progetti®
Medical Equipment Solutions

USER MANUAL

Semi-Automated External Defibrillator (AED)

Rescue SAM 4.0^{d}

ENG

Doc. No. TF-RescueSAM4.0d-0.3/3.1ENG-0.4

CE 0068

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Disclaimer

PROGETTI S.r.l., as Manufacturer of the Rescue SAM 4.0d medical device and dedicated accessories, is responsible for their safety and performance for the duration of their expected service life, unless the customer cannot prove that he has complied with the requirements of use, maintenance and storage of this User Manual.

PROGETTI S.r.l. shall not be held liable for any accidental damage caused to the AED Rescue SAM 4.0d and its accessories during transport to the customer or during use.

PROGETTI S.r.l. is at the customer's disposal for any further information.

⚠ PROGETTI S.r.l. recommends that the AED Rescue SAM 4.0d be subject to an **annual preventive maintenance** plan (functional check and electrical safety check) and that during the service period of the AED Rescue SAM 4.0d the following be checked:

- intactness of the enclosure of the main unit and of the battery;
- intactness of the packaging of the disposable multifunction electrodes and their cable as well as their validity (see expiry date on labelling);
- colour and flashing of the status LED;
- readability of the labelling on the main unit and on all accessories.

For further information, please contact the PROGETTI technical assistance service at **service@progettimedical.com** or on the telephone number **+39.011.644.738.**

The information in this user manual may be subject to change by the Manufacturer without notice. In this case, the changes are notified to the customer.

Limited Warranty

The "Limited Warranty" shipped with PROGETTI products is the sole warranty regarding the product.

Useful contacts

- COMPANY - **info@progettimedical.com**
- SALES - **sales@progettimedical.com**
- TECHNICAL SUPPORT - **service@progettimedical.com**
- QUALITY & REGULATORY - **quality@progettimedical.com**

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

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THANK YOU FOR CHOOSING THE AED RESCUE SAM 4.0D!

The AED (semi-Automatic External Defibrillator) Rescue SAM 4.0d is an emergency medical device designed for patient management in accordance with the *European Resuscitation Council* (ERC) guidelines "*Basic Life Support - Defibrillation*" (BLSD).

In general, AED users must be trained on correct use in conjunction with the above-mentioned protocol.

This user manual contains instructions on how to safely use and store the AED Rescue SAM 4.0d.

Rescue SAM 4.0d is CE marked pursuant to Directive 93/42/EEC as amended, that is it conforms to the applicable harmonized standards, guaranteeing safety and performance in keeping with the State of the Art.

In order to maintain safety and performance throughout the life of your devices, use only the components and accessories recommended by the manufacturer.

Only technical personnel trained and authorized by the manufacturer must perform corrective maintenance on Rescue SAM 4.0d and its dedicated accessories.

1. INTRODUCTION

This User Manual provides information for the safe and proper use of the semi-Automatic External Defibrillator ("**AED**") Rescue SAM 4.0d and its accessories.

When connected to a person who is not conscious and breathing, Rescue SAM 4.0d is intended to perform the following functions:

- guide the responder through the preliminary actions of BLS-D;
- automatically classify the acquired ECG, that is determine whether the rhythm is defibrillable or non-defibrillable and respectively enable or disable the defibrillation energy discharge (shock) button;
- guide the responder through Cardiopulmonary Resuscitation (CPR).

Rescue SAM 4.0d uses a pair of disposable multifunction electrodes (adult or paediatric patients) for both ECG signal acquisition and electric discharge (shock) delivery. These electrodes are supplied in a single-use state together with Rescue SAM 4.0d.

Rescue SAM 4.0d verifies that the electrode-to-skin coupling is correct by measuring the electrical impedance between the two disposable multifunction electrodes after they have been applied to the patient. Audio-visual messages inform the user of possible contact problems with the patient. Rescue SAM 4.0d is designed to operate correctly in the patient impedance range **25–200 Ω.**

Defibrillation energy can be released into the patient by means of an electrical pulse characterized by a "***BTE (Biphasic Truncated Exponential)***" compensated type of waveform. **200 J** nominal or **50 J** nominal are released by Rescue SAM 4.0d if disposable multifunction electrodes are used for adult or paediatric patients respectively. With the Rescue SAM 4.0d compensation capability, the duration of the defibrillation pulse is variable so that the defibrillation energy released is 200 J nominal or 50 J nominal (depending on the electrodes used) regardless of the patient impedance measured.

Rescue SAM 4.0d is powered by a non-rechargeable lithium battery, with an expiry date on the dedicated label.

Rescue SAM 4.0d can be enabled or disabled for environmental audio recording (in compliance with the applicable privacy regulations).

1.1 INTENDED USE

1.1.1 INTENDED CLINICAL CONDITIONS

The AED Rescue SAM 4.0d is intended to be used for the **external cardiac defibrillation** of a victim of sudden cardiac arrest (SCA), who is thus in the following state:

- unconscious and
- not breathing.

The cardiac arrhythmias for which the AED Rescue SAM 4.0d is effective are therefore **Ventricular Fibrillation** and **rapid Ventricular Tachycardia (heart rate > 150 BPM).**

1.1.2 INTENDED CLASSES OF PATIENTS

Rescue SAM 4.0d is intended for use on the following patient classes:

- **adult**, that is age ≥ 8 years and weight ≥ 25 kg (including pregnant women);
- **paediatric,** that is aged 1 to 8 years and weighing < 25 kg.

Rescue SAM 4.0d is **not** intended for use on **infants** (age < 1 year).

1.1.3 INTENDED USERS

The AED Rescue SAM 4.0d is intended to be used by a layman or healthcare professional. In any case, the user should meet the following requirements:

- be qualified by a competent body to operate the AED in accordance with the applicable BLS-D protocols (e.g., ERC);
- be trained in correctly using the AED Rescue SAM 4.0d;
- be informed of the hazards involved in using the AED Rescue SAM 4.0d and of everything else in this User Manual.

1.1.4 INTENDED USE ENVIRONMENTS

Rescue SAM 4.0d is not intended to be used in the following environments:

- with a high oxygen concentration;
- in the presence of flammable substances in the immediate vicinity of the AED Rescue SAM 4.0d;
- in water.

1.2 CONTRAINDICATIONS

The AED Rescue SAM 4.0d *must* not be used if the person is in the following state:

- conscious;
- breathing;
- with a pulse.

Rescue SAM 4.0d **is NOT intended to be used for ECG monitoring**.

1.3 SIDE EFFECTS

Depending on its intended use, the AED Rescue SAM 4.0d has no significant side effects.

1.4 SAFETY WARNINGS

LEGEND

	**DANGER**	Immediate risks that could lead to serious personal injury or death.
	**WARNING**	Unsafe conditions, risks, or behaviour that could lead to serious personal injury or death.
	**CAUTION**	Unsafe conditions, risks or behaviour that could lead to minor personal injury, damage to Rescue SAM 4.0d, or a loss of information.

1.4.1 ELECTRICITY

 **DANGER**	Dangerous leakage of electricity. This device should only be used by personnel trained in the rescue protocol.

1.4.2 ENVIRONMENTAL CONDITIONS OF USE

 **DANGER**	Risk of device explosion when used in the presence of flammable anaesthetics or concentrated oxygen. Rescue SAM 4.0d has not been evaluated or approved for use in locations considered hazardous pursuant to *National Electric Code* standards.
 **WARNING**	Radio interference such as that of mobile phones or radio transmitters may cause Rescue SAM 4.0d to function improperly. In accordance with IEC 801.3, a distance of 2 metres is recommended between Rescue SAM 4.0d and any radio equipment.

CAUTION	Although Rescue SAM 4.0d is designed for a wide range of usage conditions, treating the device roughly could damage it.
CAUTION	Do not immerse any part of this product in water or any other liquid. Do not allow any fluids to get inside the device. Avoid spilling fluids onto this device or its accessories. Spilling liquids onto Rescue SAM 4.0d can damage it or cause fire or risks of electric shock.
CAUTION	Rescue SAM 4.0d should only be stored and used in the environmental conditions stated in these technical specifications.

1.4.3 CLEANING AND DISINFECTION

CAUTION	Clean and sanitize the enclosure of the main unit of Rescue SAM 4.0d after each use. Use a soft cloth.
CAUTION	Do not immerse Rescue SAM 4.0d and its accessories in any liquid. Do not allow any liquids to get inside it.
CAUTION	Do not use abrasive materials or strong solvents such as acetone and/or its derivatives.
CAUTION	Use the following products for both the Rescue SAM 4.0d bag and the socket: • Soap and water; • Ammonia-based products; • Hydrogen peroxide; • Isopropyl alcohol (70% solution); • Bleach (30ml/litre of water).
CAUTION	Do not autoclave or gas sterilize Rescue SAM 4.0d or its accessories.

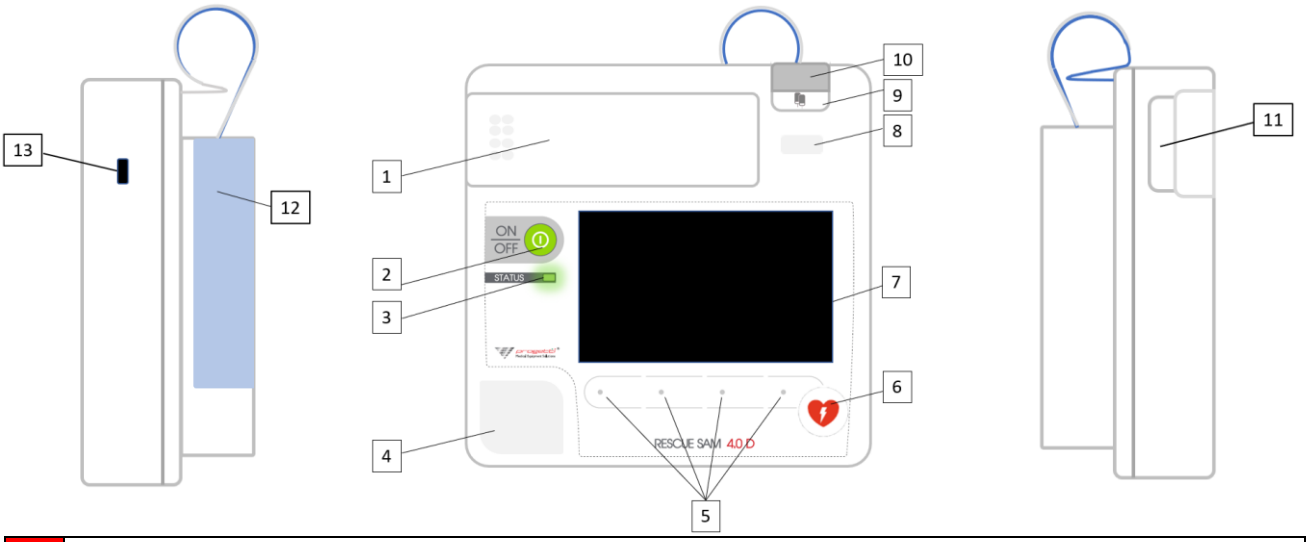
1.4.4 MAINTENANCE

WARNING	Do not open the unit, remove the covers, or attempt to make repairs or modifications without the Manufacturer's permission. If replacement and/or repair of Rescue SAM 4.0d or any of its accessories is necessary, contact the manufacturer PROGETTI S.r.l.
WARNING	Rescue SAM 4.0d is designed to perform automatic periodic checks and to allow the people who handle it to check its status. In any case, no level of control can ensure performance or detect any misuse, damage or defect occurring since the most recent check completed.

 **WARNING**	Using damaged devices or accessories may cause the device to function incorrectly and may result in injury to the patient or operator.
 **CAUTION**	Improper maintenance can cause Rescue SAM 4.0d to not function properly. Store Rescue SAM 4.0d only as described in this User Manual.

2. DESCRIPTION OF THE MEDICAL DEVICE

2.1 VIEWS

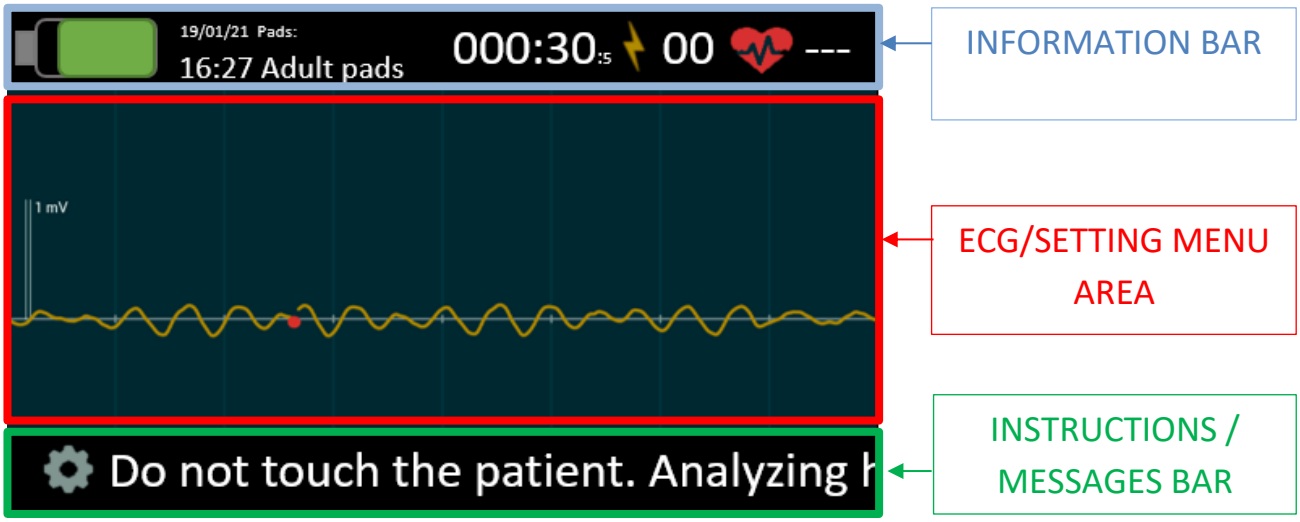


1	**BATTERY** When inserted and charged, it powers Rescue SAM 4.0d.
2	**ON/OFF BUTTON** If pressed for 2 seconds, it turns Rescue SAM 4.0d on from off or if pressed for 4 seconds it turns Rescue SAM 4.0d off from on.
3	**STATUS LED** Indicates the status of Rescue SAM 4.0d; flashes green when the device is ready for use but on standby (see par. “STATUS LED” for further information).
4	**SPEAKER** Emits voice instructions when Rescue SAM 4.0d is on.
5	**KEYBOARD** It allows the user to interact with the Rescue SAM 4.0d.
6	**SHOCK BUTTON** If illuminated red and then pressed, it enables the defibrillation discharge (shock). This button is disabled in all other cases.
7	**DISPLAY** It allows the user to see instructions and review other information.
8	**MICROPHONE** Records environmental sounds near Rescue SAM 4.0d during its use (if enabled).
9	**DISPOSABLE MULTIFUNCTION ELECTRODES CONNECTOR SOCKET**
10	**DISPOSABLE MULTIFUNCTION ELECTRODES CONNECTOR**
11	**BATTERY UNLOCK BUTTON** If pressed, the battery can be removed from the main unit.
12	**MULTIFUNCTION DISPOSABLE ELECTRODES HOLDER COMPARTMENT** Houses the disposable electrodes package while the AED is on standby.
13	**PLUG-IN** If the supplied cable is inserted, it allows the AED to be connected to a PC for a firmware upgrade or for transferring the data recorded during use, only when the AED is not being used on the patient.

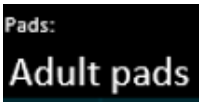
2.2 GRAPHICAL USER INTERFACE

2.2.1 DISPLAY

The Rescue SAM 4.0d display is organized as shown in the following picture:



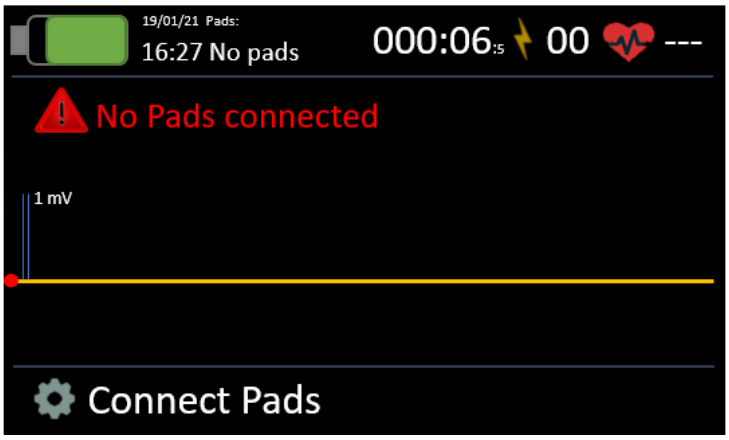
The following table describes the icons that can be displayed on the Rescue SAM 4.0d display, as graphic information that the user can observe when using the device on a patient.

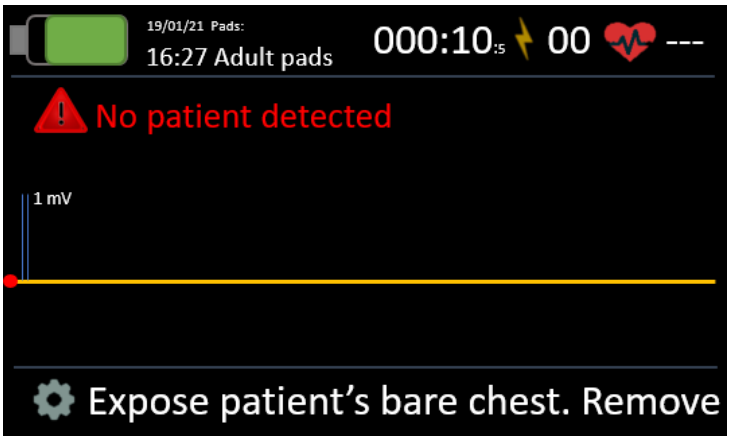
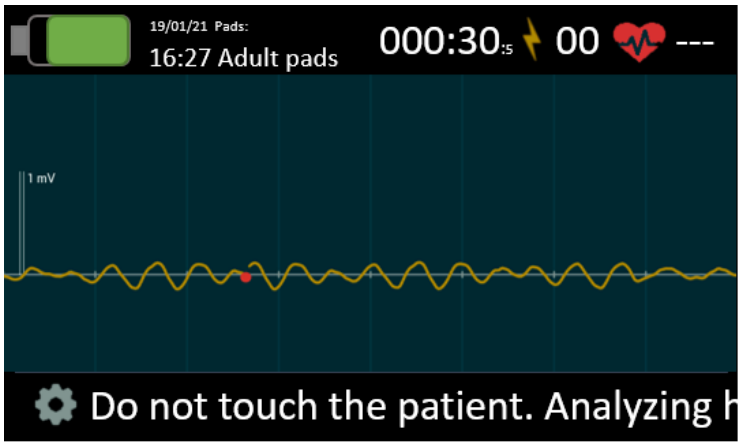
ICON	POSITION	MEANING
	INFORMATION BAR	Battery charge level
	INFORMATION BAR	Date (DD-MM-YY) Hour and minutes [hh:mm]
	INFORMATION BAR	Type of connected disposable multifunction electrodes. Possible cases are: “Adult pads”, “Pediatric pads”, “No pads”.
	INFORMATION BAR	Time scored from the powering-on of the AED [min:sec]
	INFORMATION BAR	Number of discharged shocks
	INFORMATION BAR	Heart rate [BPM]
	INSTRUCTIONS / MESSAGES BAR	Setup

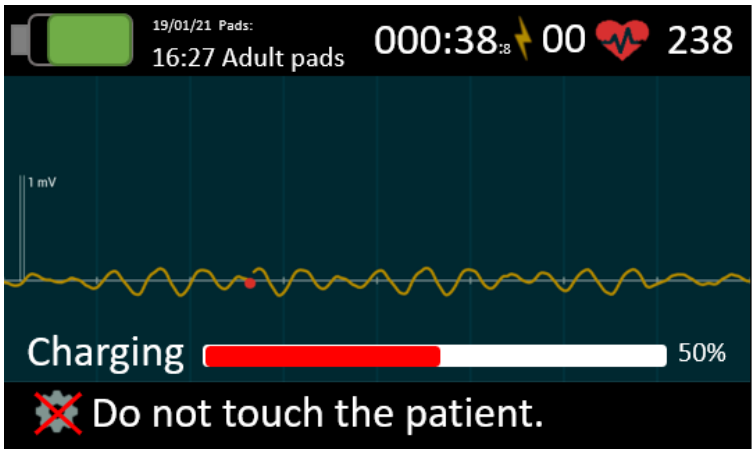
	INSTRUCTIONS / MESSAGES BAR	Arrows to navigate the setting menu
	ECG/MENU AREA	1 mV reference lines for ECG
	ECG/MENU AREA	Warning (if occurred)

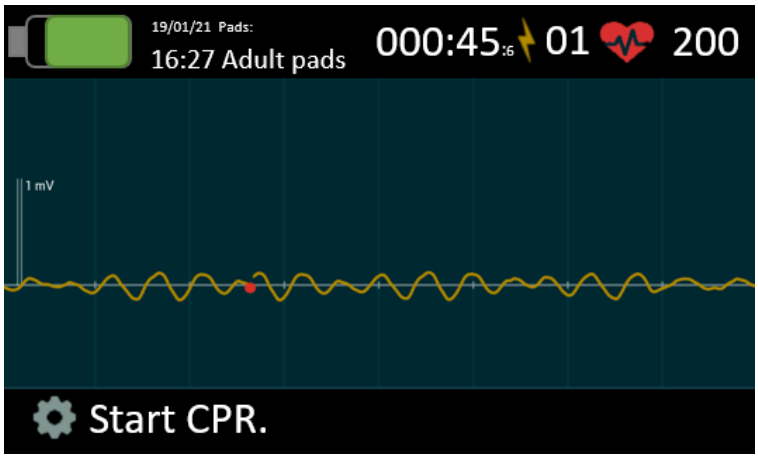
Patient's acquired ECG is shown in yellow. A red ball indicates the instant upload of the ECG trace and the ECG amplitude level with reference to 1 mV reference lines.

The instructions for BLSD are written in the display of Rescue SAM 4.0d and reproduced as vocal instructions. The possible cases are summarized below.

#	INSTRUCTIONS	MEANING
A	 Vocal Instructions: << ***Connect Pads*** >>	The disposable multifunction electrodes are not connected to the main unit.

#	INSTRUCTIONS	MEANING
B	 Vocal instructions: << ***Expose patient's bare chest. Remove or cut clothing if needed. Shave the chest if needed. Take the pads package. Tear open package and remove pads. Peel one pad from plastic liner and place it as illustrated. Peel the second pad from plastic liner and place it as illustrated.*** >>	The disposable multifunction electrodes are not applied to the patient (patient impedance not detected).
C	 Vocal instructions: << ***Do not touch the patient. Analyzing heart rhythm.>>***	Do not touch the patient: ECG analysis is in progress.

#	INSTRUCTIONS	MEANING
D	 Vocal instructions: << ***Shock advised.*** >>	The shock is advised and the charging of defibrillation energy starts. A rapid succession of high-pitch tones is reproduced. However, ECG analysis continues: don't touch the patient.
E	 Vocal instructions: << ***Do not touch the patient.*** >>	The charging of defibrillation energy is in progress. A rapid succession of high-pitch tones is reproduced. However, ECG analysis continues: don't touch the patient.
F	 Vocal instructions: << ***Press the red shock button.*** >>	The charging of defibrillation energy is in finished. The lighted red shock button waits to be pressed by the user for discharge. However, ECG analysis continues: don't touch the patient.

#	INSTRUCTIONS	MEANING
G	 Vocal instructions: << ***Shock delivered. It is now safe to touch the patient.*** >>	The defibrillation energy is delivered. Now, it is possible to touch the patient.
H	 Vocal instructions: << ***Start CPR*** >>	Perform Cardiopulmonary Resuscitation (CPR) on the patient, synchronizing with the sound metronome.
I		Perform Cardiopulmonary Resuscitation (CPR) on the patient, synchronizing with the sound metronome for 120 seconds.

2.2.2 SETTING MENU

By pressing the Setup icon the user can review the following parameters:

- *Brightness;*
- *Time;*
- *Language* (editable only if the multilingual configuration has been requested by the customer*);*
- *Pads* (editable only for RS4-DFB01PRC, that is both adult and pediatric disposable multifuction electrodes);
- *Serial Number* (no edit is allowed).

The user must press the appropriate arrows on the keyboard to enable the following described commands:

▲	To sliding from the bottom to the top
▼	To sliding from the top to the bottom
▶	To confirm (enter)
↩	To exit

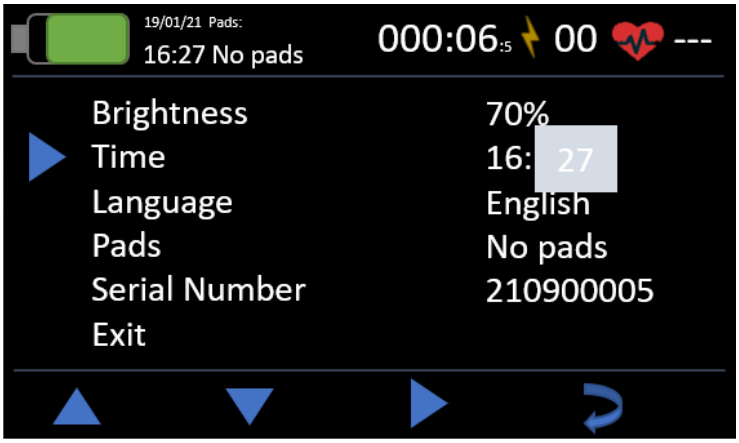
BRIGHTNESS SETUP

1. Press on the keyboard's button;
2. Press ▶ on the keyboard's button to confirm;

3. Press ▲ or ▼ on the keyboard's button to regulate the brightness;
4. Press ▶ on the keyboard's button to confirm the value;
5. Press ↩ on the keyboard's button to save and exit.

TIME SETUP

1. Press  on the keyboard's button;
2. Press ▼ on the keyboard's button for positioning on "Time";
3. Press ▶ on the keyboard's button to confirm;

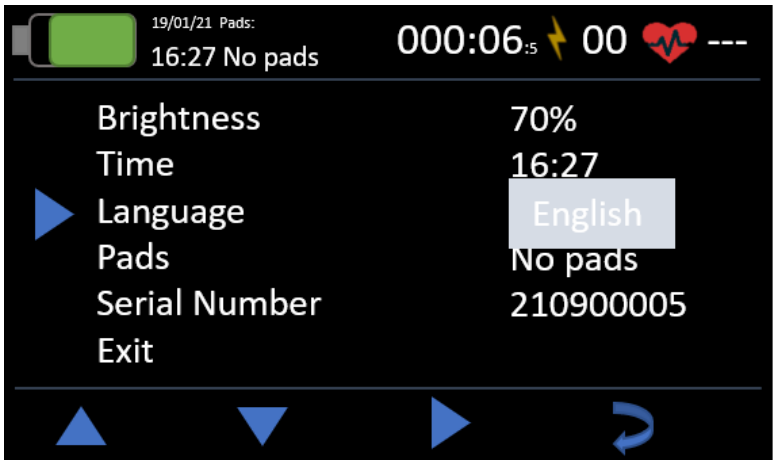


4. Press ▲ or ▼ on the keyboard's button for set "minutes";
5. Press ▶ on the keyboard's button to slide on the "hour";
6. Press ▲ or ▼ on the keyboard's button for set "hours";
7. Press 2 times ↩ on the keyboard's button to confirm the value, save and exit.

LANGUAGE SETUP (if multiple languages are available)

Language is editable only if the multilingual configuration has been requested by the customer.

1. Press  on the keyboard's button;
2. Press 2 times  on the keyboard's button for positioning on "Language";
3. Press  on the keyboard's button to confirm;

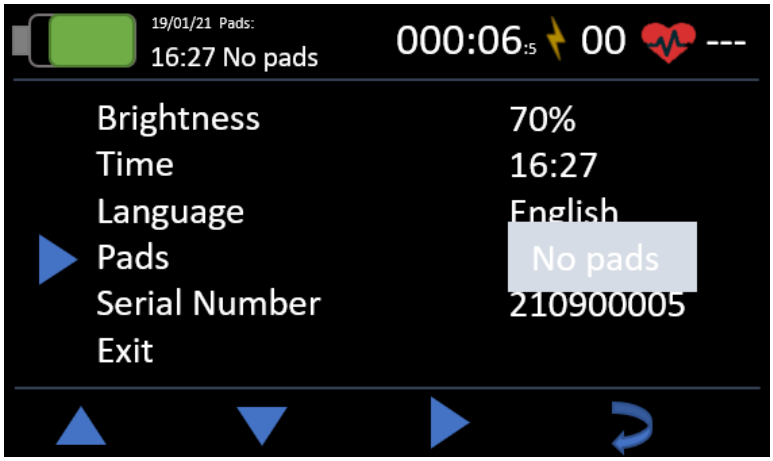


4. Press  or  on the keyboard's button for set the language;
5. Press  on the keyboard's button to confirm the value;
6. Press  on the keyboard's button to save and exit.

PADS SETUP (editable only with RS4-DFB01PRC Disposable Electrodes)

Type of pads is editable only for RS4-DFB01PRC, that is both adult and pediatric disposable multifuction electrodes.

1. Press  on the keyboard's button;
2. Press 3 times  on the keyboard's button for positioning on "Pads";
3. Press  on the keyboard's button to confirm;



4. Press  or  on the keyboard's button to set "Adult pads" or "Pediatric pads";
5. Press  on the keyboard's button to confirm the type;
6. Press  on the keyboard's button to save and exit.

2.2.3 STATUS LEDs

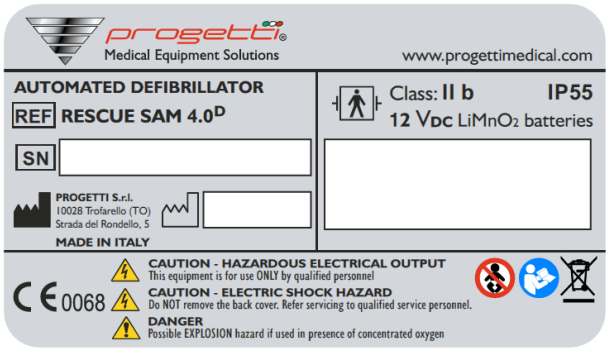
The following table describes the meaning of each colour taken on by the status LED.

STATUS LED COLOUR		MEANING
GREEN		Rescue SAM 4.0d is ready for use
ORANGE		In descending order of priority: a) Rescue SAM 4.0d is not ready for use: the disposable multifunction electrodes are not connected to the main unit; b) if case (a) is not applicable, Rescue SAM 4.0d's battery level is low, but at least 20 shocks are still ensured; c) if cases (a) and (b) are not applicable, scheduled maintenance is due;
RED		Rescue SAM 4.0d is not ready for use: there is a fault, or the battery level is critically low. If the battery is low the device will keep operating until it is turned off, but will not turn on again until the battery is changed. In this way the device ensures a minimum of 10-20 shocks in all conditions or up to 1h of monitoring.
OFF		Rescue SAM 4.0d is not ready for use: the battery is completely depleted or is not inserted correctly, so the device will not turn on.

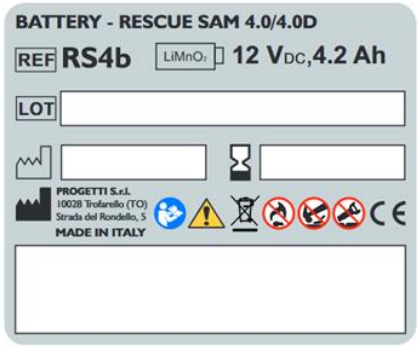
If Rescue SAM 4.0d is in stand-by mode the status LED will be flashing, whereas if Rescue SAM 4.0d is on the LED will be on steady.

2.2.4 LABELS

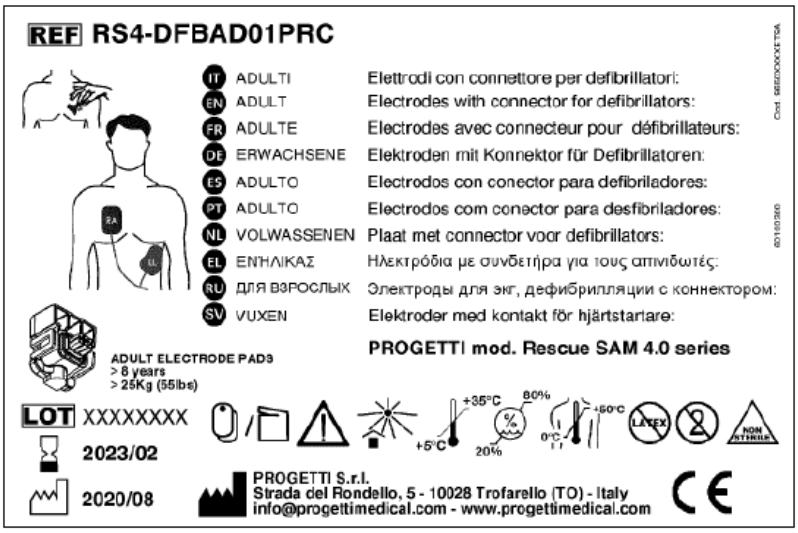
The following label is attached to the back of Rescue SAM 4.0d as accompanying documentation.



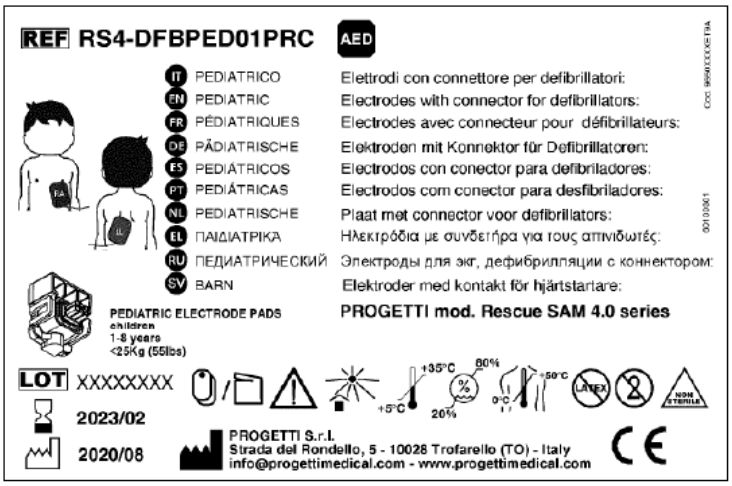
The following label is attached to the back of the Rescue SAM 4.0d battery as accompanying documentation.



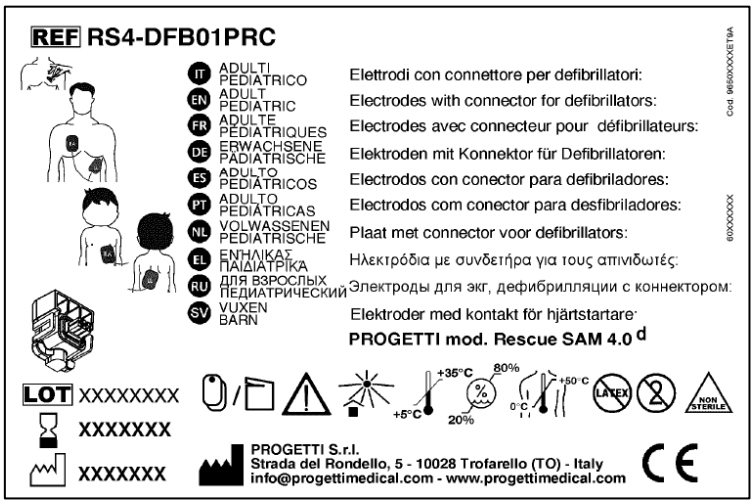
The following label is attached to the back of the package of disposable multifunction electrodes for **adults** as accompanying documentation.



The following label is attached to the back of the package of disposable multifunction electrodes for **paediatrics** as accompanying documentation.

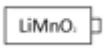


The following label is attached to the back of the package of disposable multifunction electrodes for **adult/paediatrics** as accompanying documentation.



The following table specifies the meaning of each symbol on the labels illustrated above and on the labels of the packaging.

SYMBOL	DESCRIPTION
REF	Identification of the medical device (Ref. EN ISO 15223-1:2016-11)
SN	Serial number (Ref. EN ISO 15223-1:2016-11)
LOT	Batch number (Ref. EN ISO 15223-1:2016-11)

	Date of manufacture of the medical device (Ref. EN ISO 15223-1:2016-11)
	Identification of the Manufacturer of the medical device (Ref. EN ISO 15223-1:2016-11)
	BF-type applied part protected against the effects of defibrillator discharge (Ref. EN ISO 60601-1:2006)
CE 0068	CE Marking & Identification of the Notified Body.
	General warning (Ref. EN ISO 60601-1:2006)
	Caution: hazardous voltage (Ref. EN ISO 60601-1:2006)
	DO NOT use the device on Infants
	Comply with local laws for disposal and recycling (Ref. Directive 2012/19/EU on Waste Electrical and Electronic Equipment - WEEE)
	Obligation to read the Instructions for Use (Ref. EN ISO 60601-1:2006)
	Expiry date after which the device must not be used, as performance and safety are no longer guaranteed (Ref. EN ISO 15223-1:2016-11)
	$LiMnO_2$ cell type
	DO NOT damage or open the batteries
	DO NOT expose the batteries to high temperatures or open flames DO NOT set fire to the batteries
	DO NOT crush the batteries
CE	CE marking
	Keep away from sunlight (Ref. EN ISO 15223-1:2016-11)
	Temperature limitation (Ref. EN ISO 15223-1:2016-11)

	Humidity limitation (Ref. EN ISO 15223-1:2016-11)
	Latex free
	Single-use: do not reuse (Ref. EN ISO 15223-1:2016-11)
	Non-sterile device

2.3 BATTERY

The lithium battery powers Rescue SAM 4.0d. It can be inserted or removed from the main unit independently.
The remaining charge can be deduced from the colour of the status LED (see “Status LED” chapter).

MODEL (REF)	RS4b
TYPE	12V_{DC}, 4.2Ah, $LiMnO_2$, non-rechargeable.
CAPACITY	200 discharges at maximum energy 200 J.
EXPIRY	5 years from the date of manufacture
ESTIMATED DURATION ON STAND-BY (AFTER INSERTION INTO THE MAIN UNIT)	5 years after insertion into the main unit

WARNING	The lithium battery is not rechargeable. Any attempt to recharge the lithium batteries can lead to fire or explosion.
WARNING	Do not immerse the battery in water or any other liquid (immersion could lead to fire or explosion).
WARNING	Do not short-circuit, drill holes or deform the battery.
WARNING	Do not expose the battery to temperatures above 50°C.
WARNING	Dispose of the battery in accordance with national regulations when it is depleted. Do not burn the battery.
CAUTION	Follow all the instructions on the battery label.
CAUTION	Do not use the battery after the expiry date stated on the label. Contact the manufacturer PROGETTI S.r.l. to request replacement.

2.4 CARRYING BAG

The carrying bag is an optional accessory of Rescue SAM 4.0d, supplied on request by PROGETTI. It is intended to be used to facilitate transport and to improve protection from knocks and/or from the ingress of water or foreign substances into Rescue SAM 4.0d and its accessories throughout stand-by. When the bag is open, the AED can still be used even if it is contained in the bag.

Insert the main unit (with the battery inserted) into the left side of the bag, inside the protective layer. Insert the package of pre-connected disposable multifunction electrodes into the pocket on the right side of the bag.

2.5 DISPOSABLE MULTIFUNCTION ELECTRODES

Rescue SAM 4.0d is for use with disposable multifunction electrodes for adults PROGETTI® (REF: RS4-DFBAD01PRC) or with disposable multifunction electrodes for paediatrics (REF: RS4-DFBPED01PRC) or with disposable multifunction electrodes for adults and pediatrics (REF: RS4-DFB01PRC) branded PROGETTI®. The table below lists the types and characteristics of the disposable multifunction electrodes that can be used with Rescue SAM 4.0d.

	DISPOSABLE MULTIFUNCTION ELECTRODES FOR ADULT PATIENTS	**DISPOSABLE MULTIFUNCTION ELECTRODES FOR PAEDIATRICS PATIENTS**	**DISPOSABLE MULTIFUNCTION ELECTRODES FOR ADULT and PEDIATRIC PATIENTS**
REF	**RS4-DFBAD01PRC**	**RS4-DFBPED01PRC**	**RS4-DFB01PRC**
IMAGE			
PATIENT CLASS	For adult patients (≥8 years and ≥25 kg)	For pediatric patients (<25 kg)	For adult and pediatric patients
DESIGNED USE	Single-use		
ADHESION	Self-adhesive		
ACTIVE SURFACE OF THE GEL	94 cm^2 each (nominal)	40 cm^2 each (nominal)	95 cm^2 each (nominal)
SUPPORT MATERIAL	Medical foam, thickness 1 mm		
CONDUCTIVE MATERIAL	Metal foil		
ELECTROCONDUCTIVE GEL	Low impedance conductive adhesive gel		
CABLE/CONNECTOR	Integrated		
CABLE LENGTH	120 cm		
TYPE OF APPLIED PART	BF		
STORAGE TEMPERATURE	5°C – 35°C		
STORAGE HUMIDITY	20% – 80% (non-condensing)		
EXPIRY	30 months from the date of manufacture (if the package is not opened or damaged)		

WARNING	Use only PROGETTI® disposable multifunction electrodes that are compatible with Rescue SAM 4.0d.
WARNING	Do not reuse disposable multifunction electrodes: they are single-use and must be disposed of after use. Reuse can cause: cross-infection, incorrect device operation, inadequate therapy, and injury to the patient or operator.
WARNING	DO NOT remove the disposable multifunction electrodes from the sealed packaging until they are to be used. The packaging should only be used immediately before use, otherwise the disposable multifunction electrodes may dry out and become unusable.
CAUTION	Observe all the information on the disposable multifunction electrodes package. Do not use the disposable multifunction electrodes beyond the expiry date specified on the back of the package.
CAUTION	If you notice any irregularities on the packaging, cable or connector of the disposable multifunction electrodes, contact the manufacturer PROGETTI S.r.l.
CAUTION	Check the expiry date on the label before using the disposable multifunction electrodes. If the disposable multifunction electrodes have expired, they are no longer usable.

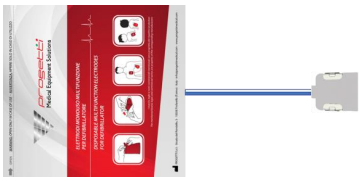
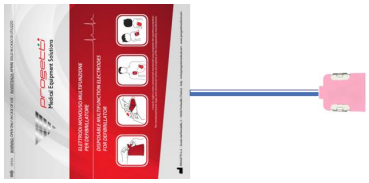
Rescue SAM 4.0d can automatically distinguish between the types of electrodes connected to the main unit, distinguishing between disposable multifunction electrodes for adults and disposable multifunction electrodes for paediatrics and automatically programmes charging at either 200 J nominal or 50 J nominal respectively.

Also, it allows the selection between adult patient and pediatric patient in case of use of adult/pediatric disposable electrodes, so the automatically charging at nominal 200J (adults) or nominal 50J (pediatrics).

The disposable multifunction electrodes are supplied in a sealed package with the connector and part of the external cable that allows the device to be stored with the electrodes pre-connected (pre-connection state) for quick use in an emergency. When Rescue SAM 4.0d is used, the operator only needs to open the package of electrodes, switch on the device, remove the protection from the electrodes and apply them to the patient.

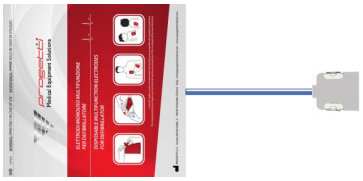
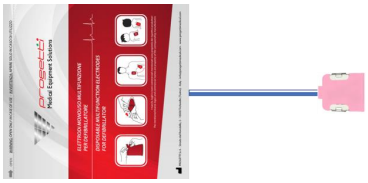
3. PARTS OF RESCUE SAM 4.0D

The table below identifies the parts of Rescue SAM 4.0d.

PART NUMBER (REF)	PART	STANDARD/ OPTIONAL	REFERENCE PICTURE
RS4D	**Main unit**	☒standard ☐optional	
RS4b	**Battery**	☒standard ☐optional	
RS4bag	**Carrying bag**	☐standard ☒optional	
RS4-DFBAD01PRC	**Disposable Multifunction Electrodes for Adults**	☒standard ☐optional	
RS4-DFBPED01PRC	**Disposable Multifunction Electrodes for Pediatrics**	☐standard ☒optional	
RS4-DFB01PRC	**Disposable Multifunction Electrodes for Adult and Pediatrics**	☐standard ☒optional	
TF-RescueSAM4.0-0.0/3.1ENG4.0D	**User Manual**	☒standard ☐optional	
PG Data Manager	**PG Data Manager**	☐standard ☒optional	

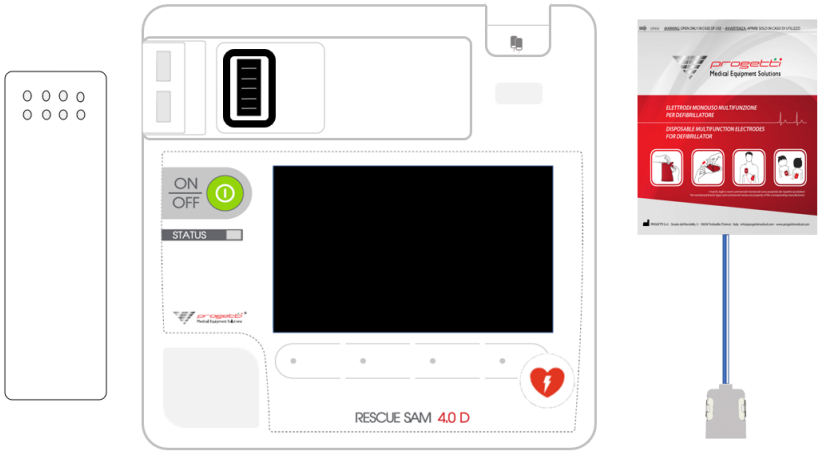
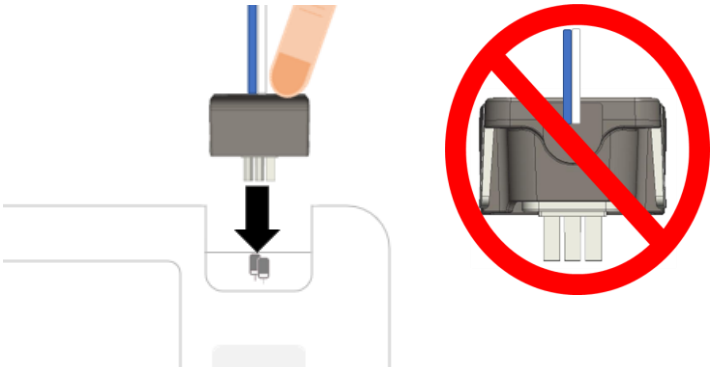
3.1 Accessories / Spare Parts

The manufacturer PROGETTI S.r.l. recommends purchasing only PROGETTI® accessories / spare parts, namely those indicated in the following table.
For any information or request please contact technical support service of PROGETTI S.r.l.

PART NUMBER (REF)	SPARE PART	IMAGE
RS4b	**Battery** It is reckoned that this spare part is to be requested from the manufacturer in the following cases: • Depleted battery charge; • Battery failure.	
RS4bag	**Carrying bag** It is reckoned that this spare part is to be requested from the manufacturer in the following cases: • broken bag; • lost bag.	
RS4-DFBAD01PRC	**Disposable Multifunction Electrodes for Adults** It is reckoned that this spare part is to be requested from the manufacturer in the following cases: • expired electrodes; • electrodes already used; • damaged cable; • damaged packaging.	
RS4-DFBPED01PRC	**Disposable Multifunction Electrodes for Pediatrics** It is reckoned that this spare part is to be requested from the manufacturer in the following cases: • expired electrodes; • electrodes already used; • damaged cable; • damaged packaging.	
RS4-DFB01PRC	**Disposable Multifunction Electrodes for Adults and Pediatrics** It is reckoned that this spare part is to be requested from the manufacturer in the following cases: • expired electrodes; • electrodes already used; • damaged cable; • damaged packaging.	

4. COMMISSIONING PROCEDURE

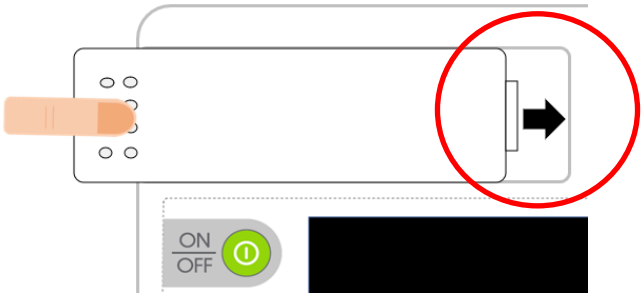
When commissioning the AED Rescue SAM 4.0d, follow these steps in sequence:

1	**Remove Rescue SAM 4.0d and its accessories** from the packaging. 
2	**Insert the** available (adult or pediatric or adult/pediatric) **disposable electrodes connector** into the specific socket respecting the guides. Make sure that the connector is locked by pushing it in all the way.  **WARNING: connect the disposable electrodes only as shown in the figure. The blue-white cable must flows toward the rear of the AED and <u>not to the front</u>.**

3

Insert the battery into the specific compartment as follows:

- place the right side of the battery in the right side of the compartment;



- lower the left side of the battery into the compartment to lock the battery in it (you will hear a «CLACK» when the battery is properly inserted and locked).

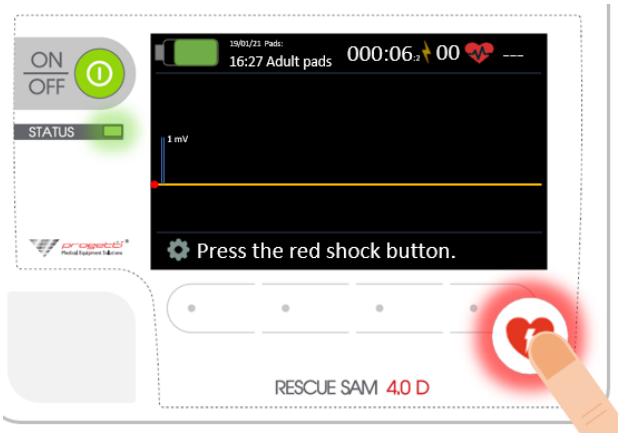
4

Check the self-test has been passed.

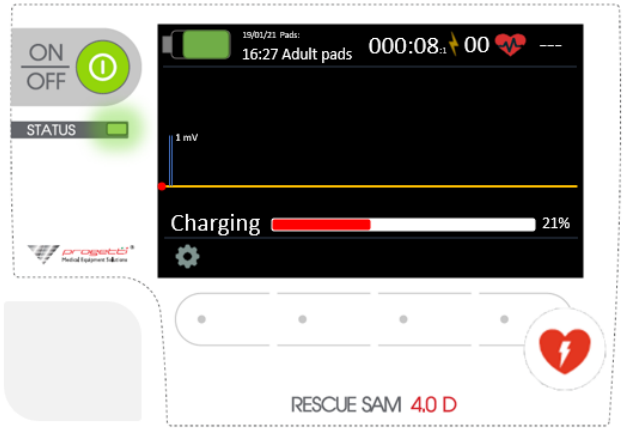
As soon as the battery is correctly locked in the compartment, Rescue SAM 4.0d switches on and automatically starts the self-test, which requires action by the user.

The "***Self Test***" voice and written message will be emitted and the status LED will light up green.

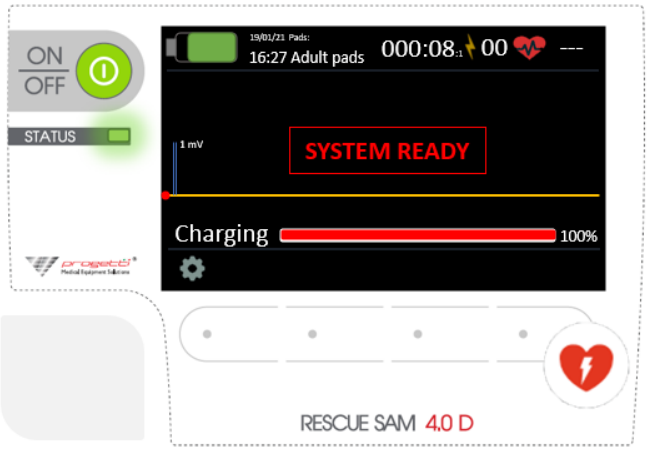
Follow the voice and written prompts, i.e., press the SHOCK button when prompted to ***"Press the red shock button."***



Wait for completion accompanied by a rising sound.



If the self-test result is positive (passed), the "***System ok***" voice message will be emitted and the message SYSTEM READY is shown on the display;



then the "***Powering down***" voice message will be emitted and the machine will enter standby mode.

The status LED will start flashing GREEN: Rescue SAM 4.0d has been successfully put into service and is now ready for use.

If the result of the self-test is negative (failed), the "***System Error. Service required.***" voice message will be emitted, then the "***Powering down***" voice message will be emitted and the machine will enter standby mode.

The LED will start flashing RED: in this case the device cannot be put into service and it is necessary to contact the technical support service of PROGETTI S.r.l.

5

Make Rescue SAM 4.0d available together with the disposable multifunction electrodes so that it is easily visible and accessible:

- hanging on a wall or resting on a surface without its dedicated bag (Fig. A)
- hanging on a wall or resting on a surface protected by its dedicated bag (Fig. B)
- stored protected by its dedicated bag inside a dedicated cabinet (Fig. C)

In addition, Rescue SAM 4.0d together with the disposable multifunction electrodes should be stored by observing the limitations specified by the manufacturer (see par. 1.1.4 "*Intended use environments*" and chapter 8 "*Technical specifications*").

Fig. A

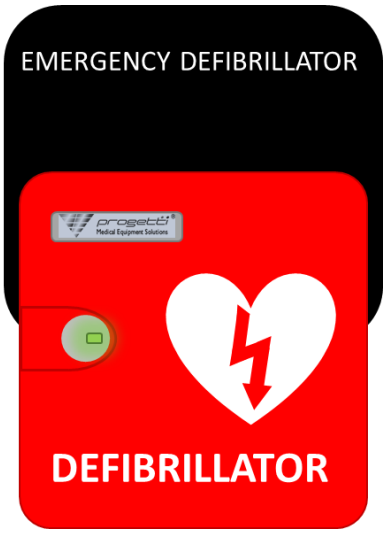
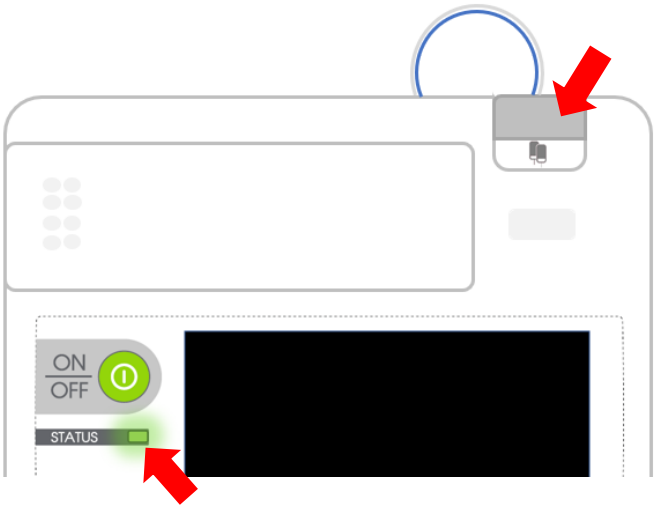


Fig. B

Fig. C

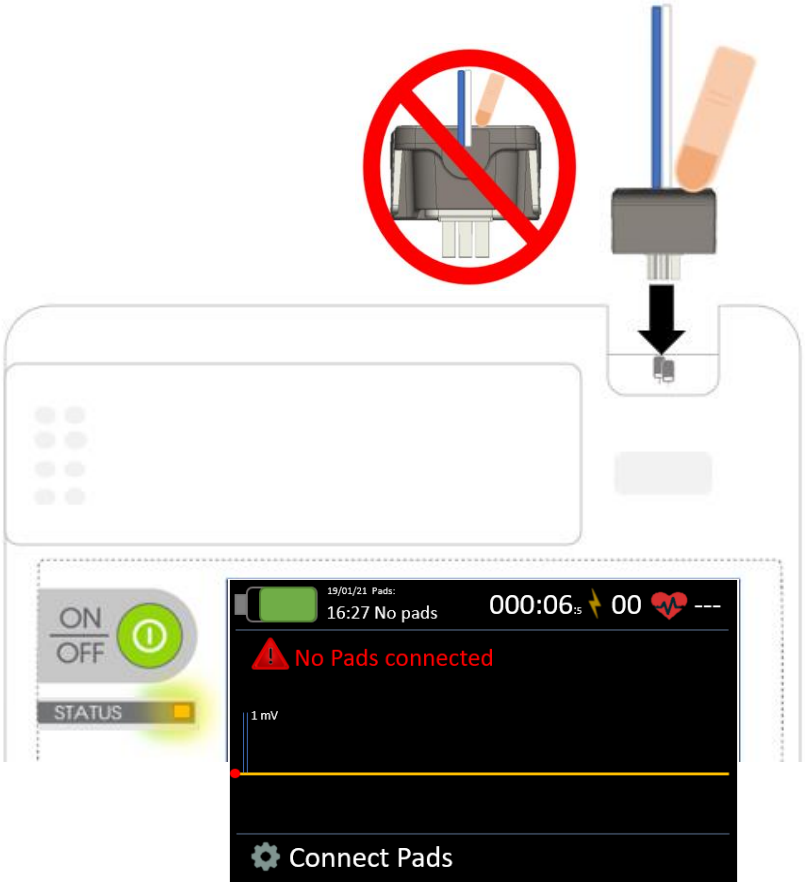
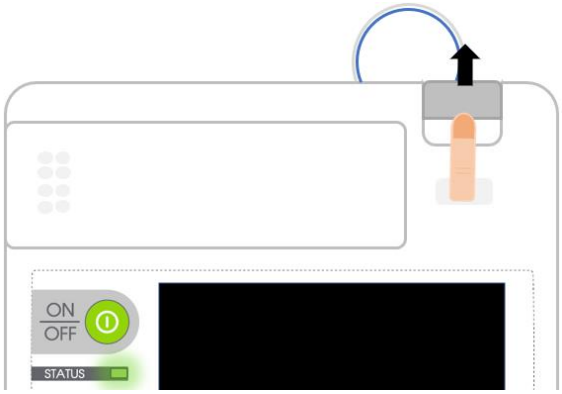
5. DEFIBRILLATION PROCEDURE

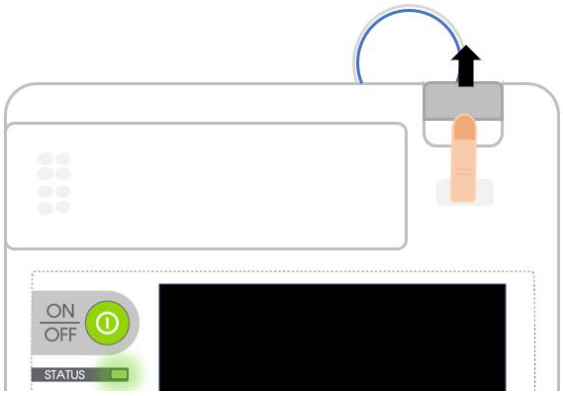
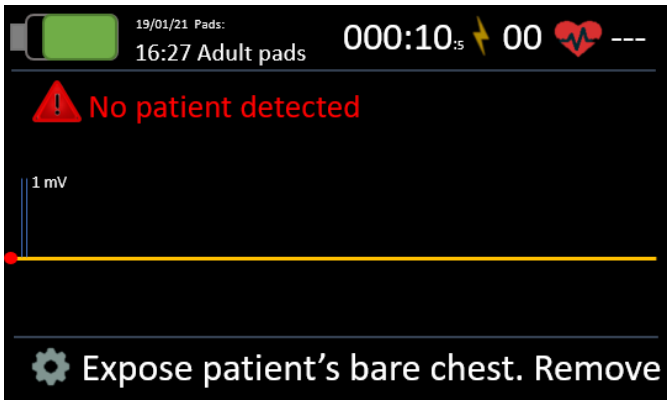
	STEP DESCRIPTION
1	Check that the STATUS LED flashes GREEN (meaning that the inserted battery is sufficiently charged and that the Disposable Multifunction Electrodes are already connected to the AED, i.e. the AED is ready for use);  In addition, verify that the disposable multifunction electrodes are appropriate for the type of patient (adult or pediatric), taking into account the summary in the table below:

REF DISPOSABLE MULTIFUNCTION ELECTRODES	SUITABLE PATIENT CLASS
RS4-DFBAD01PRC  (GREY CONNECTOR)	**ADULT**: age ≥ 8 years and weight ≥ 25 kg (including pregnant women). Do not delay the procedure to determine the patient's exact weight or age.

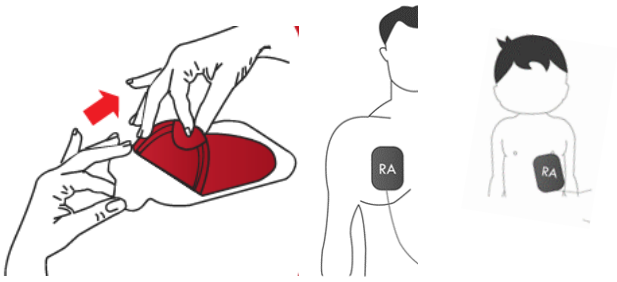
RS4-DFBPED01PRC  (PINK CONNECTOR)	**PEDIATRIC**: aged between 1 and 8 years and weighing < 25 kg. Do not delay the procedure to determine the patient's exact weight or age.
RS4-DFB01PRC  (WHITE CONNECTOR)	**ADULT**: age ≥ 8 years and weight ≥ 25 kg (including pregnant women). **PEDIATRIC**: aged between 1 and 8 years and weighing < 25 kg. Do not delay the procedure to determine the patient's exact weight or age. **WARNING: pads type is automatically set on "adult" (200J nominal) type when these pads are connected. If "pediatric" (50J nominal) type is needed then change pads type in Setting Menu.** **See §2.2.2 SETTING MENU**

Depending on the cases found, observe the following table, in other words the actions to be taken for each case. If no case is applicable, skip to the next step (2).

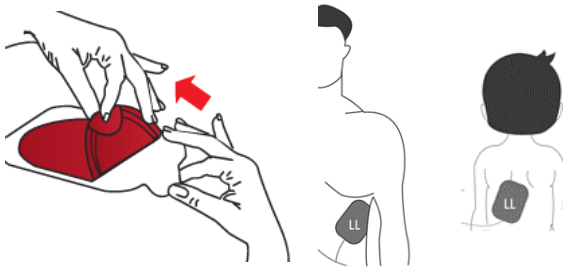
CASE		ACTIONS TO BE TAKEN
A	Disposable multifunction electrodes **not connected**	Connect the Disposable Multifunction Electrodes to the AED as shown below. 
B	Disposable multifunction electrodes already connected but **not suitable for the type of patient**	Disconnect the unsuitable disposable multifunction electrodes from the AED by firmly pulling the connector and **connect the suitable ones** for the type of patient (see the previous case for the procedure) 

	C	Disposable multifunction electrodes already connected and suitable for the type of patient but **expired**	Disconnect the expired disposable multifunction electrodes from the AED by firmly pulling the connector and **connect valid ones** (see the previous case for the procedure). 
2	Press the ON/OFF button until the AED switches on. Verify that the STATUS LED is lit GREEN. 		
3	Follow the voice and written instructions of step 1 (APPLYING ELECTRODES TO THE PATIENT): 3.0 "***Stay calm. Follow the voice instructions. Make sure emergency services are called now.***" 3.1 "***Expose the patient's bare chest. Remove or cut clothing if needed. Shave the chest if needed.***  3.2 "***Take the pads package.***" *3.3* "***Tear open package and remove pads.***" 	

3.4 "***Peel one pad from plastic liner and place it as illustrated.***" on the patient (adult or paediatric) as shown below (in other words as indicated on the disposable multifunction electrodes package). Check that no objects are directly under the area where the electrode is to be placed.



3.5 "***Peel the second pad from plastic liner and place it as illustrated***."



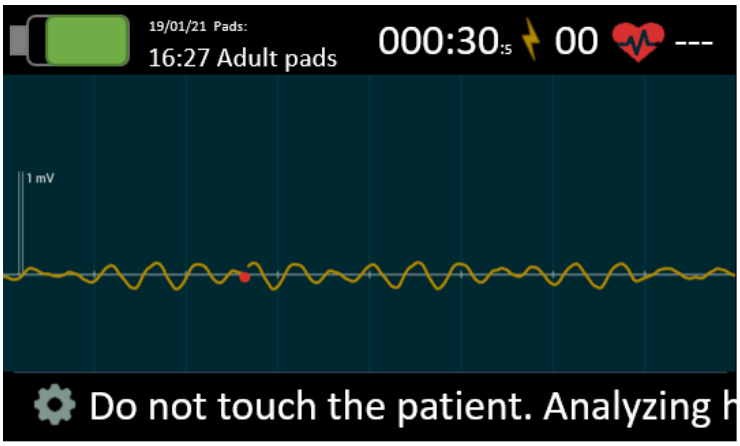
➔ Make sure that the electrodes do not touch each other.

➔ Check that the electrodes show no obvious signs of damage, are clean, dry, and not expired.

4

Follow the voice and visual instructions of step 2 (ECG ANALYSIS):

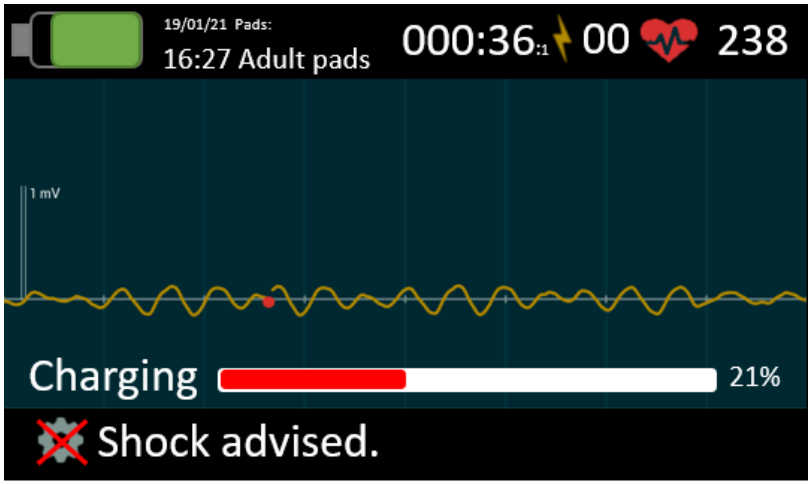
4.1 "***Do not touch the patient. Analyzing heart rhythm.***"



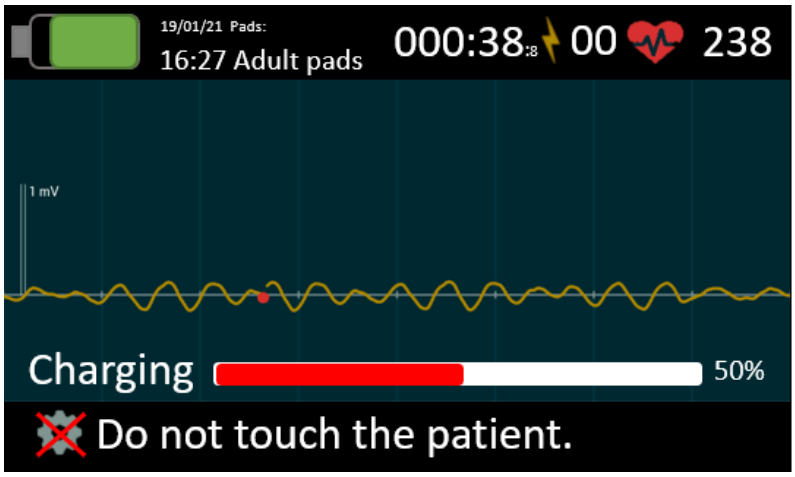
4.2 Follow the voice instructions:

CASE A – SHOCKABLE RHYTHM

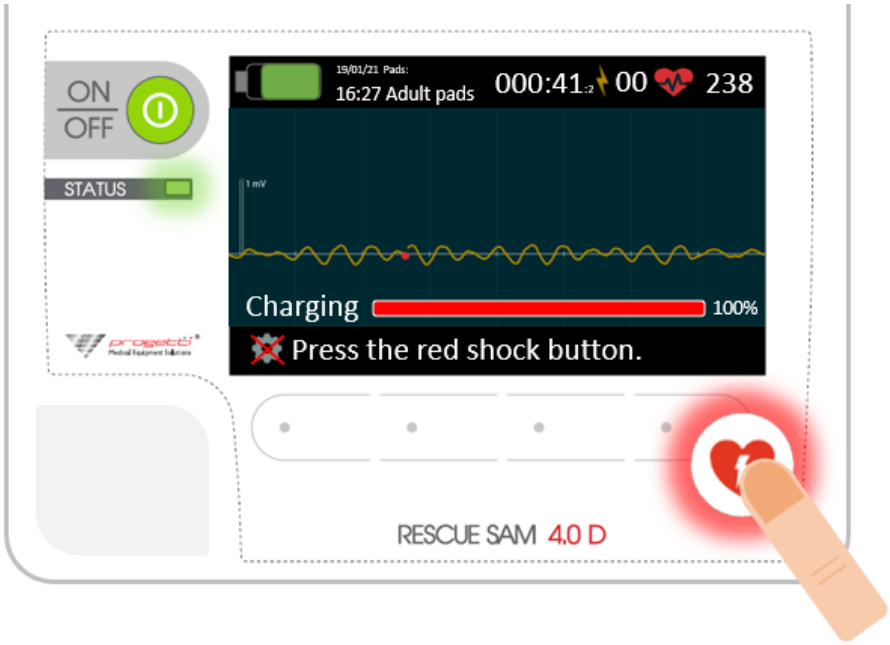
4.A.1 "***Shock advised.***"



4.A.2 "***Do not touch the patient.***"

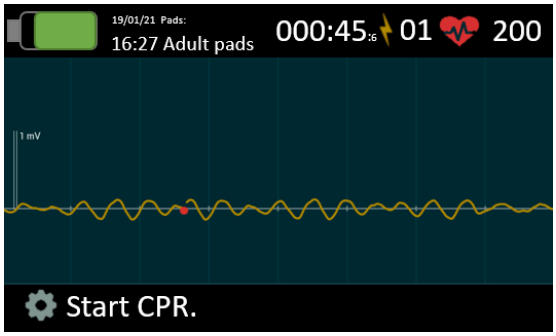


4.A.3. "***Press the red shock button.***"



If the red shock button is pressed within 15 seconds, the shock is delivered to the patient and the voice prompt: "***Shock delivered***" is emitted. While if the red button is not pressed within 15 seconds, the available defibrillation energy is automatically discharged inside the main unit, the shock button is disabled and the voice prompt: "***No shock delivered***" is emitted. In both cases, the voice prompt: "***It is now safe to touch the patient***" will be emitted and the AED will guide you to the next step (CPR).

4.A.4. "***Start CPR.***"



4.A.5 *"**Place heel of one hand on center of chest**"*

4.A.6 "***Place heel of other hand directly on top of first hand***"

4.A.7 "***Lean over patient with elbows straight***"

4.A.8 "***Press patient's chest down rapidly***": a compression rate in the range of 100–120 compressions/min and a compression depth in the range of 5–6 cm for a duration of 2 minutes is recommended.[1]

➔ **Now repeat the steps starting from point 4.1**

[1] Ref. ERC Guidelines 2021 "*Basic Life Support*"

CASE B – NON-DEFIBRILLABLE RHYTHM (moving onto step 3 "CPR")

4.B.1 "***No shock advised***."

4.B.2 "***Start CPR.***"

4.B.3 "***Place heel of one hand on the center of chest.***"

4.B.4 "***Place heel of other hand directly on top of first hand.***"

4.B.5 "***Lean over patient with elbows straight.***"

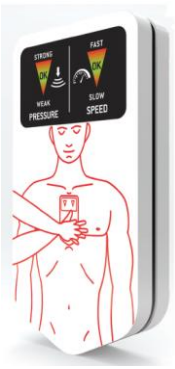
4.B.6 "***Press patient's chest down rapidly.***": a compression rate in the range of 100–120 compressions/min and a compression depth in the range of 5–6 cm for a duration of 2 minutes is recommended.[2]

→ **Now repeat the steps starting from point 4.1**

As described, after performing Cardiopulmonary Resuscitation (CPR) Rescue SAM 4.0d will re-perform the **rhythm analysis** and you then need to **repeat the steps starting from point 4.1**

It is essential that all responders, whether trained or not, perform efficient chest compressions. Trained responders should also alternate the compressions with ventilation (2 insufflations every 30 chest compressions) during the two minutes of CPR. Untrained responders should only perform chest compressions if they cannot or are unable to perform ventilation. Rescue SAM 4.0d provides only an indication of the start of CPR and of the rhythm to be maintained, with an audible signal for the entire duration of 2 minutes, but it does not provide any indication of when to perform the ventilations that are to be handled by a trained responder.

To perform quality CPR, the Manufacturer recommends using *Chest-eR®*, a medical device intended to be used in the "CPR" (Cardiopulmonary Resuscitation) procedure, in order to:



- improve the **quality** of the cardiac massage by providing feedback to the responder performing CPR;
- improve the **safety** of the cardiac massage for both the responder and the patient.

For more information, please contact the Manufacturer PROGETTI S.r.l. – info@progettimedical.com

[2] Ref. ERC Guidelines 2021 "*Basic Life Support*"

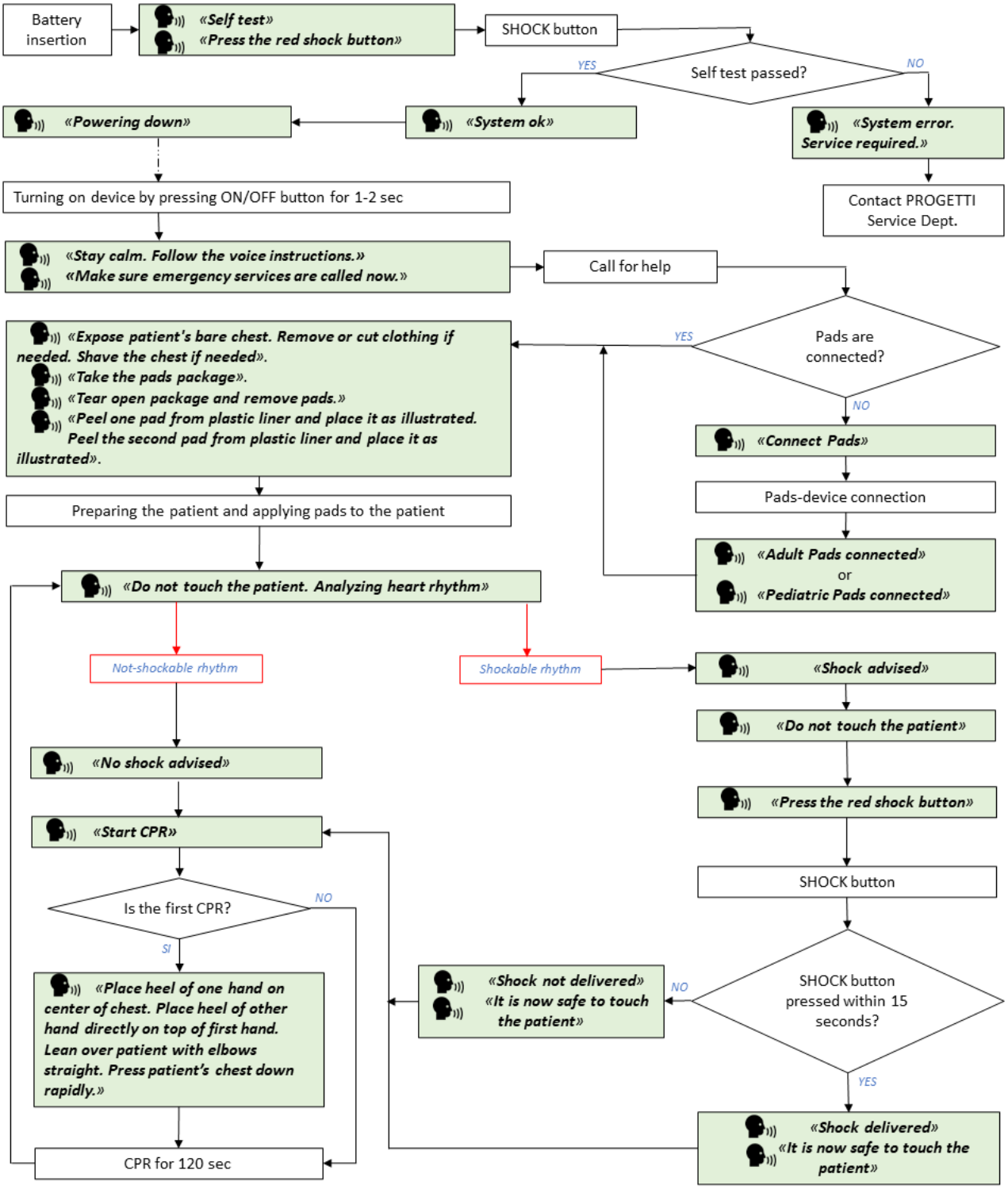
5	After using Rescue SAM 4.0d, press the green **ON/OFF** button for **4 seconds** and the device will announce its shutdown with the "***Powering down.***" voice and written message. 
6	**Detach the disposable multifunction electrodes** from the patient's chest.
7	**Disconnect the connector** of the disposable multifunction electrodes used: firmly pull the connector to disconnect them. 
8	**Report using** Rescue SAM 4.0d and its accessories to the staff or the body responsible for their management so that an operator can put the device back into service by connecting a new pair of disposable multifunction electrodes and, if necessary, a new battery.

 **DANGER**	**Defibrillation energy** can cause death or injury if used or discharged improperly if the recommendations given in this manual are not followed. Do not touch the patient during defibrillation. Do not touch the equipment connected to the patient or any metal objects in contact with the patient during defibrillation. Disconnect other electrical devices from the patient during defibrillation. Disconnect the Rescue SAM 4.0d disposable electrodes from the patient before using another defibrillator if necessary.
 **WARNING**	Use Rescue SAM 4.0d only as indicated in this User Manual: incorrect use may cause injury. Rescue SAM 4.0d releases electrical energy that can potentially cause death or injury if used or discharged improperly. Do not discharge if the disposable electrodes touch each other.
 **WARNING**	**Disconnect all devices** that are not defibrillator-proof (not equipped with an applied "defibrillator shock protected" part – ref. IEC 60601-1) from the patient prior to defibrillation to reduce the risk of electric shock or potential damage to them as far as possible.
 **WARNING**	**Do not allow the disposable multifunction electrodes for defibrillation to touch each other** or touch other ECG electrodes, cables, medications, transdermal patches, etc. These contacts may cause arcing and skin burns during defibrillation and may divert the defibrillation pulse from the heart.
 **WARNING**	**During defibrillation, air pockets** between the skin and the disposable multifunction electrodes for defibrillation can cause skin burns to the patient. To prevent air pockets from forming, make sure the self-adhesive electrodes fully adhere to the skin. Do not use dry or expired electrodes.
 **CAUTION**	**Avoid contact between parts of the patient's body** and conductive fluids such as water, gel, blood or saline solutions and metal objects, which could be undesired means of propagation of the defibrillation current.
 **WARNING**	**Aggressive or prolonged cardiac resuscitation** to a patient who has disposable multifunction electrodes attached can cause damage to the electrodes. Replace the electrodes if they get damaged during use.
 **WARNING**	**A cardiopulmonary resuscitation rate greater than 100 compressions per minute**, according to the *American Heart Association* guidelines, may result in an incorrect or delayed diagnosis of the patient's analysis system.
 **WARNING**	**Do not place** the disposable multifunction electrodes **on an adult patient** in the anterior-posterior (front-back) arrangement. Rescue SAM 4.0d requires the disposable multifunction electrodes for adults to be placed in the anterior-anterior (front-front) arrangement. If, after the patient has been evaluated, the user decides that the disposable multifunction electrodes should be applied to the patient in an arrangement other than as recommended in this User Manual, the user is entirely liable.
 **WARNING**	**A very low amplitude** or low frequency rhythm might not be interpreted as defibrillable VF (Ventricular Fibrillation) rhythms. Even some VT (Ventricular Tachycardia) rhythms might also be interpreted as non-defibrillable rhythms.

WARNING	**Moving or transporting the patient** during ECG analysis may cause an incorrect or delayed diagnosis, especially if very low amplitude or low rhythm frequencies are present. During analysis and from the time of “recommended shock” to the time of “delivered shock”, patient movements should be kept to a minimum.
WARNING	**If a patient has an implanted cardiac pacemaker**, do not place the disposable multifunction electrodes on top of the pacemaker. Rescue SAM 4.0d could be less sensitive and therefore unable to detect defibrillable rhythms.

5.1 Summary of the Rescue SAM 4.0d algorithm

Below there is a flowchart summary of how Rescue SAM 4.0d works, where the green boxes show the voice suggestions emitted by Rescue SAM 4.0d.



A description of the voice prompts (associated with messages on the display) is given in the table below.

"Self Test."	The device is performing the self-test to verify its functionality.
"Press the red shock button."	Indicates that the operator should press the SHOCK button to deliver the shock. The SHOCK button will be illuminated red during this stage.
"System error. Service required."	Indicates that the self-test was failed. It is then necessary to contact the PROGETTI technical support service.
"System ok."	The device has passed the self-test and is operational.
"Powering down."	Rescue SAM 4.0d has started to shut down.
"Stay calm. Follow the voice instructions." *"Make sure emergency services are called now."*	The device alerts you to keep calm and follow the voice and written prompts issued by Rescue SAM 4.0d. It is advisable to call for help because the first step in a rescue should always be to contact a professional emergency service. If someone else is available, the operator should send that person to call for help and continue the rescue without delay.
"Connect Pads."	If the disposable multifunction electrodes are not connected to the device, please connect them.
"Adult Pads connected." Or *"Pediatric Pads connected."*	The device alerts you that the disposable multifunction electrodes (adult or pediatric) have been connected to Rescue SAM 4.0d. In case of adult/pediatric disposable multifunction electrodes, pads type is automatically set on "adult" type when these pads are connected. If "pediatric" type is needed then change pads type in Setting Menu.

 ***"Expose patient's bare chest. Remove or cut clothing if needed."*** ***"Shave the chest if needed."*** ***"Take the pads package."*** ***"Tear open package and remove pads."*** ***"Peel one pad from plastic liner and place it as illustrated."*** ***"Peel the second pad from plastic liner and place it as illustrated."***	The device alerts you to prepare the patient for application of the disposable multifunction electrodes, and then apply the electrodes as illustrated in the electrode instructions. Check that the electrodes are positioned correctly, that they fully adhere to the patient, and that there are no air bubbles between the electrodes and the patient. Make sure that the electrodes do not touch each other. If the electrodes do not stick due to sweat, dry the patient. If the electrodes do not stick due to excessive hair, shave or cut off the excess hair. If the prompt continues, try replacing the electrodes with a new set.
 ***"Do not touch the patient."***	Indicates that the operator must not touch the patient.
 ***"Analyzing heart rhythm."***	Indicates the start of ECG (electrocardiogram) signal analysis to be able to determine whether a defibrillable (shockable) or non-defibrillable (non-shockable) rhythm is present. During the analysis, Rescue SAM 4.0d will continue monitoring the electrode connection and stop the analysis if it finds any problems. You must not touch the patient in this phase.
 ***"No shock advised."***	Indicates that Rescue SAM 4.0d has determined that no shock is required. The unit will not charge and the SHOCK button will not be enabled. The user will then be advised to begin cardiopulmonary resuscitation (CPR) for 2 minutes.
 ***"Shock advised."***	Indicates that Rescue SAM 4.0d has determined that a shock is recommended and that the unit will start charging in preparation for the defibrillation shock and then the SHOCK button will be enabled.

 ***"No shock delivered."***	Indicates that Rescue SAM 4.0d stopped the defibrillation procedure and discharged internally. This can occur if a change in rhythm occurs, i.e. from defibrillable to non-defibrillable, or if the SHOCK button is not pressed within 15 seconds of the initial prompt to "*Press the red shock button*".
 ***"Shock delivered."***	Indicates that Rescue SAM 4.0d has correctly delivered the defibrillation shock to the patient.
 ***"It is now safe to touch the patient."***	The device alerts you that from now on you can touch the patient to go ahead with resuscitation.
 ***"Start CPR."***	Indicates that the user must perform cardiopulmonary resuscitation (CPR) for 2 minutes (120 seconds). As a guide to the frequency, a rhythmical sound will be emitted at 100 beats per minute.
 ***"Place heel of one hand on center of chest. Place heel of other hand directly on top of first hand. Lean over patient with elbows straight."*** ***"Press patient's chest down rapidly. "***	The first time Rescue SAM 4.0d suggests CPR, voice prompts will be emitted to help you perform the CPR.

6. MEMORY AND DATA TRANSFER

Rescue SAM 4.0d has a memory in which it can record:

- the patient's electrocardiogram (ECG),
- information relating to the rescue (date and time, number of shocks delivered, etc.),
- the events and ambient noise that occurred during the rescue phase in its vicinity, thanks to the microphone recording that starts when the device is turned on.

6.1 Technical Specifications

INTERNAL MEMORY	200 MB
ECG AND EVENT RECORDING	Up to 16 hours of ECG plotting and event logging
ENVIRONMENTAL RECORDING	Up to 2 hours (if enabled)
SAVING REPORT	Available by using the specific software *PG DATA MANAGER*

6.2 Viewing recorded events

PROGETTI S.r.l. offers the possibility of viewing the various recordings on a personal computer through a data management software program (*PG Data Manager*), available as an optional accessory on request for Rescue SAM 4.0d.

PG Data Manager is a Windows-based software application that can read the data stored in Rescue SAM 4.0d, make it visible and manageable on a PC.

It allows you to reprocess the ECG data and other parameters related to the resuscitated patients and the Rescue SAM 4.0d performance following an emergency situation.

PG Data Manager can be installed on a variety of Windows® platforms. The minimum system requirements for adequate performance are as follows:

(1) Pentium dual core processor;
(2) 1 GB RAM;
(3) 100 MBytes of free hard disk space.

PROGETTI S.r.l. can, among the optional accessories for Rescue SAM 4.0d, in addition to the PG Data Manager data management software, also provide a USB cable in order to connect the device to your personal computer.

The supplied kit (PG Data Manager + USB cable) allows the user to download the data recorded by Rescue SAM 4.0d and transfer it to a PC for reading, management and archiving.

NOTE: Do not use the USB cable inappropriately, outside its intended use. Updates can only be carried out by PROGETTI S.r.l. and specially trained technicians (authorized personnel).

PG Data Manager offers the following benefits:

- By using the software, the rescue personnel can reconstruct a cardiac event from the time Rescue SAM 4.0d was turned on and connected to the patient until it was turned off.
- The software allows medical personnel to review the emergency event at any time.
- The software allows technical support to make a clear and detailed reconstruction of all the events during the use of Rescue SAM 4.0d, by analysing the performances of the device.
- The software provides the service technicians with additional parameters to identify faults in devices suspected of malfunctioning.

NOTE: PG Data Manager is a software application that must not be used if Rescue SAM 4.0d is operating in an emergency and it has the sole purpose of supporting post-event analysis of the data recorded in the internal memory of Rescue SAM 4.0d.

PG Data Manager can be downloaded by accessing the reserved area of PROGETTI S.r.l.'s website: www.progettimedical.com

6.3 Data download procedure

You can download data from Rescue SAM 4.0d and transfer it to your personal computer by following these simple steps:

1. If the disposable multifunction electrodes are connected to Rescue SAM 4.0d, disconnect them;
2. Plug the USB cable into the dedicated PLUG-IN on Rescue SAM 4.0d;
3. Connect the USB cable to the PC;
4. Check that on the display “USB” message is shown on the display to confirm that the connection with the PC has been made;
5. Download the data to your PC;
6. Disconnect the USB cable;
7. Run the *PG DATA MANAGER* program on your PC to view and manage the downloaded data.

However, for further details on the data download procedure, please read the user manual for the *PG DATA MANAGER* software.

7. STORAGE AND MAINTENANCE

7.1 Storage

Rescue SAM 4.0d should be stored in an easy-to-access place, oriented so that the status LED, located in the middle on the left of the front panel of the device, can be easily observed.

In general, Rescue SAM 4.0d should be stored in a clean, dry environment at a moderate temperature.

Ensure that the environmental conditions of the storage location are within the limits specified in par. 1.1.4 "*Intended use environments*".

7.2 Cleaning

It is considered necessary to periodically clean Rescue SAM 4.0d of any dirt or contaminants on the case and connector socket. Follow the guidelines given here when cleaning the device:

- The Rescue SAM 4.0d battery pack should be installed.
- Do not immerse Rescue SAM 4.0d in any liquid or allow liquids to get into the unit. Use a soft cloth to clean the case.
- Do not use abrasive materials or strong solvents such as acetone or acetone-based products. The following cleaning products are recommended for cleaning the Rescue SAM 4.0d case and connector socket:
  - Soap and water
  - Ammonia-based products
  - Hydrogen peroxide
  - Isopropyl alcohol (70% solution)
  - Bleach (30ml/litre of water)
- Make sure the electrodes connector compartment is completely dry before reconnecting electrodes.

7.3 Maintenance

Rescue SAM 4.0d does not contain any user-repairable parts. Only technical personnel authorized by PROGETTI S.r.l. can carry out corrective maintenance on Rescue SAM 4.0d. Therefore, in case of need, contact PROGETTI S.r.l. technical support.

Although Rescue SAM 4.0d is designed to require little maintenance, some simple routine maintenance must be performed regularly by a designated person in order to ensure the expected safety and performance when needed.

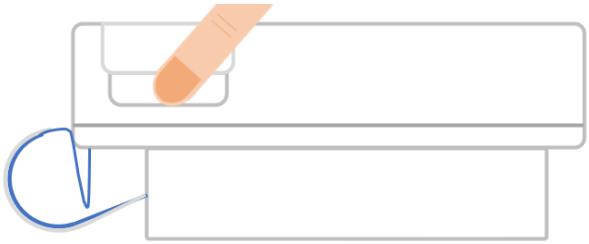
The table below lists the actions to be performed and their frequency for the routine maintenance of Rescue SAM 4.0d.

EVERY DAY	EVERY MONTH	AFTER EACH USE	ACTION
✓	✓	✓	Check that the status LED blinks green.
	✓	✓	Check the condition of the device and its accessories.
		✓	• Replace the disposable multifunction electrodes (for adults or paediatrics or adults/paediatrics) • Check the battery capacity.
	✓		• Check the expiry date of the disposable multifunction electrodes. • Check the battery expiry date.
		✓	Run the self-test.

7.3.1 AUTOTEST

Remove the battery from the specific compartment as follows:

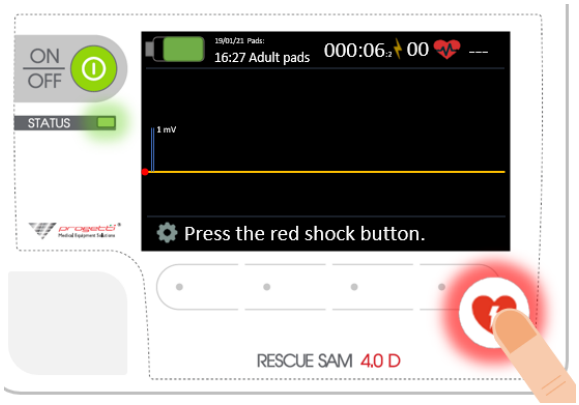
1. press the BATTERY UNLOCK BUTTON to unlock the battery;



2. remove the battery from its housing;
3. wait at least 5 seconds and reinsert the battery;
4. follow the self-test instructions;
5. wait for the self-test to be passed. In the event of a failure, contact the manufacturer PROGETTI S.r.l.

As soon as the battery is correctly locked in the compartment, Rescue SAM 4.0d switches on and automatically starts the self-test, which requires action by the user.
The "***Self Test***" voice and written message will be emitted and the status LED will light up green.

Follow the voice and written prompts, i.e., press the SHOCK button when prompted to ***"Press the red shock button."***



Wait for completion accompanied by a rising sound.

If the self-test result is positive (passed), the "***System ok***" voice message will be emitted and the message SYSTEM READY is shown on the display; then the "***Powering down.***" voice message will be emitted and the machine will enter standby mode.

The status LED will start flashing GREEN: Rescue SAM 4.0d has been successfully put into service and is now ready for use.

If the result of the self-test is negative (failed), the "***System Error. Service required.***" voice message will be emitted, then the "***Powering down.***" voice message will be emitted and the machine will enter standby mode.

The power-on self-tests are performed each time the unit is switched on, and they test the unit's basic operations. The unit also performs daily, weekly and monthly automatic self-tests (without any action by the operator) to check the integrity of the unit's components.

NOTE: The manual self-tests will use a certain amount of energy from the batteries, so running a manual test will reduce the energy capacity of the batteries.

7.3.2. CHECKLIST

The staff of the organization where the AED Rescue SAM 4.0d has been put into service, in particular the person in charge of managing the AED, should document the periodic checks carried out on the device or keep a record of the results of each test carried out. Therefore, as an example, the following checklist is given for reference (not exhaustive).

Each activity should be ticked once completed.

AED CHECKLIST REF: RESCUE SAM 4.0D				
Serial number (SN)				
Place				
Date	**DD-MM-YYYY**			
STATUS LED BLINKING GREEN	✓			
AVAILABLE DISPOSABLE MULTIFUNCTION ELECTRODES	✓			
VALID DISPOSABLE MULTIFUNCTION ELECTRODES	✓			
NO DAMAGE OF DISPOSABLE MULTIFUNCTION ELECTRODES CABLE	✓			
VALID BATTERY	✓			
CLEAN MAIN UNIT	✓			
NO DAMAGE OF THE DISPLAY	✓			
Additional check [Please specify]	✓			
COMMENTS				
SIGNED BY VERIFIER				
Inspected by: [Signature]				

7.3.3 FAULT REPAIRS

The following table lists some causes of common problems, possible causes, and possible actions that the user is authorized to perform independently to restore operation.

NOTE Rescue SAM 4.0d does not contain any user-repairable parts. If the unit needs repair, take it to an authorized technical support centre. Refer to Chapter 9 "*Manufacturer's Contacts*" for contact information.

To send Rescue SAM 4.0d for repair, please contact the PROGETTI technical support service.

PROBLEM	POSSIBLE CAUSE	REPARATIVE ACTION
The device fails to turn on	The battery is not inserted.	Insert the battery by following the instructions.
	The battery is not functioning.	Replace the battery by following the instructions.
	The main unit is not working.	Contact the PROGETTI technical support service.
The device suddenly switches off	The battery is depleted.	Replace the battery by following the instructions.
	The main unit is not working.	Contact the PROGETTI technical support service.
The status LED is lit red	The unit has a fault.	Contact the PROGETTI technical support service.
The status LED blinks red	Battery depleted.	Replace the battery by following the instructions.
The status LED fails to blink	The battery is not inserted.	Insert the battery by following the instructions.
	The battery is not functioning.	Replace the battery by following the instructions.
	The main unit is not working.	Contact the PROGETTI technical support service.
Self-test failed	The unit has a fault.	Contact the PROGETTI technical support service.

8. TECHNICAL SPECIFICATIONS

8.1 General characteristics

DIMENSIONS	250 x 260 x 80 mm
WEIGHT	Approx. 2.2 kg, with the battery pack
PROTECTION CLASS	IP55
DISPLAY	7” colour LCD, resolution 800 x 480 pixels
SOFTWARE	It is contained in the internal flash memory of the CPU and is an integral part of the operation of the device. Class C as per EN 62304:2006 +A1:2015 Software version: 3.0

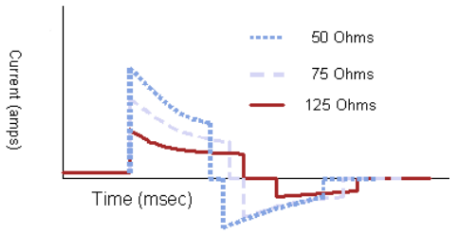
8.2 Use environment

OPERATIONAL	TEMPERATURE	0 – 50°C
	HUMIDITY	20% – 80% (*non-condensing*)
	ATMOSPHERIC PRESSURE	80 – 101 kPa
STAND-BY (without disposable multifunction electrodes)	TEMPERATURE	-20 – 50°C
	HUMIDITY	5% – 95% (*non-condensing*)
	ATMOSPHERIC PRESSURE	80 – 101 kPa
STAND-BY (with disposable multifunction electrodes)	TEMPERATURE	5 – 35°C
	HUMIDITY	20% – 80% (*non-condensing*)
	ATMOSPHERIC PRESSURE	80 – 101 kPa
EMC (Emission)	EN 60601-1-2:2015 Group 1 Class b	
EMC (Immunity)	EN 60601-1-2:2015 Level 3	

8.3 Applied standards

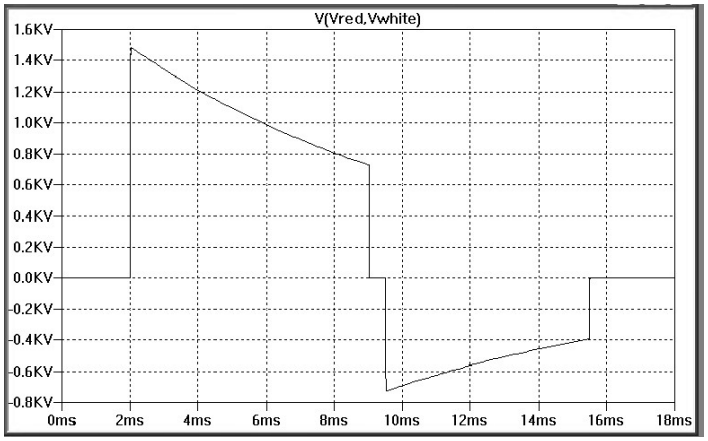
EN 60601-1:2006+A1:2012+A12:2014	GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE
EN 60601-1-2:2015 & EN 60601-2-4:2011+A1:2019 (§2.2)	GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: ELECTROMAGNETIC COMPATIBILITY - REQUIREMENTS AND TESTS
EN 60601-2-4:2011+A1:2019	PARTICULAR STANDARD FOR THE SAFETY OF CARDIAC DEFIBRILLATORS.
EN 15223-1:2016	MEDICAL DEVICES - SYMBOLS TO BE USED ON MEDICAL DEVICE LABELS, LABELLING AND IN THE INFORMATION TO BE PROVIDED - PART 1: GENERAL REQUIREMENTS
EN ISO 14971:2019	MEDICAL DEVICES - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
EN ISO 62366-1:2015	MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES.
EN 60601-1-6:2010+A1:2015	PART 1 - GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - COLLATERAL STANDARD: USABILITY
EN ISO 62304:2006+A1:2015	SOFTWARE LIFE CYCLE
MEDDEV 2.7.1 REV. 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES.
MEDDEV 2.12-1 REV. 8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM
MEDDEV 2.12/2 REV.2	POST-MARKET FOLLOW-UP STUDIES: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES
EN ISO 13485:2016+A11:2021	MEDICAL DEVICES – QUALITY MANAGEMENT SYSTEMS – REQUIREMENTS FOR REGULATORY PURPOSES

8.4 Characteristics of defibrillation

Operating procedure	Semi-automatic external defibrillation for adult and pediatric use.
Energy	200 J nominal released through a load of 50 Ω (50 J nominal in the paediatric case)
Energy charging time	≤ 10 s (200 J) ≤ 5s (50 J) The charging time may increase with used batteries.
Charging complete indication	– Red backlighting of the SHOCK button – Voice prompt "*Press the red shock button*" – Rapid succession of high-pitch tones
Defibrillation pulse waveform	Biphasic truncated exponential (BTE) with fixed energy of 200 J (50 J in the paediatric case) and compensation by measuring patient impedance and varying shock time: as soon as the patient's impedance (Rp) changes, the shock time also changes, so as to always have the same amount of energy released (area under the curve). 
Shock release	Arrhythmia detection and automatic charge test performed by the software. Shock release occurs by pressing a dedicated shock button.
Accuracy of the discharge energy	± 10%, in compliance with EN 60601-2-4
Disarming	Once charged, disarming will start automatically: – if the rhythm is no longer defibrillable, or – if within 15 seconds of completion of charging the user has not pressed the SHOCK button, or – if the ON/OFF button is pressed to turn off the defibrillator, or – if the disposable multifunction electrodes are disconnected from the defibrillator or from the patient.
BLS-D protocol	Audible indicators, voice prompts guide the user through the protocol. The language can be changed and the CPR guidelines updated.

Rescue SAM 4.0d delivers a biphasic truncated exponential waveform pulse of 200 J to the patient if the patient's impedance is in the range 25–200 Ω.

When used on a paediatric patient, with the paediatric disposable multifunction electrodes, the energy is automatically reduced to 50 J nominal.



The waveform is adjusted to compensate for the patient's measured impedance.

The nominal phase times and the released energy for adult patients are shown in the table below.

Patient impedance [Ω]	positive phase duration [ms]	negative phase duration [ms]	Energy released (with adult disposable electrodes) [J]
25	6	6	200±10%
50	8	6	200±10%
75	8	8	200±10%
100	10	8	200±10%
125	10	10	200±10%
150	12	10	200±12%
175	12	10	200±12%
200	12	10	200±12%

The nominal phase times and the released energy for pediatric patients are shown in the table below.

Patient impedance [Ω]	positive phase duration [ms]	negative phase duration [ms]	Energy released (with pediatric disposable electrodes) [J]
25	8	8	50±10%
50	10	8	50±10%
75	10	10	50±10%
100	12	10	50±10%
125	12	12	50±10%
150	14	12	50±12%
175	14	12	50±12%
200	14	12	50±12%

8.5 ECG acquisition characteristics

Band	0.25 - 160 Hz
CMRR	120 dB
Input impedance	>500 MΩ
Amplitude	25 mm/mV
Speed	37.5 mm/s
Filtering	Fixed filters for removing environmental AC lines interferences, baseline wandering and signal conditioning
Heart rate range	20 - 300 BPM

8.6 ECG analysis characteristics

The Rescue SAM 4.0d patient ECG analysis system analyses the patient's ECG rhythm to determine whether or not a shock is required to resuscitate the patient.
The ECG signal is processed by the ECG signal analysis program. The arrhythmia detection process determines whether or not to recommend shock delivery by examining the data processed by this analysis.
The software carrying out this analysis is class C software as per EN 62304:2006, since any incorrect operation could pose serious risks to the patient or the operator.
The performance of the patient's ECG analysis system is shown in the following table.

TYPE OF RHYTHM	DECLARED PERFORMANCE	REQUIREMENT (EN 60601-2-4)
NON-DEFIBRILLABLE RHYTHM		
Sinus rhythm (normal)	• SENSITIVITY: **NA** • SPECIFICITY: **100%**	• SENSITIVITY: **NA** • SPECIFICITY: **> 95%**
Supraventricular arrhythmia	• SENSITIVITY: **NA** • SPECIFICITY: **99.96%**	• SENSITIVITY: **NA** • SPECIFICITY: **> 95%**
DEFIBRILLABLE RHYTHM		
Combination of: Ventricular tachycardia (VT) & Ventricular fibrillation (VF)	• SENSITIVITY: **97.35%** • SPECIFICITY: **99.87%**	• SENSITIVITY: **> 90%** for recognising VF • SENSITIVITY: **> 75%** for recognising VT • SPECIFICITY: **> 95%**
Combination of: Sinus rhythm (normal) & Premature ventricular contraction (PVC)	• SENSITIVITY: **97.35%** • SPECIFICITY: **99.87%**	• SENSITIVITY: **> 90%** for recognising VF • SENSITIVITY: **> 75%** for recognising VT • SPECIFICITY: **> 95%**
COMBINED RHYTHM		
Combination of non-defibrillable rhythms & defibrillable rhythms	• SENSITIVITY: **97.348%** • SPECIFICITY: **99.997%**	• SENSITIVITY: **> 90%** for recognising VF • SENSITIVITY: **> 75%** for recognising VT • SPECIFICITY: **> 95%**

8.7 Electromagnetic emissions

RESCUE SAM 4.0D is designed for use in the electromagnetic environment specified below.

The user or operator must ensure that it is used in such an environment.

EMISSION TEST	CONFORMITY	SUPPORT FOR ELECTROMAGNETIC CONDITIONS
RF emissions [CISPR 11/EN 55011]	Group 1 Class B	Rescue SAM 4.0d uses radiofrequency (RF) energy only for its internal functions. Therefore, its RF emissions are very low and no interference is expected in surrounding electronic equipment. Rescue SAM 4.0d is designed to be used in any environment, including domestic environments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions [IEC 61000-3-2]	Not applicable	
Voltage fluctuations [IEC 61000-3-3]		

8.8 Electromagnetic immunity

Immunity test	**EN 60601-1-2 test level**	**Compliance level**	**Electromagnetic conditions - support**
Electrostatic discharge (ESD) EN 60601-4-2	±8 kV direct contact ±8 kV indirect contact ±2 kV in air ±4 kV in air ±8 kV in air ±15 kV in air	±8 kV direct contact ±8 kV indirect contact ±2 kV in air ±4 kV in air ±8 kV in air ±15 kV in air	No other ESD requirements are necessary.
Electrical fast transient/burst EN 61000-4-4	±2 kV for power supply line support lines ±1 kV for input/output lines		Not applicable
Wave EN 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth		Not applicable

Immunity Test	EN 60601 test level	Compliance level	Electromagnetic conditions - support
Voltage drops, short interruptions, and voltage variations on the power reserve input lines IEC 61000-4-11	Not applicable	Not applicable	
Magnetic field power supply frequency (50/60 Hz) IEC 61000-4-8:2009	30 A/m	30 A/m	
Radiated radiofrequency IEC 61000-4-3:2006+A1:2007+A2:2010	3 V/m 10 V/m 20 V/m From 80 MHz to 2700 MHz	3 V/m 10 V/m 20 V/m	Portable or mobile RF communications equipment should not be used near parts of Rescue SAM 4.0d, including cables, if necessary. The recommended distance calculated with the equation applicable to the frequency of the transmitter is shown in the following table. Interference may occur in the vicinity of equipment with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the highest frequency range is applied. **Note 2:** These guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reverberation of structures, objects and people.			
The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz, respectively. Field strength from fixed transmitters, such as base stations for mobile or cordless phones and mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted precisely. An electromagnetic site survey should be considered to assess the electromagnetic environment generated by fixed RF transmitters. If the measured field strength in the location where Rescue SAM 4.0d is used exceeds the above RF compliance level, Rescue SAM 4.0d should be observed to check it is working normally. If any abnormal operation is observed, additional measures may be required, such as reorienting or relocating Rescue SAM 4.0d.			

8.9 Separation distances

Rescue SAM 4.0d is intended for use in an electromagnetic environment in which RF interference is controlled. The owner or user of Rescue SAM 4.0d can prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Rescue SAM 4.0d as recommended below, according to the maximum power of the communications equipment.

Recommended distances between RF communications equipment and Rescue SAM 4.0d				
Separation distances according to the frequency of the transmitter (m)				
Maximum nominal output power of the transmitter (W)	**From 150 kHz to 80 MHz outside ISM bands** **d = 1.16√P**	**From 150 kHz to 80 MHz within ISM bands** **d = 1.2√P**	**From 80 MHz to 800 MHz** **d = 1.2√P**	**From 800 MHz to 2.5 GHz** **d = 2.3√P**
0.01	0.01	0.12	0.12	0.23
0.1	0.1	0.37	0.38	0.73
1	1	1.17	1.2	2.3
10	10	3.69	3.79	7.27
100	100	11.67	12	23

For transmitters with a maximum output power not listed above, the recommended separation distance d in metres (m) can be determined by using the equation applicable to the frequency of the transmitter, where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 2: The ISM bands between 150 kHz and 80 MHz range from 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 is used to calculate the recommended distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency ranges from 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable equipment may cause interference if inadvertently brought into the areas where the patients are.

Note 4: These guidelines may not apply to all situations. Electromagnetic propagation is affected by the absorption and reverberation of structures, objects and people.

9. MANUFACTURER'S CONTACTS

PROGETTI S.r.l. is the manufacturer of Rescue SAM 4.0d and is responsible for placing the AED Rescue SAM 4.0d on the market.

The following are the contacts you can refer to for communicating with PROGETTI S.r.l.

REGISTERED HEADQUARTERS	Strada del Rondello, 5 10028 TROFARELLO (TO) ITALY
ADMINISTRATIVE HEADQUARTERS	Strada del Rondello, 5 10028 TROFARELLO (TO) ITALY
WEBSITE	**www.progettimedical.com**
PHONE	+39 011 644738
FAX	+39 011 645822
GENERAL INFORMATION	info@progettimedical.com
SALES	sales@progettimedical.com
TECHNICAL SUPPORT	service@progettimedical.com
QUALITY & REGULATORY	quality@progettimedical.com

10. LIMITED WARRANTY INFORMATION

Cover

PROGETTI S.r.l. provides a limited warranty that the defibrillator and its accessories, if purchased at the same time as the defibrillator or separately, will be substantially free from defects in materials and workmanship. The PROGETTI S.r.l. limited warranty refers only to the original consumer who purchased the articles from a dealer authorized by PROGETTI S.r.l.
This limited warranty cannot be entrusted or transferred. The terms of the limited warranty in effect on the original purchase date will apply to all warranty rights.

Duration

The length of limited warranty depends on the contractual conditions agreed with PROGETTI S.r.l. with respect to the sale of Rescue SAM 4.0d.

Restrictions

This limited warranty does not cover damage of any kind resulting from, but not limited to, accidents, improper storage, misuse, alterations, unauthorized service, tampering, abuse, negligence, fire, floods, or wars. In addition, this limited warranty does not cover damage of any kind to the defibrillator or its accessories resulting from using the defibrillator with non-approved accessories or using the accessories with non-approved medical devices. It is not guaranteed that the defibrillator and its accessories are compatible with other medical devices.

Cancellation

The limited warranty will be cancelled immediately if:

- Rescue SAM 4.0d or its accessories are overhauled or repaired by entities or persons not authorized by PROGETTI S.r.l.;
- no specific maintenance is carried out on Rescue SAM 4.0d;
- Rescue SAM 4.0d is used with one or more unauthorized accessories;
- the accessories are used with an unauthorized defibrillator/medical device;
- Rescue SAM 4.0d or its accessories are not used in accordance with the instructions provided by PROGETTI S.r.l.

Exclusive right to remedy

At its sole discretion, PROGETTI S.r.l. will have the right to repair or replace the Automatic External Defibrillator (AED) Rescue SAM 4.0d.

In the event of replacement, PROGETTI S.r.l. will have the right, at its sole discretion, to repair the part with a new or repaired or identical or similar part. The choice of such a part will be at the sole discretion of PROGETTI S.r.l. In the event of replacement, the replacement part will under no circumstances have a limited warranty period that goes beyond the limited warranty period of the part being replaced.

Warranty service

Only PROGETTI S.r.l. or its authorized representatives can repair the device. If any unauthorized personnel repair the device during the warranty period, the warranty will be cancelled and voided. If the device does not function properly, it must be repaired immediately. If any technical faults are found in the device or if there is a risk of personal injury, the device must be repaired quickly and properly by authorized personnel.

If maintenance is required, please contact PROGETTI S.r.l. or its authorized representatives immediately. Prepare a summary of the problems. Also include the model's name, serial number, date of purchase, the dealer's name, and your details.

Technical support service

For PROGETTI s.r.l. contacts, in particular the technical support department, please refer to Chapter 9 “Manufacturer’s Contacts”.

Obligations and limits of warranty

The above-mentioned limited warranty expressly supersedes and excludes, to the extent permitted by the applicable state law, any other express or implied warranties, including, but not limited to, warranties of merchantability and fitness for a particular purpose. No one (including any dealer, agent or representative of PROGETTI s.r.l.) is authorized to make any representations or warranties relating to the Automatic External Defibrillator (AED) Rescue SAM 4.0d or its accessories, except by referring to this limited warranty.

The exclusive remedy for any loss or damage arising from any cause shall be as specified above. PROGETTI s.r.l. shall in no event be liable for consequential or incidental damage of any kind, including, but not limited to, exemplary, special, punitive damages, or financial losses of any kind, business interruption, loss of profits or personal injury, even if PROGETTI S.r.l. has been informed of the possibility of such damage, caused in any way, by negligence or other causes, except when the applicable state law precludes such exclusions or limitations.

Warranty Certificate

PROGETTI S.r.l.

AED RESCUE SAM 4.0D WARRANTY CERTIFICATE

This medical device is guaranteed against defects in materials and workmanship.

The warranty shall not apply if the product has not been used properly as indicated in this manual, has been damaged by accident or misuse, has been damaged as a result of modifications or repairs not carried out by PROGETTI S.r.l.

This warranty does not cover any accessories.

PROGETTI undertakes, at its sole choice, to replace parts and components free of charge and under warranty in its own laboratories.

CUSTOMER	…….. ……
AED RESCUE SAM 4.0D	SN: ……
Validity (warranty start date)	……. / …….. / ……..
Date of delivery	……. / …….. / ……..
Invoice No.	……
Invoice date	……. / …….. / ……..

EU DECLARATION OF CONFORMITY

progetti® Medical Equipment Solutions

Doc. N. FT-RescueSAM4.0-0.3/8.1_4.0d-0.4
Rev. 0.4

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DECLARATION OF EU CONFORMITY
DICHIARAZIONE DI CONFORMITA' UE

This declaration is issued under exclusive responsibility of the Manufacturer.
Questa dichiarazione è rilasciata sotto la responsabilità esclusiva del Fabbricante.

TYPE OF MEDICAL DEVICE ***TIPO DEL DISPOSITIVO MEDICO***	**Defibrillator** *Defibrillatore* 
NAME OF MEDICAL DEVICEs (REF) ***NOME DEI DISPOSITIVI MEDICI***	***Rescue SAM 4.0d***
INTENDED USE ***DESTINAZIONE D'USO***	Semi-automated external cardiac defibrillation *Defibrillazione cardiaca esterna semi-automatica*
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)*	**805414531DEF-RSAM4.0RW**
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+A11:2021, EN ISO 14971:2019, 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 60601-1-6:2010+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 to receive a dedicated declaration of conformity with the serial number of your device and/or an updated one, please contact Progetti S.r.l. at the email address **info@progettimedical.com**. *Per ricevere la dichiarazione di conformità dedicata allo specifico numero di serie del dispositivo e/o una dichiarazione aggiornata, si prega di contattare Progetti s.r.l. all'indirizzo e-mail **info@progettimedical.com***
MANUFACTURER (trademark, name, address) ***FABBRICANTE*** *(marchio, nome, indirizzo)*	progetti® Medical Equipment Solutions **PROGETTI 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-000008116**
NOTIFIED BODY ***ENTE NOTIFICATO***	MTIC INTERCERT 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
N° EC CERTIFICATE ***N° CERTIFICATO CE***	**0068/QCO-DM/025-2015 Rev.04**
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 declare that the above-mentioned medical device is compliant with **Directive 93/42/EEC and subsequent amendments** and it can be placed on the market according to **art.120 of Regulation (EU) 2017/745,** amended by Regulation (EU) 2020/561 of 23/04/2020 and Regulation (EU) 2023/607 of 15/03/2023.
Also, the device complies with the applicable requirements of **Directive 2011/65/EU** (RoHS) and subsequent amendments.

*Si dichiara 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,** modificato dal Regolamento (UE) 2020/561 del 23/04/2020 e dal Regolamento (UE) 2023/607 del 15/03/2023.*
*Inoltre, il dispositivo 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), **27/11/2023**
SIGNATURE ***FIRMA***	Dr. CESARE MANGONE PRESIDENT & PRRC

PROGETTI S.r.l.
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Medical Equipment Solutions

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