

In **asynchronous defibrillation**, the RESCUE LIFE 9 is indicated for use on patients with the following symptoms:

- Unconsciousness
- Absence of normal breathing and
- Lack of detectable pulse.
- Ventricular Fibrillation and Fast Ventricular Tachycardia (>150 bpm). Please refer to paragraph INTENDED USE.

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

In **synchronous defibrillation**, the RESCUE LIFE [9] is indicated for use on patients with ECG's that show the presence of Atrial Fibrillation.

1.4 CONTRAINDICATIONS

From results of Clinical Evaluation activity, no substantial contraindication and no substantial collateral effects are applicable to the use of Rescue Life [9] within the Intended Use if it is used in compliance to recommendations of Manufacturer in the present Instruction for Use.

1.5 GENERAL AND SAFETY INFORMATION

Thank you for choosing the RESCUE LIFE [9].

The RESCUE LIFE [9] is a complete acute cardiac care response system designed for basic life support (BLS) and advanced life support (ALS) patient management protocols.

RESCUE LIFE [9] is designed also to acquire the patient ECG signals and to deliver defibrillation therapy in MANUAL, ADVISORY or AED mode. This Operator's Manual contains all the information that a user needs to operate the RESCUE LIFE 9 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 [9].

Your RESCUE LIFE [9] may not have all of these features or optional.

Please read this Operator's Manual carefully and thoroughly before using the RESCUE LIFE [9]. This Manual contains instructions on how to operate and maintain the RESCUE LIFE [9].

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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 compliance to Directives 2007/47/EC and 93/42/EEC concerning Medical Devices.

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.**

THE EXPECTED SERVICE LIFE OF RESCUE LIFE [9] IS 10 YEARS SINCE THE DATE OF PRODUCTION (IF RECOMMENDED PREVENTIVE MAINTENANCE IS PERFORMED). AFTER THIS PERIOD, IN CASE OF COMPONENT FAILURE, THE MANUFACTURER DOES NOT ENSURE THE AVAILABILITY OF REPLACEMENT PARTS; SO, IN THIS CASE, THE MANUFACTURER WILL SUGGEST TO PUT THE EQUIPMENT IN "OUT SERVICE" STATE AND TO REPLACE IT WITH THE LATEST VERSION.

THE RESCUE LIFE [9] AND ITS ACCESSORIES ARE INTENDED TO BE USED AS "SURFACE DEVICE" WHICH CAN CONTACT BY "SKIN" FOR 24 HOURS AS MAXIMUM TIME (REF. ISO 10993-1)

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. recommendes to make one functional check, preventive maintenance and electrical safety test at least once a year.

WHEN THE RESCUE LIFE 9 IS CHARGED WITH THE STANDARD ELECTRODES 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.
TO OBTAIN THE BEST SHOCK RESULT IT IS STRONGLY RECOMMENDED TO CHARGE THE ENERGY WITH THE STANDARD ELECTRODES ATTACHED TO THE PATIENT.
NEVER CHARGE THE DEFIBRILLATOR WITH THE STANDARD ELECTRODES IN CONTACT BETWEEN THEM.

MAKE SURE THAT THE CONTACT GEL IS SPREAD ONLY ON THE STANDARD ELECTRODE'S STEEL SURFACE 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.

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1.5.1 DANGER, WARNINGS AND CAUTIONS

This chapter includes a list of danger, warning, and caution messages related to *Rescue Life [9]* and its accessories. Many of these messages could be repeated elsewhere in this user manual and on the equipment. The entire list is presented here for convenience.

LEGEND

ICON	IDENTIFICATION	DESCRIPTION
	**DANGER**	IMMEDIATE HAZARDS THAT WILL RESULT IN SERIOUS PERSONAL INJURY OR DEATH.
	**WARNING**	CONDITIONS, HAZARDS OR UNSAFE PRACTICES THAT MAY RESULT IN SERIOUS PERSONAL INJURY OR DEATH.
	**CAUTION**	CONDITIONS, HAZARDS OR UNSAFE PRACTICES THAT MAY RESULT IN MINOR PERSONAL INJURY, DEVICE DAMAGE OR DATA LOSS.

1.5.2 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.

1.5.3 GENERAL

Assure yourself prior and after the use of the RESCUE LIFE 9 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 9 is not intended for use in areas of highly inflammable anesthetics or other inflammable substances, especially in high concentration of oxygen areas.

RESCUE LIFE 9 does not have to be put or used nearby a nuclear spin tomography plant, which is turned on.

 **DANGER**	**ELECTRICITY**	Hazardous electrical output. this equipment is for use only by qualified personnel. Do not attempt to operate this device unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.
 **DANGER**	**ENVIRONMENT**	1. Possible explosion hazard if used in the presence of flammable anesthetics or concentrated oxygen. 2. 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. 3. The equipment has not been evaluated or approved for use in hazardous locations as defined in the national electric code standard. In compliance with EN classification the equipment is not to be used in the presence of flammable substance/air mixtures.

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 **WARNING**	**BATTERY**	Do not immerse battery in water or other liquids. Immersion in fluids may result in fire or explosion.
 **WARNING**	**DEFIBRILLATION ENERGY**	1. Defibrillation current (shock) can cause operator or bystander injury. 2. Do not touch the patient during defibrillation. 3. Disconnect other electrical equipment from the patient before defibrillating. 4. Improper use can cause injury. Use the rescue life 9only as instructed in the user manual. The rescue life 9 delivers electrical energy that can potentially cause death or injury if it is used or discharged improperly. 5. Do not discharge with disposable multifunction electrodes (pads) touching each other or with exposed gel surface. 6. Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock hazard and potential damage to that equipment. 7. IN MANUAL MODE IN PEDIATRIC PATIENTS (LESS THAN 8 YEARS OF AGE AND LESS THAN 25 KG) NOT MORE THAN 4 J/KG.
 **WARNING**	**DISPOSABLE MULTIFUNCTION ELECTRODES**	1. Use only PROGETTI® disposable multifunction electrodes (pads), or by its authorized distributors. No-approved accessories may cause improper performance of the medical device. 2. The disposable multifunction electrodes (pads) are intended for one time use only and must be discarded after use. Reuse can lead to potential cross infection, improper performance of the device, inadequate delivery of therapy and/or injury to the patient or operator. 3. Do not open disposable multifunction electrodes (pads)'s package if their use is not be required. 4. Do not use advisory mode or automated mode (aed) in pediatric patients without the "disposable multifunction electrodes" 5. In automated mode (AED) use only Disposable Multifunctional Electrodes.

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 **WARNING**	**ENVIRONMENT**	1. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally 2. Portable rf communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the rescue life 9, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. 3. Radio frequency (rf) interference from rf devices such as cellular phones and two-way radios can cause improper *rescue life* [9] operation. In accordance with IEC 801.3, a distance of 2 meters between RF devices and the Rescue Life[9] is recommended. 4. Using cables, electrodes, or accessories not specified for use with this defibrillator may result in increase of emissions or decrease 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.
 **WARNING**	**MAINTENANCE**	1. This defibrillator may cause electromagnetic interference (emi) especially during charge and energy transfers. Emi may affect the performance of equipment operating in close proximity. 2. Verify the effects of defibrillator discharge on other equipment prior to using the defibrillator in an emergency, if possible. 3. Do not open unit, remove covers, or attempt repair. There are no user serviceable components in the rescue life 9. Refer servicing to qualified service personnel. 4. Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator.

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 **WARNING**	**PATIENT ANALYSIS**	1. Aggressive or prolonged CPR to a patient with disposable self-adhesive defibrillation/monitoring electrodes (pads) attached can cause damage to the pads. Replace the defibrillation pads if they become damaged during use. 2. CPR rates above guidelines's recommended values can cause incorrect or delayed diagnosis by the patient analysis system. 3. <u>Do not</u> place adult disposable self-adhesive defibrillation/monitoring electrodes (adult pads) in the anterior-posterior (front-back) position. A shock or no shock decision may be inappropriately advised. The Rescue Life[9] requires that the adult disposable self-adhesive defibrillation/monitoring electrodes (adult pads) be placed in the anterior-anterior (front-front) position. 4. In AED mode, some very low amplitude or low frequency rhythms may not be interpreted as shockable VF rhythms. Also some VT rhythms may not be interpreted as shockable rhythms. 5. Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis, especially if very low amplitude or low frequency rhythms are present. 6. When the device is applied on the patient movement and vibration must be minimized. 7. In patients with cardiac pacemakers, the Rescue Life[9] set in AED mode may have reduced sensitivity and not detect all shockable rhythms. If you know the patient has an implanted pacemaker, do not place defibrillation electrodes directly over an implanted device.
 **WARNING**	**ECG ANALYSIS**	Pacemaker patients – Rate meter (ECG HR) may continue to count the pacemaker rate during occurrence of cardiac arrest or some arrhythmia. Do not rely entirely upon HR meter alarm signals. Keep pacemaker patients under close surveillance. See this manual for disclosure of pacemaker pulse rejection capability of this instrument.
 **CAUTION**	**PATIENT MANAGEMENT**	1. 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. 2. Disconnect from the patient every device that is equipped with patient connections not defibrillation protected.
 **CAUTION**	**DEFIBRILLATION PROCEDURE**	1. "Manual mode" defibrillation must be performed only by highly trained medical personnel. 2. During defibrillation with connected ECG cable ensure that all binding clips are connected with the patient.
 **CAUTION**	**BATTERY**	Recycle or dispose of lithium battery in accordance with local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

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 **CAUTION**	**CLEANING**	1. <u>Do not</u> clean with ketones or other flammable agents. 2. <u>Do not</u> autoclave or sterilize this defibrillator or accessories unless otherwise specified.
 **CAUTION**	**DEFIBRILLATION ENERGY**	Avoid contact between parts of the patient's body and conductive fluids such as water, gel, blood or saline, and metal objects, which may provide unwanted pathways for shock current.
 **CAUTION**	**STANDARD DEFIBRILLATION ELECTRODES**	1. <u>Do not</u> put in contact the STANDARD DEFIBRILLATION ELECTRODES between themselves (short circuit) 2. Be sure that both STANDARD DEFIBRILLATION ELECTRODES' metal plates are completely moistened with gel, before the use 3. the STANDARD DEFIBRILLATION ELECTRODES 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 the shock energy away from the heart muscle 4. the STANDARD DEFIBRILLATION ELECTRODES including handles should always be cleaned thoroughly after use.
 **CAUTION**	**DISPOSABLE MULTIFUNCTION ELECTRODES**	1. Follow all disposable multifunction electrodes (pads)'s label instructions. 2. Use disposable multifunction electrodes (pads) before their "expire date". 3. <u>Do not</u> re-use disposable multifunction electrodes (pads). Check that the PACKAGE is in good condition and that the disposable MULTIFUNCTION ELECTRODES have not yet reached their expiration date. 4. Discard disposable multifunction electrodes (pads) after use (in the event of suspected malfunction, return them to the manufacturer for testing).
 **CAUTION**	**ENVIRONMENT**	1. <u>Do not</u> immerse any portion of this product in water or other fluids. 2. <u>Do not</u> allow fluids to enter the device. Avoid spilling any fluids on this device or accessories. Spilling fluids into the Rescue Life[9] may damage it or present a fire or shock hazard. 3. <u>Do not</u> autoclave or gas sterilize the Rescue Life[9] or its accessories. 4. The Rescue Life[9] should be stored and used only within the range of environmental conditions specified in the technical specifications. 5. Although the Rescue Life[9] is designed for a wide variety of field use conditions, rough handling beyond specifications can result in damage to the unit.

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 **CAUTION**	**MAINTENANCE**	1. <u>Do not</u> disassemble the defibrillator or its accessories. It contains no user serviceable parts. High voltage may be present. Contact authorized service personnel for professional maintenance. 2. User can maintain the defibrillator or its accessories only as described in this user manual.

1.5.4 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.

1.5.5 POSSIBLE DEVICE SHUTDOWN OR NOT SWITCHING ON

Always check that the battery is fully charged.

IF A BATTERY LOW MESSAGE APPEARS ON THE MONITOR SCREEN, THE OPERATOR HAS TO CONNECT IMMEDIATELY THE AC POWER CORD TO AN OUTLET.

1.5.6 ELECTRICAL SAFETY GUIDELINES

Use only the original power cord during recharging.

The right value for the AC power supply is: **100 - 240 V_{AC} , 50 - 60 Hz**.

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 9 is classified as follows:

- **Class II** equipment;
- Applied parts:
  - **Type Defibrillation-proof BF** for Defibrillation electrodes, SpO2 module, NIBP module, TEMP module, $EtCO_2$ module
  - **Type Defibrillation-proof CF** for ECG module;
- The Electromagnetic compatibility level is **Class B group 1** according to the EN 60601-1-2 (Electromagnetic Compatibility Requirements).

1.6 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 9 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.

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.

1.7 DEVICE OPERATION AND STORAGE GUIDELINES

The defibrillator & monitor Rescue Life 9 must be used and managed according to the following environmental conditions who ensure safety and performance without hazardous situations:

- **Operating Conditions**

Temperature +10 °C to +40 °C
Humidity 30 % to 75 % (non-condensing)
Pressure 80kPa (2000 m) to 101 kPa (sea level)

- **Transport Conditions**

Temperature: from -20°C to +50°C
Humidity: from 10% to 95%
Pressure: from 80 kPa (2000 m) to 101 kPa (sea level)

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

Temperature -20 °C to 50 °C
Humidity 10 % to 95 % (non-condensing)
Pressure: from 80 kPa (2000 m) to 101 kPa (sea level)

- **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

1.8 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.
- Chlorhexidine and water mixture (30 ml Chlorhexidine /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 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.

1.9 CONNECTING TO POWER

The Rescue Life[9] can be supplied by:

- AC line (100-240 V_{AC} | 50-60 Hz);
- Li-Ion battery (15 V_{DC} | 3200 mAh).

AC LINE ALIMENTATION

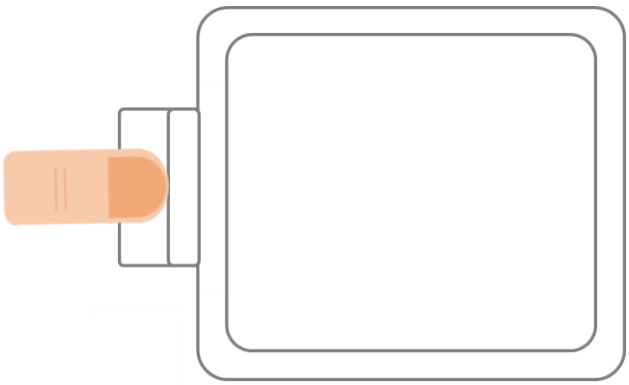
The connection of Rescue Life[9] to AC line can be done according to the following instructions:

1. Insert the AC POWER CABLE's female pole into AC POWER port;
2. Connect the AC POWER CABLE's male pole to an AC line port (100-240 VAC | 50-60 Hz). The AC POWER LED will light itself in blue and "AC" is on the display.

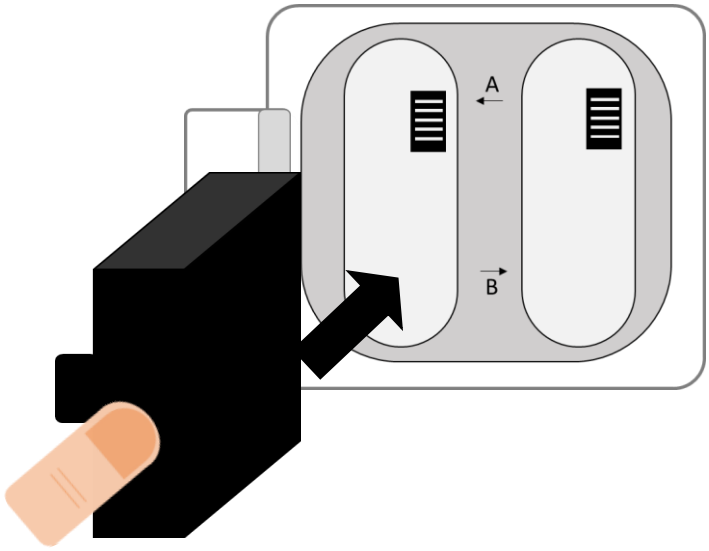
AC POWER LED status	DESCRIPTION
state A 	When the blue AC POWER LED is ON, it informs that the defibrillator is connected to AC line.
state B 	When the blue AC POWER LED is OFF, it means that the defibrillator is not connected to AC line.

LI-ION BATTERY REPLACEMENT

1. Open the rear BATTERIES CASE DOOR pressing on the lock-up lever;



2. Insert at least 1 BATTERY in one of two free slot. If the second battery is available then repeat the same operation for the second battery.



Pay attention to the battery alignment with the internal connector and the case guides.

3. Push and slide the battery into the slot until a “CLICK” is audible. If the second battery is available then repeat the same operation for the second battery.

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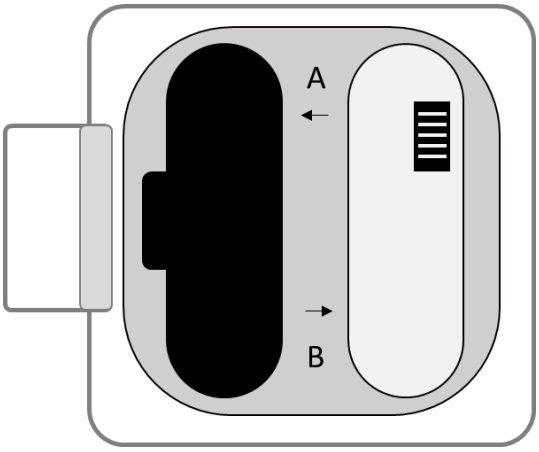
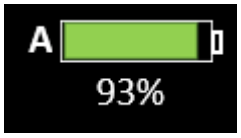


To remove the battery/batteries pull and slide it/them.

4. Close the door until the lever does "CLICK" that means it is locked.
5. Check on the display the charge level of the batteries.

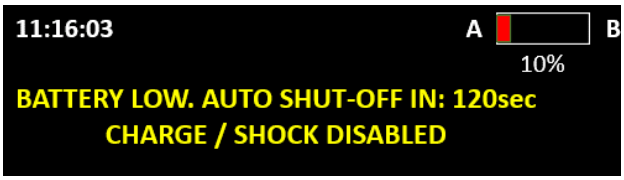


A new full charged battery can supply for around 150 defibrillation shocks at 230 J, 3 hours of pacing or around 6 hours of continuous monitoring before the defibrillator turns off.

If the battery charge level is less than 50% it is recommended to connect the device to the AC line and recharge the battery.

1.10 BATTERY CHARGING

When the battery charge level is 10%, the message "**BATTERY LOW. AUTO SHUT-OFF IN: 120sec. CHARGE / SHOCK DISABLED**" is shown on the display and a pulsed sound is played, so the battery or batteries need to be recharged. The value of countdown seconds (sec) is updated every 10 seconds. After 120 seconds the defibrillator will do shut-off automatically.



After this warning it is no longer possible to perform defibrillation shocks..

Connect the defibrillator to the AC line to start the battery or batteries recharge and to continue the use of defibrillator.

Tipically, new fully depleted batteries recharge time is 2.5 hours (per battery) to regain full capacity.

When the charging is finished BATTERY LED will turn off.

BATTERY LED status	DESCRPTION
statement A 	When the orange BATTERY LED is ON it informs that the battery are in charging (by connection to AC line).
statement B 	When the battery charge is finished the BATTERY LED is OFF. Only AC POWER LED will be ON until AC line will be disconnected.

WHEN THE DEVICE IS IN POWER-OFF, DO NOT LEAVE THE AC POWER CABLE 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.

1.11 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.
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 9 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.

1.12 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.

The technical personnel authorized by ELPRO S.r.l., in case of need for software updates, after having carried out the update, will carry out all the tests necessary for the functional testing.

Regularly maintenance and testing of the RESCUE LIFE 9 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.

ELPRO S.r.l.
Strada del Rondello 5
10028 Trofarello (TO) - Italy

1.13 RECYCLING

According to article n.26 of Directive 2012/19/UE, the manufacturer informs that:

- The user must not to waste the Rescue Life[9] and its electrical/electronic accessories on the municipal waste but to perform recycling for them;
- Rescue Life[9] and its accessories are classified as “electrical/electronic equipment”; so, according to European Directive 2012/19/UE and 75/442/CEE, applicable identification code is 200136 “NO DANGEROUS” (“Electrical and electronic equipment in out of service life state”).
- RRC2054 Lithium Battery must be wasted as no-charged in the dedicated waste point; if the RRC2054 Lithium battery is not fully discharged before to waste it, is present the electrical short-circuit hazard. So, to insulate the electrical contacts with a scotch tape before to waste it.

2 THERAPY

2 - THERAPY

2.1 EXTERNAL DEFIBRILLATION

2.1.1 GENERAL INFORMATION FOR PROFESSIONAL USER

A direct current defibrillator applies a brief, intense pulse of electricity to the heart muscle. The RESCUE LIFE 9 defibrillator delivers this energy through STANDARD ELECTRODES or DISPOSABLE ELECTRODES 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 (AHA) has identified the following as critical links in the chain of survival from cardiac arrest:

1. Early access
2. Early CPR by first responders or bystanders
3. Early defibrillation
4. Early advanced life support (ALS)

Depending on the situation, other supportive measures may include:

1. Cardiopulmonary resuscitation (CPR)
2. Administration of supplemental oxygen
3. 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.

2.1.2 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.

2.1.3 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.

2.1.4 HOW TO PREPARE THE ADULT PATIENT

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

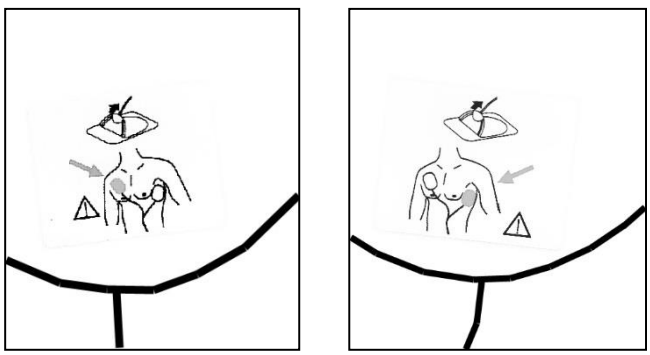
- Unconsciousness and
- Absence of normal breathing and
- Lack of detectable pulse.

If the patient exhibits the above symptoms, do the following:

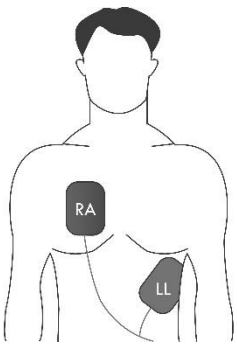
1. remove clothing from the patient's chest.
2. dry the area;
3. clip or shave excessive chest hair.
4. apply the pads.

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.

In case of use DISPOSABLE C, 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.
In the pictures below, correct pads position is shown.



DISPOSABLE ELECTRODES position marking



DISPOSABLE ELECTRODES placement

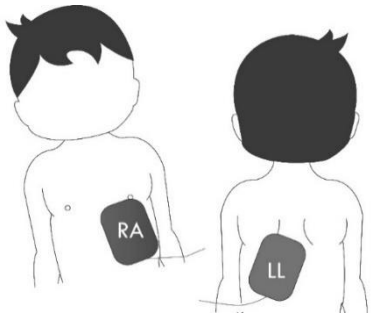
2.1.5 HOW TO PREPARE THE PEDIATRIC PATIENT (WITH DISPOSABLE MULTIFUNCTION ELECTRODES)

Apply the pads as shown in the picture. In the case of use of DISPOSABLE MULTIFUNCTION ELECTRODES.

1. Open the package by tearing along the dotted line near the end of the pack.
2. Remove the DISPOSABLE PAIR ELECTRODES from the package and follow the directions and the schema for the correct placement of defibrillation electrodes placed on the packaging and on the themself.
3. Remove the protective coating from each electrode before placing them.
4. Remove the coating only when the electrode is ready to be applied.
5. Put the electrodes with the adhesive side of the patient's skin.
6. Place the electrodes as shown in the follow picture. 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.

If the patient is an infant or a child under the age of 8 years or weight less than 25kg (55 lbs), defibrillation therapy requires DISPOSABLE MULTIFUNCTION ELECTRODES – PEDIATRIC PATIENT. 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.

2.1.6 DEFIBRILLATION MODES

With RESCUE LIFE 9 users can choose between 3 operating modes:

MODE	DESCRIPTION
MANUAL	Users have to analyze heart rhythm, decide time and energy value to use for the defibrillation.
ADVISORY (ADV)	RESCUE LIFE 9 only analyzes and suggest if patient needs defibrillation, after that users have to choose energy value, charge defibrillator and deliver the shock.
AUTOMATIC (AED)	RESCUE LIFE 9 analyzes heart rhythm and helps operators with visible and audible prompts. If patient needs a defibrillation RESCUE LIFE 9 automatically charge with energy value of 200 Joule. Operators only should to deliver shock and perform CPR when indicated.

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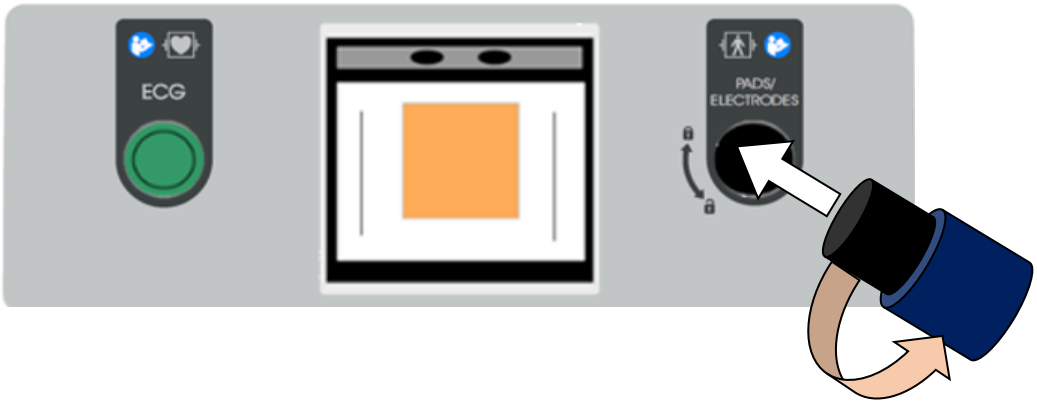
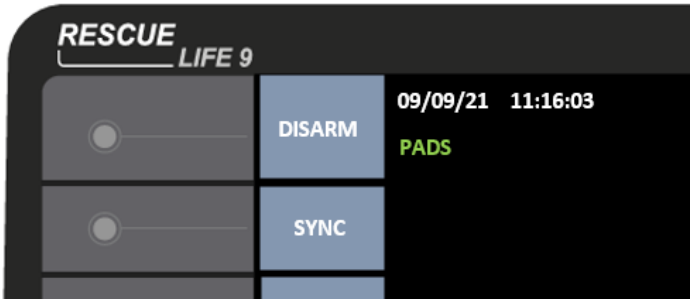
DEFIBRILLATION ELECTRODES CONNECTION



1. Insert the connector into “SHOCK PADS” port;
2. Lock the connector by clockwise rotation until a «CLACK» sound is audible. To unlock the connector, pull the button the connector and do counterclockwise rotation;
3. Verify if “PADS” appears on the display, up to the left side.

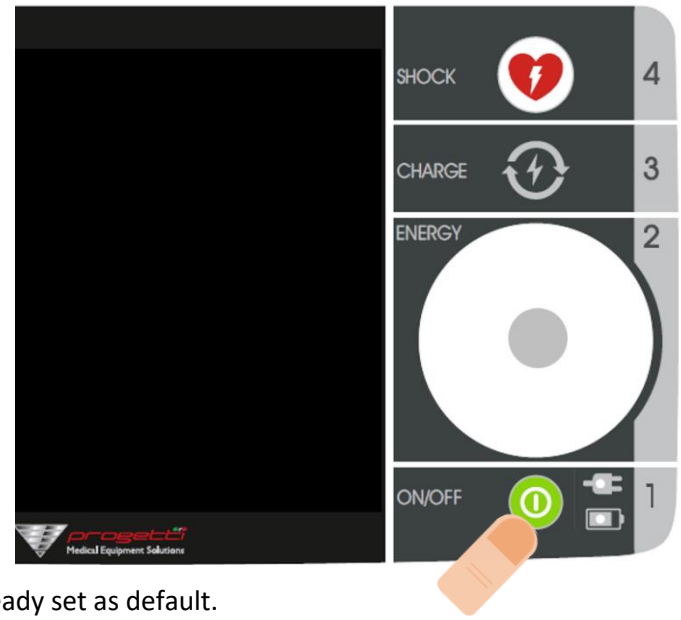


2.1.6.1 “MANUAL” MODE (default mode)

DEFIBRILLATION PROCEDURE IN “MANUAL” MODE

1. POWER ON

Switch on the device pressing **ON/OFF BUTTON** [1];



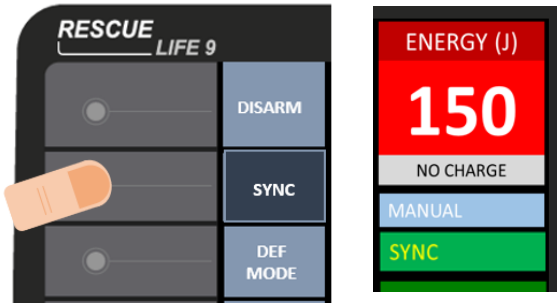
MANUAL mode is already set as default.

2. DEFIBRILLATION ELECTRODES CONNECTION

Insert and hold the STANDARD or DISPOSABLE DEFIBRILLATION ELECTRODES's connector into "SHOCK PADS" port [10] (as explained in previous section) if they are not connected already to the main unit (see section 2.1.6);

3. SET SYNC OR NO SYNC

Press "SYNC" function to synchronize the shock to ECG R-peak. Otherwise "NO SYNC" is set as default.



In SYNC mode follow the sync red marker on the top of the screen and proceed with the shock only if the marker is pointing to the R-peak of the ECG graph.

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 DEFIBRILLATION ELECTRODES INPUT FOR THE BEST RESULT.

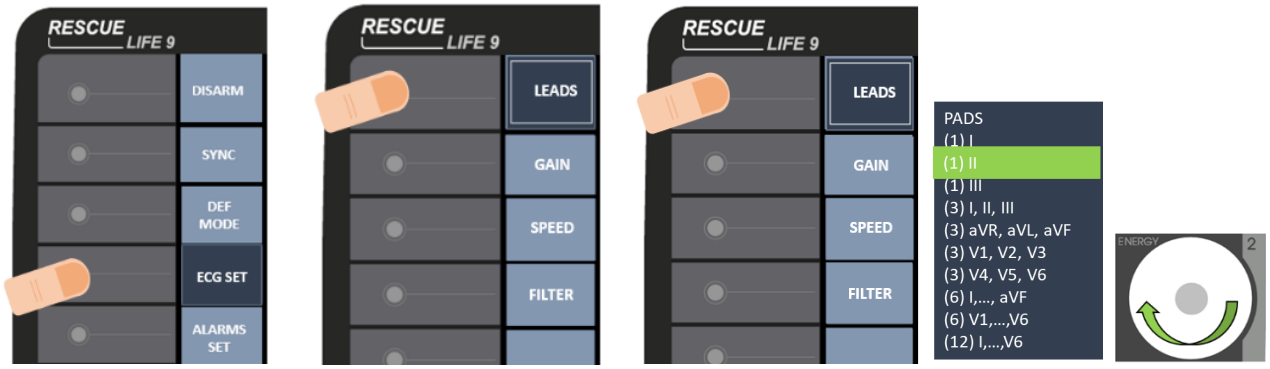
4. SET ECG SOURCE

Case A) DEFIBRILLATION ELECTRODES as ECG source

In this case no other settings are required to the user: "PADS" are default ECG source and it is show on the left top of the display.

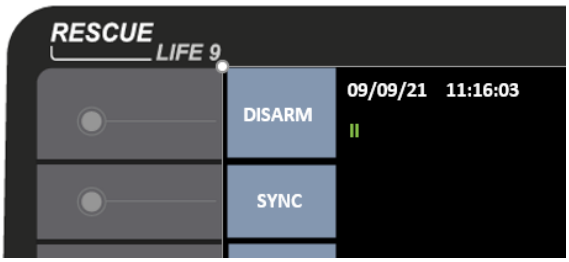
Case B) ECG ELECTRODES as ECG source

1. Press “ECG SET” function, 2. Press “LEADS”, 3. Select from “(1)” to “(12)” by rotating the KNOB;



4. Press the KNOB to confirm.

5. On the left top of display will be shown the set ECG source (“II” for example)



5. ATTACHMENT OF ECG SENSOR TO THE PATIENT

Case A) DEFIBRILLATION ELECTRODES as ECG source

Attach the DEFIBRILLATION ELECTRODES on the patient chest for ECG acquisition.

Case B) ECG ELECTRODES as ECG source

ECG acquisition can be performed by DISPOSABLE ECG ELECTRODES alternatively:

1. insert the ECG CABLE’s connector into “ECG” port (see paragraph 3.1.2 “ECG CONNECTION”);

2. attach DISPOSABLE ECG ELECTRODES to the patient chest;

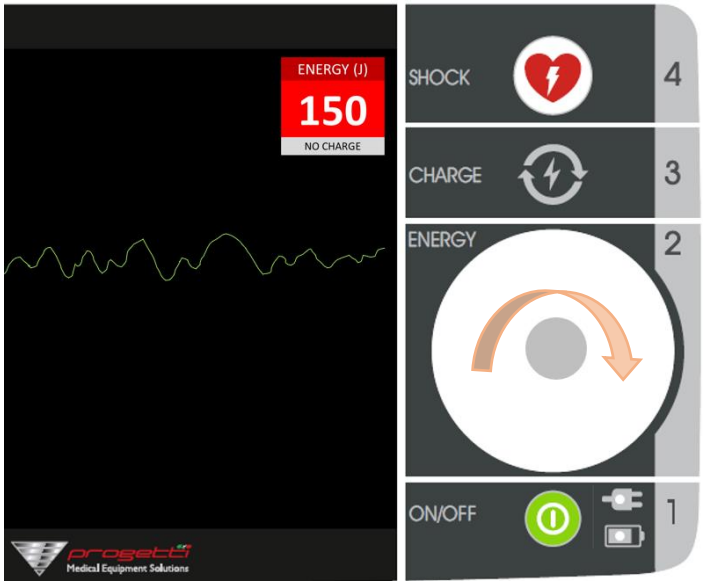
3. connect ECG CABLE’s distal terminals to the already attached DISPOSABLE ECG ELECTRODES.

6. ECG CLASSIFICATION

View acquired ECG signal on the display, classify it and establish if defibrillation therapy is needed or not.

7. SET DEFIBRILLATION ENERGY

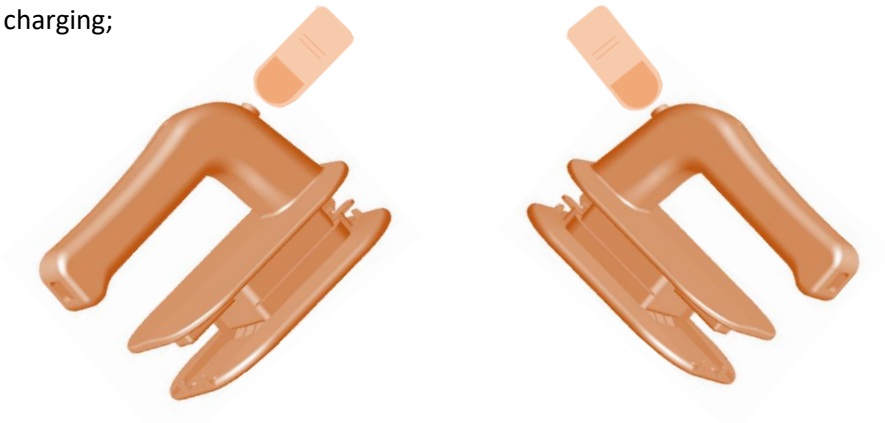
Rotate the **KNOB** to set the energy value (from 1 to 230 J) if defibrillation therapy is needed.



6. CHARGE DEFIBRILLATION ENERGY

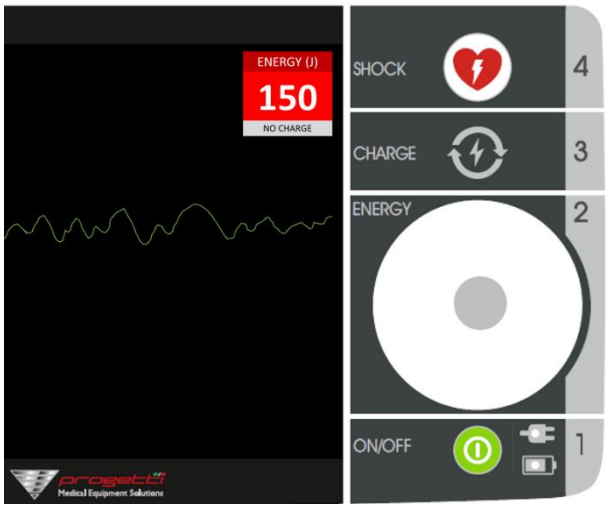
Case A) Defibrillation with STANDARD DEFIBRILLATION ELECTRODES

If STANDARD DEFIBRILLATION ELECTRODES are used, then press both push buttons on the handles to start energy charging;

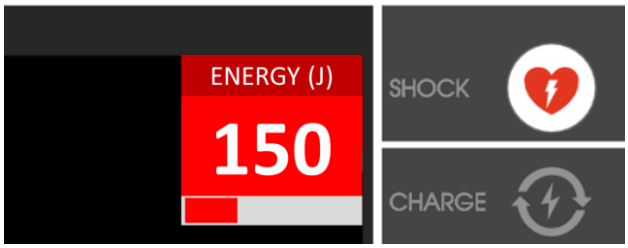


Case B) Defibrillation with DISPOSABLE DEFIBRILLATION ELECTRODES

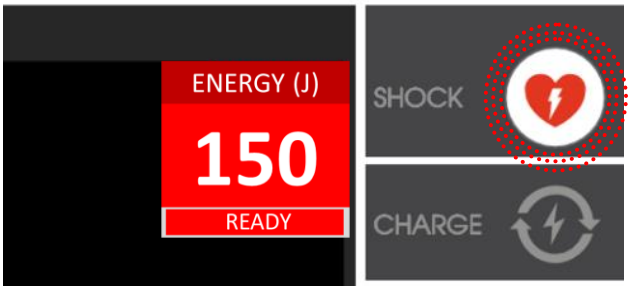
If DISPOSABLE MULTIFUNCTION ELECTRODES are used, then press the **CHARGE BUTTON** [3] on the keyboard to start charging;



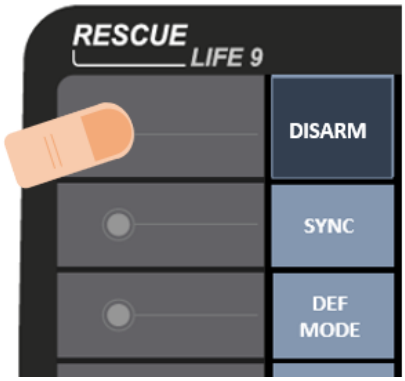
On the display the charge status bar is shown together a pulsed sound.



When the charging ends on the charge status bar is shown “READY”, SHOCK BUTTON [4] will lights in red and the sound is more frequent.



If defibrillation is not required but defibrillation energy is already charged, press “DISARM” function to internal discharge.



7. DISCHARGE DEFIBRILLATION ENERGY

Case A) Defibrillation with STANDARD DEFIBRILLATION ELECTRODES

If STANDARD DEFIBRILLATION ELECTRODES are used, then press both push buttons on the handles **t**o release the defibrillation shock**. If SYNC mode is selected, keep pushing both buttons until shock is delivered (on ECG R-peak).**

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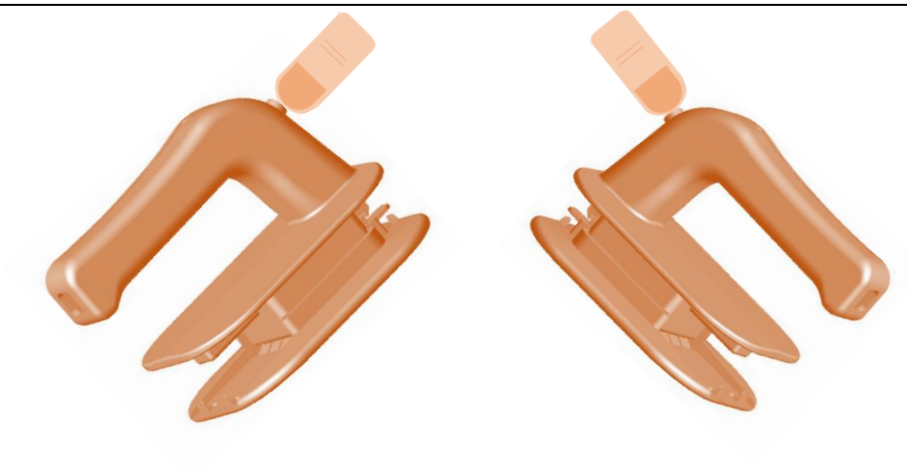


Case B) Defibrillation with DISPOSABLE DEFIBRILLATION ELECTRODES

If DISPOSABLE MULTIFUNCTION ELECTRODES are used, then push **SHOCK BUTTON within 15 seconds from the charge completed**. "SHOCK DELIVERED" will show on the top of the display.

If no push occurs on SHOCK BUTTON within 15 seconds from the charge completed, then the energy will be discharge internally.

2 - THERAPY

WARNINGS

DO NOT TOUCH THE PATIENT DURING DEFIBRILLATION.

IF THE MESSAGE "**ATTACH PADS**" IS SHOWN ON THE TOP OF THE DISPLAY AND THE CHARGING OF ENERGY IS IN PROGRESS (FOR EXAMPLE, BECAUSE DEFIBRILLATION ELECTRODES ARE NOT WELL CONNECTED TO THE PATIENT), WHEN THE USER PRESS TO DISCHARGE ENERGY THEN THE INTERNAL DISARM IS ACTIVED AUTOMATICALLY AND "**INTERNAL DISARM**" IS SHOWN ON THE DISPLAY.

IF THE MESSAGE "CONNECT PADS" IS SHOWN ON THE TOP OF THE DISPLAY AND THE CHARGING OF ENERGY IS IN PROGRESS THEN THE INTERNAL DISARM IS ACTIVED AUTOMATICALLY AND "INTERNAL DISARM" IS SHOWN ON THE DISPLAY.
THE MESSAGE "**CONNECT PADS**" CAN BE DISPLAYED ALSO IN PRESENCE OF A NO SUFFICIENT ELECTRIC CONTACT BETWEEN THE DEFIBRILLATION ELECTRODES AND THE PATIENT SKIN; IN THIS CASE ADD CONDUCTIVE GEL AND PRESS STRONGLY THE DEFIBRILLATION ELECTRODES ON THE PATIENT SKIN.

2.1.6.2 "ADV" MODE

DESCRIPTION

The "ADV" (Advisory) mode allows the user to:

- do the same operations as the "Manual" mode;
- establish if a defibrillation discharge is needed or not following messages shown on the "MESSAGES" box of the display ("SHOCK ADVISED" or "NO SHOCK ADVISED") or played as sound.

DEFIBRILLATION PROCEDURE IN ADV MODE

1. POWER ON

See "Manual" mode.

2. DEFIBRILLATION ELECTRODES CONNECTION

See "Manual" mode.

3. SET SYNCHRONISM OR NO SYNCHRONISM

See "Manual" mode.

4. SET ECG SOURCE

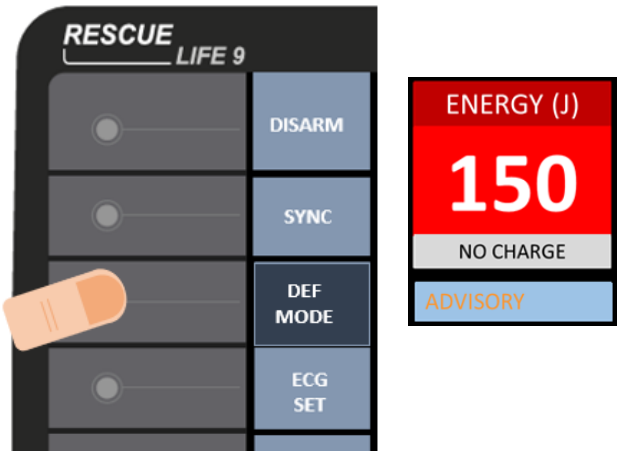
See "Manual" mode.

5. ATTACHMENT OF ECG SENSOR TO THE PATIENT

See "Manual" mode.

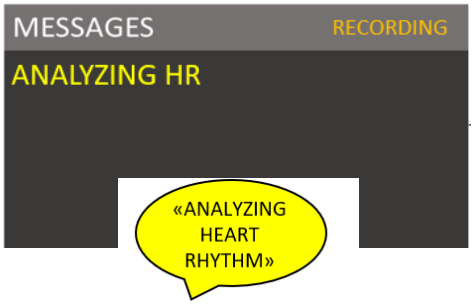
6. "ADV" MODE SELECTION

Press "DEF MODE" function to change from "MANUAL" (default) to "ADV".



7. ECG ANALYSIS

The defibrillator starts to ECG acquisition and classification: "ANALYZING HR" is shown on the MESSAGES box of the display and it is played as sound message. Also, recording of data starts automatically.



8. ECG CLASSIFICATION

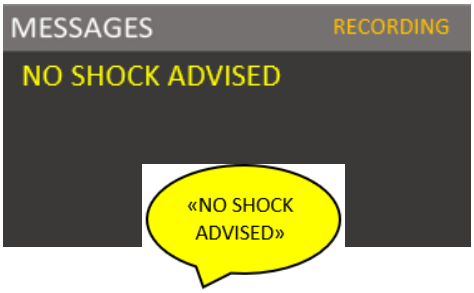
Two cases are possible:

CASE A) SHOCKABLE RHYTHM

"SHOCK ADVISED" is shown in the MESSAGES box of the display and it is played as sound message.

CASE B) NO SHOCKABLE RHYTHM

In this case "NO SHOCK ADVISED" is shown on the MESSAGES box of the display and it is played as sound message.



9. CHARGE DEFIBRILLATION ENERGY

See “Manual” mode.

10. DISCHARGE DEFIBRILLATION ENERGY

See “Manual” mode.

WARNINGS

DO NOT TOUCH THE PATIENT DURING ECG ANALYSIS

DO NOT TOUCH THE PATIENT DURING DEFIBRILLATION.

ENSURE A GOOD CONNECTION BETWEEN DISPOSABLE MULTIFUNCTION ELECTRODES AND PATIENT SKIN TO PROVIDE AN EFFECTIVE DEFIBRILLATION.

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

2.1.6.3 "AED" MODE

DESCRIPTION

In "AED" (Automated External Defibrillation) mode the defibrillator drives the operator through the rescue procedure using visible and audio guide (according to ERC Guidelines) and, if a ventricular fibrillation or ventricular tachycardia pulseless (heart rate > 150 BPM) are detected, automatically the defibrillator charges to 200 J the defibrillation energy and it enables the SHOCK BUTTON. The user cannot set another value as defibrillation energy, but it can use recommended DISPOSABLE MULTIFUNCTION ELECTRODES for PEDIATRIC patients, if the patient is pediatric, to deliver 50J as defibrillation energy, thanks to their attenuator.

After the initialization of defibrillator in AED mode, the operator should only deliver the shock and perform CPR when indicated.

If the patient is breathing post-resuscitation, the defibrillator should be left attached to allow for ECG acquisition and detection.

INTENDED USE

The AED mode is intended for emergency treatment of victims (adult or pediatric) of a sudden cardiac arrest, so with the following symptoms:

- un-consciousness;
- absence of normal breathing;
- lack of detectable pulse.

The AED mode is intended to be used by trained personnel: the operator should be qualified by training in Basic Life Support (BLS), Cardio-Pulmonary Resuscitation (CPR), Automated External Defibrillator (AED).

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, Ed. 2015

DO NOT USE THE AED MODE IN NEONATAL PATIENTS (0-1 YEARS OLD).

DO NOT USE STANDARD DEFIBRILLATION ELECTRODES IN "AED" MODE BUT USE ONLY DISPOSABLE MULTIFUNCTION ELECTRODES. **DO NOT** CREATE A SHORT CIRCUIT BETWEEN THE DISPOSABLE MULTIFUCTION ELCTRODES.

DO NOT PLACE THE DISPOSABLE MULTIFUNCTION ELECTRODES TOO CLOSE BETWEEN THEM. MAKE SURE THAT THEM ARE NOT TOUCHING THE ECG CABLE LEADS OR OTHER METALLIC PARTS THAT CAN CAUSE PATIENT SKIN BURNS.

DO NOT TOUCH THE PATIENT DURING ECG ANALYSIS

DO NOT TOUCH THE PATIENT DURING DEFIBRILLATION.

ENSURE A GOOD CONNECTION BETWEEN DISPOSABLE MULTIFUNCTION ELECTRODES AND PATIENT SKIN TO PROVIDE AN EFFECTIVE DEFIBRILLATION.

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

DEFIBRILLATION PROCEDURE IN "AED" MODE

1. POWER ON

Switch on the device pressing **ON/OFF BUTTON** [1];

2.DISPOSABLE ELECTRODES CONNECTION

1. Open the package of ADULT or PEDIATRIC DISPOSABLE MULTIFUNCTION ELECTRODES and pull out them;

2. Attach the pair of DISPOSABLE MULTIFUNCTION ELECTRODES to the patient (according to applicable protocol).

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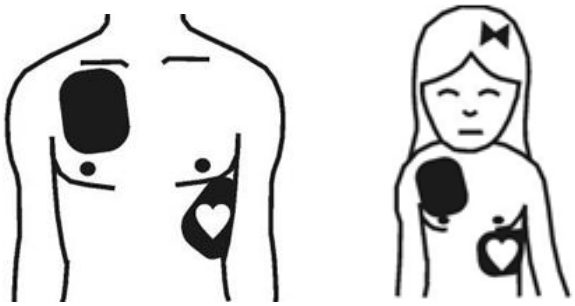
In the following, the two alternative solutions for attachment of the DISPOSABLE MULTIFUNCTION ELECTRODES to the patient are listed:

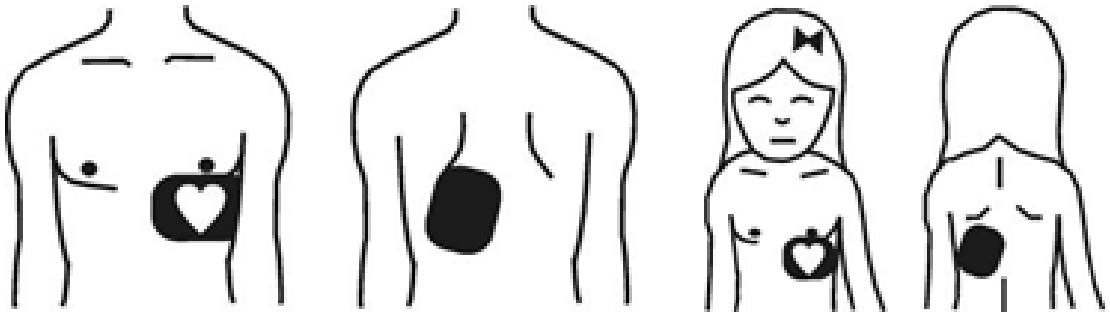
A) ANTERIOR-ANTERIOR



Front pad positioned below the right clavicle.

Lateral plate positioned on the middle axillary line at the height of his left nipple, position V6.

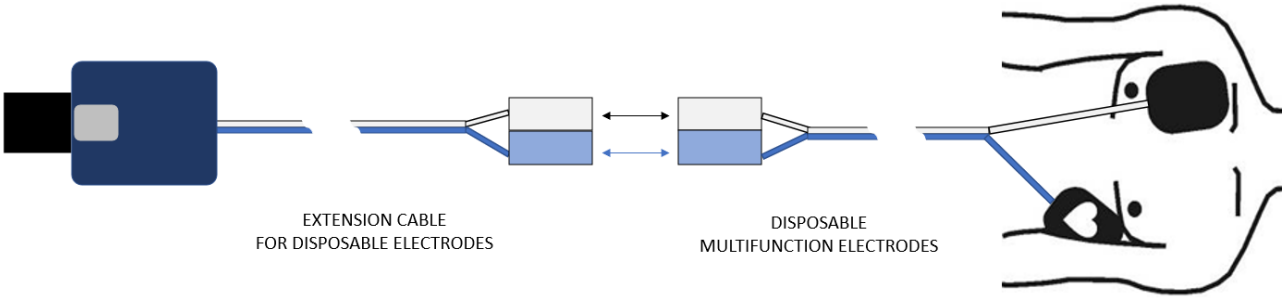
B) ANTERIOR-POSTERIOR



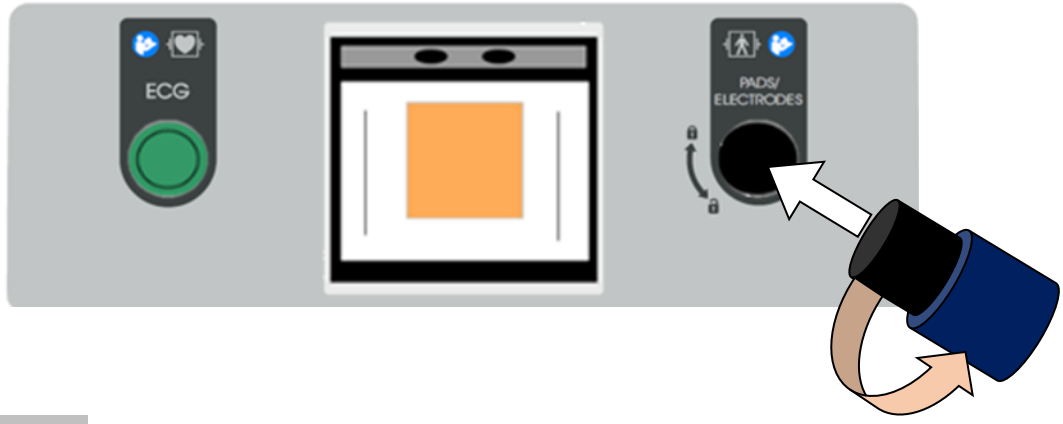
Front pad positioned on the left part of the chest, halfway between the xiphoid apophysis and the left nipple at the sites V2-V3.

Back pad positioned immediately below the left shoulder blade side of the spine at the same level than the front.

3. Connect the EXTENSION CABLE FOR DISPOSABLE ELECTRODES's connector to DISPOSABLE ELECTRODE'S connector;

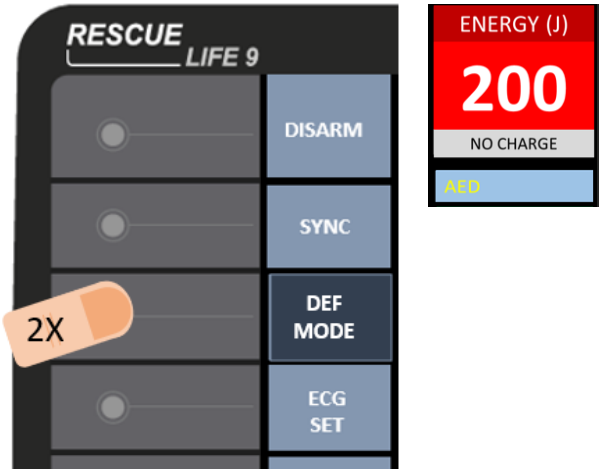


4. Insert and hold the EXTENSION CABLE FOR DISPOSABLE ELECTRODES's connector into "SHOCK PADS" port [10] (as explained in previous section) if it is not connected already to the main unit (see section 2.1.6).



3. AED MODE SELECTION

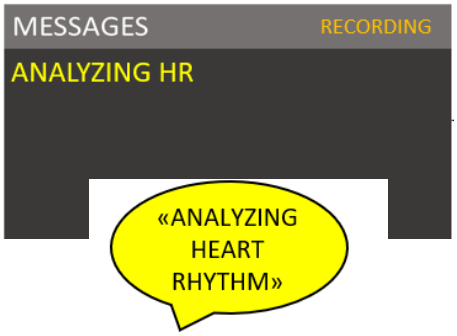
Press "DEF MODE" for 2 times; when "AED" will be shown on the display, this defibrillation mode is set. Automatically, the defibrillator set defibrillation energy to 200 J and it will start the ECG analysis.



2 - THERAPY

4. ECG ANALYSIS

The defibrillator starts to ECG acquisition and classification: “ANALYZING HR” is shown on the MESSAGES box of the display and it is played as sound guide. Also, recording of data starts automatically.

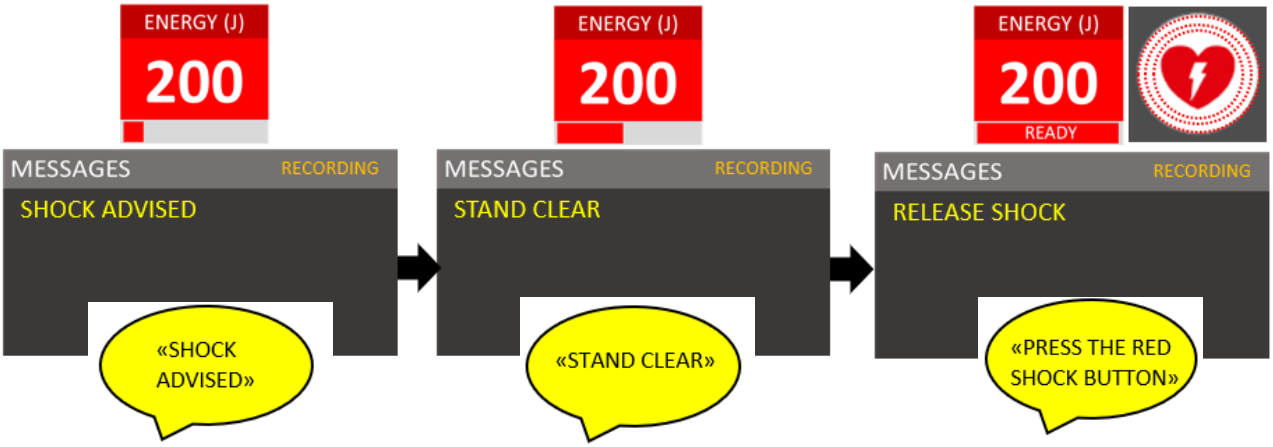


5. ECG CLASSIFICATION

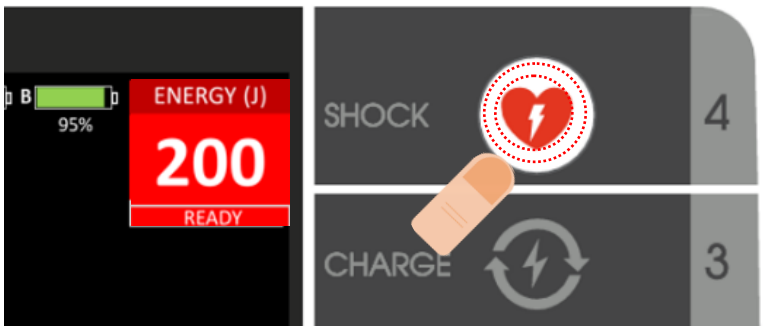
Two cases are possible:

CASE A) SHOCKABLE RHYTHM

1. Automatically defibrillator starts the defibrillation energy charging and “SHOCK ADVISED” is shown in the MESSAGES box of the display and it is played as sound guide. Also, a pulsed sound is reproduced and a red charge status bar starts.
2. Defibrillation energy “STAND CLEAR” is shown in the MESSAGES box of the display and it is played as sound guide.
3. When 200J defibrillation energy are charged completely it is available for patient: “READY” is shown in the red charge status bar, the red shock button is lighted and enabled for the user, “RELEASE SHOCK” is shown in the MESSAGES box of the display and “PRESS THE RED SHOCK BUTTON” is played as sound guide.



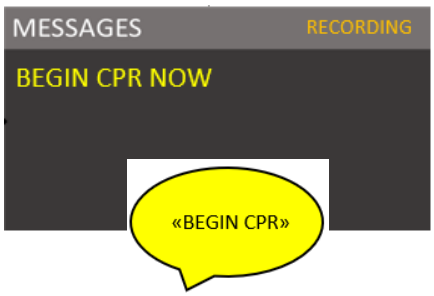
4. Press the SHOCK BUTTON to discharge 200J in the patient, within 15 seconds.



After 15 seconds the INTERNAL DISARM will be done automatically, if the SHOCK BUTTON is not pressed.

5. "SHOCK DELIVERED" is shown in the MESSAGES box of the display and it is played as sound messages when defibrillation energy is delivered.

6. "BEGIN CPR NOW" is shown in the MESSAGES box of the display and it is played as sound guide: the user must start the cardio-pulmonary resuscitation (according to applicable protocol).



The 100 compression/min metronome will play as sound guide for the user. After 2 minutes it will stop and the new cycle of ECG analysis re-start (see point 1).

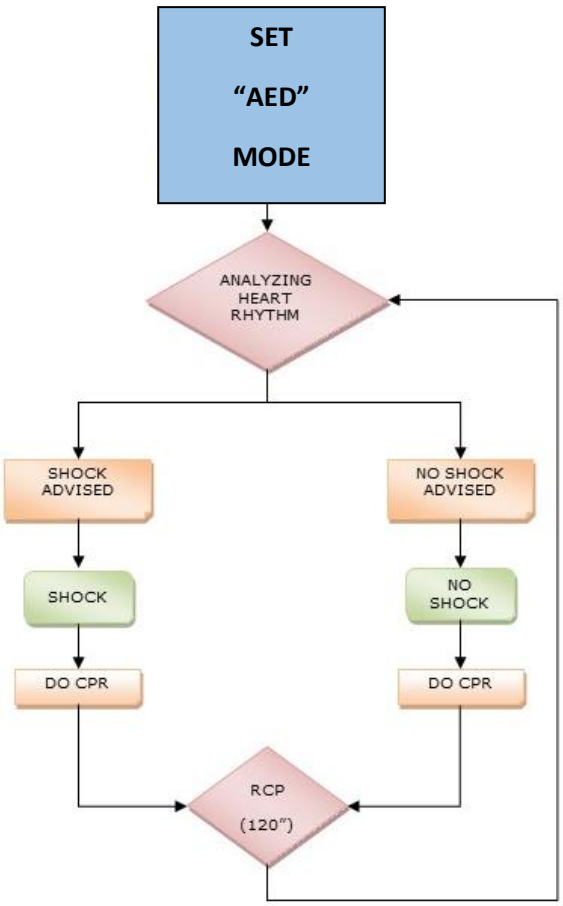
CASE B) NO SHOCKABLE RHYTHM

In this case "NO SHOCK ADVISED" is shown on the MESSAGES box of the display and it is played as sound message.

So, the defibrillator starts from point (6) of the previous case: "BEGIN CPR NOW".

IF ACQUIRED ECG PEAK-PEAK VOLTAGE IS LESS THAN 0.15 mV, THE ECG RECOGNITION IS NOT AVAILABLE.

AED MODE FLOW CHART



2.1.7 ESSENTIAL PERFORMANCE (REF. EN 60601-2-4:2011)

- Delivering defibrillation therapy;
- Delivering synchronized defibrillation therapy;
- Accurately differentiate between shockable and non-shockable rhythms

2.2 EXTERNAL PACING (OPTIONAL)

DESCRIPTION

The Rescue Life[9] offers a pacemaker module, also. It allows to delivers an external electrical stimulus to the heart. The energy must be delivered through the recommended DISPOSABLE MULTIFUNCTION ELECTRODES placed on the patient's chest (according to applicable protocol). In addition to non-invasive 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.

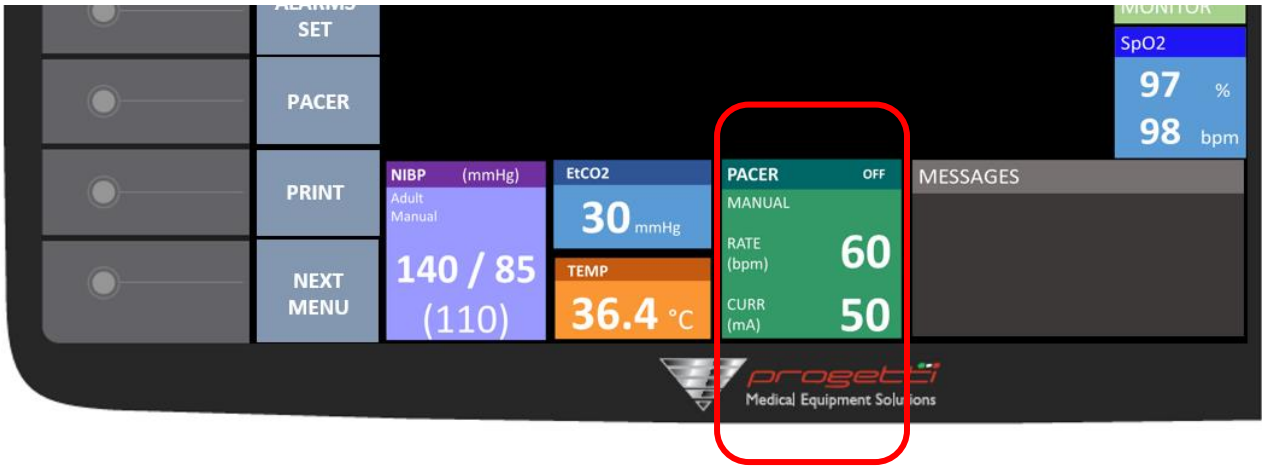
INTENDED USE

External pacing is intended to be used for treatment of symptomatic bradycardia in patients with a pulse.

External pacing is not intended for the treatment of ventricular fibrillation and asystole.

THE ECG TRACE WILL BE DISPLAYED AND THE DEMAND MODE IS AVAILABLE ONLY IF THE PATIENT CABLE IS CONNECTED (THE DISPOSABLE MULTINFUNCTION ELECTRODES ARE USED FOR PACING SO THEY CANNOT ACQUIRE THE ECG TRACE).

In the PACEMAKER FIELD you can review set pacemaker parameters.

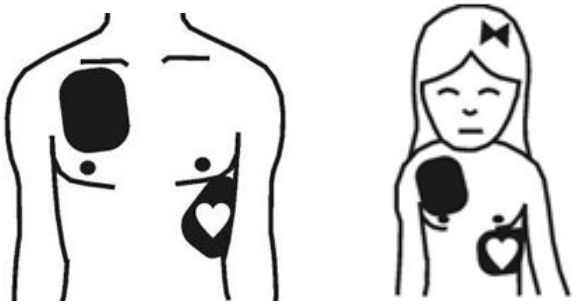


2.2.3 PACING PROCEDURE

1. Power ON the device pressing the **ON/OFF** button;
2. Attach the DISPOSABLE MULTIFUNCTION ELECTRODES on the patient's chest.

   In the following, the two alternative solutions for attachment of the DISPOSABLE MULTIFUNCTION ELECTRODES to the patient are listed:

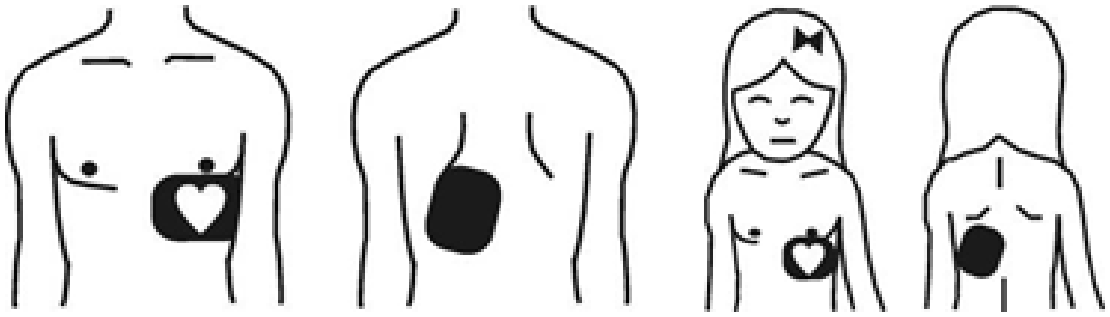
ANTERIOR-ANTERIOR



Front pad positioned below the right clavicle.

Lateral plate positioned on the middle axillary line at the height of his left nipple, position V6.

ANTERIOR-POSTERIOR

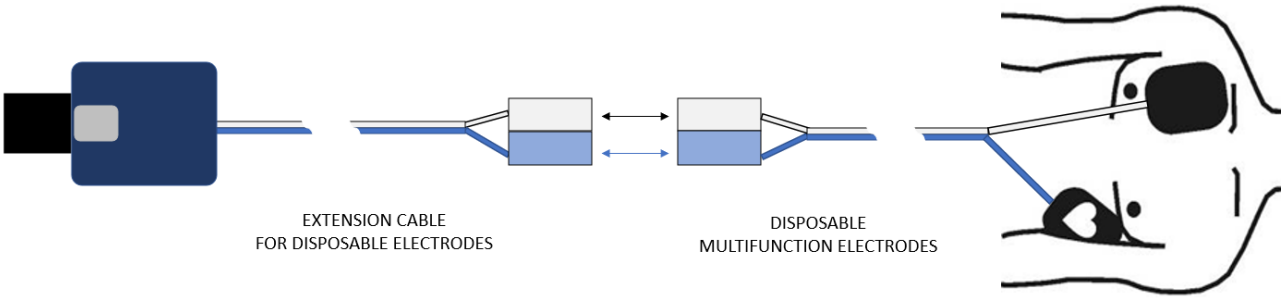


Front pad positioned on the left part of the chest, halfway between the xiphoid apophysis and the left nipple at the sites V2-V3.

Back pad positioned immediately below the left shoulder blade side of the spine at the same level than the front.

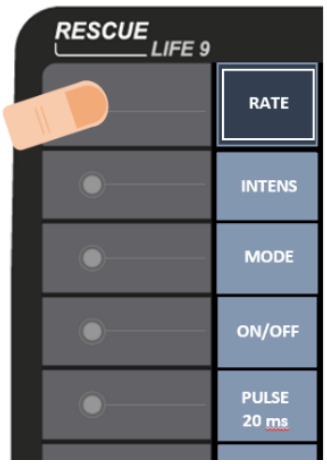
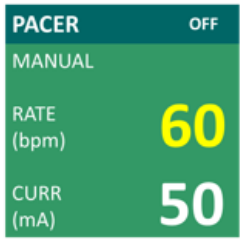
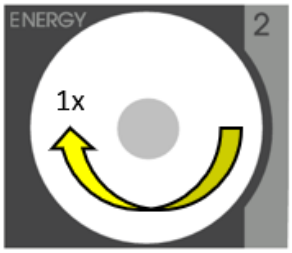
3. Insert and hold the EXTENSION CABLE FOR DISPOSABLE ELECTRODES' connector in "SHOCK PADS" port;

4. Connect DISPOSABLE MULTIFUNCTION ELECTRODES's connector to EXTENSION CABLE FOR DISPOSABLE ELECTRODES's connector;

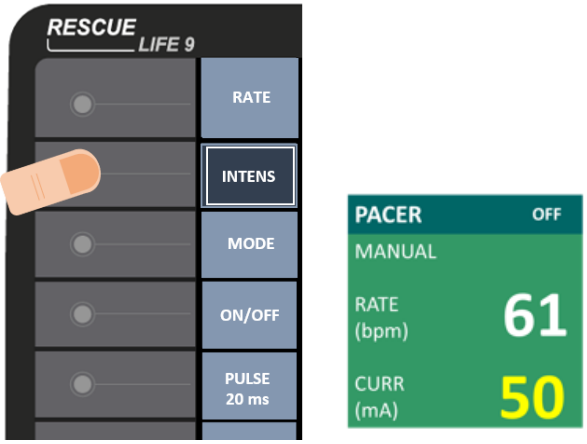
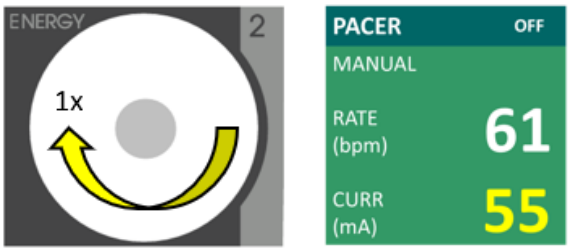
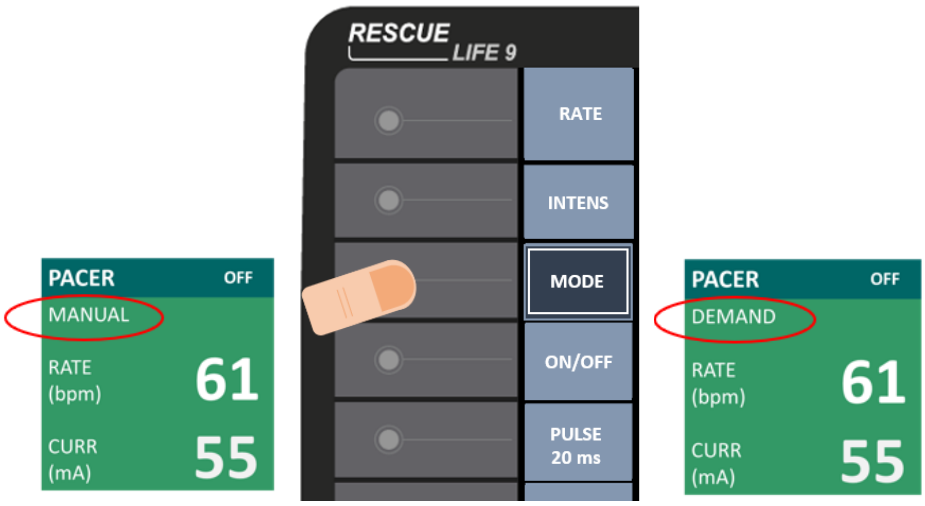


5. Press "**PACER" function** to set pacemaker parameters: RATE, CURRENT, MODE, ON/OFF

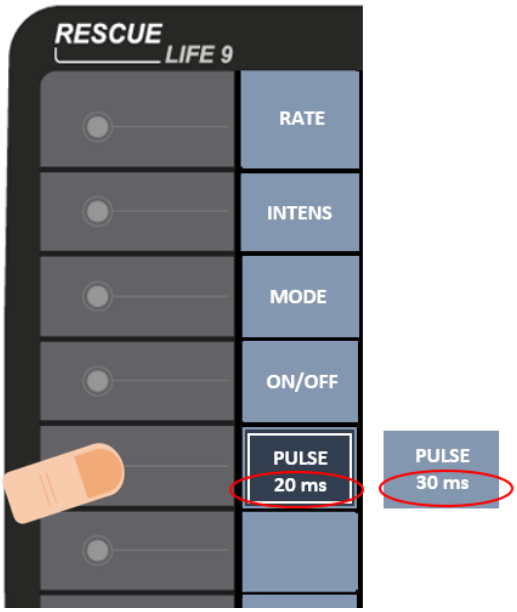
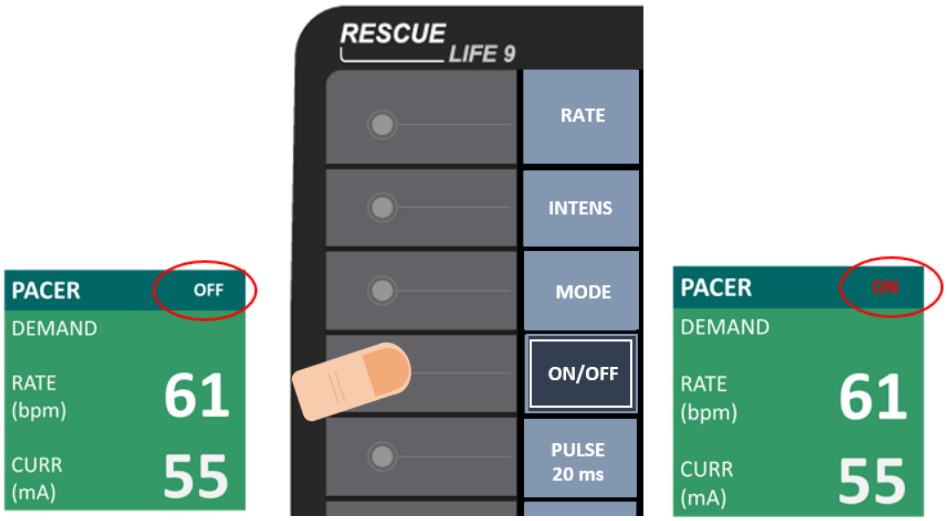
2 - THERAPY

PARAMETER	INSTRUCTION
RATE	1. Press “RATE” BUTTON to change the rate value: it will be highlighted in yellow.   2. Rotate KNOB [2] to change rate value [BPM].   3. Press “RATE” BUTTON again to save the new rate value.

2 - THERAPY

PARAMETER	INSTRUCTION
INTENSITY	1. Press “INTENS” BUTTON to change intensity value: it will be highlighted in yellow.  2. Rotate KNOB [2] to change current value [mA] and save it.  3. Press “INTENS” BUTTON again to save the new current value.
MODE	Press “MODE” BUTTON to change pacing mode (manual, demand). 

2 - THERAPY

PARAMETER	INSTRUCTION
PULSE	Press “PULSE” BUTTON to change time of pulse (20, 30, 40 ms). 
ON / OFF	Press “ON /OFF” BUTTON to enable/disable pacemaker. 
EXIT	Press “EXIT” BUTTON to exit.

3
ACQUISITION OF BIOMEDICAL PARAMETERS

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

3.1 ECG ACQUSITION

3.1.1 ECG PATIENT CABLE CONNECTION AND ELECTRODES PLACEMENT

The ECG is a record of the electrical activity of the heart. The ECG is obtained by placing either STANDARD ELECTRODES or DISPOSABLE ELECTRODES on the patient's chest 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 measurement of heart rate (HR).

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.

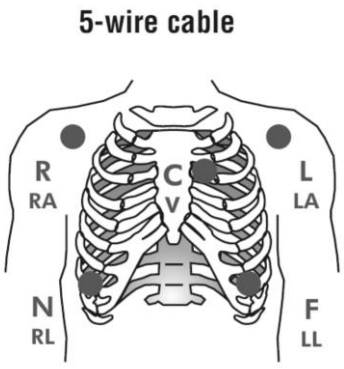
The frequency response of the monitor screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for diagnostic and ST segment interpretation. For diagnostic or ST segment interpretation, or to enhance internal pacemaker pulse visibility, attach the ECG cable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

3.1.2 PROCEDURE

1. ECG ELECTRODES ATTACHMENT

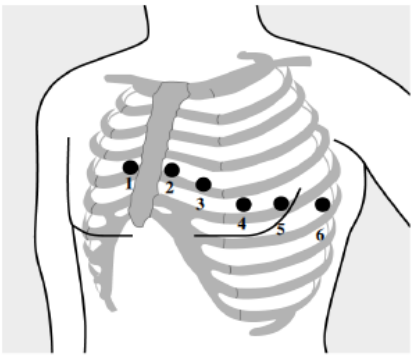
Follow the drawings below for the disposable ECG electrodes position on the patient's body.

Limb lead electrodes placement:



3 – ACQUISITION OF BIOMEDICAL PARAMETERS

Precordial lead electrodes sites for the 10 wires ECG cable:



V1/C1 placement: fourth intercostal space at right sternal margin.

V2/C2 placement: fourth intercostal space at left sternal margin.

V3/C3 placement: midway between V2 and V4.

V4/C4 placement: fifth intercostal space at left midclavicular line.

V5/C5 placement: same level as V4 on anterior axillary line.

V6/C6 placement: same level as V4 at left mid axillary line.

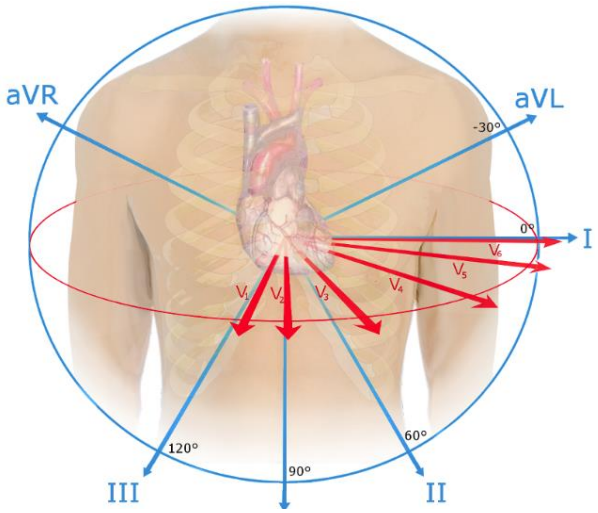


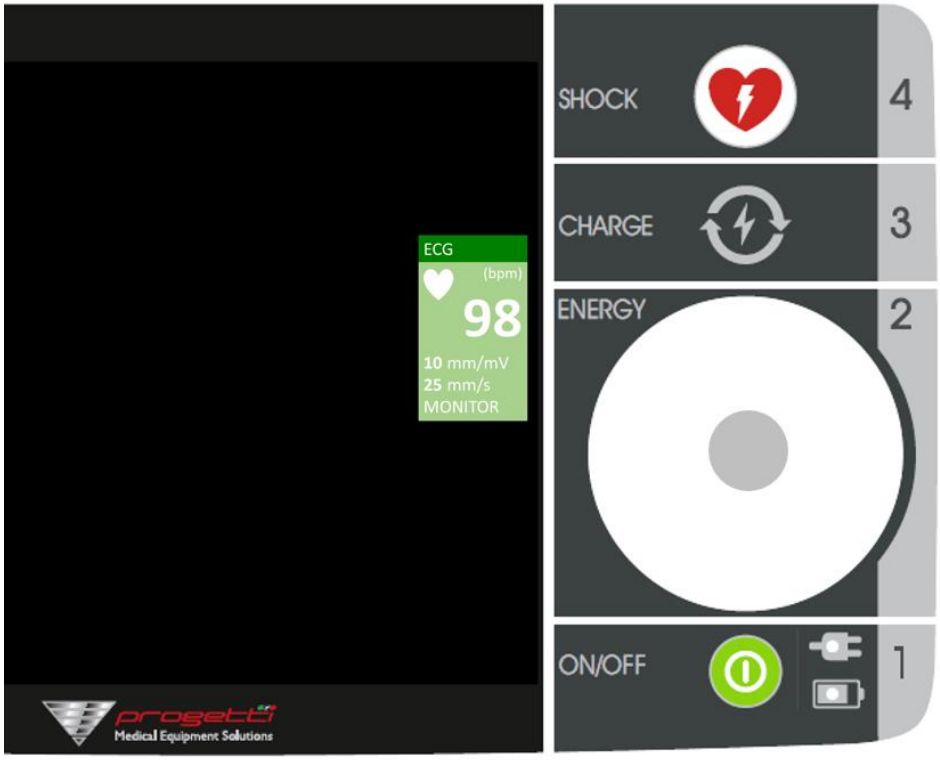
Figure. I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5, V6 derivations on frontal and orizzontal planes.

2. ECG CABLE CONNECTION

1. Insert ECG CABLE's connector in ECG port (intended ECG CABLE has 3, 5 or 10 wires).

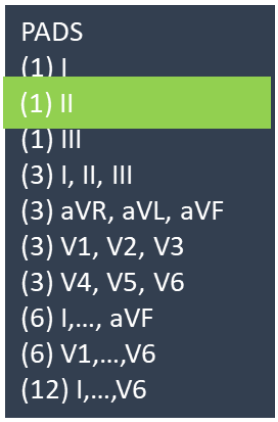
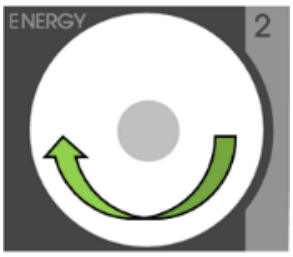
3 – ACQUISITION OF BIOMEDICAL PARAMETERS

2. Connect ECG CABLE's terminals to ECG ELECTRODES attached on the patient and check the ECG field on the display.

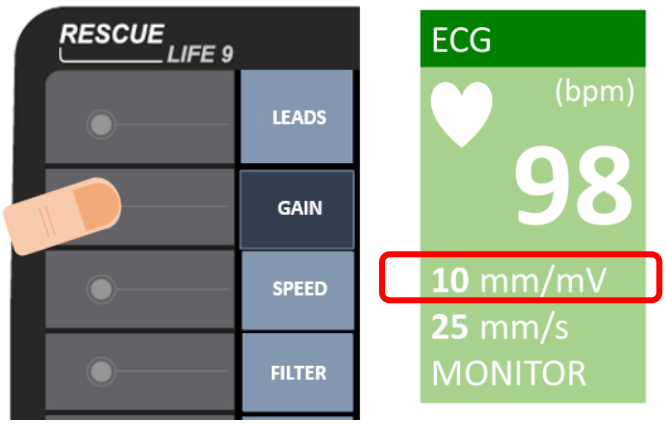
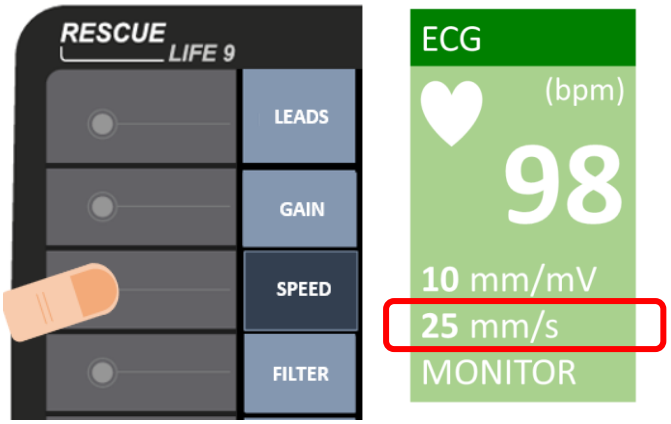


3. Press "ECG SET" function to set ECG parameters: leads, gain, speed and filter.

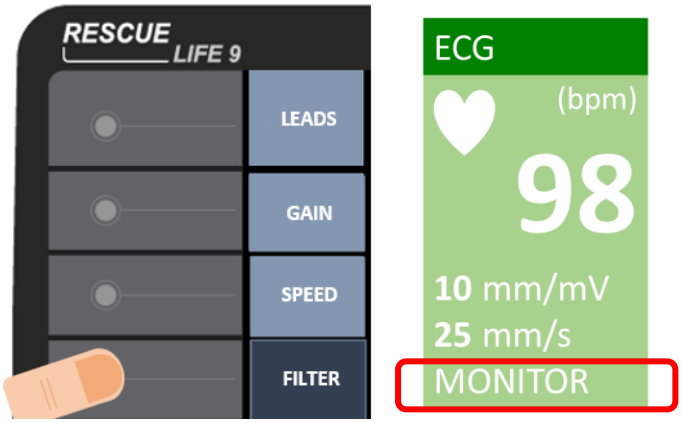
3 – ACQUISITION OF BIOMEDICAL PARAMETERS

PARAMETER	INSTRUCTION
LEADS	1. Press “LEADS” button;  2. Rotate KNOB to select the source leads to show on the display. Available visualizations are: I, II, III, I+II+III, aVR+aVL+aVF, V1+V2+V3, V4+V5+V6, I+II+III+aVR+aVL+aVF, V1+V2+V3+V4+V5+V6, I+II+III+aVR+aVL+aVF+V1+V2+V3+V4+V5+V6,   3. Press KNOB to confirm the selected view. On the display will be shown the selected leads.

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

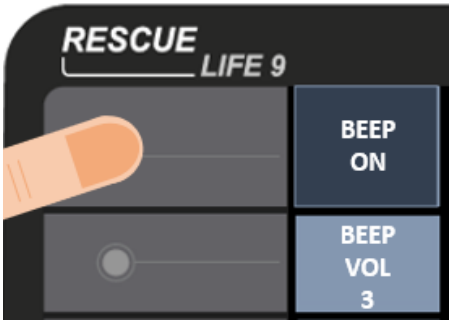
PARAMETER	INSTRUCTION
GAIN	Press "GAIN" button to change the value of gain (shown on the ECG field). Available gain values are: 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV. 
SPEED	Press "SPEED" button to change the value of speed (shown on the ECG field). Available speed values are: 5 mm/s, 10 mm/s, 25 mm/s, 50 mm/s. 

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

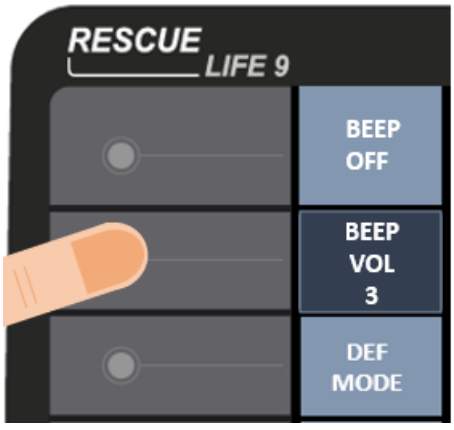
PARAMETER	INSTRUCTION
FILTER	Press “FILTER” button to change the type of filter. Available filters are: “MONITOR” (default) and “DIAGNOSTIC”. The change of filter is not possible if “PADS” is set. 

BEEP SETUP

The user can disable/enable the sound “BEEP” by pressing the “BEEP” button, as in the following figure:



The user can set the “BEEP” volume from level “1” (lowest) to “4” (highest) by pressing the “BEEP VOL”. For each push the intensity changes of 1 level

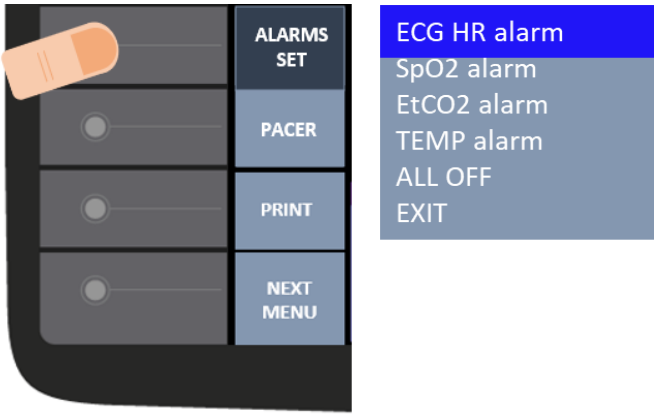


3 – ACQUISITION OF BIOMEDICAL PARAMETERS

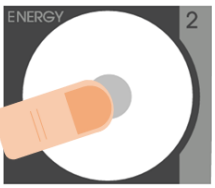
3.1.3. ECG ALARMS SETTING

ECG alarms can be enabled/disabled/reset pressing on “ALARMS SET” button.

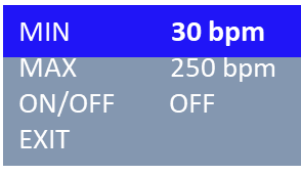
1. Press “ALARMS SET” and will be opened the list of alarms: “ECG HR alarm”, “SpO2 alarm”, “EtCO2 alarm”, “TEMP alarm”, “ALL OFF”;



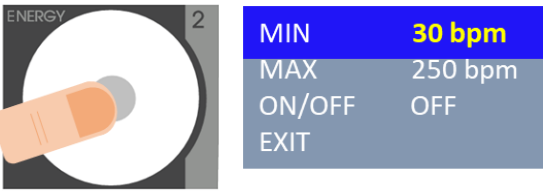
2. Press the KNOB to confirm “ECG HR alarm”;



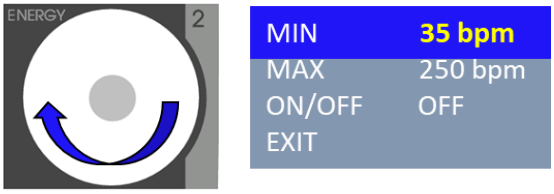
3. Rotate the KNOB to select the parameter to change between “MIN”, “MAX”, “ON/OFF”;



4. Press the KNOB to confirm the parameter to change. It will be shown in yellow;



5. Rotate the KNOB to change the value (default superior limit: 250 bpm, default inferior limit: 30 bpm);



6. Press the KNOB to confirm;
7. Rotate the KNOB to change another parameter;
8. Select "EXIT" to save and exit.

3.1.4 ECG PERFORMANCE (REF. §201.7.9.2.9.101 OF EN 60601-2-27:2016)

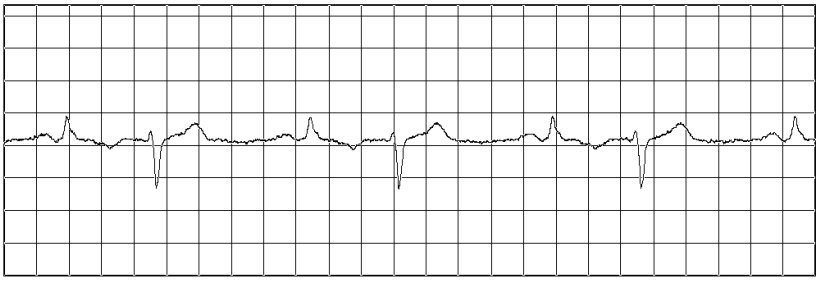
Heart Rate averaging (ref. b3):

- Heart Rate is averaged over the last 3 'R' peaks detected.

- Heart Rate update depends on the actual 'R' peaks repetition period (example: for 60 bpm the update is 3 seconds).

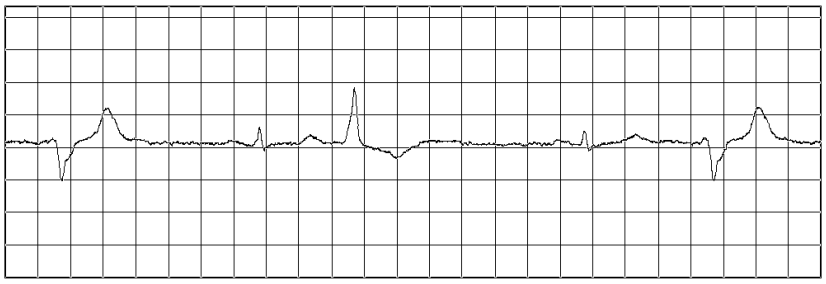
Heart Rate accuracy (ref. b4): (Fig. 201.101 of EN 60601-2-27)

- Waveform A1 (**Ventricular bigeminy**): HR = 40 bpm, larger R peaks counted

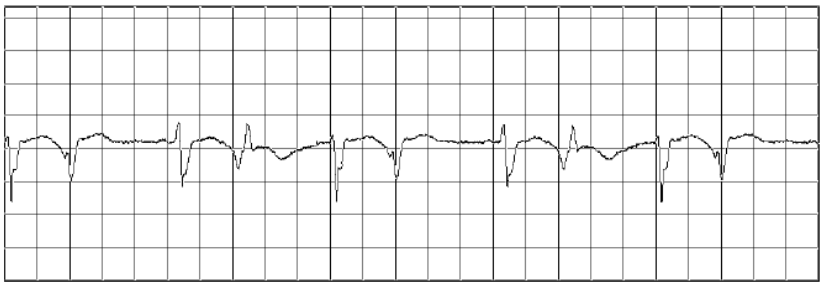


- Waveform A2 (**Slow alternating ventricular bigeminy**): HR = 30 bpm, only large complexes counted

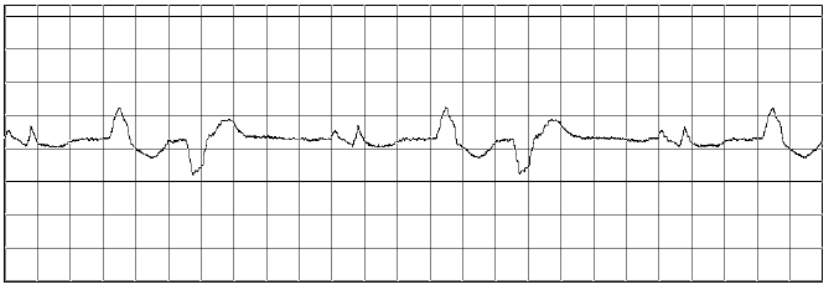
3 – ACQUISITION OF BIOMEDICAL PARAMETERS



- Waveform A3 (**Rapid alternating ventricular bigeminy**): HR = 120 bpm, all complexes counted



- Waveform A4 (**Bidirectional systoles**): HR = 45 bpm, large complexes are counted



Response time of Heart Rate (ref. b5):

- HR change from 80 to 120 bpm: 3.5 seconds, maximum 4 seconds

- HR change from 80bpm to 40 bpm: 3 seconds, maximum 3.5 seconds

Time to alarm (ref. b6):

The tachycardia (VT) as well as VF arrhythmia is detected when the defibrillator is set on “ADV” (advisory) or “AED” mode. The time for analysis and alarm is 6 seconds for ECG wave amplitude from 0.2 mV to 5 mV.

Visual and auditory alarms (ref. b8):

- Visual and auditory alarms are provided locally (on the device).

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

- The alarms are implemented for ECG HR, SpO2, O2 saturation, EtCO2 concentration and TEMPERATURE for monitoring functions.

- Technical alarms.

- Arrhythmia alarms (VF and VT) for defibrillator functions when in “AED” or “ADV” operation mode, visual and voice prompts.

- All alarms are high priority and independently can be disabled/reset.

- For all alarms with filter set as “MONITOR” including technical alarms audio tones are implemented following EN 60601-1-8 tones and timing:

ECG HR ALARM	:	C4 E4 G4 – A4 F4 repeated 2 times at 2 seconds interval
SpO2 ALARM	:	C5 B4 A4 – G4 F4 repeated 2 times at 2 seconds interval
EtCO2 ALARM	:	C4 A4 F4 – A4 F4 repeated 2 times at 2 seconds interval
TEMPERATURE ALARM	:	C4 D4 E4 – F4 G4 repeated 2 times at 2 seconds interval
TECHNICAL ALARM	:	C5 C4 C4 – C5 C4 repeated 2 times at 2 seconds interval

ALARM BURST example:

Internally powered equipment (ref. b9):

- One battery charge time: 120 min, two batteries 240 min

- Battery autonomy (with device switched on but without carrying out any operation): one battery 5 hours, two batteries 10 hours

- Number of 230 J shocks with fully charged one battery: 150, two batteries: 300

- Battery expected number of charging cycles: 300. After the maximum cycles numbers the battery will hold less than 75% energy.

Auxiliary output (ref. b10):

Not applicable, no signal output provided.

Sweep speeds (ref. b12):

- For the display and printer the selectable sweep speeds are:

5 mm/s, 10 mm/s, 25 mm/s, 50 mm/s.

3.1.5 ECG ESSENTIAL PERFORMANCE (REF. EN 60601-2-27:2014)

1. **Defibrillation protection**

2. **Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT**: If the SUPPLY MAINS to the ME EQUIPMENT is interrupted for 30 s or less, no change of OPERATOR settings occur, including the mode of operation, and all stored PATIENT data shall remain available.

3. **Protection against depletation of battery**: ME EQUIPMENT powered from an INTERNAL ELECTRICAL POWER SOURCE shall not cause a HAZARDOUS SITUATION to the PATIENT when the state of discharge can no longer maintain the NORMAL USE of the ME EQUIPMENT.

4. **Accuracy of signal reproduction:** Input signals in the range of ±5 mV, varying at a rate up to 125 mV/s, is reproduced on the output with an error of ≤ ±20 % of the nominal value of the output or ±100 µV, whichever is greater.

5. **Input dynamic range and differential offset voltage:** with a d.c. offset voltage in the range of ±300 mV and differential input signal voltages of ±5 mV that vary at rates up to 320 mV/s, when applied to any LEAD WIRE, the time-varying output signal amplitude not changes by more than ±10 % over the specified range of d.c. offset.

6. **Input impedance:** The input impedance is at least 2,5 MΩ within a d.c. offset voltage range of ±300 mV.

7. **Input noise**: The signal NOISE caused by the ECG amplifier and PATIENT CABLE shall not exceed 30 µV peak-to-valley referred to the input (RTI) for a period of at least 10 s. Any mains frequency notch filter, if provided, is to be turned on during this test.

8. **Multichannel crosstalk:** When an input signal limited in amplitude and rate as per 201.12.1.101.2 is applied to selected LEAD of the multi-channel ME EQUIPMENT, with all other LEAD WIRES connected to the N (RL) LEAD WIRE, the unwanted output in the unused LEADS is not greater than 5 % of the applied input signal.

9. **Gain control:** ME EQUIPMENT having PERMANENT and NON-PERMANENT DISPLAYS provides at least one fixed GAIN setting of (10 ± 1,0) mm/mV. In addition, continuously variable GAIN control is provided, if this mode is clearly indicated on all provided displays.

10. **Sweep speed:** ME EQUIPMENT with provides at least one sweep speed of 25 mm/s ±10 %. The sweep speed accuracy for any settings not varies by more than ±10 % over the complete horizontal ECG-channel width.

11. **Frequency response:** ME EQUIPMENT meet the requirement for a frequency response (bandwidth) of at least 0,67 Hz to 40 Hz when tested with the input signals from methods A and B.

12. **Impulse response**: The extended low-frequency response not produces a displacement greater than 0,1 mV RTI, nor a slope exceeding 0,3 mV/s immediately following the end of the impulse on the output when an input impulse of 0,3 mV•s (3 mV for 100 ms) is applied.

13. **Gain indicator:** A GAIN INDICATOR is provided that indicates the amplitude of an input voltage of 1 mV for each GAIN setting on PERMANENT and NON-PERMANENT DISPLAYS. The amplitude variation in display output shall be within ±10 % when applying a (1,00 ± 0,01) mV input signal at the appropriate LEAD. It is available for all LEADS. The GAIN setting may be provided alternatively as a numerical value expressed in mm/mV. ME EQUIPMENT providing only one fixed GAIN is exempt from the requirement to provide a GAIN INDICATOR.
14. **Common mode rejection**: A 10 V r.m.s. signal at mains frequency with 200 pF source capacitance, connected between earth and all LEAD WIRES connected together not produces an output signal greater than10 mm peak-to-valley at a GAIN setting of 10 mm/mV for not less than 15 s. In series with each ELECTRODE shall be a 51 kΩ resistor in parallel with a 47 nF capacitor. The PATIENT CABLE specified by the MANUFACTURER is used.

15. **Baseline reset**: means shall be provided for restoring the ME EQUIPMENT to its normal operating condition within 3 s after applying a 1 V peak-to-valley 50/60 Hz overload voltage for at least 1 s.

16. **Pacemaker pulse display capability:** ME EQUIPMENT is capable of displaying the ECG signal in the presence of pacemaker pulses with amplitudes of ±2 mV to ±700 mV and durations of 0,5 ms to 2,0 ms. An indication of the pacemaker pulse shall be visible on the display with an amplitude of no less than 0,2 mV referred to input (RTI). Alternatively, the position of pacemaker pulses may be indicated by artificially inserted pacemaker pulse flags. If the display capability of pacemaker pulses is affected by patient modes such as neonatal mode or filter settings the positions of these inserted pacemaker flags in these modes shall be verified.

17. **Rejection of pacemaker pulses**

18. **Syncronizing pulse for cardioversion:** If a pulse is available on a SIGNAL OUTPUT PART in order to synchronize a defibrillator discharge, the time interval from the R wave peak to the start of the synchronizing pulse shall not be greater than 35 ms. Pulse characteristics of amplitude, duration, shape and output impedance shall be disclosed in the ACCOMPANYING DOCUMENTS.

19. **Heart rate range, accuracy and QRS detection range:** The heart rate display range is at least 30 1/min to 200 1/min for adults and 30 1/min to 250 1/min for neonatal and paediatric use. The accuracy of the detected heart rate is at least±10% or ±5 1/min, whichever is greater. ECG input signals at rates that are lower than the specified lower display range limit not indicates a heart rate greater than this lower limit. ECG input signals at rates above the upper limit of the specified display range, up to 300 1/min for adults and 350 1/min for neonatal and paediatric use not detects heart rates lower than the specified upper limits. The minimum detection range of QRS amplitudes is 0,5 mV to 5 mV for durations of the QRS wave between 70 ms and 120 ms (40 ms and 120 ms for neonatal/paediatric ME EQUIPMENT). For ME EQUIPMENT set for adult PATIENTS, the heart rate meter not respond to ECG signals having a QRS amplitude of 0,15 mV or less, or a duration of 10 ms or less with an amplitude of 1 mV. Response to either or both of these types of signals is permitted in ME EQUIPMENT set for neonatal/paediatric PATIENTS.

20. **Channel height and aspect ratio**

21. **Tall T-wave rejection capability:** Disclosure is made of the maximum T-wave amplitude (aT) for which heart rate indication is within the error limits (specified in 201.12.1.101.15.). If the maximum T-wave amplitude (aT) that can be rejected is affected by bandwidth chosen, also disclose separately the maximum T-wave amplitude rejected for each bandwidth.

22. **Electrosurgery interference**: When the ME EQUIPMENT is used together with HF SURGICAL EQUIPMENT it returns to its previous operating mode within 10 s after exposure to the field produced by the HF SURGICAL EQUIPMENT without loss of any stored data.

23. **Time to alarm for heart rate alarm conditions**: The ALARM SIGNAL GENERATION DELAY for cardiac standstill (asystole) not exceeds 10 s. The sum of ALARM CONDITION DELAY and ALARM SIGNAL GENERATION DELAY for ALARM SIGNALS for low heart rate or high heart rate ALARM CONDITIONS not exceeds 10 s.

24. **Technical alarm condition indicating inoperable ME EQUIPMENT**: ME EQUIPMENT is provided with means to indicate within 10 s that the ME EQUIPMENT is inoperable due to an overload or saturation of any part of the ECG amplifier and due to disconnected ECG LEAD WIRES.

3.1.6 CAUTION (REF. 201.7.9.2.9.101 OF EN 60601-2-27:2014)

Heart rate affection (ref. a9)

The heart rate may be affected by pacemaker pulses with an ineffective paced QRS pattern.

The heart rate will be affected by arrhythmia. When the defibrillation mode is set in “AED” or “ADV” the VF or VT with heart rate more than 150 bpm rhythm are recommended as shockable.

Default settings (ref. a10):

- Alarms: all OFF, ECG HR alarm: min 30 bpm – max 250 bpm, SpO2 alarm: min 70%, EtCO2 alarm: max 120 mmHg, TEMP alarm: min 20°C – max 40°C.

- ECG gain: 10 mm/mV, sweep speed: 25 mm/s, filters: “MONITOR” mode, defibrillation mode: “MANUAL”, energy: 150 J, pace rate: 60 bpm, pace current: 50 mA.

Fault finding methods (ref. a12)

- In case of ECG base line fluctuation:
  - Verify the disposable ECG electrodes placement;
  - Make sure patient is not moving.
- In case of ECG with line noise:
  - Verify that the electrodes are not touching metallic parts or grounded parts;
  - Set filter as “MONITOR”.
- In case of impedance error (“ATTACH PADS” message is shown on the display) verify the positioning of the STANDARD DEFIBRILLATION ELECTRODES. If DISPOSABLE MULTIFUNCTION ELECTRODES are in use make sure enough conductive gel is applied on each electrode.
- In case of SpO2 values missing, verify the positioning of the SPO2 sensor.
- In case of EtCO2 values missing verify the sensor positioning and check the tubing for obstructions.

PMK pulses rejected (ref. a13)

- 13.a - Rejects pace pulses alone from ± 2 mV to ± 700 mV and width of 0.1 ms to 2 ms;
- 13.b - Rejects pace pulses with normally paced QRS and T-wave range as per 13.a

PS interruption (ref. a14):

After interruption of SUPPLY MAINS more than 30 seconds the device continues to operate on the batteries supply without loss of functionality or setup.

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

Technical alarms (ref. a15):

Technical alarms cannot be disabled.

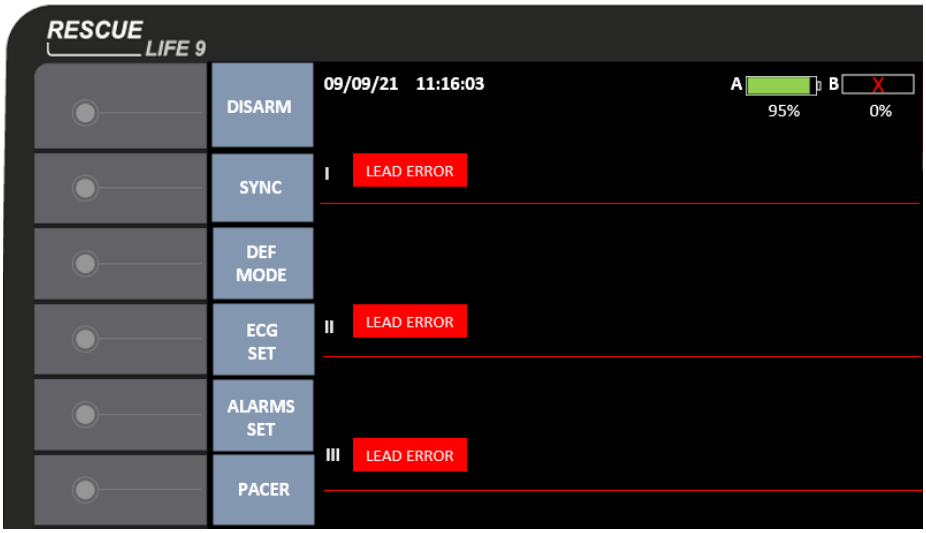
Advise on alarm settings (ref. a16):

It is recommended to activate the ECG HR alarm and to use “ADV” mode if monitoring patients that are not continuously attended by a clinical OPERATOR.

Respiration, Leads off (ref. b1):

- No respiration detection is implemented.

- Lead off detection is implemented by a DC current of 6 nA, 2.5 V maximum, applied on each ECG lead. “LEAD ERROR” is shown on the red line. In this case, check the connection skin-electrodes or electrode-ECG cable or ECG CABLE-defibrillator.



- The transthoracic impedance is measured by applying an AC sinusoidal waveform, 30 kHz, 5µA_{RMS}, maximum 2.5 V_{PP} between the DEFIBRILLATION ELECTRODES.

Tall T-wave (ref. b2):

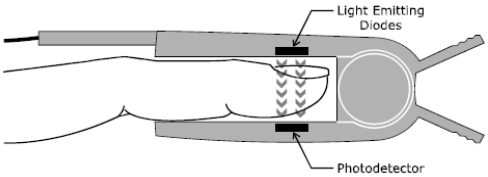
T-wave with amplitude up to 100% of ‘R’ peak is rejected.

PMK pulse rejection disabling (ref. b11):

- Pulse rejection cannot be disabled. For rejection disclosure see a13).

3.2 SpO_2 ACQUISITION (optional)

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-pulsed absorbers such as tissue, bone, and venous blood.

SPO_2 SENSORS

The RESCUE LIFE 9 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 9.

The following table shows all available sensors that may be used with the RESCUE LIFE 9. Choose the sensors to suit the weight of the patient.

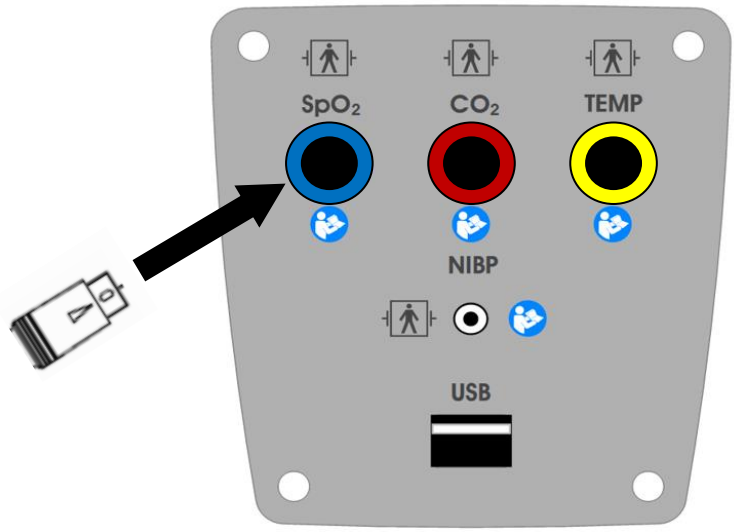
Reusable sensors may be reused on different patients after cleaning and disinfecting.

Do not use other sensors aside from the ones recommended.

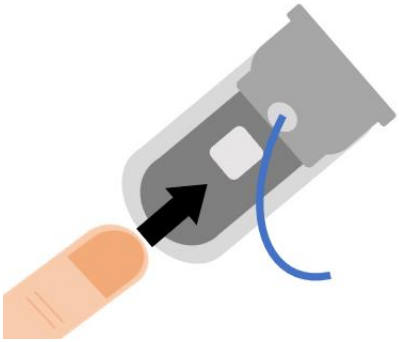
3 – ACQUISITION OF BIOMEDICAL PARAMETERS

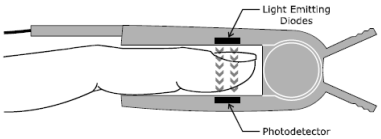
3.2.1 PROCEDURE

1. Insert SpO2 SENSOR's connector in SpO2 PORT, as shown in the follow picture:



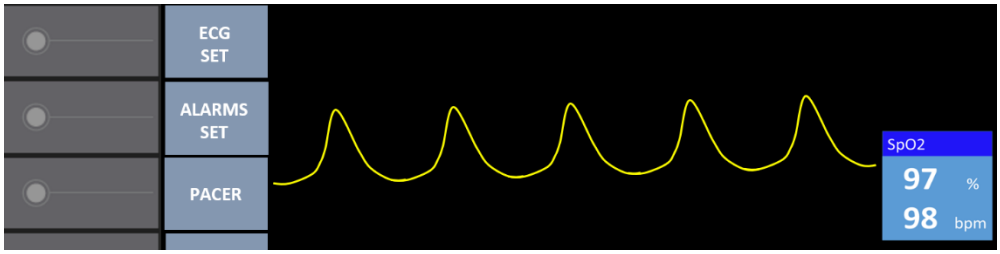
2. Apply SpO2 SENSOR to patient's finger, as shown in the follow picture.





3. Read measures on the display's SpO2 box: "%" and "BPM".

   If only one ECG lead is set to show on the display ("PADS" for example) then SpO2 waveform (yellow) is shown on the display automatically. About 10 seconds from the application to the patient's finger are needed to view the stable waveform.

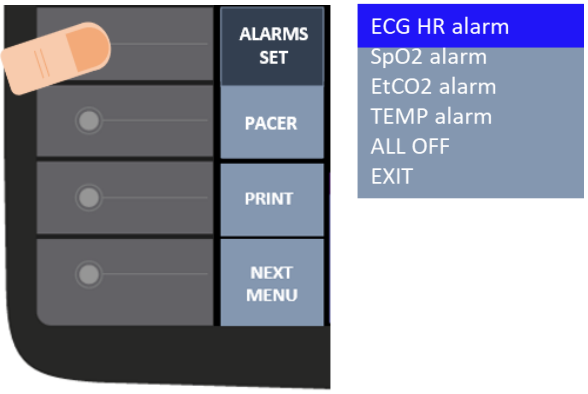


3.2.2. SPO2 ALARMS SETTING

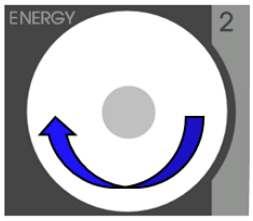
The SpO_2 alarm can be set to warn if the SpO_2 value goes outside of the set inferior limit. If the SPO_2 value is lower than the inferior limits, an alarm tone alerts the user.

SpO2 alarms can be enabled/disabled/reset pressing on “ALARMS SET” button.

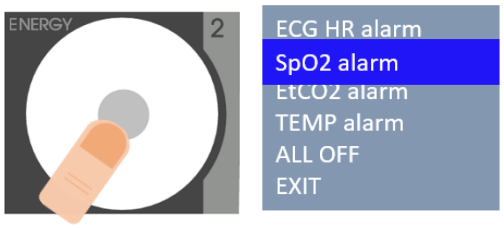
1. Press “ALARMS SET” and will be opened the list of alarms: “ECG HR alarm”, “SpO2 alarm”, “EtCO2 alarm”, “TEMP alarm”, “ALL OFF”;



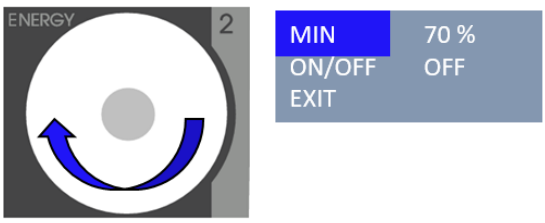
2. Rotate the KNOB to select “SpO2 alarm”;



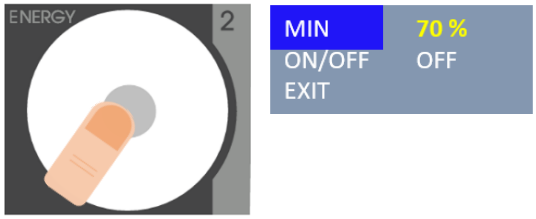
3. Press the KNOB to confirm “SpO2 alarm”;



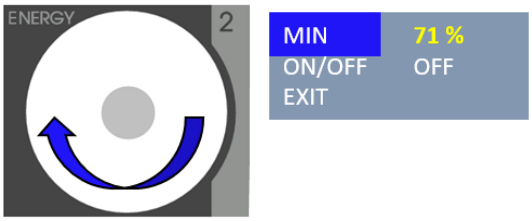
4. Rotate the KNOB to select the parameter to change between “MIN” and “ON/OFF”;



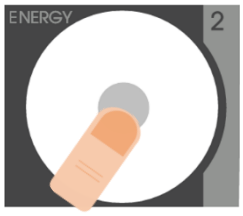
5. Press the KNOB to confirm the parameter to change. It will be shown in yellow;



6. Rotate the KNOB to change the value (default inferior limit: 70%);



7. Press the KNOB to confirm;



8. Rotate the KNOB to change another parameter;
9. Select “EXIT” to save and exit.

3.2.3 SPO_2 ESSENTIAL PERFORMANCE (REF. ISO 80601-2-61:2017)

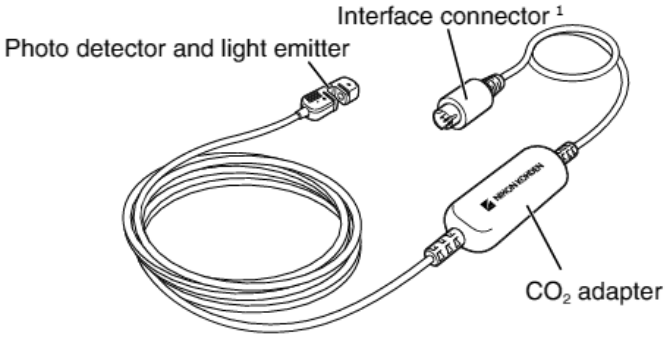
- SpO_2 accuracy
- Pulse rate accuracy
- Limit alarm condition

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

3.3 $EtCO_2$ ACQUISITION (optional)[2]

The TG-981T CO_2 sensor kit is intended for medical purposes to measure the concentration of expired CO_2 in a gas mixture of a patient and send the processed digital data such as end tidal CO_2 ($EtCO_2$) and respiration rate to the Rescue LIFE[9].

The mainstream CO_2 measurement principle is based on the fact that CO_2 absorbs 4.3 µm wavelength infrared light well. Infrared light is emitted from the emitter on the CO_2 sensor, passes through the CO_2 sensor cell where some is absorbed by CO_2 in the cell, then the unabsorbed light is detected by the detector. The CO_2 concentration in the respiration is calculated from the ratio of unabsorbed infrared light that passed through the CO_2 sensor cell and reference infrared light that does not go through the CO_2 sensor cell (single wave spectroscopic method).



Model	Weight	Dead Space	Flow Resistance
YG-211TW	7 kg or more	4 mL	0.1 kPa (10 mmH_2O) or less at 50 L/min
YG-213TW[1]	—	0.5 mL	0.08 kPa (8 mmH_2O) or less at 10 L/min
YG-214TW[1]	—	1.8 mL	

WARNING - Never disassemble or modify the CO_2 sensor kit. If the CO_2 sensor kit is disassembled or modified, the patient and operator may receive electrical shock or skin burn.

WARNING – Do not diagnose a patient based only on data acquired by the connected instrument. Overall judgement must be performed by a physician who understands the features and limitations.

CAUTION – Never autoclave or perform EOG gas sterilization for the CO_2 sensor kit because this damages the airway adapter and the CO_2 sensor kit and safety cannot be guaranteed.

[2] Ref. TG-981T Instruction for Use - 7th edition of 26/02/2020

CAUTION – Do not pull or bend the CO_2 sensor cable, and do not let caster feet run over the cable. Failure to follow these instructions may cause cable discontinuity, short circuit, skin burn on the patient form the sensor temperature increase due to the short circuit of the cable and measurement cannot be performed. If the CO_2 sensor is broken, replace it with a new one.

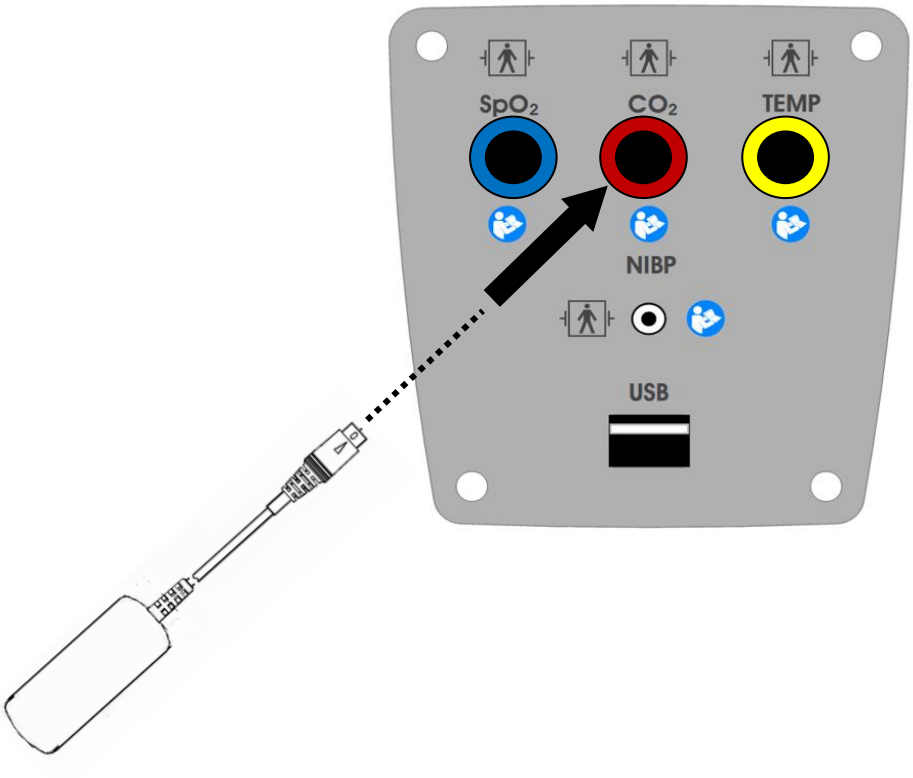
CAUTION – This CO_2 sensor kit is calibrated by taking the expired gas to be 37°C temperature and 100% humidity. Measured data varies about -0.4%/°C.

CAUTION – Keep magnetic objects away from the CO_2 sensor. The magnetic objects may cause an incorrect waveform and measurement value to be displayed.

CAUTION – The measured value may be incorrect when the operating temperature changes greatly.

3.3.1 PROCEDURE

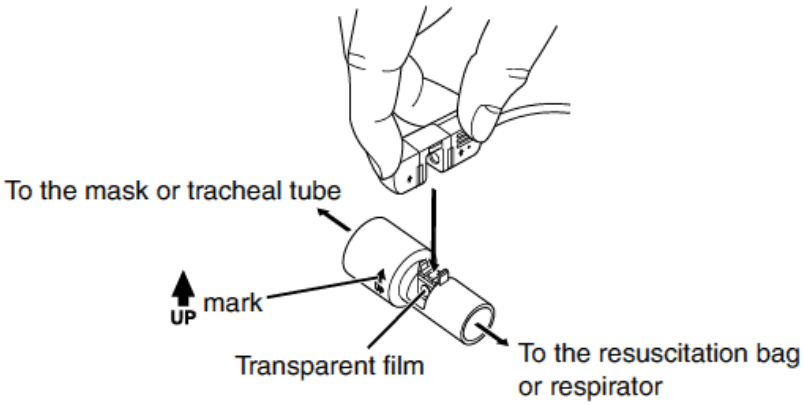
1. Insert $EtCO_2$ ADAPTER's connector in $EtCO_2$ PORT



3 – ACQUISITION OF BIOMEDICAL PARAMETERS

The calibration starts and ends automatically. If “LEADS” are set on “PADS”, the display changes himself as in the following picture:

2. Hold the CO_2 SENSOR as shown and attach the sensor to recommended DISPOSABLE AIRWAY ADAPTER until it clicks. You can attach the sensor in either direction.



NOTE: When connecting the airway adapter to the CO2 sensor, avoid touching the transparent film of the airway adapter with your fingers or any hard object, and avoid the transparent film from dust or chemical solutions. Otherwise measurement may be inaccurate.

3. Connect the airway adapter to the respiration circuit of the respirator.

Connect the larger end of the airway adapter to the mask or tracheal tube of the patient, and the smaller end to the resuscitation bag or respirator.

WARNING – Do not use the YG-211TW airway adapter on a neonate because the dead space of the airway adapter is about 4 ml.

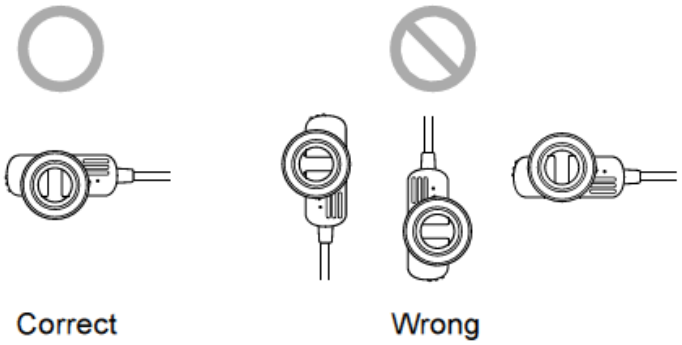
3 – ACQUISITION OF BIOMEDICAL PARAMETERS

CAUTION – Only use the specified airway adapter. Otherwise, the maximum performance cannot be guaranteed due to larger dead space, leak or insecure circuit connection, etc.

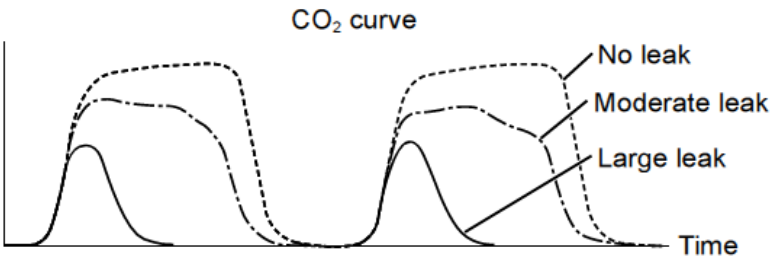
CAUTION – Use the YG-211TW airway adapter with patients over 7 kg.

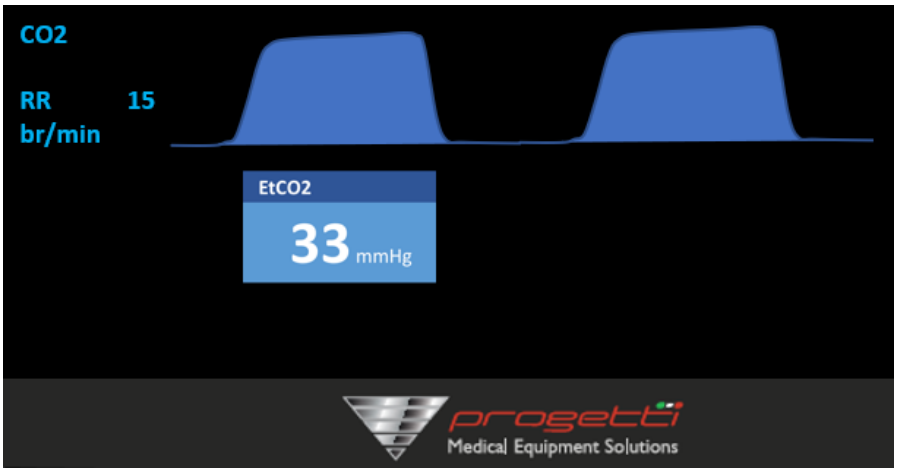
CAUTION - When using the YG-213TW or YG-214TW airway adapter, fix an endotracheal tube to the respiration circuit so as not to bend the tube.

CAUTION - Secure the CO_2 sensor to the respiration circuit so that the arrow of the UP mark on the airway adapter is pointing upward. Otherwise, water droplets may accumulate inside the airway adapter and affect the measurement accuracy.



4. Check that there is no leak in the respiration circuit.
5. Attach the CO_2 sensor to a support arm so that the weight of the CO_2 sensor does not affect the patient. Secure it properly.
6. Read measurement on display's EtCO2 box and RR Waveform [br/min] and check that the $EtCO_2$ is measured correctly.



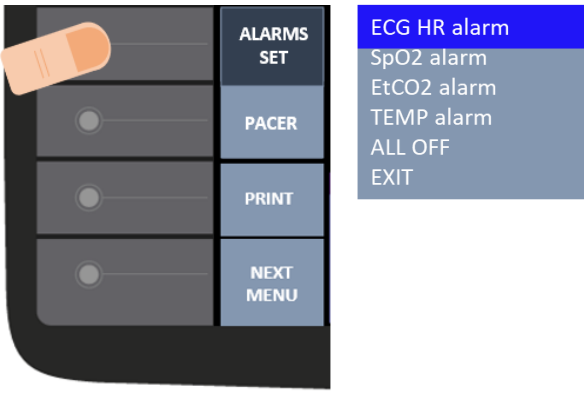


3.3.2. $ETCO_2$ ALARM SETTING

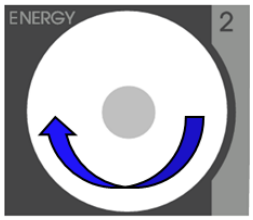
The $EtCO_2$ alarm can be set to warn if the $EtCO_2$ value goes outside of the set superior limit. If the $EtCO_2$ value is higher than superior limit, then an alarm tone alerts the user.

$EtCO_2$ alarm can be enabled/disabled/reset pressing on “ALARMS SET” button.

1. Press “ALARMS SET” and will be opened the list of alarms: “ECG HR alarm”, “SpO2 alarm”, “EtCO2 alarm”, “TEMP alarm”, “ALL OFF”;

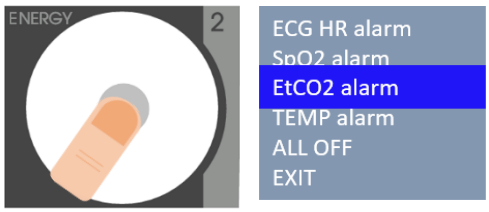


2. Rotate the KNOB to select “EtCO2 alarm”;

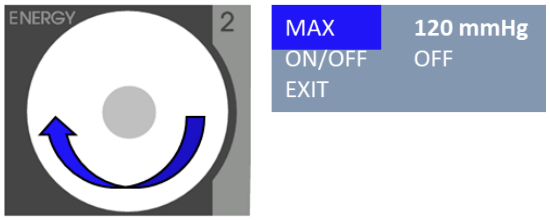


3 – ACQUISITION OF BIOMEDICAL PARAMETERS

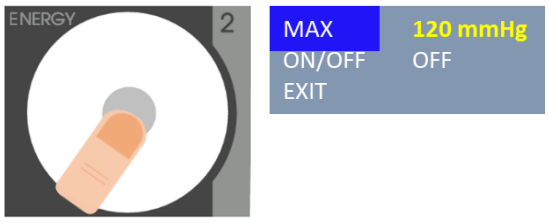
3. Press the KNOB to confirm “EtCO2 alarm”;



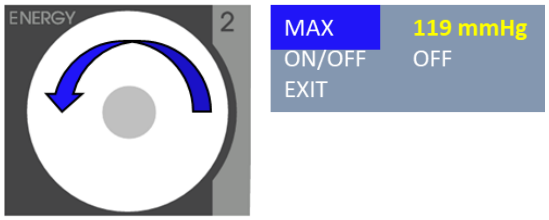
4. Rotate the KNOB to select the parameter to change between “MAX” and “ON/OFF”;



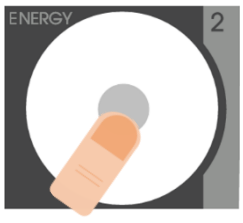
5. Press the KNOB to confirm the parameter to change. It will be shown in yellow;



6. Rotate the KNOB to change the value (default superior limit: 120 mmHg);



7. Press the KNOB to confirm;



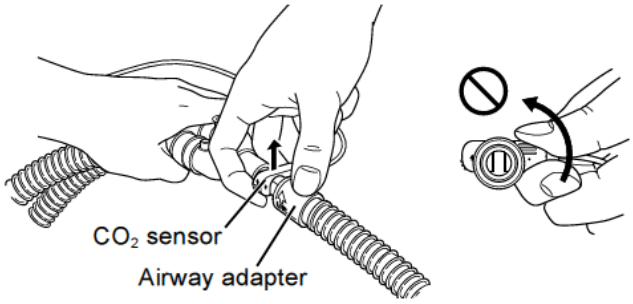
8. Rotate the KNOB to change another parameter;

9. Select “EXIT” to save and exit.

3.3.4. REMOVING THE ETCO$_2$ SENSOR KIT

CAUTION - When removing the CO_2 sensor, do not hold the cable or one side of the sensor. The cable may break or excessive force may damage the CO_2 sensor.

When removing the CO_2 sensor from the airway adapter, hold the respiration circuit firmly with one hand and hold the CO_2 sensor straight up with the index finger and middle finger.



3.3.5. CHECK BEFORE AND AFTER USE

To use the CO_2 sensor kit safely and properly, check the following items:

- No scratches, damage or dirt on the CO_2 sensor kit and cables
- No fluid or blood on the CO_2 sensor kit and cables
- No dirt on the photo detector and light emitter on the CO_2 sensor and transparent film on the airway adapter
- Airway adapter is not damaged or deformed

3.3.6 CLEANING AND DISINFECTION

CAUTION - Do not use corrosive solutions or solutions with polishing agents.

CAUTION - Do not clean the CO_2 sensor with steel wool or sharp objects because it scratches the sensor and causes incorrect measurement.

CAUTION - Do not use volatile liquids such as thinner, benzine or industrial alcohol because these damage the sensor surface.

After using the CO_2 sensor, clean the CO_2 sensor with a cotton swab moistened with any of the following liquids and leave it to dry. Clean and disinfect the other parts of the CO_2 sensor with any of the following liquids:

- Ethanol (15°C (59 F), 76.9 to 81.4% by vol)
- Diluted mild detergent

You cannot clean, disinfect or sterilize them. Immediately replace them with ones when they become dirty.

NOTE: When using flammable solvent such as ethanol for cleaning and disinfecting, ventilate the room adequately.

3.3.7 $ETCO_2$ MODULE SPECIFICATIONS

Measuring method	Mainstream
Measuring range	0 to 20 kPa (0 to 150 mmHg)
Measuring accuracy	± 0.27 kPa (0≤ CO_2 ≤ 5.33 kPa) ± 2 mmHg (0≤ CO_2 ≤ 40 mmHg) ± 5% of gas level (5.33 < CO_2 ≤ 9.33 kPa) ± 5% of gas level (40 < CO_2 ≤ 70 mmHg) ± 7% of gas level (9.33 < CO_2 ≤ 13.3 kPa) ± 7% of gas level (70 < CO_2 ≤ 100 mmHg) ± 10% of gas level (13.3 < CO_2 ≤ 20 kPa) ± 10% of gas level (100 < CO_2 ≤ 150 mmHg) (noncondensing)
Accuracy stability	Measurement accuracy is guaranteed for 6 hours after power on
Total system response time	≤ 0.5 s
Powe source	3.3 V_{DC} ± 5% to 5 V_{DC} ± 5%
Detectable respiration rate	0-150 breaths/min ± 1 breath/min
Rise time	< 60 ms for 10% to 90%
$EtCO_2$ calculation	Calculated from the maximum CO_2 in expiration
Data sampling rate	40 Hz
Warm-up time	about 10 s
Degree of protection provided by enclosures	Sensor part: IP67 (not protected during use) Adapter part: IP34
Degree of protection against shock	MIL STD 810G: 2008 516.6 4.6.5 (except interface connector) Shock resistance: 100 drops from 2 m (except interface connector)
Degree of protection against electrical shock	Defibrillator-proof type BF applied part
Degree of safety of application in the presence of FLAMMABLE ANAESHETIC MIXTURE WITH AIR, OR OXYGEN, OR NITRUS OXIDE	Equipment not suitable for use in the presence of FLAMMABLE ANAESHETIC MIXTURE WITH AIR, OR OXYGEN, OR NITRUS OXIDE
Mode of operation	CONTINUOUS OPERATION
Applicable patients (weight)	≥ 7kg (Adult) with YG-211TW airway adapter < 7kg (Infant/neonatal) with YG-213TW or YG-214TW airway adapter. In this case the endotracheal tube size must be 4.0 mm or less
Operating environment	Temperature: 0 to 40°C (32 to 104 F) Humidity: 15 to 95% RH (noncondensing) Atmospheric pressure: 70 to 106 kPa

Transport and storage environment	Temperature: -25 to +65°C (-13 to 149 F) Humidity: 10 to 95% RH (noncondensing) Atmospheric pressure: 70 to 106 kPa
Atmospheric compensation	Automatic
Lifetime of the optional disposable items	36 months from the month of manufacture
Safety standards	IEC 60601-1:2005+A1:2012 IEC 60601-1-2:2014 ISO 80601-2-55:2011
Electromagnetic Compatibility	Refer to Rescue Life[9]

3.3.8 ETCO2 ESSENTIAL PERFORMANCE (REF. ISO 80601-2-55:2011)

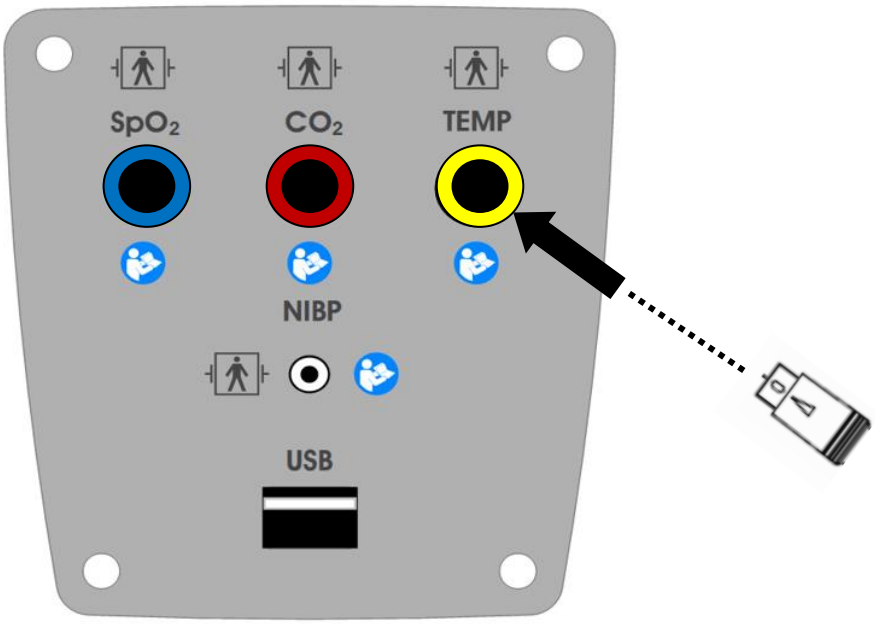
- Measurement accuracy;
- Gas reading alarm condition.

3.4 TEMPERATURE ACQUISITION (optional)

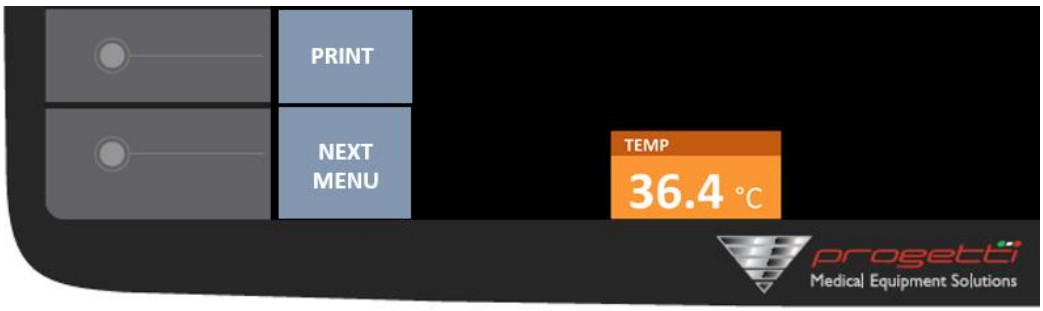
The Skin temperature sensor provides accurate measurement of skin surface temperature and may be placed on the skin surface at any site on the body; recommended placement sites are axilla, forehead or any other skin surface as clinically indicated.

3.4.1 PROCEDURE

1. Insert connector of SKIN TEMPERATURE SENSOR in TEMPERATURE PORT;



2. Apply the SKIN TEMPERATURE SENSOR on patient's skin;
3. Read measurement on the display's TEMPERATURE box.

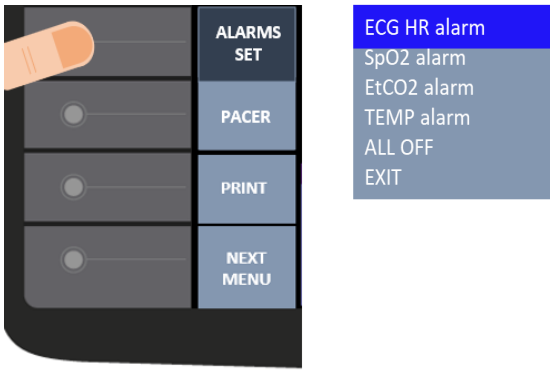


3.4.2 TEMP ALARM SETTING

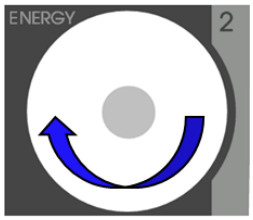
The TEMP alarm can be set to warn if the TEMP value goes outside of the set inferior limit and superior limit. If the TEMP value is lower than inferior limit or higher than superior limit, then an alarm tone alerts the user.

TEMP alarm can be enabled/disabled/reset pressing on “ALARMS SET” button.

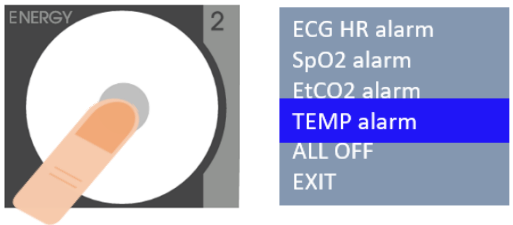
1. Press “ALARMS SET” and will be opened the list of alarms: “ECG HR alarm”, “SpO2 alarm”, “EtCO2 alarm”, “TEMP alarm”, “ALL OFF”;



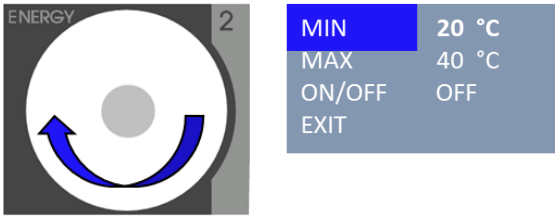
2. Rotate the KNOB to select “TEMP alarm”;



3. Press the KNOB to confirm “TEMP alarm”;

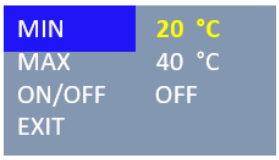


4. Rotate the KNOB to select the parameter to change between “MIN”, “MAX” and “ON/OFF”;

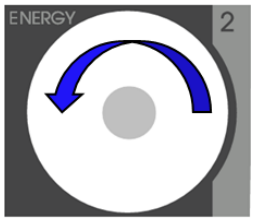


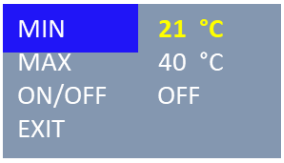
3 – ACQUISITION OF BIOMEDICAL PARAMETERS

5. Press the KNOB to confirm the parameter to change. It will be shown in yellow;



6. Rotate the KNOB to change the value (default inferior limit: 20°C, default superior limit: 40 °C);





7. Press the KNOB to confirm;

8. Rotate the KNOB to change another parameter;

9. Select “EXIT” to save and exit.

3.4.3 ESSENTIAL PERFORMANCE (REF. ISO 80601-2-56:2009)

- Accuracy of the skin temperature sensor
- Generation of a technical alarm condition

3.5 NIBP ACQUISITION (optional)

3.5.1 INTRODUCTION

The NIBP module is performed by *Advantage A+* module available in the series of oscillometric *SunTech Medical®* NIBP technologies. 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.

Oscillometry

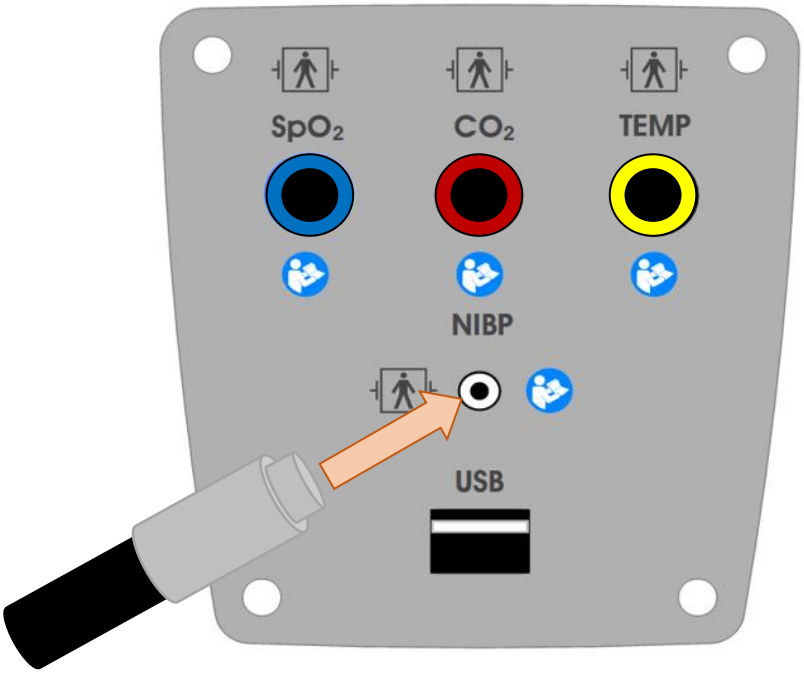
The oscillometric method of blood pressure measurement is a non-invasive method that monitors the amplitude of cuff pressure changes during cuff deflation to determine arterial blood pressure. The cuff pressure is first elevated above the patient systolic blood pressure level and the cuff begins to deflate 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.

Patient Populations

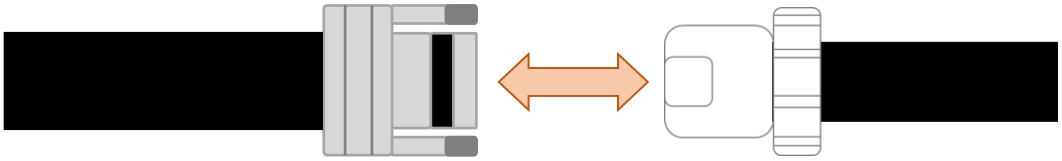
There are three major patient groups which are formally defined as neonate (up to 28 days), pediatric (29 days to 12 years) and adult (13 years and older).

3.5.2 PROCEDURE

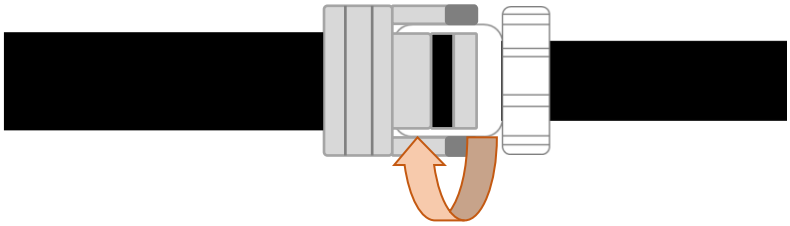
1. Insert the of NIBP EXTENSION CABLE's connector to NIBP PORT;



2. Insert the male quick connector of NIBP EXTENSION CABLE in female quick connnector of NIBP CUFF



3. Rotate female quick connector into the male quick connector of NIBP CUFF to hold the connection.



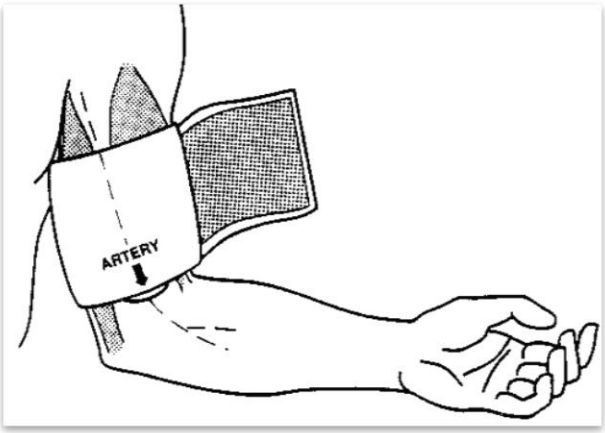
4. Apply the NIBP cuff on the patient as described in the follow instructions:

3.1 Place open cuff around the inner portion of the upper arm (or thigh);

3.2 Align artery symbol ARTERY symbol 

to the brachial (or femoral) artery;

3 – ACQUISITION OF BIOMEDICAL PARAMETERS



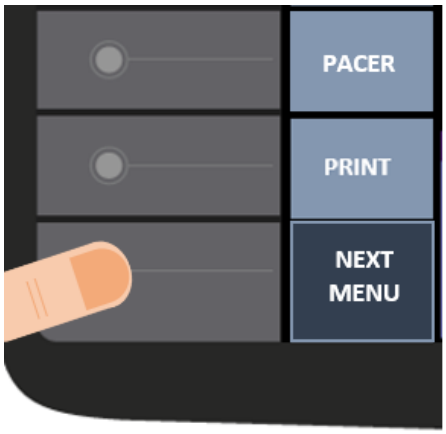
3.3 Use the RANGE indicator 

with the INDEX line 

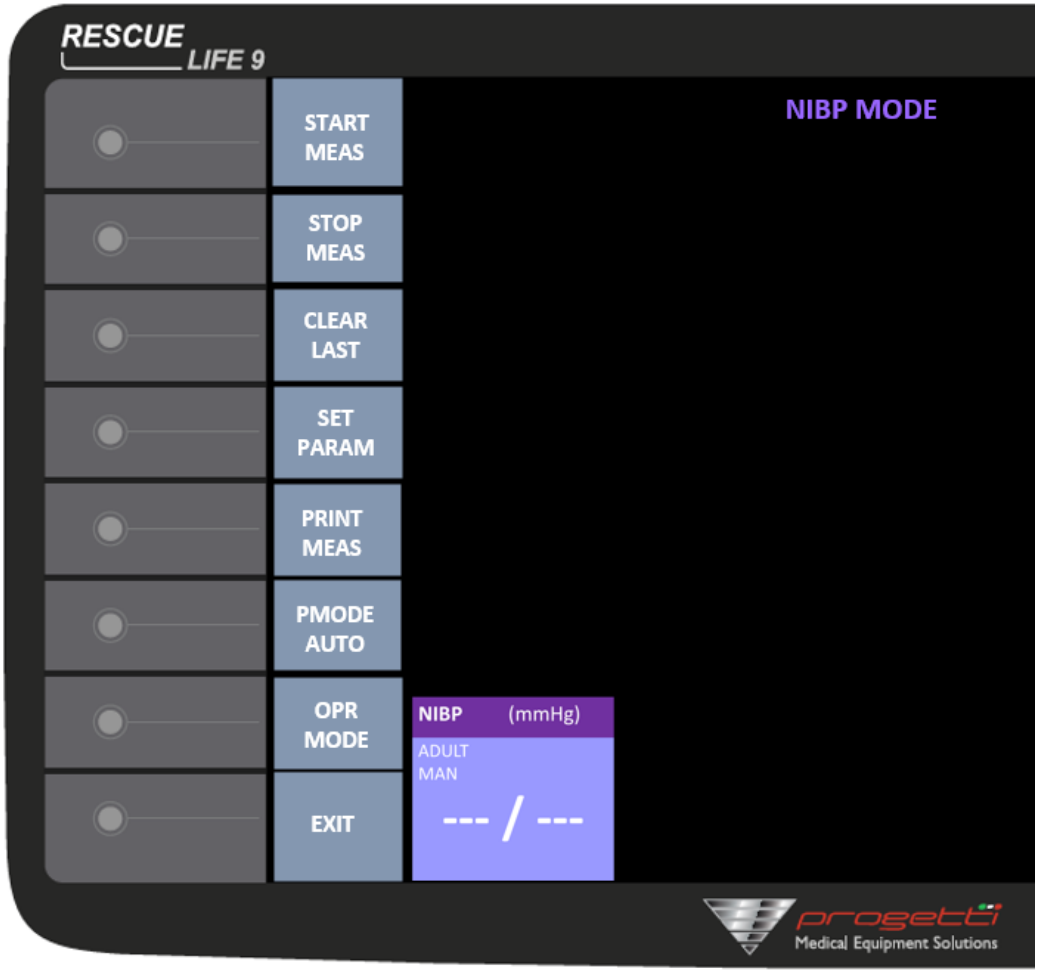
to check that the arm falls within the specified range of that cuff. If it does not, select a cuff that better accomadates the limb circumference. Ensure that the air hose from the monitor to the cuff is not compressed, crimped or damaged.

3.4 Wrap the cuff snugly around the arm (or thigh).

5. Press “NEXT MENU” button



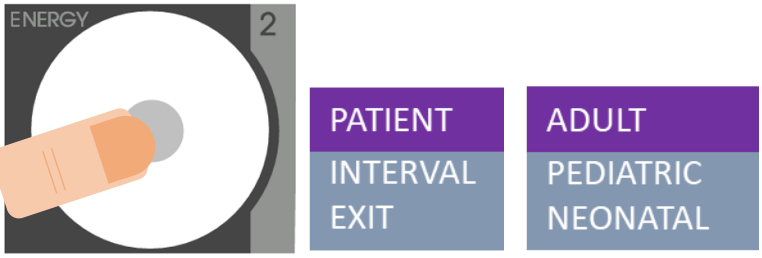
6. Press “NIBP” to set NIBP parameter: “NIBP MODE” will be enabled automatically.



3 – ACQUISITION OF BIOMEDICAL PARAMETERS

7. Press “SET PARAM” to set the type of patient;

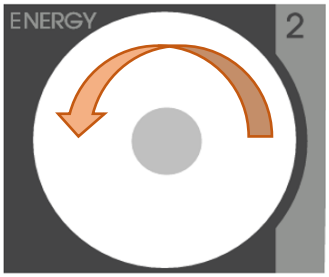
8. Press the KNOB to select “PATIENT”;



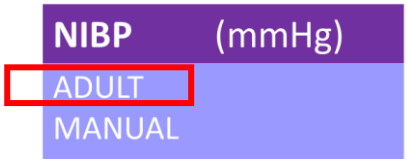
9. Rotate the KNOB to select the type of patient between “ADULT”, “PEDIATRIC” and “NEONATAL”;

10. Press the KNOB to confirm the type of patient;

11. Rotate the KNOB to select “EXIT” and save;



12. Check on the display’s NIBP box the set type of patient;

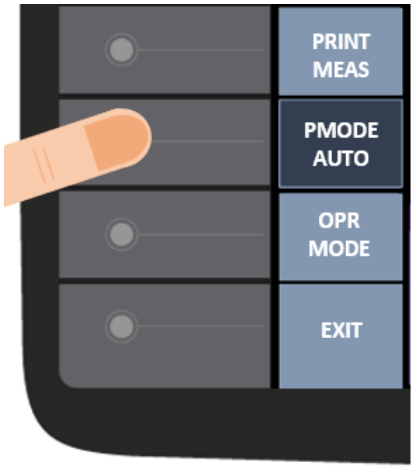


3 – ACQUISITION OF BIOMEDICAL PARAMETERS

13. PRINT MODE SETTING

Two print modes are available: a) manual (“MAN”), b) automatic (“AUTO”). Before to start the NIBP measurements it’s recommended to set the modality. “MAN” is set as default.

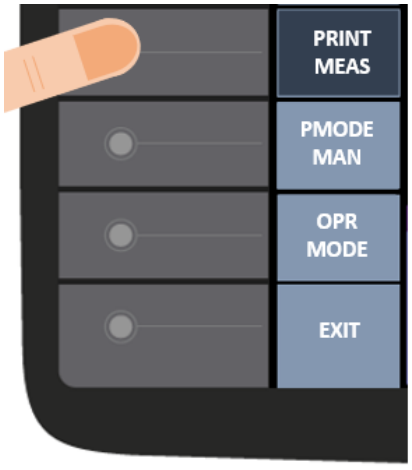
a. Press “PMODE” button;



b. Check in “PMODE” button the set mode.

It is possible to print the measures when needed; so:

a. Press “PRINT MEAS”;



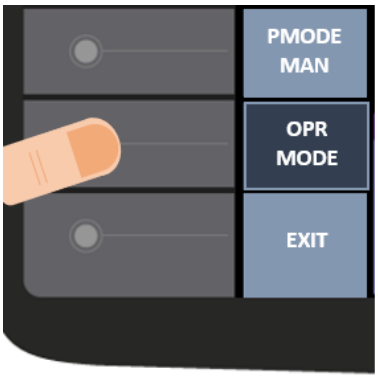
b. Check the NIBP measures on the printed paper.

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

14. SELECTION OF MEASUREMENT TYPE

Case A) AUTOMATIC MEASUREMENTS

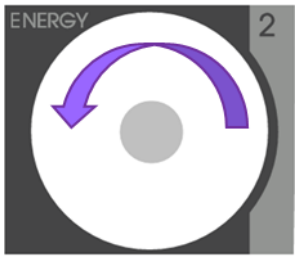
14.A.1 Press "OPR MODE" if automated measurements are needed ("manual" mode is set as default).



In this case "AUTO" in shown in the display's NIBP box.

14.A.2 To change the measurement interval time ("5 min" are set as default), press "SET PARAM" button ;

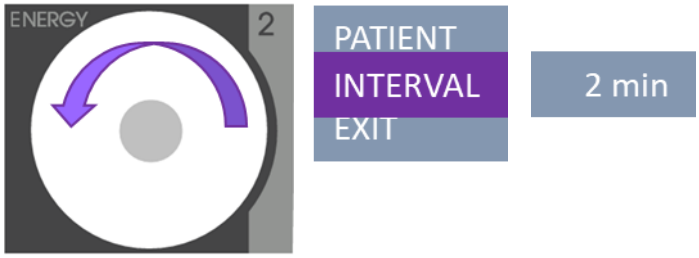
14.A.3 Rotate the KNOB to select "INTERVAL";



14.A.4 Press the KNOB to confirm "INTERVAL" ;

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

14.A.5 Rotate the KNOB to change the time INTERVAL;



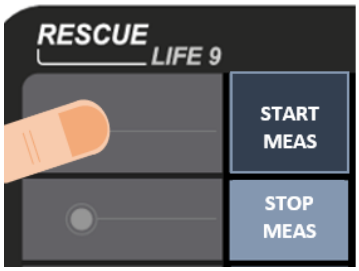
14.A.6 Press the KNOB to save;

14.A.7 Rotate the KNOB to select “EXIT”;

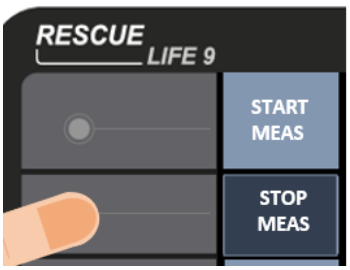
14.A.8 Press the KNOB to confirm and save.

14.A.9 Check on the display’s NIBP box the set time interval;

14.A.10 Press “START MEAS” to start the 1st NIBP measurement. From the end of this one starts the countdown for the next measurement;

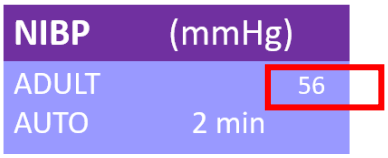


Press “STOP MEAS” to stop the NIBP measurement. In this case all value will be “0” in the display’s NIBP box.

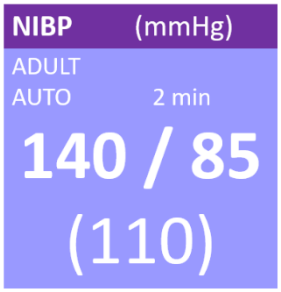


Press “CLEAR LAST” to cancel the NIBP measures from display’s NIBP box.

14.A.11 Check the NIBP cuff pressure value (mmHg) shown in the display’s NIBP box;

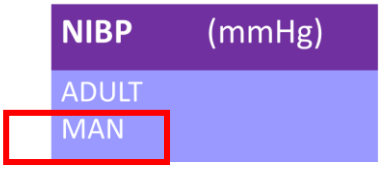


14.A.12 Check the NIBP measures (mmHg) shown in the display’s NIBP box: systolic pressure, diastolic pressure and mean arterial pressure



Case B) MANUAL MEASUREMENTS (default)

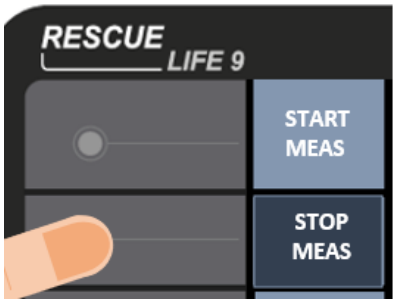
14.B.1 No operation are needed for the user to set this mode because “MANUAL” mode is set as default. However, if the change is requred from “AUTO”, press “OPR MODE” button and check on the display’s NIBP box the set type of measurement.



14.B.2 Press “START MEAS” button to start the measurement.

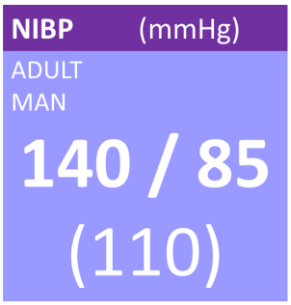
3 – ACQUISITION OF BIOMEDICAL PARAMETERS

Press “STOP MEAS” to stop the NIBP measurement. In this case all value will be “0” in the display’s NIBP box.



Press “CLEAR LAST” to cancel the NIBP measures from display’s NIBP box.

14.B.3 Check the NIBP measures (mmHg) in display’s NIBP box: systolic pressure, diastolic pressure and mean arterial pressure



14.B.4 Press “PRINT MEAS” if “PMODE” is set in “MAN”. The printed paper shows NIBP measures as the follow picture:

```
28/09/21
13:07:43

NIBP
ADULT
---------------
SYS:    140mmHg
DIA:     85mmHg
MEAN:   110mmHg
HR:      67BPM
```

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.

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.

3.5.3 WARNINGS AND PRECAUTIONS DURING THE NIBP MESURAMENT

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

DO NOT USE THE NIBP MODULE FOR ANY OTHER PURPOSE 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.

A WRONG SIZE OF NIBP CUFF MAY GIVE FALSE AND MISLEADING RESULTS WHEN USED DURING NIBP MEASUREMENTS.

THE NIBP MODULE IS DESIGNED TO WORK WITH SUNTECH® CUFFS AND HOSES. THE USE OF OTHER BRANDS MAY COMPROMISE PERFORMANCE AND ACCURACY.

THE REPLACEMENT OF A DIFFERENT PART FROM THAT RECOMMENDED AND/OR 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.

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.

3.5.4 ESSENTIAL PERFORMANCE (REF. IEC 80601-2-30:2018)

- Reproducibility of the blood pressure determination

Accessories

PART #	DESCRIPTION	MEASURE
91-0028-69	3 m Patient Hose w/CPC connectors	
98-0092-02	APC Cuff, Infant (red)	Range: 8 – 13 cm
98-0093-03	APC Cuff, Child (green)	Range: 12 – 19 cm
98-0095-04	APC Cuff, Small Adult (blue)	Range: 17 – 25 cm
98-0097-04	APC Cuff, Adult (dark blue)	Range: 23 – 33 cm

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.

3 – ACQUISITION OF BIOMEDICAL PARAMETERS

- 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

4 OTHER FUNCTIONS

4 – OTHER FUNCTIONS

4.1 DATA BASE

The Rescue Life[9] can keep 25 records maximum. From 26[th] record the replacement of the oldest record starts.

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

The recording is available in ADV mode and in AED mode. Each time the ANALISYS starts, the recording will start automatically.

When Rescue Life[9] is recording, the message "RECORDING" is shown on MESSAGES box.

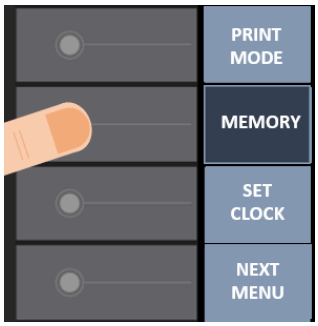
4.1.1 FILES REVIEW

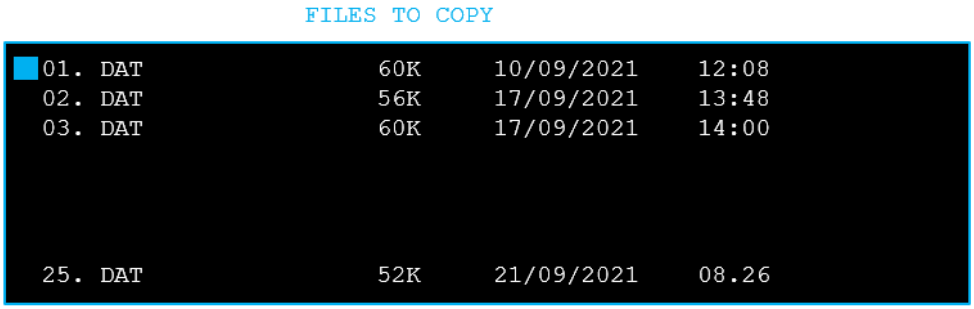
To review the recorded files the user needs of the "*PG DATA MANAGER*" application. This is intended only for PC. So, the user must:

1. Copy the file or files in USB PEN;
2. Import the file or files into the *"PG DATA MANAGER"* application from USB PEN;
3. Follow the instruction for use of *"PG DATA MANAGER" application.*

4.1.1.1 FILES COPY

1. Press "NEXT MENU" button;
2. Press "MEMORY" button. The "FILES TRANSFER INTERFACE" will be opened: the list of records will be shown on the display;

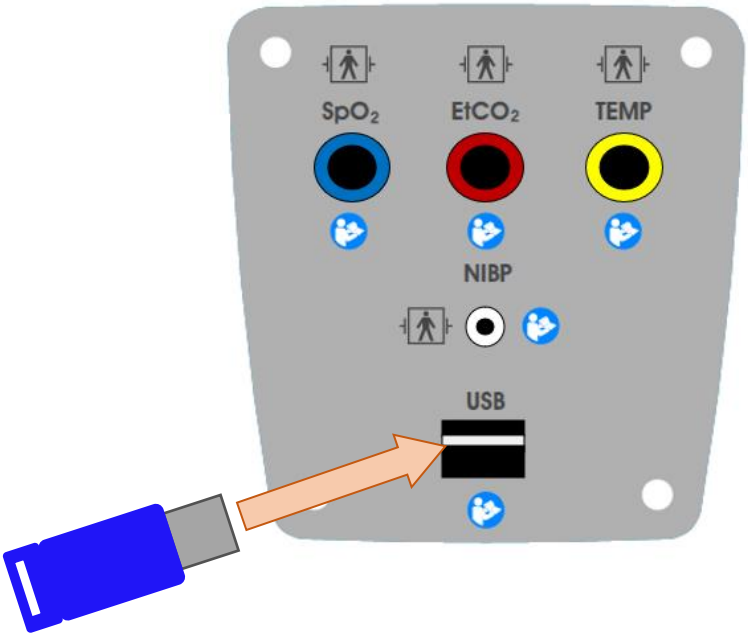




4 – OTHER FUNCTIONS

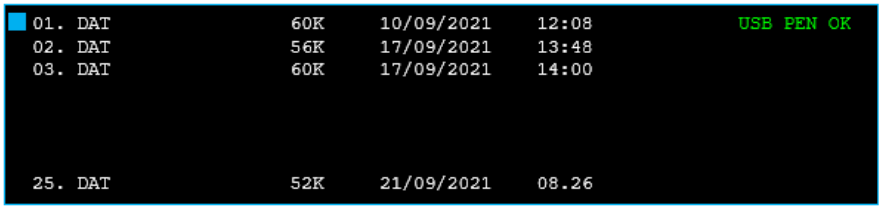
3. The user can copy one or more records in the USB PEN.

3.1 Insert a USB PEN as in the following picture.



As the first use, it's recommended the use of an empty USB PEN; also, it's recommended to not use the same USB PEN for saving other types of files from other devices.

3.2 Press "CHECK USB PEN"; "USB PEN OK" will be shown on the display as confirmation that USB PEN is connected and ready for copy.

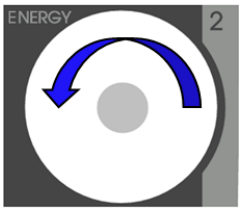


3.3. Select the record to copy

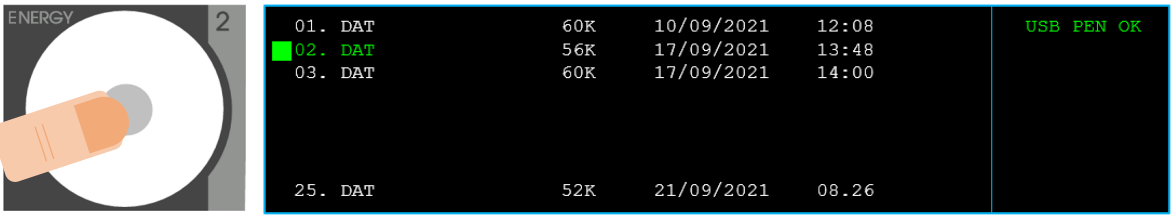
4 – OTHER FUNCTIONS

Case A – one record to copy

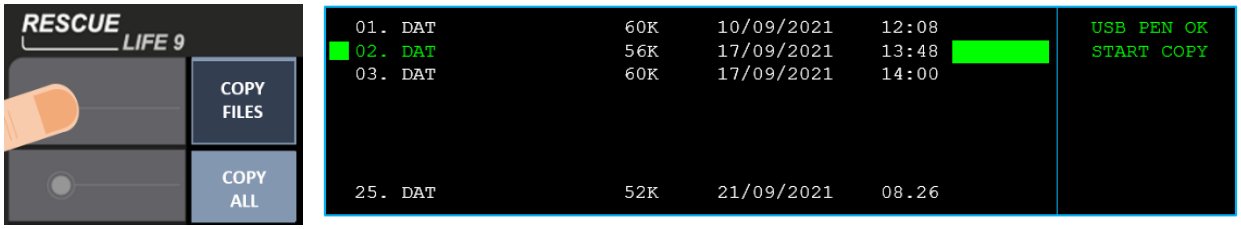
A.1. Rotate the KNOB to select the record to copy;



A.2. Press the KNOB to confirm the record to copy. The selected record will be highlighted in green;



A.3. Press "COPY FILES" button. A green status bar will be shown on the right of record. If needed, press "STOP COPY": copy will be stopped at the end of the process.



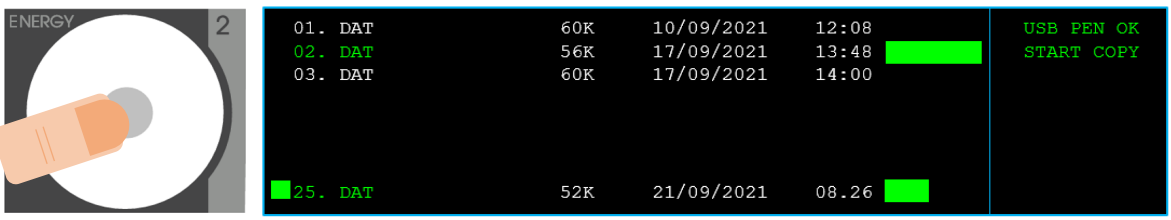
Case B – more records to copy

B.1. Rotate the KNOB select the 1st record to copy and press the KNOB to confirm;

B.2. Rotate the KNOB to select another record to copy and press the KNOB to confirm;

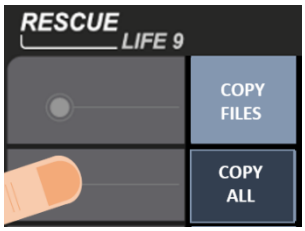
B.3. repeat (B.2.) for other records;

B.4. Press "COPY FILES" button. A green status bar and "START COPY" will be shown on the right of the record. If needed, press "STOP COPY": copy will be stopped at the end of the process.



Case C – all records to copy

C.1. Press "COPY ALL" button. The user must wait the end of copy for all records. If needed, press "STOP COPY": copy will be stopped at the end of the process.



4.2 PATIENT DATA LOADING

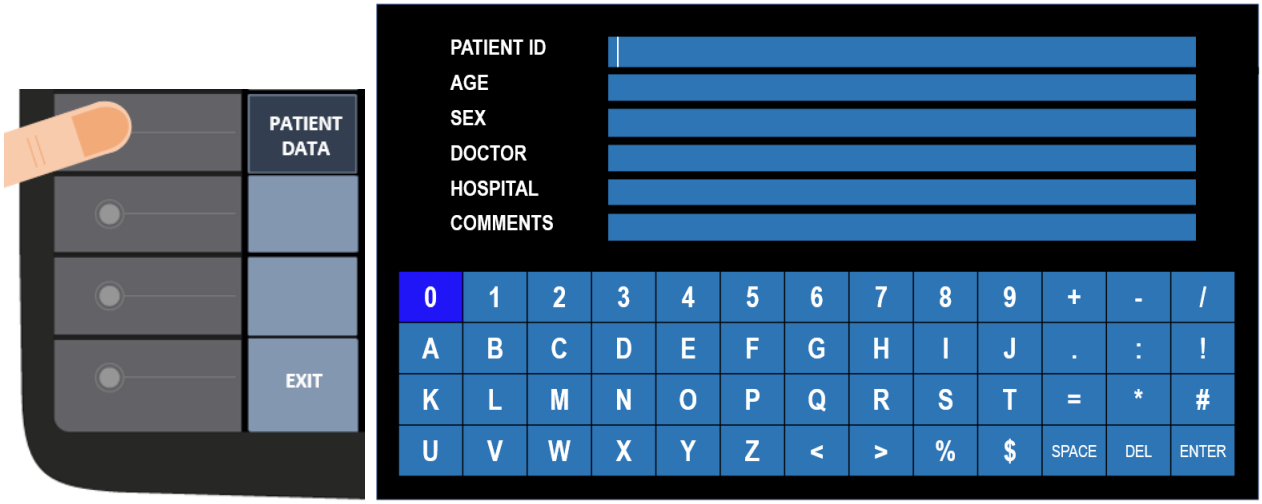
The user can load the following information about the patient:

- "PATIENT ID";
- "AGE";
- "SEX";
- "DOCTOR";
- "HOSPITAL";
- "COMMENTS".

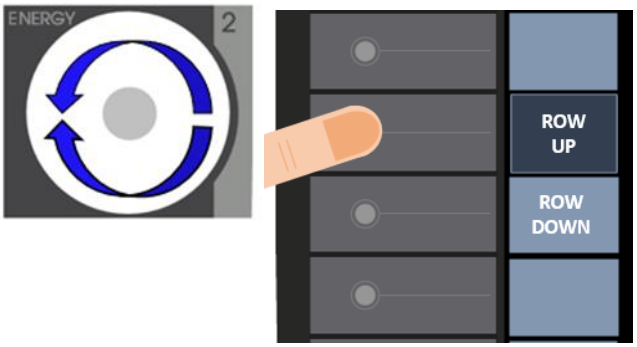
They are shown in the printed paper (see "PRINTING" section).

4.2.1 PROCEDURE

1. Press "PATIENT DATA" button: the following interface will be shown;

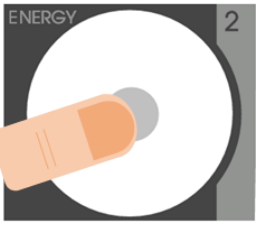


2. Rotate the KNOB to select a character of the keyboard. For a faster procedure, press "ROW UP" or "ROW DOWN" buttons to select the interested keyboard's row.



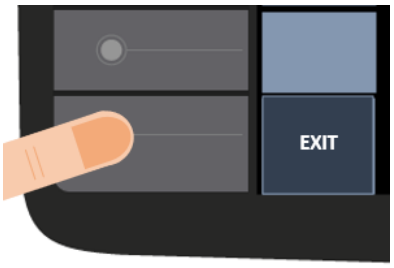
4 – OTHER FUNCTIONS

3. Press the KNOB to confirm the set character. Select “DEL” on the keyboard to cancel the set character or, for a faster procedure, press “DEL” button.



4. Press “ENTER” button to move the cursor on the next field, so to write here.

5. Press “EXIT” to save and exit.

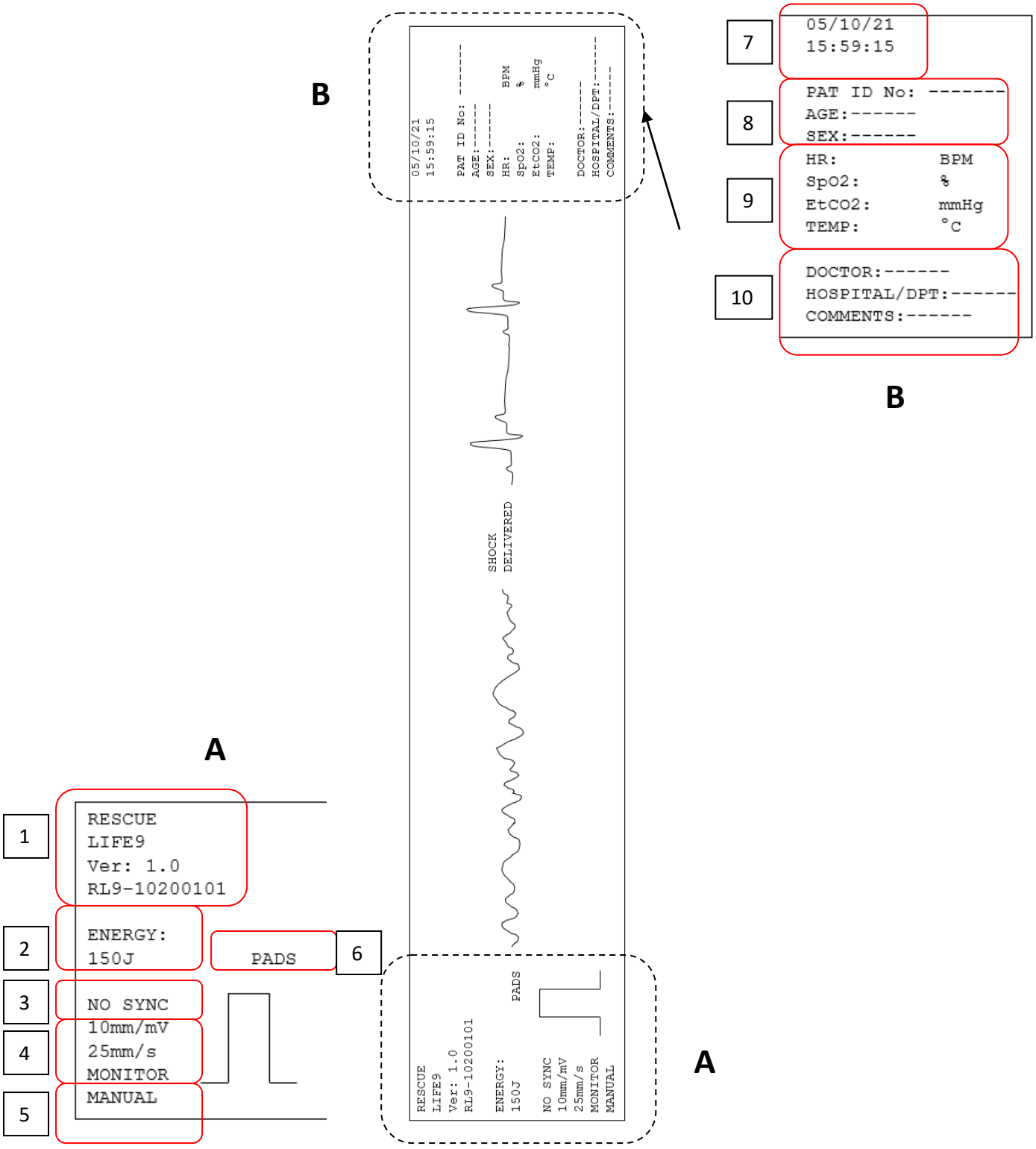


4.3 PRINTING

The printing is available in the following 2 modes:

a) Automatic;
b) Manual (default setting).

The data are shown in printed paper as following:

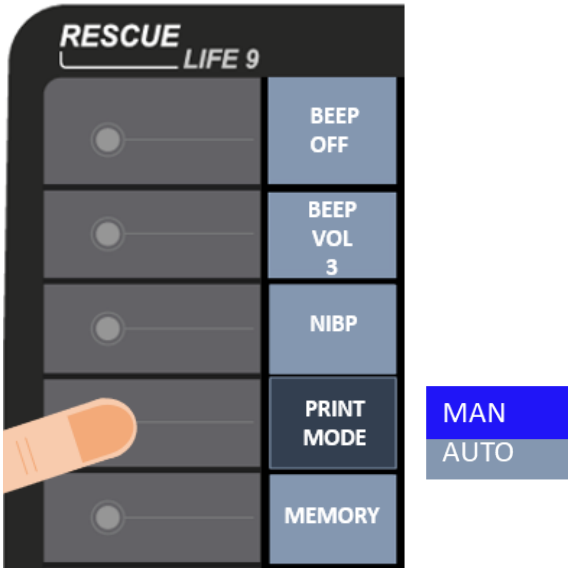


1	IDENTIFICATION OF DEVICE (REF, SW VERSION, SERIAL NUMBER)
2	SET DEFIBRILLATION ENERGY
3	SYNC STATE
4	SET ECG PARAMETER (GAIN, SPEED, FILTER)
5	SET DEFIBRILLATION MODE
6	SET ECG SOURCE
7	DATE AND HOUR AT THE END OF THE PRINTING
8	PATIENT DATA
9	BIOMEDICAL PARAMETERS
10	ADDITIONAL INFORMATIONS

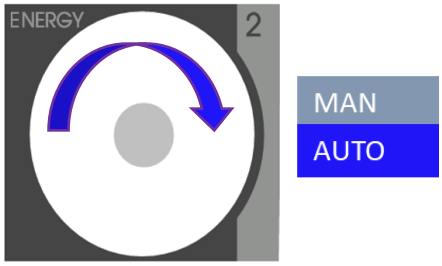
4.3.1 AUTOMATIC PRINTING

To set automatic printing:

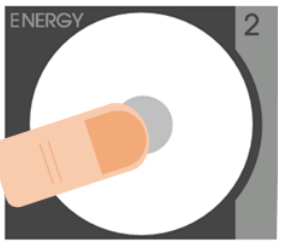
1. Press “PRINT MODE” button. The choosing window will be opened.



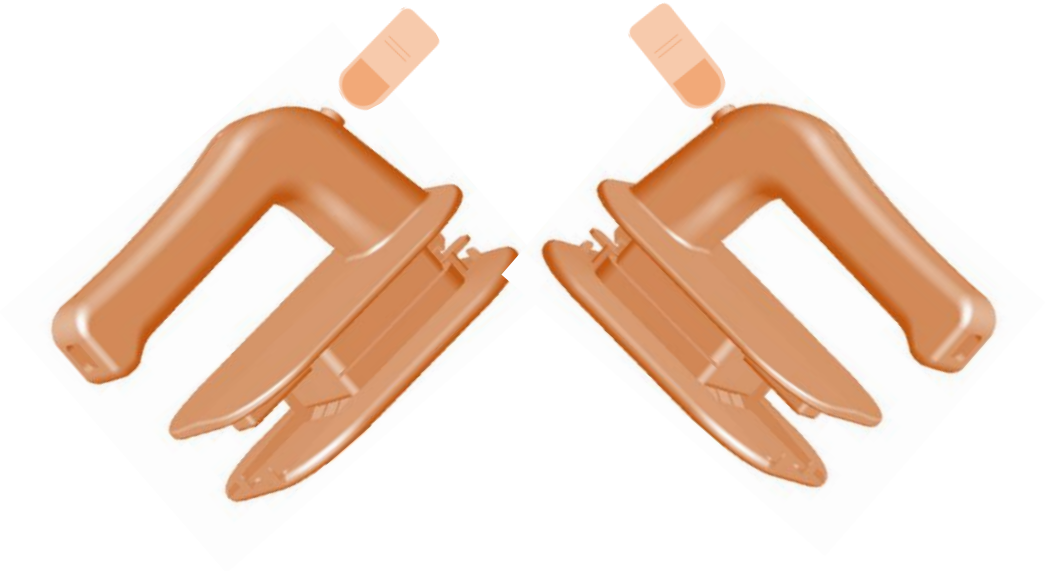
2. Rotate the KNOB to select “AUTO”;



3. Press the KNOB to confirm the mode and save.



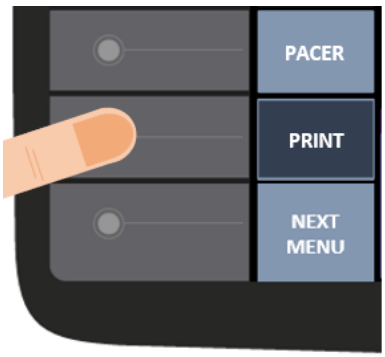
Automatic printing starts when buttons on the standard defibrillation electrodes are pressed for charge defibrillation energy.



4.3.2 MANUAL PRINTING (default setting)

To set manual printing repeat from (1) to (2) of the previous mode.

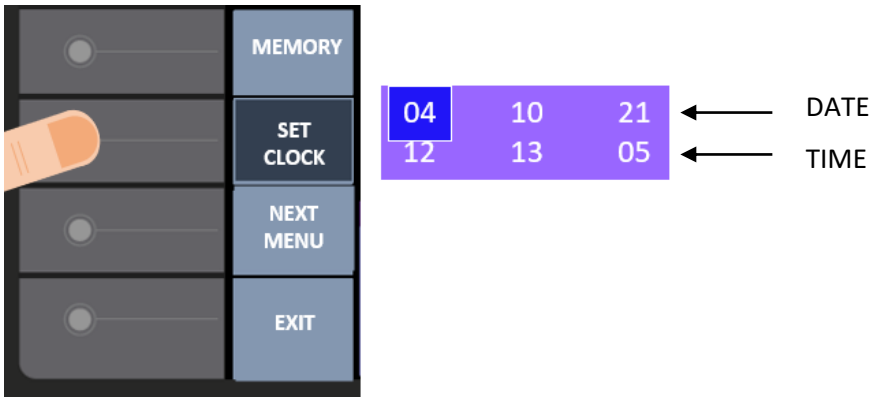
Manual mode starts when “PRINT” button is pressed.



4.4 DATE AND TIME SETUP

On the screen will be displayed the battery status, the date and time.

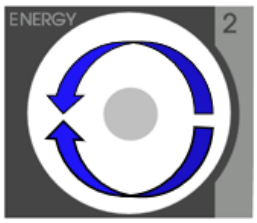
1. Press “NEXT MENU” button and “SET CLOCK” button to change day and hour.



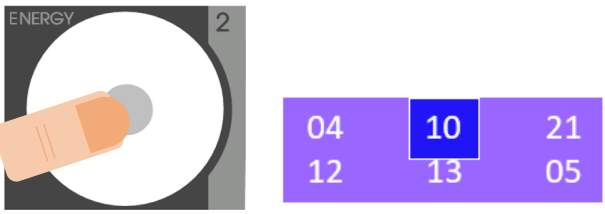
Case A) DATE SETUP

The day is shown in the format [dd-mm-yyyy].

A.1 Rotate KNOB to select the day;



A.2 Press KNOB to confirm the set day and sliding the blue indicator to month;



A.3 Rotate KNOB to change the value of the month;

A.4 Press KNOB to confirm the selection and sliding the blue indicator to year;

A.5 Repeat (A.3) and (A.4) to change year.

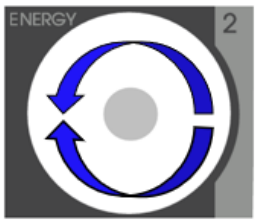
Case B) TIME SETUP

The hour is shown in the format [hh:mm:ss]

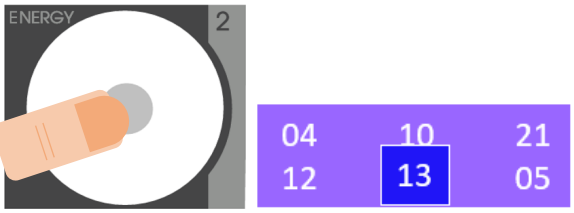
B.1 Press KNOB to position the blue indicator on the hour;

B.2 Rotate KNOB to select the hour;

4 – OTHER FUNCTIONS



B.3 Press KNOB to confirm the set hour and sliding the blue indicator to minutes;



B.4 Rotate KNOB to change the minutes

B.5 Press KNOB to confirm the selection and sliding the blue indicator to seconds;

B.6 Repeat (B.4) and (B.5) to change seconds.

2. Press “SET CLOCK” to save and close.

4.5 SYSTEM TEST

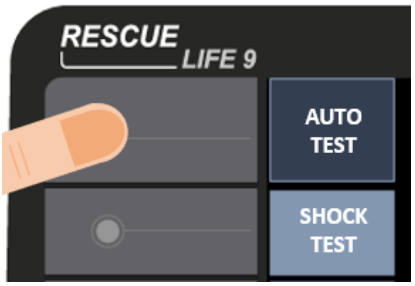
Press “SYSTEM TEST” button to select:

- “AUTO TEST” or
- “SHOCK TEST”.

4.5.1 AUTO TEST

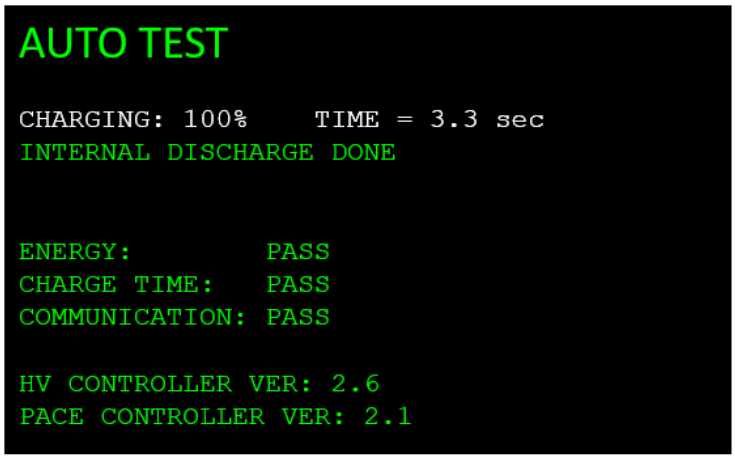
PROCEDURE

1. Press “AUTO TEST” button;

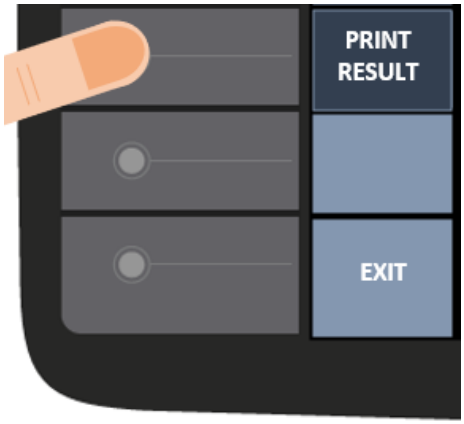


Automatically, the following tests starts:

- Energy (50J);
- Defibrillation energy charge time;
- Internal processors communication.



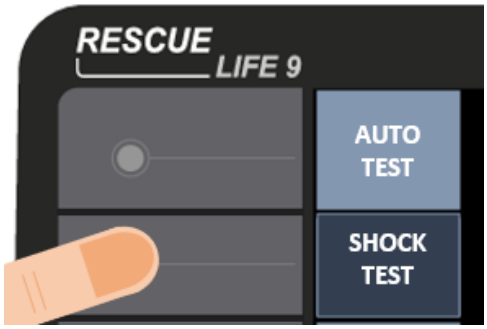
To print the results of “AUTO TEST”, press “PRINT RESULT” button:



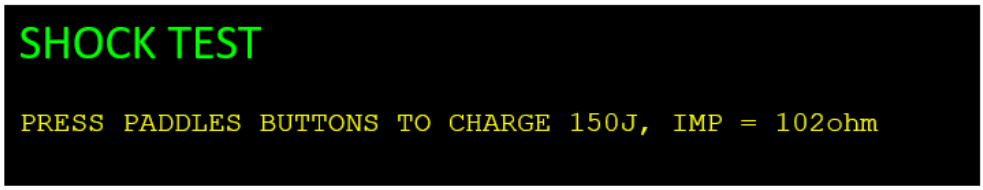
4.5.2 SHOCK TEST

PROCEDURE

1. Press “SHOCK TEST” button;

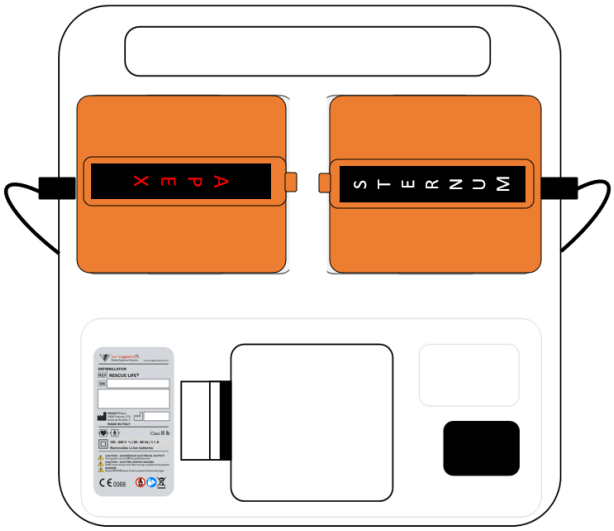


The following message will be shown on the top of the display:

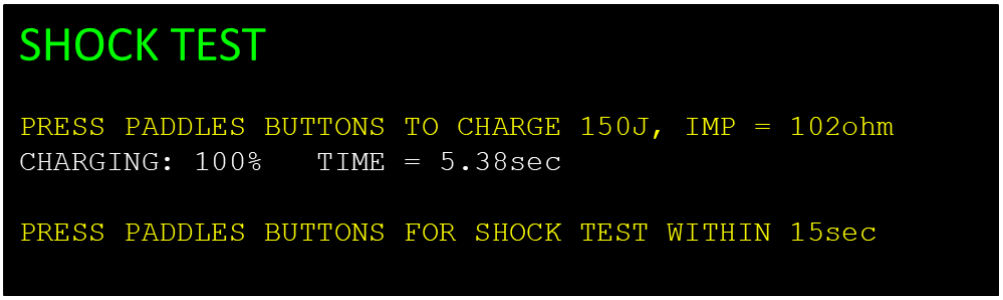


2. Follow the instructions: press buttons on the standard defibrillation electrodes to charge 150J while they are in their side of the rear

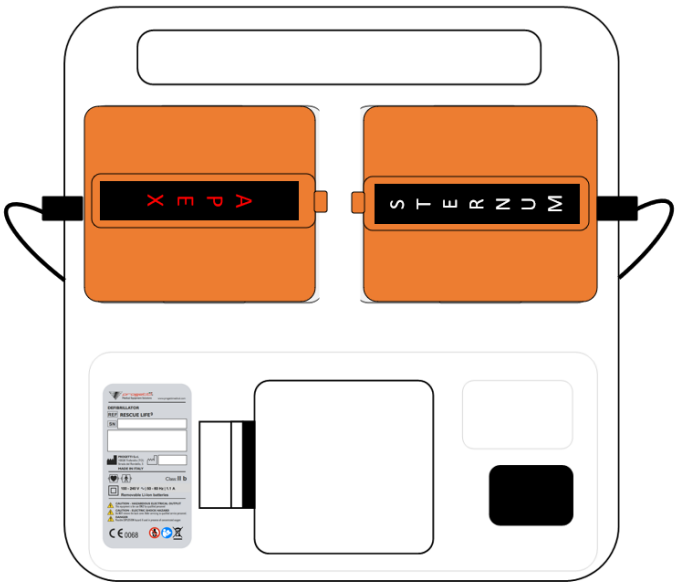
4 – OTHER FUNCTIONS



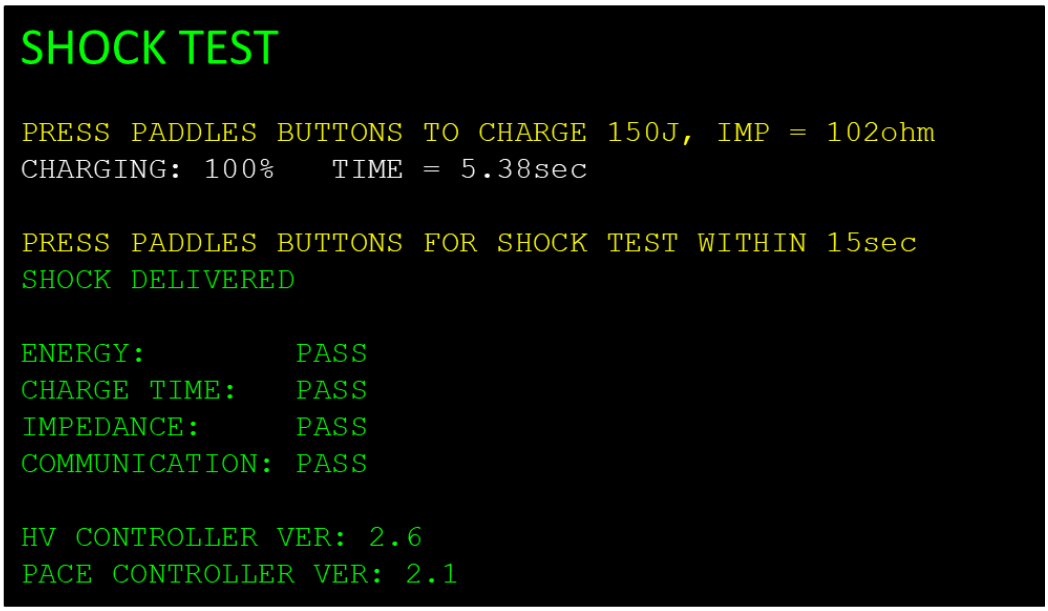
150 J (default) will be charged and the following instructions will be shown on the display:



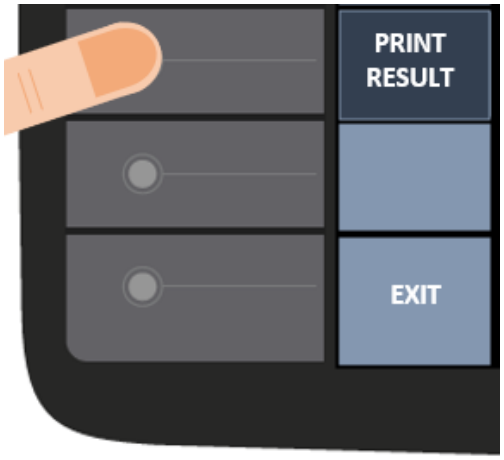
3. Follow the instructions: press buttons on the standard defibrillation electrodes to discharge 150J while they are in their side of the rear.



4 – OTHER FUNCTIONS

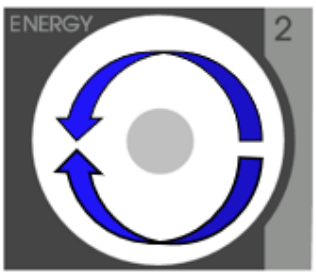


To print the results of “SHOCK TEST”, press “PRINT RESULT” button:



To repeat the auto test with a different energy value (10 J - 230 J) than default energy (150 J):

1. Press “EXIT” button;
2. Press “SYSTEM DATA” button;
3. Rotate the KNOB to select the energy value to test;



4. Rotate the KNOB to select the energy value to test;
5. Press “AUTO TEST” button.

4.6 SAVING AND LOADING SETUP

4.6.1 SAVE SETUP

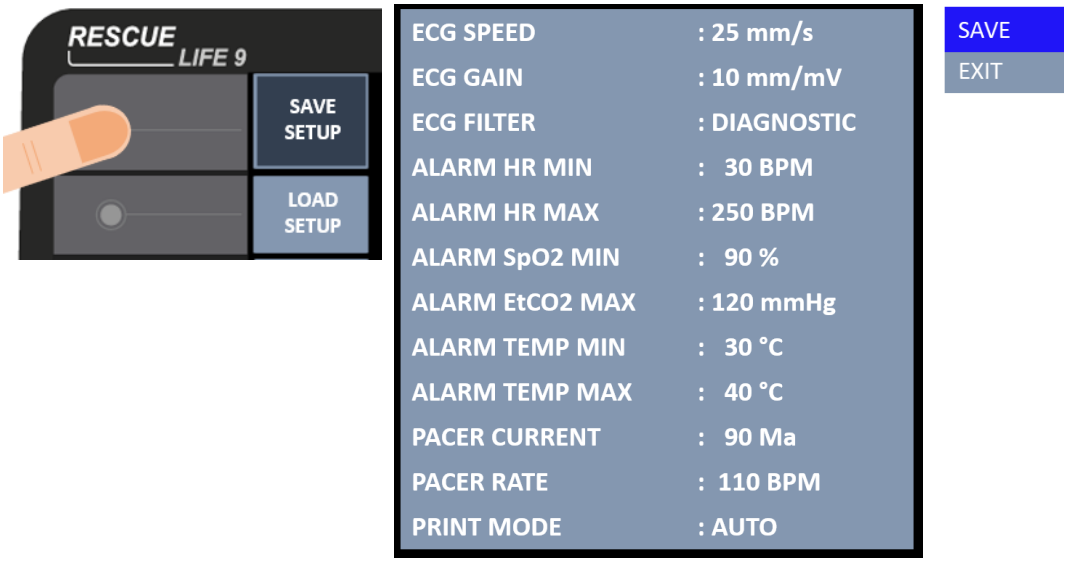
The user can save the current setup of the Rescue Life9, so to save the following parameters:

- "ECG SPEED";
- "ECG GAIN";
- "ECG FILTER";
- "ALARM HR MIN";
- "ALARM HR MAX";
- "ALARM SpO2 MIN";
- "ALARM EtCO2 MAX";
- "ALARM TEMP MIN";
- "ALARM TEMP MAX";
- "PACER CURRENT";
- "PACER RATE";
- "PRINT MODE".

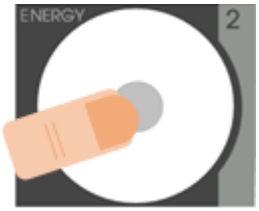
Only one setup is possible to save.

4.6.1.1 PROCEDURE

1. Press "SAVE SETUP" button: the resume setup window will be shown.



2. Press the KNOB to confirm "SAVE".



4.6.2 LOAD SETUP

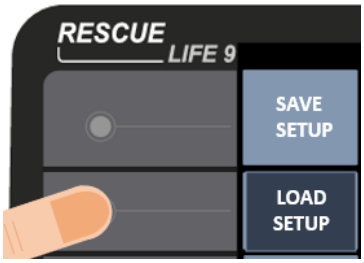
The user can load the previous saved setup of the Rescue Life[9] (see previous section "SAVE SETUP"), so to load the following parameters:

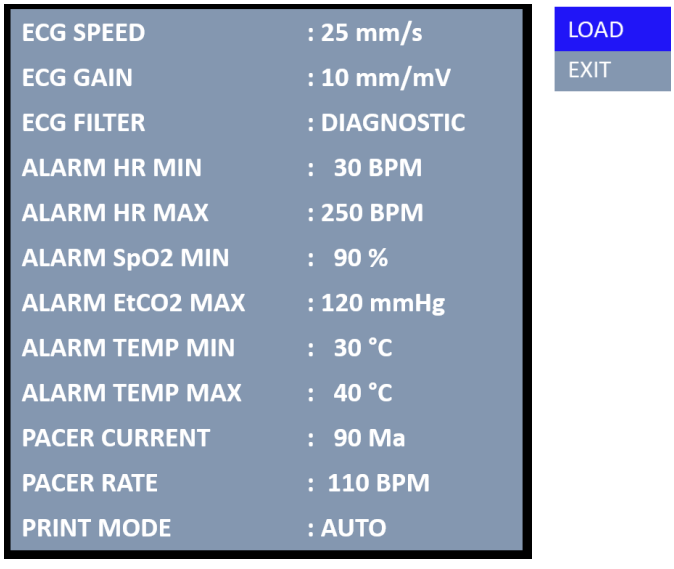
- "ECG SPEED";
- "ECG GAIN";
- "ECG FILTER";
- "ALARM HR MIN";
- "ALARM HR MAX";
- "ALARM SpO2 MIN";
- "ALARM EtCO2 MAX";
- "ALARM TEMP MIN";
- "ALARM TEMP MAX";
- "PACER CURRENT";
- "PACER RATE";
- "PRINT MODE".

Only one setup is possible to load.

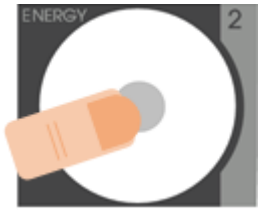
4.6.2.1 PROCEDURE

1. Press "LOAD SETUP" button: the resume setup window will be shown.





2. Press the KNOB to confirm "LOAD".



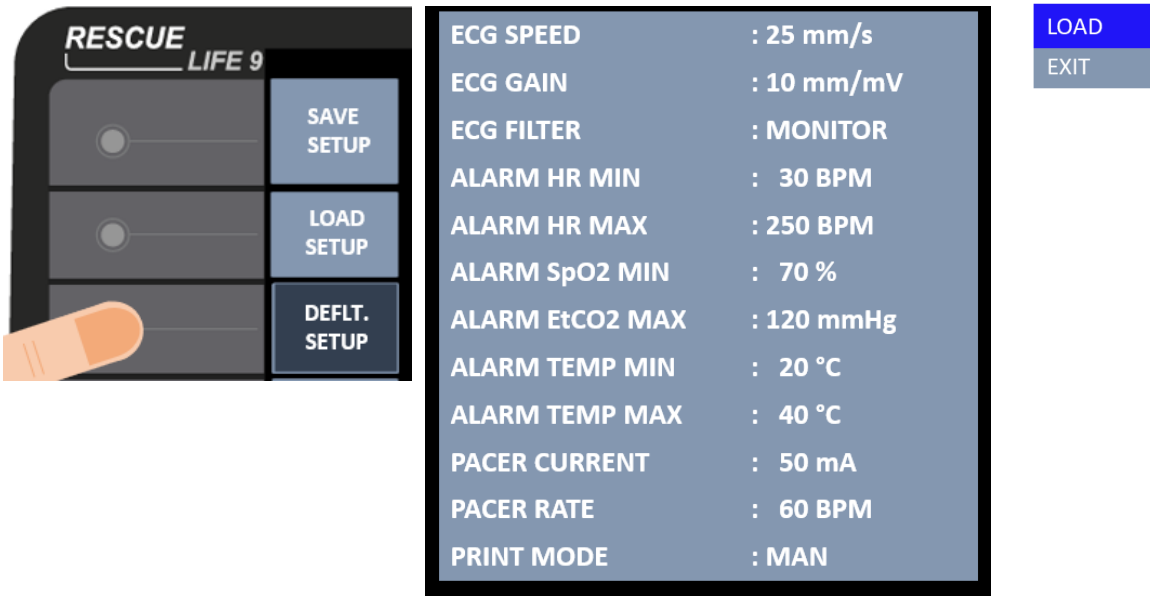
4.6.3 DEFAULT SETUP

The user can load the manufacturer setup of the Rescue Life[9] (see previous section "LOAD SETUP"), so to load the following manufacturer parameters:

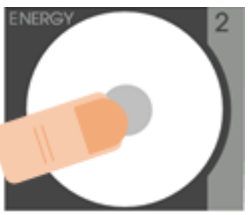
- "ECG SPEED";
- "ECG GAIN";
- "ECG FILTER";
- "ALARM HR MIN";
- "ALARM HR MAX";
- "ALARM SpO2 MIN";
- "ALARM EtCO2 MAX";
- "ALARM TEMP MIN";
- "ALARM TEMP MAX";
- "PACER CURRENT";
- "PACER RATE";
- "PRINT MODE".

4.6.3.1 PROCEDURE

1. Press "DEFLT SETUP" button to set the manufacturer setup: the resume setup will be shown.



2. Press the KNOB to confirm "LOAD".



RESCUE LIFE 9 CHECKLIST

ELPRO S.r.l. recommend using the following checklist to monitor the status of RESCUE LIFE 9. 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, SPO2, TEMP, ETCO2, NIBP cable and sensor. Check expiration date of DISPOSABLE MULTIFUNCTION ELECTRODES.	OK	KO
AUTO TEST		
Perform auto test as explained in the section 4.5 “SYSTEM TEST”	OK	KO
ELECTRODES		
Check the integrity of the ELECTRODES, the connector and the cable. Make sure the ELECTRODES 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 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.

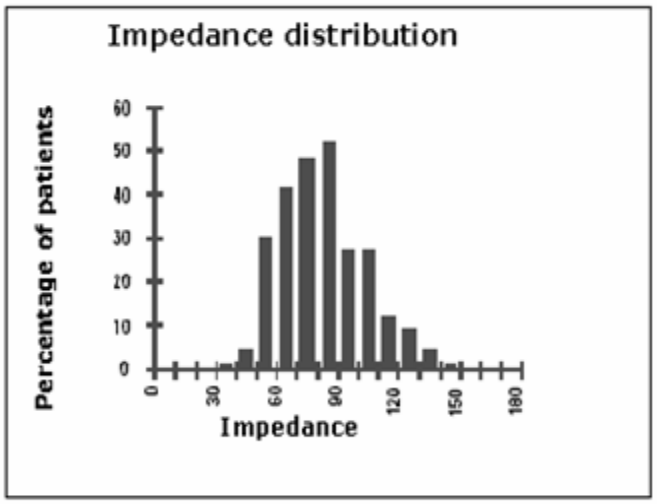
Successful defibrillation would be done when the cell membranes of the heart are “coated” with positive ions on one side and negative ions on the other side, enough to depolarize nearly 100 percent of the cardiac cells at the same instant. Optimal current is determined with the pressure (this means electric 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.

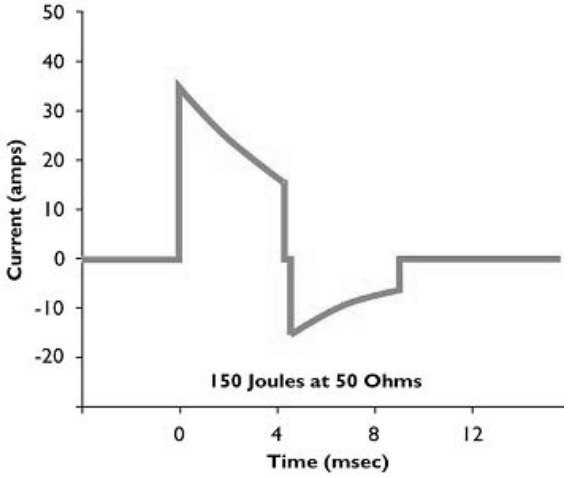
EASE IN COMPENSATION OF PATIENT IMPEDANCE

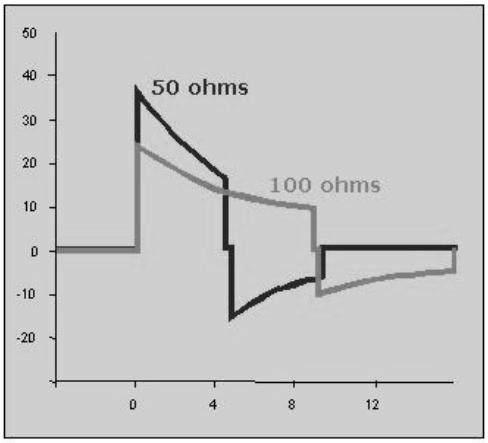
Through Biphasic technology, defibrillation shock delivery is controlled while taking into consideration the patient's impedance. The patient's impedance is measured through the defibrillator electrodes. According to the measured patient's impedance, e-cube Biphasic technology adjusts the duration of 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.

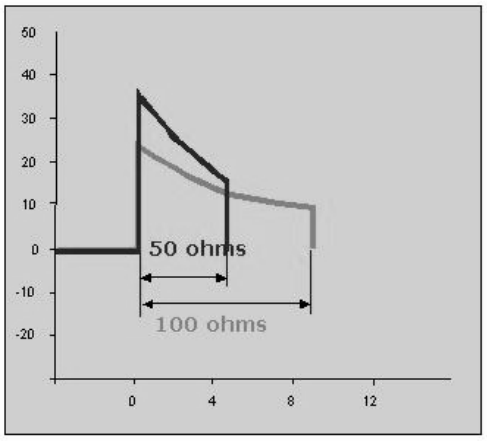
These technologies can adjust the parameters of the shock waveform to match the transthoracic impedance of the patient. Biphasic technology increases the duration of current flow for patients with high impedance. When escalating energy, for example 150J to 180J, it delivers the electrical energy with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

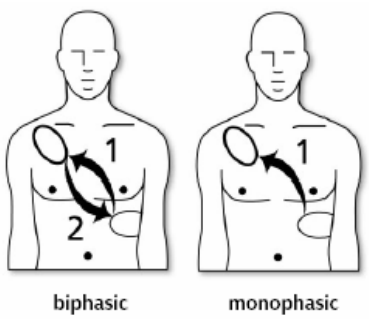
MORE EFFICIENT THAN MONOPHASIC WAVEFORM

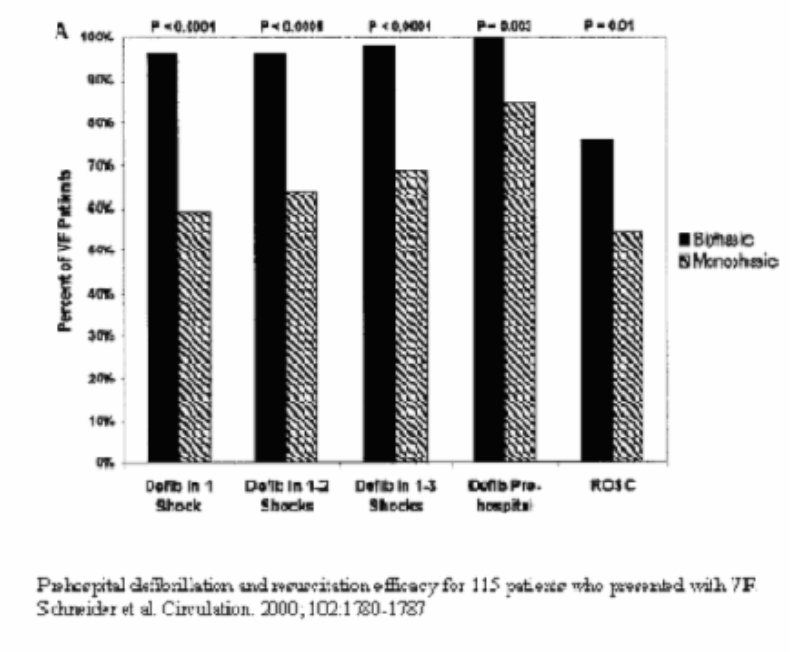
The electrical therapy delivered by transthoracic cardiac defibrillators has changed little since the introduction of direct-current defibrillation more than 30 years ago. Throughout this time, the industry-standard shock waveform for external defibrillators has been a monophasic damped sine (MDS) waveform, 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].







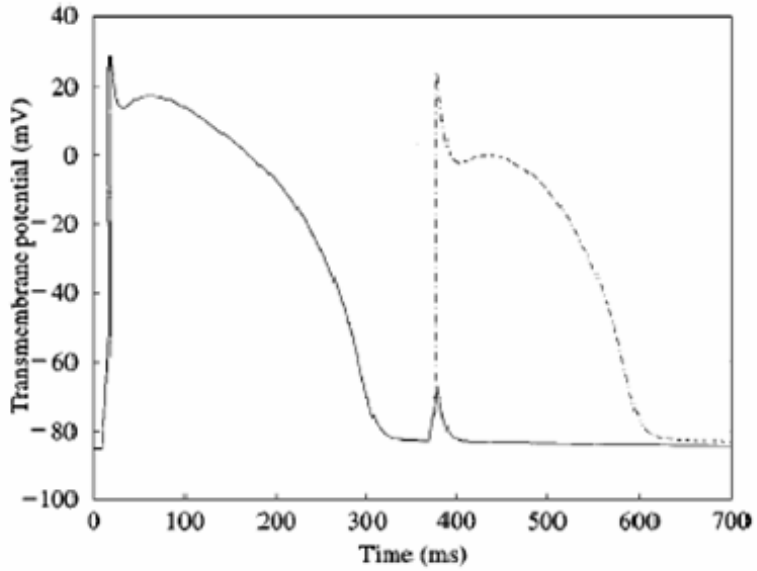




Prehospital defibrillation and resuscitation efficacy for 115 patients who presented with VF
Schneider et al. Circulation. 2000; 102:1780-1787

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].

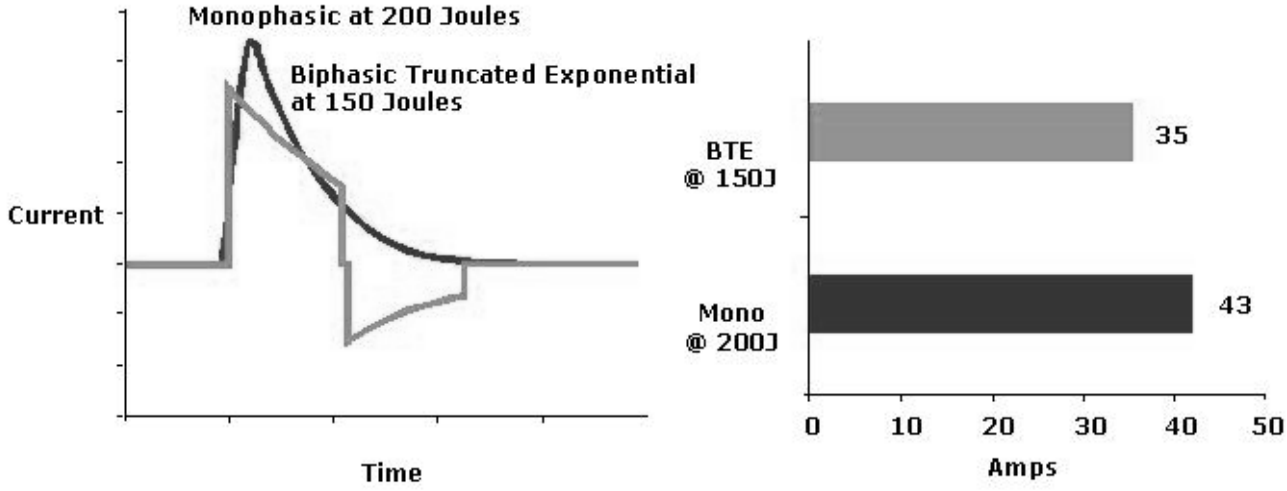


Transmembrane potential for a single Beeler-Reuter cell subject to monophasic and biphasic. Each stimulus amplitude (A) is 17.0 mV, duration is 10 ms and is applied 360 ms after the initial action potential. Notice that for a stimulus of the same amplitude, duration and timing, the biphasic stimulus 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].

THE EFFECT OF TIME TO DEFIBRILLATION AND TARGETED TEMPERATURE MANAGEMENT ON FUNCTIONAL SURVIVAL AFTER OUT-OF-HOSPITAL CARDIAC ARREST

Cardiac arrest physiology can be divided into three phases: electrical, circulatory and metabolic. Survival from cardiac arrests in the electrical phase are dependent upon rapid defibrillation, whereas cardiac arrests in the circulatory phase may benefit from an initial method of oxygen delivery (chest compressions and ventilations) prior to defibrillation. Cardiac arrests that enter the metabolic phase generally have poor survival.

The purpose of the study is to demonstrate the effect of post- cardiac arrest targeted temperature management (TTM) on functional survival during each phase.

The study wants to be a retrospective, observational analysis using data from the Toronto regional RescuNet Epistry database, based on the Resuscitation Outcomes Consortium (ROC) Epistry-Cardiac Arrest database.

Baseline descriptive statistics were calculated for all variables of interest. Continuous measures (e.g. age and time to initial defibrillation) were summarized using median and interquartile range, while categorical measures (e.g. gender) were measured using counts and percentages.

Results:

From January 1, 2007 to April 30, 2013, there were a total of 20,165 adult OHCA treated by EMS personnel. Of these patients,871 were eligible for post-cardiac arrest TTM and met the study inclusion criteria . There were 622 (71.4%) patients who survived to hospital discharge and of these patients, 487 (78.1%) had a good functional survival (mRS 0–3).

Patient demographics for functional survival ($n = 772$).

Characteristics	Good functional survival $n = 487$	Poor functional survival $n = 285$	*P* value
Age (yr), median (IQR)	59.0 (51.0–68.0)	68.0 (60.0–79.0)	<0.01
Male gender, *n* (%)	395 (81.1)	224 (78.6)	0.45
Public location, *n* (%)	212 (43.6)	102 (35.8)	0.04
EMS witnessed, *n* (%)	78 (16.0)	34 (11.9)	0.15
Bystander CPR, *n* (%)	265 (54.4)	141 (49.5)	0.21
Targeted temperature management, *n* (%)	346 (71.0)	188 (66.0)	0.16
Time to initial defibrillation (min), median (IQR)	8.3 (6.7–10.5)	10.0 (7.9–12.1)	<0.01
EMS response interval (min), median (IQR)	5.7 (4.6–6.5)	6.2 (4.7–6.9)	0.01

Effect of time to defibrillation and targeted temperature management on functional survival.

Time from collapse to defibrillation	Good functional outcome, *n* (%)			*P* value
	Overall	Targeted Temp Man.	No targeted Temp. Man.	
<4 min	68 (65.3%)	10 (33.3%)	58 (62.4%)	<0.001
4–10 min	214 (61.7%)	178 (66.1%)	36 (46.2%)	
>10 min	134 (50.2%)	118 (57.6%)	18 (27.3%)	

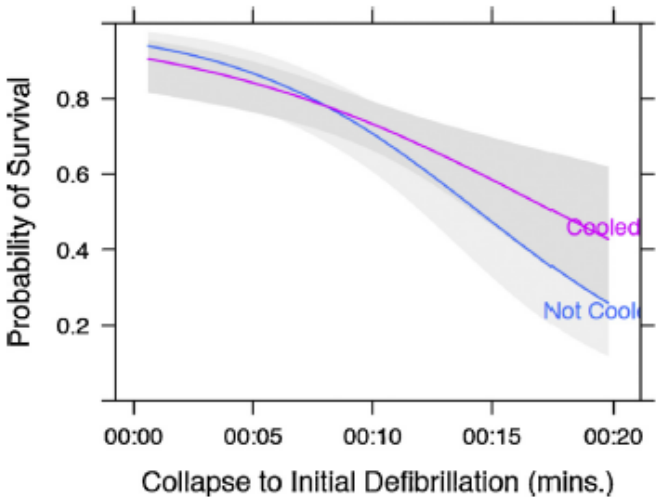


Fig. 3. Effect of time to initial difibrillation and targeted temperature management on survival to hospital discharge.

Limitations:

As a retrospective observational study, there was a risk of measurement bias in data collection, although the data presented derived from a large population. This risk was minimized with the use of trained data guardians and standardized data and other precautions. Another limitation was that we did not analyze specific processes of care information related to the use of TTM for individual cases. We did not specifically evaluate whether patient temperature reached a target temperature of 34◦C within 6 h or was maintained for 12–24 h. However, overall TTM was initiated with a median of 76 min (IQR 27–200 min) after ROSC, had a median duration of 24 h (IQR 19–27 h) and more than 85% of patients reached a target temperature of less than 34◦C.

The study highlights the effect of TTM on functional survival and this effect was dependent upon the time of initial defibrillation.

The results validates the importance to have the temperature sensor on the defibrillator Rescue Life 9. In order to attend on temperature management, the measurement is needed.

END-TIDAL CARBON DIOXIDE AND OUTCOME OF OUT-OF-HOSPITAL CARDIAC

Normally, levels of alveolar carbon dioxide and therefore end-tidal carbon dioxide are determined by carbon dioxide production, alveolar ventilation, and pulmonary blood flow. During low-flow states, end-tidal carbon dioxide levels reflect predominantly pulmonary blood flow; in cardiac arrest, the level is determined entirely by the cardiac output generated by cardiopulmonary resuscitation.

The purpose of the study is to highlights the possibility to predict the death by monitoring end-tidal carbon dioxide during resuscitation after cardiac arrest.

A prospective observational study in 150 consecutive victims of cardiac arrest outside the hospital who had electrical activity but no pulse. The patients were intubated and evaluated by mainstream end-tidal carbon dioxide monitoring.

A persistent end-tidal carbon dioxide level of 10 mm Hg or less after 20 minutes of advanced cardiac life support was chosen a priori as a threshold that would separate patients who did not survive to hospital admission (non-survivors) from those who survived to be admitted (survivors), because it represents an extremely low cardiac output over a prolonged period.

Results:

After 20 minutes of advanced cardiac life support, end-tidal carbon dioxide levels clearly discriminated between non-survivors and survivors, averaging

4.4 ± 2.9 mm Hg (range, 0 to 10) in non-survivors and 32.8 ±7.4 mm Hg (range, 18 to 58) in survivors ($P < 0.001$).

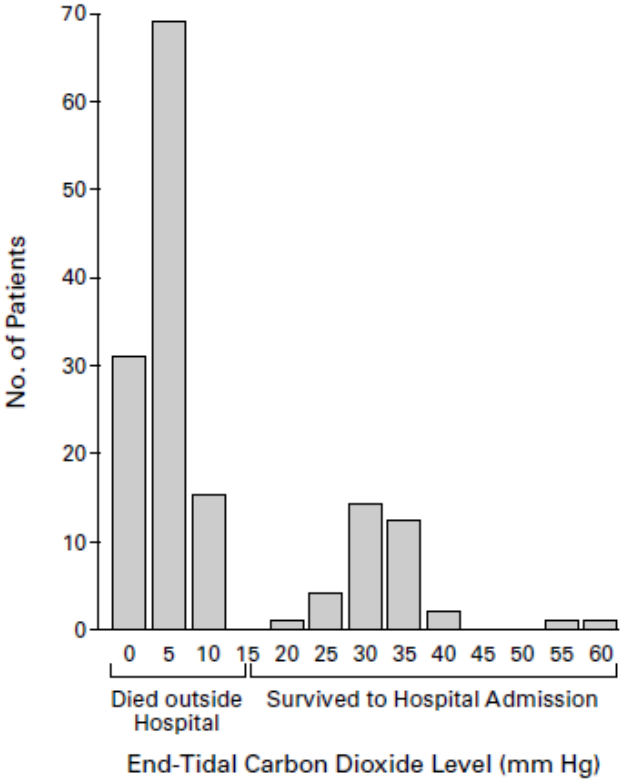
None of the patients with electrical activity but no pulse after 20 minutes of cardiopulmonary resuscitation could be resuscitated.

TABLE 1. END-TIDAL CARBON DIOXIDE VALUES IN PATIENTS WHO SURVIVED TO HOSPITAL ADMISSION AND IN THOSE WHO DID NOT.

VARIABLE	NONSURVIVORS (N = 115)	SURVIVORS (N = 35)	P VALUE*
	mean ±SD (range)		
Age (yr)	68.0±13.8 (31–95)	71.5±13.0 (27–90)	0.19
End-tidal carbon dioxide (mm Hg)†			
Initial	12.3±6.9 (2–50)	12.2±4.6 (5–22)	0.93
Final	4.4±2.9 (0–10)	32.8±7.4 (18–58)	<0.001

*P values were calculated with the Wilcoxon rank–sum statistic.

†Initial end-tidal carbon dioxide levels were determined immediately upon intubation. Final end-tidal carbon dioxide levels were determined after 20 minutes of advanced cardiac life support.



Limitations:

The data derived from a well-define population with pulseless electrical activity. Other dysrhythmias and patient populations need to be studied before our conclusions can be extended to other patients with cardiac arrest.

The data projects the possibility to use an end-tidal carbon dioxide level of 7 mm Hg, for examples, as reason to discontinue cardiopulmonary resuscitation after 20 minutes of advanced cardiac life support.

Use of this criterion would greatly reduce the number of patients with cardiac arrest who undergo prolonged, futile resuscitative efforts in the field and in the hospital, resulting in substantial savings of money and health care resources.

Despite data supporting an end-tidal carbon dioxide threshold of 10 mm Hg or less as indicative of death in victims of prolonged cardiac arrest, clinicians have been reluctant to incorporate end-tidal carbon dioxide monitoring into advanced cardiac life-support algorithms. This is perhaps because of isolated reports of survivors of lengthy resuscitative efforts who have persistently low end-tidal carbon dioxide values.

The end- tidal implants on Rescue Life 9 proves itself as a necessary instrument to predict the success of the rescue measurement on the patient and, equally important, a means to decrease resource wastage.

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

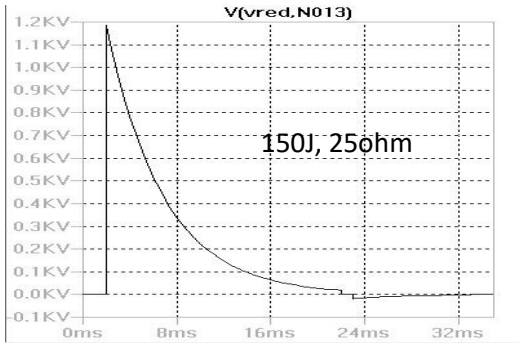
[14] *European Resuscitation Council* Guidelines for Resuscitation 2015 Section 6. Paediatric life support

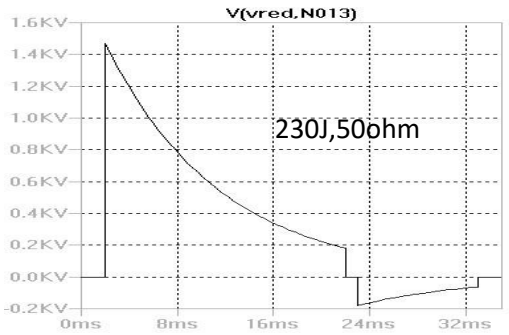
APPENDIX B

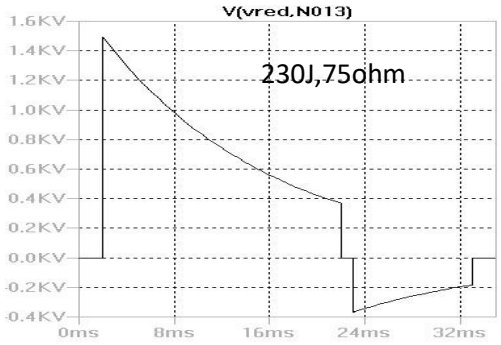
TECHNICAL SPECIFICATIONS

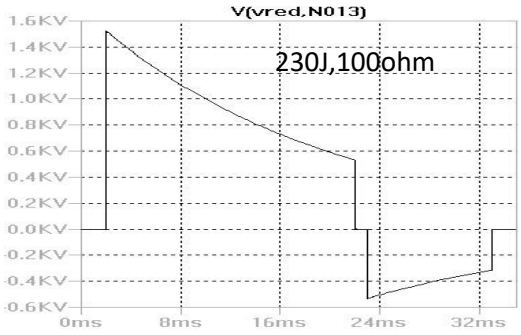
Waveform time-impedance

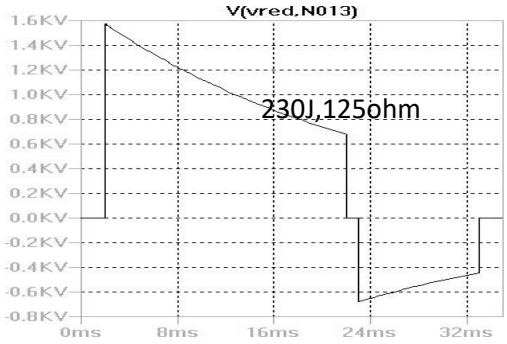
Following flow-charts show typical defibrillation impulses considering the impedance between the defibrillation electrodes for a maximum of 230 Joule:

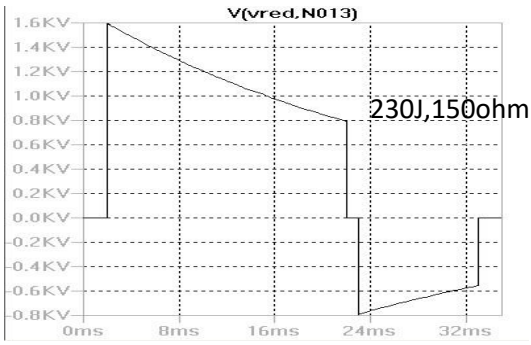


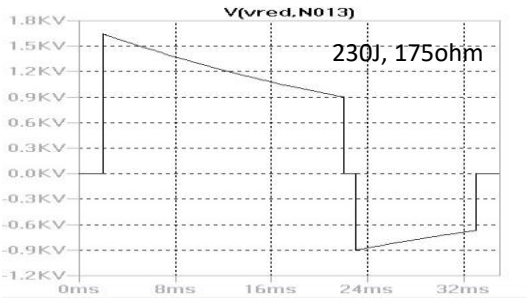












For impedance value of 40ohm or less the maximum energy is 150J. If the energy is set to a value higher then 150J the machine will set automatically the energy to 150J. For impedance values different from 50 ohm the accuracy of the released energy is +/- 15%. For impedance of 50 ohm the accuracy is +/-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

IMPENDANCE LIMITS

RESCUE LIFE 9 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 9** is switched 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 C

TECHNICAL FEATURES

Software version: V3.0

ECG Monitoring

- CMRR > 98 dB
- Input impedance: 50 Mohm
- Patient connection:
  Defibrillation pads and 3, 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:

  Speed: 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, HR min settable = 20 bpm.

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

  Trace: I or II or III with 3 wires patient cable

  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, automatic AED.
- Defibrillable impedance:

  Compensated from 25 ohm to 200 ohm.
- 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 8.4”.

• Resolution: 800 (W) x 600 (H) dots

Device Dimensions

• Dimension: 335 x 225 x 360 mm (L x W x H).

• Weight: 6.5 kg with dual batteries.

Electrical

• Input: 100 - 240 V_{AC} | 50 - 60 Hz | 1.1 A

• Absorbtion: 180 W
• Heat dissipation: 10 W

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

• Electrodes:

Standard defibrillation electrodes

Disposable multifunction electrodes

- 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 Guidelines 2021

- 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 > 99%.

- Energy charging time:

  < 8 sec (with batteries fully charged).

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.

Temperature mode (optional)

- Probe type:
  YSI400 compatible.
- Range:
  0 - 50 °C
- Resolution:
  ± 0.1 °C

External pacemaker (optional)

• Type:

rectangular wave.

• Operating mode:

Manual, on demand.

• Pulse rate:

0 bpm to 170 bpm

• Impulse time:

20, 30, 40 ms

• Pulse current:

0 to 200 mA, adjustable in steps of 5 mA.

• Refractory time:

320 ms (if pulse rate < 80 bpm)

230 ms (if pulse rate ≥ 80 bpm)

$EtCO_2$ (optional)

- Method :
  Quantitative
- Measurement range:
  0 to 150 mmHg.
- Accuracy :
  ± 2mmHg (≤ 40 mmHg]
  ± 5% readings (40 mmHg < CO_2 ≤ 70 mmHg)
  ± 7% readings (70 mmHg < CO_2 ≤ 100 mmHg)
  ± 10% readings (100 mmHg < CO_2 ≤ 150 mmHg)

Accuracy stability is guaranteed for 6 hours after power on.

- Respiratory rate:
  0 to 150 breaths/min ± 1 breath/min
- Rise time:
  120 ms (typical) for step from 10% to 90%

- Warm-up time
  About 10 seconds

Printer

• Type**:**

Integrated thermal 3 channels printer for ECG traces and events documentation

hardcopy including HR/SpO_2/NIBP/$EtCO_2$/TEMP values.

• Paper Speed:

5, 10, 25, 50 mm/sec.

• Paper width:

58 mm.

• Operating model:

Manual, automatic (12” pre and post shock recording).

Standards & Safety

• Standard:

EN 60601-2-4:2011; EN 60601-1:2006+A1:2013+A12:2014; EN 60601-1-2:2015;

Class II, Applied part type BF and CF.

• CE Mark 93/42/EEC :

Medical device, Class IIb.

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

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 (weighing less than 25kg), 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 (weighing more than 25kg);
- 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.

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.

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. Slightly abrade the skin surface to reduce the contact impedance. Avoid applying the adhesive pad on the nipple or breast tissue.
- 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.).
- 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.

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)

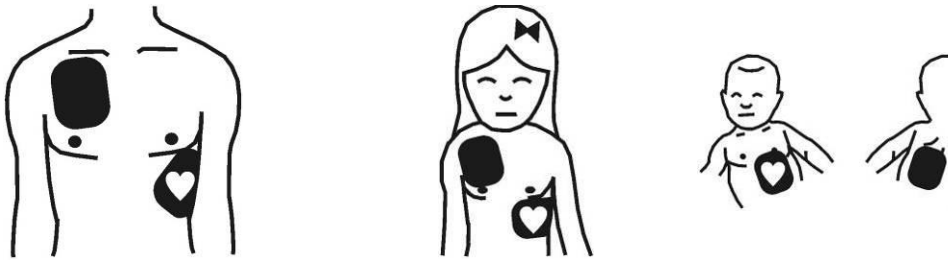
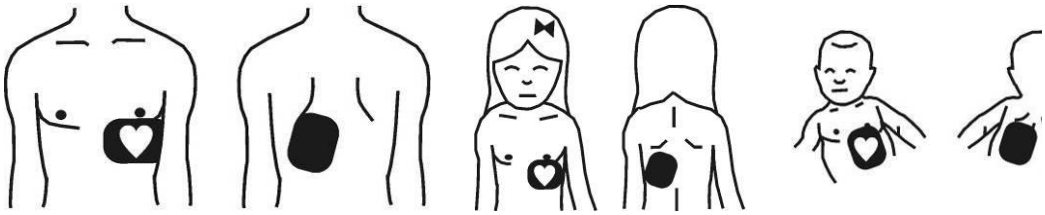


Fig.2

- 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.

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. 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.

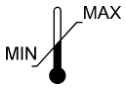
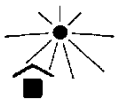
DISPOSAL

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 PROGETTI Quality Assurance Service.

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

APPENDIX E - DECLARATION OF EU CONFORMITY

DECLARATION OF EU CONFORMITY
DICHIARAZIONE DI CONFORMITÀ UE

The present declaration is issued under exclusive responsibility of the Manufacturer.
La presente dichiarazione è rilasciata sotto la responsabilità esclusiva del Fabbricante.

TYPE OF MEDICAL DEVICE ***TIPO DEL DISPOSITIVO MEDICO***	**Defibrillator** *Defibrillatore*
NAME OF MEDICAL DEVICE (REF) ***NOME DEL DISPOSITIVO MEDICO***	***Rescue LIFE 9***
INTENDED USE ***DESTINAZIONE D'USO***	External cardiac defibrillation with biomedical parameters acquisition *Defibrillazione cardiaca esterna con acquisizione di parametri biomedici*
CND CODE (ref.13/03/2018 classification) ***CODICE CND*** *(rif. classificazione del 13/03/2018)*	Z12030599
GMDN / UMDNS CODE ***CODICE GMDN / UMDNS***	17882
BASIC UDI-DI (ref. Ann.VI part C, Reg. 2017/745) ***UDI-DI di BASE*** *(rif. All.VI parte C, Reg. 2017/745)*	**805750683DEF-RLIFE9NP**
CLASS (ref. Ann. IX, Dir. 93/42/EEC) ***CLASSE*** *(rif. All. IX, Dir.93/42/CEE)*	II b
APPLIED STANDARDS ***NORME APPLICATE***	**EN 1041:2008, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 60601-1:2006+A1:2013+A12:2014, EN 60601-1-2:2015, EN 60601-2-4:2011+A1:2019, EN 60601-2-27:2014, EN IEC 80601-2-30:2019, EN ISO 80601-2-55:2011, EN ISO 80601-2-56:2017, EN 60601-1-6:2010+A1:2015, EN 62304:2006+A1:2015, EN 62366-1:2015, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12-1 Rev.8, MEDDEV 2.12/2 Rev.2**
SERIAL NUMBER (SN) ***NUMERO DI SERIE***	*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*** **Per ricevere la dichiarazione di conformità dedicata allo specifico numero di serie e/o un aggiornamento, si prega di contattare ELPRO s.r.l. all'indirizzo email **info@elpromedical.com***
MANUFACTURER (name, address) ***FABBRICANTE*** *(nome, indirizzo)*	**ELPRO S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
MANUFACTURER SRN (ref. art.31, Reg. 2017/745) ***SRN DEL FABBRICANTE*** *(rif. art. 31, Reg. 2017/745)*	**IT-MF-000021267**
NOTIFIED BODY ***ENTE NOTIFICATO***	MTIC InterCert S.r.l. (Notified Body N°**0068**) Via Moscova, 11 20017 Rho (MI) - ITALY
EC MARKING (Ref. Dir.93/42/EEC) ***MARCATURA CE*** *(Rif. Dir.93/42/CEE)*	CE 0068
EC CERTIFICATE N° ***CERTIFICATO CE N°***	**0068/QCO-DM/031-2009 Rev.08**
PROCEDURE OF EVALUATION (ref. Dir.93/42/EEC) ***PROCEDURA DI VALUTAZIONE*** *(Rif. Dir.93/42/CEE)*	**Annex II** (point 4 is excluded) **Allegato II** (punto 4 escluso)
EXPIRE DATE OF EC CERTIFICATE ***DATA DI SCADENZA DEL CERTIFICATO CE***	**27/05/2024**
FIRST ISSUE DATE OF EC CERTIFICATE ***DATA DI PRIMA EMISSIONE DEL CERTIFICATO CE***	06/05/2015

We herewith declare that the described above medical device is compliant to **Directive 93/42/EEC and subsequent amendments** and it can be put in the market according to **art.120 of Regulation (EU) 2017/745** of 05/04/2017 concerning medical device, amended by Regulation (EU) 2020/561 of 23/04/2020. Also, the product is manufactured based on **Directive 2011/65/EU** (RoHS) and subsequent amendments.

*Dichiariamo che il dispositivo medico sopra descritto è conforme alla **Direttiva 93/42/CEE e ss.mm.ii.** e può essere immesso sul mercato ai sensi dell'**art.120 del Regolamento (UE) 2017/745** del 05/04/2017 sui dispositivi medici, modificato dal Regolamento (UE) 2020/561 del 23/04/2020. Inoltre, il dispositivo medico soddisfa i requisiti applicabili della **Direttiva 2011/65/UE** (RoHS) e successive modifiche.*

PLACE AND DATE OF ISSUE ***LUOGO E DATA DI EMISSIONE***	TROFARELLO (TO), **11/03/2022**
SIGNATURE ***FIRMA***	Dr. CESARE MANGONE MANAGEMENT REPRESENTATIVE

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: Defibrillator

Model: RESCUE LIFE 9 SN _____

VALIDITY starting from : ___/___/_____

Delivery date:_____

Invoice N°_____dated_____

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