progetti®
Medical Equipment Solutions

INSTRUCTIONS FOR USE

Semi-Automated External Defibrillator (AED)

Rescue SAM 4.0

ENG

TF-RescueSAM4.0-0.3/3.1ENG4.0-1.0

CE 0068

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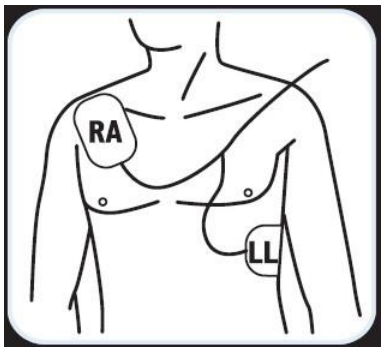
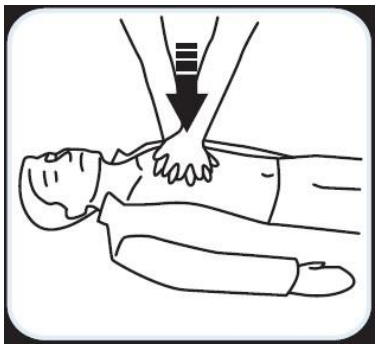
RESCUE STEPS

1. **PUSH THE ON/OFF BUTTON**
2. **FOLLOW THE VOICE INSTRUCTIONS**
3. **IF INSTRUCTED, PRESS THE RED “SHOCK” BUTTON**

1  **PUSH THE ON/OFF BUTTON**

2





FOLLOW THE VOICE INSTRUCTIONS

3  **IF INSTRUCTED, PRESS THE RED “SHOCK” BUTTON**

THANK YOU FOR CHOOSING RESCUE SAM 4.0!

Rescue SAM 4.0 is a semi-Automated External Defibrillator (AED) designed for patient management according to the *European Resuscitation Council* (ERC) guidelines "*Basic Life Support - Defibrillation*" (BLS-D). It is designed to acquire the patient's ECG signals and deliver the defibrillation therapy.

AED users should be trained on the correct use according to such protocol.

Please read this User Manual carefully and thoroughly before using the RESCUE SAM 4.0 AED. This Manual contains instructions on how to operate, maintain and store the device correctly.

It is crucial that you fully understand all the necessary instructions included in this manual, to act quickly during an emergency.

PROGETTI S.r.l. designs and manufactures all of its products following applicable standards, such as the Medical Device Directive 93/42/EEC. This ensures that PROGETTI S.r.l. provides high-quality reliable products.

To maintain safety and performance throughout the life of your device, use only the components and accessories recommended by the manufacturer.

Only technicians trained and authorized by the manufacturer shall perform preventive and corrective maintenance on Rescue SAM 4.0 and its dedicated accessories. The device does NOT contain parts reparable by the user.

Disclaimer

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

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

Please contact PROGETTI S.r.l. for any further information.

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

- integrity of the main unit (enclosure) and the battery;
- integrity of the disposable multifunction electrodes cable and the sealed pouch where they are stored as well as their validity (see expiry date on the pouch);
- colour and flashing of the status indicator LED;
- readability of the labels on the main unit and all accessories.

For further information, please contact the PROGETTI's technical assistance department at the email address **service@progettimedical.com** or by phone at **+39.011.644.738.**

Declaration

PROGETTI S.r.l. reserves the right to make changes to device specifications and/or information contained in this manual at any time, where necessary, and without notice or obligation to the Customer.

Limited Warranty

The Limited Warranty supplied by PROGETTI is the sole warranty regarding the product.

Information about this User Manual

This manual contains the instructions necessary to use the product safely and per its function and intended use. Compliance with this manual is a prerequisite for the correct performance of the product and its proper functioning and ensures the safety of the patient and the operator.

The manual refers to the complete (full optional) configuration of the medical device; therefore, some contents may not apply to the product in use. If you have any questions, please contact us by e-mail at info@progettimedical.com.

This manual is an integral part of the product and, as such, should be kept close to the medical device so that it can be easily consulted when needed.

All pictures in this manual are for illustrative purposes only and, as such, may not reflect the configuration of the product in use.

Useful contacts

- GENERAL INFORMATION - **info@progettimedical.com**
- SALES DEPT. - **sales@progettimedical.com**
- TECHNICAL ASSISTANCE DEPT. - **service@progettimedical.com**
- QUALITY & REGULATORY DEPT. - **quality@progettimedical.com**

For continuous improvement, the Manufacturer is pleased to welcome any customer's opinion and suggestions on the device and/or this user manual. Therefore, please contact PROGETTI's Quality & Regulatory department at the email address quality@progettimedical.com.

Please report any incidents[1] occurring in connection with the medical device to the Manufacturer by sending an e-mail to quality@progettimedical.com and info@progettimedical.com.

Any serious incident[2] related to the device shall be reported not only to the manufacturer but also to the relevant Competent Authority.

[1] 'Incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect (MDR 2017/745, Art.2, §64).

[2] 'Serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat (MDR 2017/745, Art.2, §65).

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1. INTRODUCTION

This User Manual provides information for the safe and proper use of the Semi-Automated External Defibrillator (AED), model Rescue SAM 4.0, and its accessories.

The defibrillator is designed to be user-friendly thanks to voice prompts and visual indicators which provide simple guidance for the operator.

When connected to a person who is neither conscious nor breathing, Rescue SAM 4.0 is intended to perform the following functions:

- guide the operator through the preliminary actions of BLS-D;
- automatically classify the acquired patient's ECG signal, that is determine whether the rhythm is shockable or non-shockable and enable or disable the defibrillation energy release (shock) button, respectively;
- prompt the operator to press the red SHOCK button when the device is ready and a shock is recommended;
- deliver the defibrillation energy (shock) once the device has determined a shock is required and the SHOCK button has been pressed;
- guide the operator through the Cardiopulmonary Resuscitation (CPR) protocol;
- repeat the procedure from the rhythm classification until the device is turned off.

Rescue SAM 4.0 acquires the patient's ECG signal and analyses it through a special algorithm. This algorithm evaluates the patient's ECG and indicates whether or not a shockable rhythm is detected. The semi-automatic version of Rescue SAM 4.0 will NOT shock a patient automatically; it will only advise the operator if the shock is necessary. The SHOCK button is enabled only when a shockable rhythm is detected and the device is charged and ready to shock. Charging occurs automatically when the device detects a shockable rhythm. The operator has to press the SHOCK button to release the defibrillation energy.

Rescue SAM 4.0 uses a pair of self-adhesive disposable multifunction electrodes (also known as pads) designed to be suitable for both adult and paediatric patients. The operator can select the patient between "adult" and "paediatric" by pressing the corresponding button located on the AED front panel. The electrodes are intended for both the patient's ECG signal acquisition and the defibrillation energy release (shock). These electrodes are supplied together with Rescue SAM 4.0 in a sealed pouch with their cable exposed so that they can be connected to the AED main unit and stored with it – ready for use in case of emergency. Dedicated electrodes for adult or paediatric patients are also available and they can be supplied upon customer's request.

Rescue SAM 4.0 verifies that the electrode-to-skin contact is correct by measuring the electrical impedance between the two disposable multifunction electrodes after they have been applied to the patient. Voice prompts and visual indicators inform the user of possible contact problems with the patient. Rescue SAM 4.0 is designed to operate with a patient's impedance ranging between 25–200 Ω.

The defibrillation energy is released to the patient through an electrical pulse characterized by a "*BTE (Biphasic Truncated Exponential)*" compensated type of waveform. The energy released by the defibrillator varies according to the protocol used. Rescue SAM 4.0 can be used in "*fixed energy mode*". In this case, it releases:

- 200 J (nominal) if the operator selects "adult patient" when using the disposable multifunction electrodes (RS4-DFB01PRC) or if the disposable multifunction electrodes for adults (RS4-DFBAD01PRC) are connected to the defibrillator.

- 50 J (nominal) if the operator selects "paediatric patient" when using the disposable multifunction electrodes (RS4-DFB01PRC) or if the disposable multifunction electrodes for paediatric patients (RS4-DFBPED01PRC) are connected to the defibrillator.

Rescue SAM 4.0 can also be used with an "*incremental energy release protocol*" (optional). This means it can deliver a sequence of shocks with increasing defibrillation energy. The number of deliverable shocks and the energy of each shock may be customized. The default incremental protocols are the following:

- Adult patients: 2 shocks - 175 J, 200 J OR 3 shocks – 150 J, 175 J, 200 J.
- Paediatric patients: 2 shocks - 50 J, 75 J OR 3 shocks – 50 J, 70 J, 90 J.

If the hearth rhythm is still deemed shockable and a 3rd/4th shock is recommended, the AED proceeds using the highest energy level, namely the same energy charged during the last shock. For instance, after 3 shocks on an adult patient (150 J, 175 J and 200 J), the AED will charge 200 J again if the 4th shock is necessary.

If the first shock is not released because the user did not press the shock button, the device prompts the operator to perform the CPR and then, analyses the patient's heart rhythm again. If a shockable rhythm is present, the AED charges the second energy level. For example, the AED charges 175 J for an adult patient with a 3-level incremental protocol. It does not charge 150 J (first energy level) again.

With the Rescue SAM 4.0 compensation capability, the duration of the defibrillation pulse is variable so that the defibrillation energy released is the expected one depending on the patient selected or the electrodes used, regardless of the measured patient's impedance.

Rescue SAM 4.0 is powered by a non-rechargeable lithium battery whose expiry date is indicated on the dedicated label.

1.1 INTENDED USE

1.1.1 INTENDED CLINICAL CONDITIONS AND CLINICAL BENEFIT

The Rescue SAM 4.0 AED is intended to be used for the external cardiac defibrillation of a victim of Sudden Cardiac Arrest (SCA), i.e. a person who is unconscious, unresponsive and not breathing. In this case, the AED will recommend to release a shock to the patient aimed at restoring the physiological heart rhythm.

The cardiac arrhythmias for which the Rescue SAM 4.0 AED is effective are Ventricular Fibrillation (VF) and Fast Ventricular Tachycardia (FVT; heart rate > 150 bpm).

1.1.2 INTENDED PATIENTS' POPULATION

Rescue SAM 4.0 is intended to be used for the following patients' classes:

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

Rescue SAM 4.0 is **NOT** intended to be used on **infants/neonates** (age < 1 year old).

Do **NOT** delay therapy to determine the exact patient's age or weight.

Rescue SAM 4.0 is a reusable medical device intended to be used for multiple patients over its expected service life of 7 years. It is forbidden to connect the defibrillator to more than one patient at a time.

1.1.3 INTENDED USERS

The Rescue SAM 4.0 AED is intended to be used by either laypeople or healthcare professionals. In any case, the user should meet the following requirements:

- be qualified by a competent organization to operate the AED according to the applicable BLS-D protocols (e.g., ERC or AHA guidelines);
- be trained in using the Rescue SAM 4.0 AED correctly;
- be informed of the hazards due to using the Rescue SAM 4.0 AED;
- be aware of the information contained in this User Manual.

NOTE: in case of emergency, the lay person shall call professional emergency services right away, following the *"Make sure emergency services are called now"* voice prompt reproduced by the AED.

NOTE: the user should be aware of any additional local legislation regulating the use of the AED by laypeople, namely nonprofessional healthcare staff.

1.1.4 INTENDED USE ENVIRONMENT

Rescue SAM 4.0 is intended to be used indoors or outdoors. However, it shall NOT be used in the following environmental conditions:

- with a high oxygen concentration;
- in the presence of flammable substances;
- underwater.

The device has not been evaluated or approved for use in locations considered hazardous according to National Electric Code standards.

For further details on the storage and operating conditions, please refer to chapter 8 *"Technical Specifications"*.

1.2 LIMITATIONS OF USE

Rescue SAM 4.0 **MUST NOT** be used if the patient shows at least one of the following conditions:

- consciousness;
- breathing;
- pulse.

Rescue SAM 4.0 **is NOT intended for ECG monitoring**.

The device shall NOT be used on test dummies. The only recommended way to test the device is in combination with proper analysers and simulators for defibrillators (e.g. FLUKE instruments).

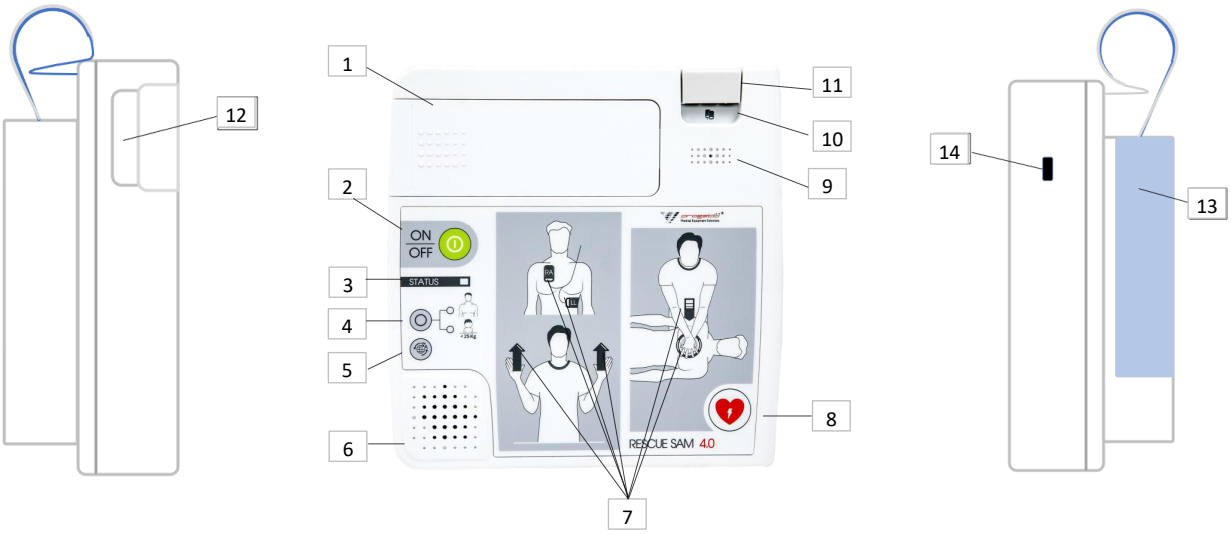
1.3 CONTRAINDICATIONS AND SIDE EFFECTS

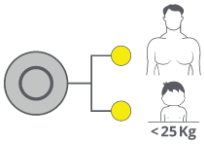
Based on the results of the clinical evaluation, there are no substantial contraindications or side effects due to the use of Rescue SAM 4.0, provided that it is used according to the Manufacturer's recommendations included in this User Manual.

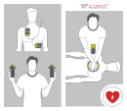
2. DESCRIPTION OF THE MEDICAL DEVICE

2.1 OVERVIEW

LEFT SIDE **FRONT VIEW** **RIGHT SIDE**



N.	IDENTIFICATION	ICON	FUNCTION
1	**BATTERY**	NA	Device power source.
2	**ON/OFF BUTTON**		Push this button to turn the device on. Push this button again for 4 seconds to turn the device off.
3	**STATUS INDICATOR**		It indicates the device's status. It flashes green when the device is in stand-by mode and ready to be used (see par. 2.2.2 "*STATUS INDICATOR*" for further information).
4	**PATIENT'S SELECTION BUTTON**		Push this button for 1 second to switch the patient's type between adult and paediatric. When the disposable multifunction universal electrodes (RS4-DFB01PRC) are connected to the AED, the patient's selection button is enabled and one of the two LEDs next to the adult's and paediatric symbols lights up indicating the selected energy profile. **When the device is turned on, the adult patient is always selected by default**. If the electrodes have already been applied to the patient's chest, the user has 15 seconds to select the patient's type. After this time, the patient's type CANNOT be changed anymore. The user shall restart the device to be able to select the patient's type again. If the electrodes have NOT been applied to the patient's chest, the user has no time limit to select the patient's type.

			However, if the user turns on the device and applies the electrodes on the patient AFTER 15 seconds, the patient's type CANNOT be changed anymore. The user shall restart the device to be able to select the patient's type again.
5	**LANGUAGE SELECTION BUTTON**		Push this button to change the device's language. If there is only a single language (standard configuration), this button has no effect. If the electrodes have already been applied to the patient's chest, the user has 15 seconds to switch the language. After this time, the language CANNOT be changed anymore. The user shall restart the device to be able to change the language again. If the electrodes have NOT been applied to the patient's chest, the user has no time limit to select the language. However, if the user turns on the device and applies the electrodes on the patient AFTER 15 seconds, the language CANNOT be changed anymore. The user shall restart the device to be able to select the language again.
6	**SPEAKER**	NA	It reproduces the voice prompts when the device is turned on.
7	**LED INSTRUCTIONS**		The LED flash to indicate the current rescue step and they follow the voice prompts (see par. 2.2.1 *"PICTOGRAMS AND LED INSTRUCTIONS"* for further information).
8	**SHOCK BUTTON**		When the AED deems that a shock is necessary and it is ready to deliver it, this button is enabled and lights up (red light). Once pressed, it delivers immediately the defibrillation energy to the patient. This button is disabled in all other cases.
9	**MICROPHONE**	NA	It records environmental sounds near the device during its use (if enabled).
10	**DISPOSABLE MULTIFUNCTION ELECTRODES CONNECTOR PORT**		Insert the connector of the disposable multifunction electrodes firmly in the port to connect the electrodes to the AED.
11	**DISPOSABLE MULTIFUNCTION ELECTRODES CONNECTOR**	NA	Insert the connector of the disposable multifunction electrodes firmly in the corresponding port to connect the electrodes to the AED.
12	**BATTERY UNLOCK BUTTON**	NA	Push this button while lifting the battery from the left side to extract it from the battery compartment.
13	**DISPOSABLE MULTIFUNCTION ELECTRODES COMPARTMENT**	NA	It houses the sealed package that contains the disposable electrodes while the AED is in stand-by mode. It allows the user to store the AED with the electrodes connected to the main unit, ready to be used in case of emergency.

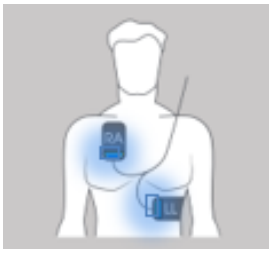
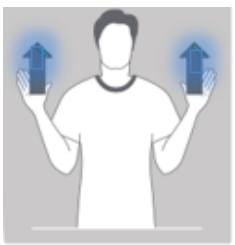
14	**DATA DOWNLOAD CABLE PORT**	NA	Insert the data download cable into this port and connect it to a computer at the other end to download the data recorded during the AED use. The AED can be connected to a computer only when the electrodes are disconnected from the main unit.

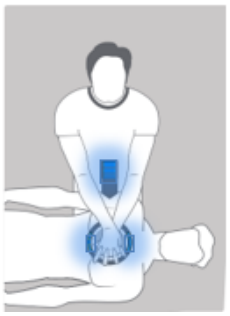
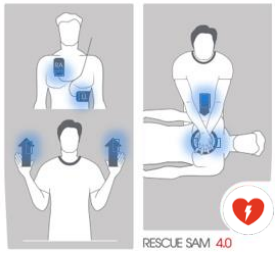
2.2 GRAPHIC USER INTERFACE

2.2.1 PICTOGRAMS AND LED INSTRUCTIONS

The AED front panel includes a sequence of pictograms which are listed according to the BLS-D protocol. LED are located by each pictogram and they light up in blue, according to the voice prompt(s) reproduced by the device and the occurring rescue step. Both the pictograms and the LED are visual instructions intended to guide the user during the rescue.

The table below summarizes the possible situations that may occur during a rescue.

PICTOGRAM AND LED INSTRUCTIONS	MEANING
 **CONNECT PADS TO THE PATIENT** LED ON	If the LED of this pictogram are flashing, it means that: • The disposable multifunction electrodes are NOT connected to the main unit. Insert the disposable multifunction electrodes connector into the corresponding port located on the top right corner of the device if the electrodes have not been connected to the AED yet. During this step, the vocal prompt “connect pads” is reproduced. • If the disposable multifunction electrodes are connected to the main unit, they are NOT applied to the patient (the device does NOT detect the patient’s impedance). Apply the disposable multifunction electrodes to the patient’s chest, following the pictograms printed on the electrodes themselves. During this step, the vocal prompts guide the user who shall expose the patient’s chest, remove the plastic liner from both electrodes and place them on the patient’s chest. • The disposable multifunction electrodes are connected to the main unit and they are applied to the patient. Check that the electrodes are positioned correctly and adhere properly to the patient’s chest.
 **DO NOT TOUCH THE PATIENT** LED ON	If the LED of this pictogram are flashing, the user shall stand clear. This means that the user shall move away from the patient and make sure that no one is touching the patient. During this step, the AED is either analysing the patient’s ECG signal or charging the defibrillation energy.

 **PERFORM CPR** LED ON	If the LED of this pictogram are flashing, the user shall begin the Cardiopulmonary Resuscitation (CPR) following the metronome sound (“beep-beep-beep”) and the LED flashing light.
 **ALL THE INSTRUCTION** LED ON	If all LED are flashing, the following situations may occur: • An operating error has occurred. Please refer to the manufacturer or an authorized servicing centre for technical assistance. In this case, the voice prompt “system error, service required” is reproduced and the status indicator LED is red. • The AED has just been turned on. All LED are flashing while the AED is saying “stay calm; follow the voice instructions; make sure emergency services are called now”. • Low battery. Please refer to the manufacturer or an authorized distributor for a new battery as a replacement. In this case, the voice prompt “low battery” is reproduced. • The device is connected to a computer and the user is downloading the data recorded previously.
 **ALL THE INSTRUCTION** LED OFF	If all LED are NOT flashing, the device is turned off.

2.2.2 STATUS INDICATOR

The status indicator is located on the front panel of the device and it provides information on its status. The LED of the status indicator may have different colours, each one with a specific meaning, described in the following table.

COLOUR OF THE STATUS INDICATOR LED		MEANING
GREEN		The device is ready for use. If the device is in stand-by mode, the status indicator will be flashing green. If the device is turned on, the status indicator will be steady and green.
YELLOW		In descending order of priority: a) The device is NOT ready for use because the disposable multifunction electrodes are NOT connected to the main unit OR b) the battery's level is low (15%), but the device can still release more than 20 shocks. If the device is in stand-by mode, the status indicator will be flashing yellow. If the device is turned on, the status indicator will be steady and yellow.
RED		The device is NOT ready for use: a fault has been detected OR the battery level is critically low (5%). If the battery's level is low, the device will still ensure at least 20 shocks or max 1 hour of normal operation from the moment the status indicator becomes red. If the device is in stand-by mode, the status indicator will be flashing red. If the device is turned on, the status indicator will be steady and red. In this case, the "System error. Service required" voice prompt is reproduced if the AED detects a fault or it shuts down if the battery is completely depleted. NOTE: if the battery goes from low to critically low (5%) while the AED is on and used, the status indicator goes from yellow to red and it flashes when the device is on.
OFF		The device is NOT ready for use: the battery is completely depleted or it is not inserted correctly. The device does NOT turn on if the ON/OFF button is pushed.

2.3 ACCESSORIES

PROGETTI recommends using the Rescue SAM 4.0 AED only in combination with the accessories listed in the table below. The use of other accessories may damage the device and affect its performance.

- Disposable accessories should be used once and on one patient only. Reuse may cause a risk of contamination and may affect measurement accuracy.
- Always check that disposable accessories have not expired by checking the expiration date on the package.
- Check accessories and their package for damage. If the accessory is damaged or worn, or its package is not intact, do not use it on the patient and contact the Manufacturer or its local authorized distributor for replacement.
- Do not prematurely open the package of the disposable accessories to avoid dryness and contamination which would compromise their performance.

For any further information or request, please contact PROGETTI's technical assistance dept.

PRODUCT CODE (REF)	DESCRIPTION	PICTURE	STANDARD / OPTIONAL
RS4-DFB01PRC	**Disposable Multifunction Electrodes for adult and paediatric patients** These electrodes are always supplied by the manufacturer together with the AED. They are self-adhesive and can be stored connected to the AED (pre-connected). They are intended to acquire the patient's electrocardiographic (ECG) signal and release the defibrillation energy to the patient if necessary. They are intended to be used for both adult and paediatric patients.		STANDARD
RS4-DFBAD01PRC	**Disposable Multifunction Electrodes for adult patients** These electrodes are supplied only upon the customer's request. They are self-adhesive and can be stored connected to the AED (pre-connected). They are intended to acquire the patient's electrocardiographic (ECG) signal and release the defibrillation energy to the patient if necessary. They are intended to be used only for adult patients.		OPTIONAL

RS4-DFBPED01PRC	**Disposable Multifunction Electrodes for paediatric patients** These electrodes are supplied only upon the customer's request. They are self-adhesive and can be stored connected to the AED (pre-connected). They are intended to acquire the patient's electrocardiographic (ECG) signal and release the defibrillation energy to the patient if necessary. They are intended to be used only for paediatric patients.		OPTIONAL
DFBSAM4.0_ CASE	**Transport bag** The transport bag is supplied only upon the customer's request. It is intended to ease the device transport and improve protection from knocks and/or the ingress of water or foreign substances into Rescue SAM 4.0 and its accessories throughout the stand-by period.		OPTIONAL
PRG005_ HANDLE_ V01_R01	**Handle** The handle is supplied only upon the customer's request. It is flexible and it is intended to ease the device transport.		OPTIONAL
DFBSAM WALL4.0	**Wall mount** The wall mount is always supplied by the manufacturer together with the AED. It is a piece of metal which is intended to be fixed on the wall allowing the user to hang the device.		STANDARD

2.4 DETACHABLE COMPONENTS

The table below summarizes the detachable components of Rescue SAM 4.0. PROGETTI recommends using the Rescue SAM 4.0 AED only in combination with the items listed in the following table to avoid damaging the device and/or affecting its performance.

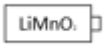
Before using each separable component, please ensure that it is intact (with no visible damage) and it has not expired yet if applicable. If the item is damaged or worn or its package is not intact, do not use it and contact the Manufacturer or its local authorized distributor for replacement.

For any further information or request, please contact PROGETTI's technical assistance dept.

PRODUCT CODE (REF)	DESCRIPTION	PICTURE	STANDARD / OPTIONAL
DFBSAM4.0RS4B	**Battery** One non-rechargeable battery is always supplied by the manufacturer together with the AED. Once it is completely depleted, please contact the manufacturer or its authorized distributor for a replacement. The battery can be inserted in and removed from the AED by the user.		STANDARD
RND 765-00054	**Data download cable** The data download cable is supplied only upon the customer's request. Alternatively, any standard USB cable type A to type micro-B is compatible with the AED. It is intended to allow the user to connect the AED to a computer. Once the AED is connected, the user can download the data that the device has recorded previously, during the rescue. The cable can be connected to the computer through the USB-A port, whereas it is connected to the AED through the micro-B USB port.		OPTIONAL

2.5 SYMBOLS

The following table explains the meaning of each symbol included on the labels of the device, its accessories and its outer carton box.

SYMBOL	DESCRIPTION	SYMBOL	DESCRIPTION
	Catalogue number		CE Marking & Notified Body's identification number
	Serial number		CE marking (for accessories within class I and battery)
	Lot number		General warning
	Manufacturing date		Electricity hazard
	Manufacturer		DO NOT use the device on infants and neonates (< 1 year old)
	Defibrillation-proof type BF applied part		Waste from Electrical and Electronic Equipment - WEEE
	Expiry date		Refer to instructions for use/user manual
	$LiMnO_2$ battery	**IP55**	Ingress protection against solid particles and liquid ingress
	DO NOT damage or open the battery		DO NOT crush the battery
	DO NOT expose the battery to high temperatures or open flames. DO NOT set fire to the batteries		Keep away from sunlight
	Humidity range		Temperature range
	Keep dry		Fragile, handle with care
	Do NOT stack more than 4 boxes. The number may vary depending on the item the symbol refers to.		This side up

	Do NOT use if the package is damaged and consult the instructions for use.		Operating temperature range (for disposable multifunction electrodes)
	Latex free		Unique device identifier
	Single-use: do not reuse		Medical device
	Non-sterile device		Number of pieces per package
	General warning sign		Number of pieces per carton box
	The disposable multifunction electrodes can be used with automated external defibrillators (AED)		

3. SAFETY INFORMATION

This chapter includes a list of hazard, warning, and caution messages related to Rescue SAM 4.0 and its accessories. Many of these messages may be repeated elsewhere within this User Manual and/or on the equipment. For your convenience, the full list is presented below.

Our customers shall ensure that the person(s) in charge within their organisation have access to information about the device, including the general safety information listed below.

3.1 GENERAL INFORMATION

Before and after using Rescue SAM 4.0, please ensure that the main unit is safe and in perfect condition (integrity of cables and electrodes, condition of the battery). Also, make sure that the battery charge is sufficient and the battery itself is in good condition.

3.2 KEY

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

3.3 MESSAGES

 **DANGER**	**ELECTRICITY**	Dangerous electricity release. This device shall only be used according to applicable local regulations. Use Rescue SAM 4.0 only as directed in the user manual. The device delivers electrical energy that has the potential to cause death or serious injuries if used without following the instructions provided in this User Manual.
 **DANGER**	**ELECTRICITY**	Defibrillation current (shock) can cause injury to bystanders or the operator. Do NOT touch the patient during defibrillation to minimize the risk of secondary shock. Avoid contact between any equipment connected to the patient, parts of the patient's body (e.g. head, limbs), conductive fluids (e.g. water, blood) or metal objects that may accidentally create undesirable alternative pathways for the defibrillation (shock) current. Disconnect the Rescue SAM 4.0 disposable electrodes from the patient before using another defibrillator if necessary.

DANGER	**ENVIRONMENT**	Risk of device explosion when used in the presence of flammable anaesthetic gas or concentrated oxygen. The device has not been evaluated or approved for use in locations considered hazardous according to National Electric Code standards. According to the EN classification, the device shall NOT be used with flammable substances and/or air mixtures.
WARNING	**ENVIRONMENT**	Radio interference such as that of mobiles or radio transmitters may cause the device to function improperly. According to IEC 801.3, a distance of 2 metres is recommended between the device and any radio equipment.
WARNING	**ENVIRONMENT**	Use of this equipment adjacent to or stacked with other equipment should be avoided as it may cause improper operation. If such use is necessary, this equipment and other equipment should be observed to verify that they are functioning normally.
WARNING	**DEFIBRILLATION ENERGY**	Disconnect all non-defibrillator-proof equipment (not equipped with an applied “defibrillator shock protected” part) from the patient before defibrillating to prevent the risk of electric shock and potential damage to such equipment. Alternative current pathways may cause electrical arches and patient skin burns during defibrillation and may divert the defibrillating energy away from the heart.
WARNING	**ELECTRODES (PADS)**	Use only PROGETTI® disposable multifunction electrodes (pads) or those purchased from authorized distributors. Unapproved accessories may affect the device’s performance.
WARNING	**ELECTRODES (PADS)**	Do not defibrillate if the disposable multifunction electrodes (pads) are in contact with each other or any portion of the gel surface is exposed. Ensure that the disposable multifunction electrodes do not 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	**ELECTRODES (PADS)**	Disposable multifunction electrodes (pads) should be used only once and should be disposed of after use. Reuse could result in cross-infection, device performance alteration, inadequate defibrillation current delivery, and/or injury to the patient or operator.
WARNING	**ELECTRODES (PADS)**	Open the bag of disposable multifunction electrodes (pads) only when needed. Do NOT open the package prematurely to avoid alteration and/or contamination of the product. Do NOT remove the disposable multifunction electrodes from the sealed packaging until they have to be used. The packaging

		should only be used immediately before use.
WARNING	**ELECTRODES (PADS)**	Do NOT use the electrodes (pads) after their expiration date. Ensure that the sealed bag that contains the electrodes (pads) is sealed and intact before using them. Otherwise, replace it with an intact one.
WARNING	**ELECTRODES (PADS)**	Prefer placement of disposable multifunction electrodes (pads) in the anterolateral (front-front) configuration for adult patients and anteroposterior (front-back) configuration for paediatric patients. Do not place the disposable multifunction electrodes on an adult patient in the anteroposterior (front-back) configuration. If the user decides that the disposable multifunction electrodes should be applied to the patient with a configuration other than the recommended one, the user is entirely liable for their decision.
WARNING	**ELECTRODES (PADS)**	During defibrillation, air pockets between the skin and the defibrillation pads can cause patient skin burns. To help prevent air pockets, verify that the self-adhesive defibrillation electrodes (pads) completely adhere to the skin. Do not use dried-out pads.
WARNING	**CPR**	Aggressive or prolonged CPR with disposable multifunction electrodes (pads) attached to the patient may damage the pads. Replace defibrillation pads if they become damaged during use.
WARNING	**ECG ANALYSIS**	Some very low amplitude or low-frequency rhythms may not be interpreted as shockable.
WARNING	**ECG ANALYSIS**	Handling, moving or transporting the patient during the ECG analysis will lead to errors or delays in diagnosis, especially if very low amplitude or low-frequency rhythms are present. When the electrodes (pads) are applied to the patient and the ECG analysis is undergoing, the patient's movement must be avoided.
WARNING	**ECG ANALYSIS**	If the patient has an implanted cardiac pacemaker, the device may not detect all shockable rhythms as such. In this case, the AED may be less sensitive and unable to detect shockable rhythms. If the patient is a pacemaker carrier, do not place the defibrillation electrodes directly over the implanted device. If the patient has a pacemaker or other implantable device, place the electrodes (pads) at least 8 cm away from the implanted device, considering that anterolateral placement is preferred in adults. If this is not possible, place the electrodes by choosing an alternative configuration.

 **WARNING**	**MAINTENANCE**	Do not open the unit, remove the enclosure or attempt to repair or modify the device without the Manufacturer's permission. The device does NOT contain any parts that can be repaired by the user. If replacement and/or repair of Rescue SAM 4.0 or any of its accessories is necessary, please contact the manufacturer or an authorized service centre. The user may perform maintenance activities only as described in this User Manual.
 **WARNING**	**MAINTENANCE**	The device is designed to perform periodic automatic checks to assess its readiness for use. In any case, no level of control can ensure performance or detect any misuse, damage or defect occurring after the most recent check is completed.
 **WARNING**	**MAINTENANCE**	Using damaged devices or accessories may cause the device to function incorrectly and may result in injury to the patient and/or the operator.
 **WARNING**	**MAINTENANCE**	Do not modify this equipment without the Manufacturer's authorization. In case of device modification, proper tests and checks are required to ensure its unchanged safety and performance.
 **WARNING**	**ENVIRONMENT / CLEANING**	Do not immerse any part of this product (including the battery) in water or any other liquid. Do not allow any fluids to get inside the device. Avoid spilling fluids onto the device or its accessories. Immersion or spilling onto the device may damage it, cause fire or risks of electric shock.
 **WARNING**	**BATTERY**	Lithium battery packs are not rechargeable. Any attempt to recharge a lithium battery pack may result in fire or explosion.
 **WARNING**	**BATTERY**	Do not immerse the battery in water or any other liquid because immersion could lead to fire or explosion.
 **WARNING**	**BATTERY**	To avoid the risk of fire and explosion, do not burn or incinerate the battery. Do not attempt to open or disassemble the battery. Do not try to recharge, short-circuit, pierce or deform the battery.
 **WARNING**	**BATTERY**	Do not expose the battery to temperatures above 50°C.
 **CAUTION**	**BATTERY**	Recycle or dispose of the lithium battery following applicable regulations.
 **CAUTION**	**BATTERY**	Follow all the instructions on the battery label.

 **CAUTION**	**BATTERY**	Do NOT use the battery after the expiration date indicated on its label. Please contact the manufacturer or its authorized distributor for a replacement.
 **CAUTION**	**ELECTRODES (PADS)**	Observe all the information on the disposable multifunction electrodes package.
 **CAUTION**	**ELECTRODES (PADS)**	In case of any anomalies on the package, cable or connector of the disposable multifunction electrodes, please contact the manufacturer or its authorized distributor.
 **CAUTION**	**ENVIRONMENT**	Although the device is designed for a wide range of usage conditions, treating the device roughly could damage it.
 **CAUTION**	**ENVIRONMENT**	The device should only be stored and used in the environmental conditions stated in this User Manual.
 **CAUTION**	**CLEANING**	Clean and sanitize the enclosure of the device's main unit after each use with a soft cloth.
 **CAUTION**	**CLEANING**	Do not use abrasive materials or strong solvents such as acetone and/or its derivatives to clean the device.
 **CAUTION**	**CLEANING**	Do not autoclave or sterilize the device and/or its accessories.
 **CAUTION**	**STORAGE**	Improper storage may lead to the device's malfunctioning. Store the device only as described in this User Manual.

4. SET-UP PROCEDURE

Before using Rescue SAM 4.0, please ensure that the main unit is safe and in operational status (integrity of cables and electrodes, battery sufficiently charged).

Rescue SAM 4.0 is designed to be stored in a “ready-to-use” condition. This section describes how to prepare the device, so that if and when you need it, few steps are required to begin using the device.

Rescue SAM 4.0 should be stored with the electrodes connected to the main unit to ease the setting up procedure and the device operations during an emergency.

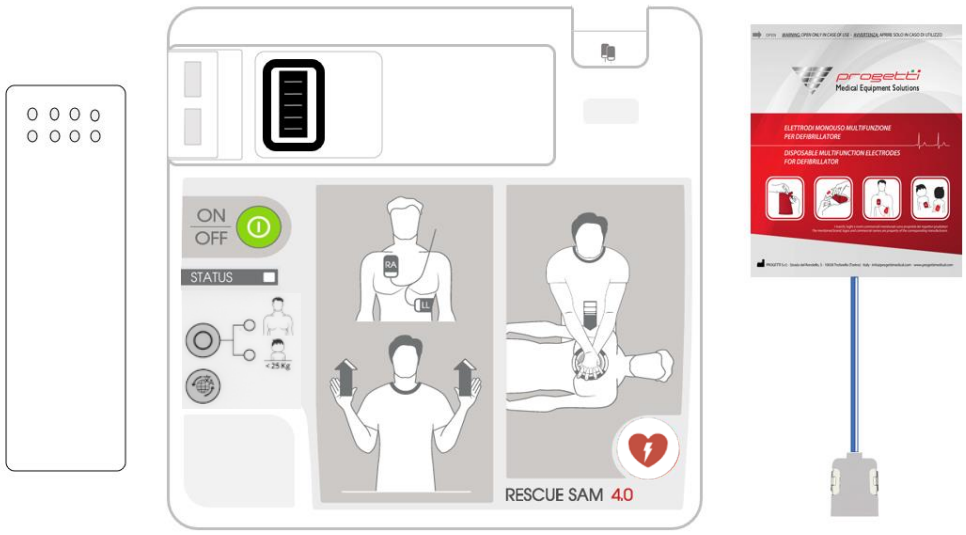
The disposable multifunction electrodes are indeed supplied in a sealed package with the connector and part of the external cable exposed, allowing the user to store the AED with the electrodes pre-connected (pre-connection state) for quick use.

When setting up the Rescue SAM 4.0 AED, follow the following steps:

1

Before unpacking, carefully inspect the packaging for signs of damage. If the package is damaged or opened prematurely, contact the carrier, the manufacturer or its authorised local distributor. If the package is intact, proceed to open it.

Remove Rescue SAM 4.0 and its accessories from the carton box.



When removing the device from the box, verify that all required parts and accessories are present. Inspect the defibrillator and its accessories for transport damage. If the device or any of its accessories is damaged, do not use it on the patient and contact the manufacturer or its authorized local distributor for assistance.

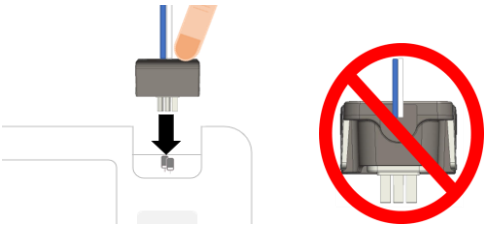
If possible, retain the shipping container in case you need to return the defibrillator in the future (e.g., for preventive maintenance checks).

2

Insert the connector of the disposable multifunction electrodes into the port located in the top right corner of the device. Make sure that the connector is orientated correctly and push it in to lock it in position.

If the connector of the electrodes does NOT enter the corresponding port, it may have been inserted upside down. Please rotate it and try again.

Do NOT remove the electrodes from their sealed package until they need to be used. The packaging should be opened only immediately before use, otherwise, the electrodes may dry out, becoming non-functional.



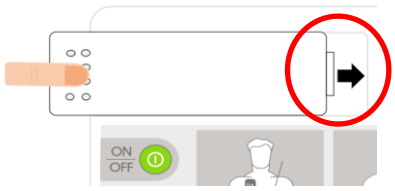
WARNING: connect the disposable multifunction electrodes only as shown in the picture above. The blue-white cable must be oriented toward the back of the AED and <u>NOT the front</u>.

WARNING: do NOT install the electrodes after the expiration date printed on their label. Do NOT use the electrodes twice. They are for single use ONLY and should be discarded and replaced after use.

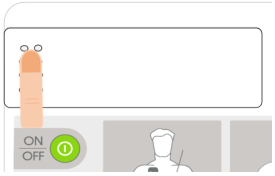
3

Insert the battery into its dedicated compartment located on the top left corner of the device, as illustrated below:

- ensure that the compartment is clean and clear from any foreign objects;
- place the right side of the battery in the right side of the battery compartment;



- lower the left side of the battery into the compartment to lock the battery in place (you will hear a “CLICK” when the battery is properly inserted and locked in the compartment).



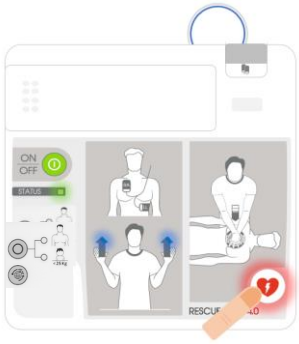
WARNING: do NOT install the battery after the expiration date printed on its label. The battery is NOT rechargeable.

4

Check that the self-test is successfully passed.

As soon as the battery is correctly locked in the battery compartment, Rescue SAM 4.0 turns on and starts an automatic self-test. The **"Self-Test"** voice prompt will be reproduced, the status indicator will light up in solid green, and the "do not touch the patient" LED instructions will be blue and flashing.

Follow the voice prompts, i.e., press the red SHOCK button once it is activated and the device reproduces the voice prompt "press the red SHOCK button".



Wait a few seconds so that the device can perform the self-test which is accompanied by a rising sound.

If the self-test result is positive (passed), the device reproduces the "**System ok"** voice prompt and all the LED instructions will be blue and flashing. Then, the device reproduces the "**Powering down**" voice prompt and enters the stand-by mode.

In stand-by mode, the status indicator will be flashing and GREEN: Rescue SAM 4.0 has been successfully put into service and is now ready for use.

If the self-test result is negative (failed), the device reproduces the "**System Error. Service required**" voice prompt and all the LED instructions will be blue and flashing. Then, the device reproduces the "**Powering down**" voice prompt and enters the stand-by mode.

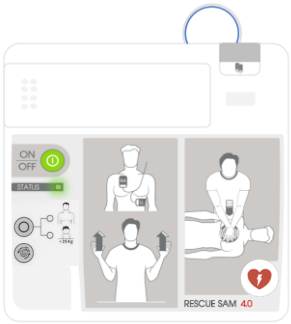
After detecting a problem, the status indicator will be flashing and RED: Rescue SAM 4.0 cannot be put into service and used on a patient. Please contact the manufacturer's technical assistance department for support.

5

Put Rescue SAM 4.0 into service together with its disposable multifunction electrodes, so that it is easily visible and accessible. The manufacturer recommends installing the device as follows:

- hanging on a wall without its dedicated bag (picture A);
- hanging on a wall or resting on a surface protected by its dedicated bag (picture B). Please refer to the following paragraph for instructions on how to insert the device into its bag;
- stored protected by its dedicated bag inside a dedicated cabinet (picture C).

In addition, the AED and its disposable multifunction electrodes shall be stored within the ranges specified by the manufacturer (see chapter 8 "*Technical specifications*" for further information).



Picture A

Picture B

Picture C

4.1 INSERTING THE DEVICE INTO ITS TRANSPORT BAG

Rescue SAM 4.0 has a dedicated transport bag where it can be stored, ready to be used.

Please follow these instructions to place the device correctly in the transport bag:

1. Ensure that the battery has been placed in its compartment and the device has passed the self-test successfully. Ensure that the status indicator is flashing and it is green.
2. Ensure that the disposable multifunction electrodes are connected to the corresponding port located on the top right corner of the device.
3. Open the transport bag and lift the transparent plastic liner located on the left side.
4. Place the AED on the left side of the transport bag and close the protective plastic liner on it, securing it in place.
5. Place the electrodes contained in the sealed pouch into the corresponding pocket located on the right side of the bag. Do NOT open the electrodes package. It shall be opened ONLY right before use.
6. Close the transport bag and ensure to be able to see the status indicator which should be green and flashing. The defibrillator can be used even if it is contained in the transport bag as long as the latter is open.

5. DEFIBRILLATION PROCEDURE

The device is designed for simple operation, allowing the operator to focus on the patient.

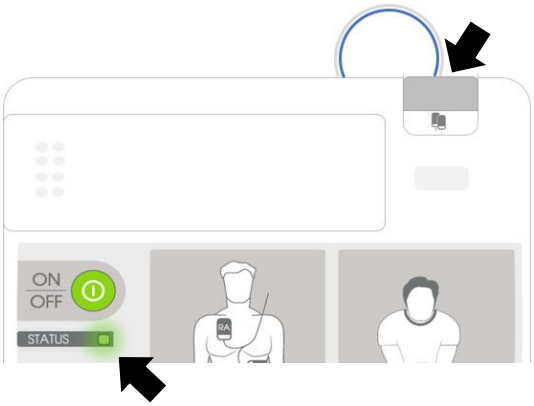
Concise and easily understandable voice prompts guide the operator through the use of the defibrillator.

Please follow the instructions to use the device correctly:

1

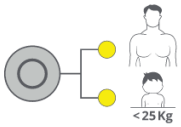
Check that the STATUS INDICATOR LED flashes GREEN (meaning that the battery is inserted, it is sufficiently charged and the disposable multifunction electrodes are connected to the AED correctly).

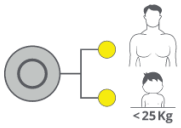
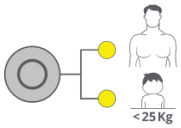
The AED is ready for use.



Rescue SAM 4.0 can automatically distinguish between the types of electrodes connected to the main unit.

3 cases are possible:

REF DISPOSABLE MULTIFUNCTION ELECTRODES	**SUITABLE PATIENT'S POPULATION**
RS4-DFB01PRC – GREY CONNECTOR 	**BOTH ADULT AND PEDIATRIC PATIENTS.** **ADULT**: age ≥ 8 years old and weight ≥ 25 kg (including pregnant women). **PEDIATRIC**: aged between 1 and 8 years old and weighing < 25 kg. The user shall select the patient's type by pressing for 1 second the dedicated button located on the front panel of the AED main unit. An LED lights up next to the patient's type selected, either adult or child. ADULT PATIENT IS SELECTED BY DEFAULT.  NOTE: if the electrodes have already been applied to the patient's chest, the user has 15 seconds to choose the patient's type, starting from the moment the device is turned on.

	After this time has elapsed, the button deactivates and the user shall restart the device to be able to select the patient's type again.
RS4-DFBAD01PRC – WHITE CONNECTOR 	**ADULT**: age ≥ 8 years old and weight ≥ 25 kg (including pregnant women). NOTE: the patient's selection button is deactivated and both the adult and paediatric LEDs are off. 
RS4-DFBPED01PRC – PINK CONNECTOR 	**PEDIATRIC**: age between 1 and 8 years old and weight < 25 kg. NOTE: the patient's selection button is deactivated and both the adult and paediatric LEDs are off. 

WARNING: Do NOT delay the procedure to determine the patient's exact weight or age.

WARNING: Do NOT release the defibrillation energy (SHOCK) on infants or neonates (patients aged < 1 year old).

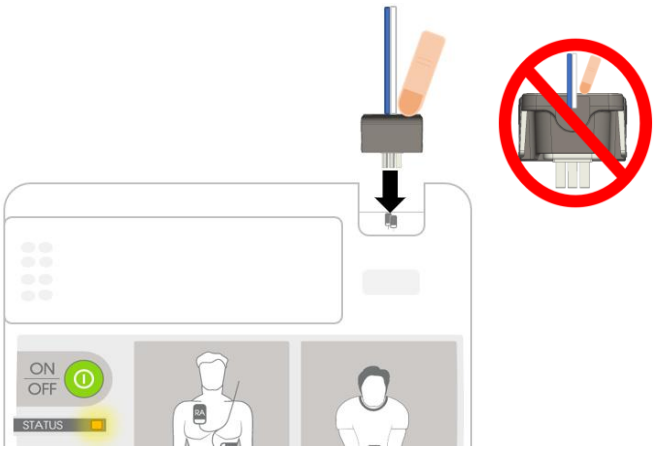
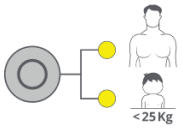
2

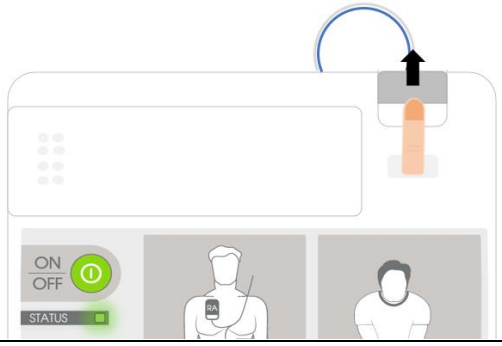
Press the ON/OFF button until the AED turns on.

Verify that the STATUS INDICATOR LED is GREEN.

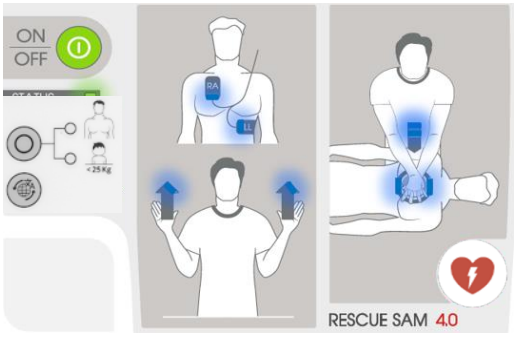
Depending on the case, please take a look at the following table that describes the actions needed to solve each situation and be able to proceed.

If the following conditions are not applicable, please skip to the next step (3).

CASE		ACTIONS TO BE TAKEN
A	Disposable multifunction electrodes are **not connected.** Status indicator: yellow LED.	Connect the disposable multifunction electrodes connector to its port located in the top right corner of the AED, as shown below.  NOTE: if the device is turned on, it indicates the type of electrodes connected by reproducing the voice prompts: “adult pads connected” or “paediatric pads connected”, based on the type of electrodes chosen. If the operator connects the electrodes suitable for BOTH adult AND paediatric patients, the adult patient’s type is selected by default and the AED will reproduce the “adult pads connected” voice prompt.
B	Disposable multifunction electrodes already connected but **not suitable for the patient’s type.** Status indicator: green LED.	1. If the disposable multifunction electrodes for BOTH adult AND paediatric patients (grey connector) are connected to the AED, just switch to the other patient’s type by pressing the patient’s selection button for 1 second. An LED will light up next to the patient’s type selected and the “adult pads connected” or the “paediatric pads connected” voice prompt will be reproduced.  2. If the electrodes dedicated to adult patients (white connector) or paediatric patients (pink connector) are connected to the AED, disconnect them from the main unit by firmly pulling their connector

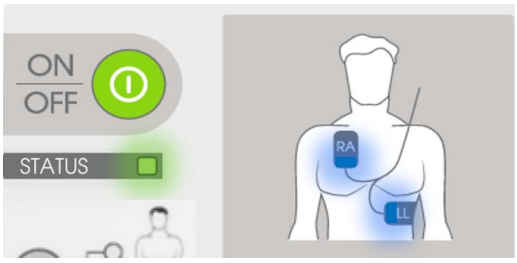
		and connect the suitable electrodes for the patient's type (see case A for the connection procedure). 
C	Disposable multifunction electrodes already connected and suitable for the patient's type but **expired.** Status indicator: green LED.	Disconnect the expired disposable multifunction electrodes from the AED by firmly pulling the connector and connecting a pair of valid ones (see case A for the connection procedure). 
D	Voice prompts in an **unknown language.**	Change the language by pressing the language selection button. If more languages are available (optional), the AED will immediately switch to the other language by reproducing the name of the language (e.g. English, Italiano, Français, etc). Press the language selection button again to continue changing the language.  NOTE: if the electrodes have already been applied to the patient's chest, the user has 15 seconds to choose the language, starting from the moment the device is turned on. After this time has elapsed, the button deactivates and the user shall restart the device to be able to select the language again.

3 Follow the voice and visual instructions to apply the electrodes to the patient correctly.



3.1 ***"Stay calm. Follow the voice instructions. Make sure emergency services are called now."***

Meaning: as soon as the AED is turned on, it is recommended to call for help. This indicates that the first step in a rescue should always be contacting professional emergency services. If another person is available, the user should ask that person to call for help and then, continue the rescue without delay.



3.2 ***"Connect pads."***

Meaning: the disposable multifunction electrodes connector is not plugged in or it is plugged in incorrectly.

Please refer to step 2, case A for instructions on how to connect the electrodes to the defibrillator.

If the electrodes are not connected to the AED within 5 minutes, the device will turn off automatically.

3.3 ***"Expose patient's bare chest. Remove or cut clothing if needed. Shave the chest if needed."***

Meaning: remove the patient's clothing to expose the chest where the electrodes shall be placed. If the pads do not adhere properly due to moisture, wipe the patient's skin. If the pads do not adhere properly due to excessive hair, shave or clip excessive chest hair. Check that no jewellery or other objects are directly underneath the site where the pads will be placed to ensure adequate skin-electrode contact.

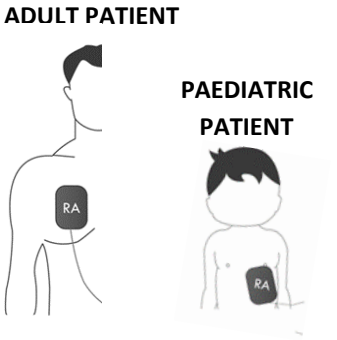
3.4 ***"Take the pads package. Tear open package and remove pads."***

Meaning: take the sealed bag where the electrodes are contained and tear it open following the dotted line on the upper side of the package.

Check that the electrodes are free from obvious signs of damage, clean of excessive debris (for example, dirt if the pad dropped) and NOT expired. Do NOT use the electrodes after the expiration date printed on the package. If one of these conditions is found, please discard the electrodes and replace them with a new pair.

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

Meaning: remove the protective liner from the first electrode and check that it has NOT dried out; the gel

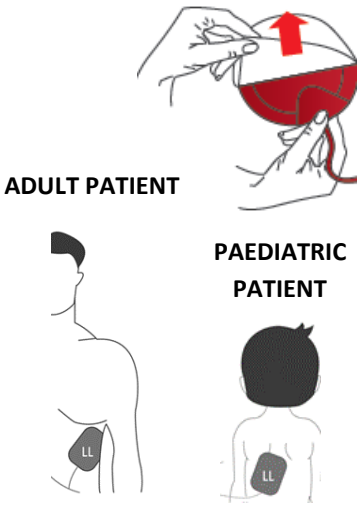


should be adhesive to ensure adequate contact with the patient's skin. Otherwise, please discard the electrodes and replace them with a new pair.

Please place the electrode on the patient (adult or paediatric) following the diagrams on the disposable multifunction electrode itself and its package.

ADULT PATIENT: anterolateral configuration preferred (front-front).

PAEDIATRIC PATIENT: anteroposterior configuration preferred (front-back).



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

Meaning: remove the protective liner from the second electrode and check again that it has NOT dried out; the gel should be adhesive to ensure adequate contact with the patient's skin. Otherwise, please discard the electrodes and replace them with a new pair.

Please place the electrode on the patient (adult or paediatric) following the diagrams on the disposable multifunction electrode itself and its package.

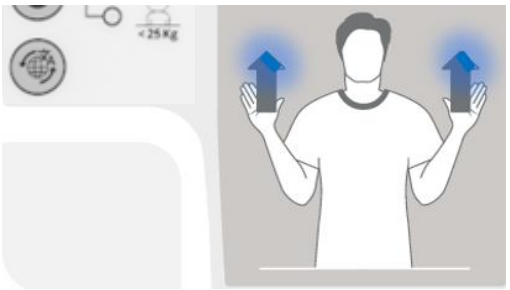
Ensure that the electrodes are properly placed and fully adhered to the patient. No air bubbles should be present between the electrodes and the patient's skin. Verify that the electrodes do NOT touch each other.

The blue "connect pads" LED will continue to flash during these prompts.

If the electrodes are not placed on the patient's chest within 5 minutes, the device will turn off automatically.

4

Follow the voice and visual instructions to allow proper ECG analysis and defibrillation energy release if necessary.



4.1 ***"Do not touch the patient. Analysing hearth rhythm."***

Meaning: once the AED has determined that the electrodes are properly applied to the patient, it starts the patient's heart rhythm analysis. The unit analyses the ECG signal detected and determines whether a shockable or non-shockable rhythm is present.

While analysing, the AED continues to monitor the electrodes' connection and stops the analysis if it detects any issue related to the electrodes' connection.

During this step, the operator shall NOT touch the patient.

The blue "do not touch the patient" LED will continue to flash during these prompts.

CASE A – SHOCKABLE RHYTHM

4.A.1 **"*Shock advised. Do not touch the patient*"**

Meaning: the AED has determined that a shock is recommended and the unit is going to begin charging, preparing for a defibrillation shock. The user and the bystanders should stand clear of the patient.

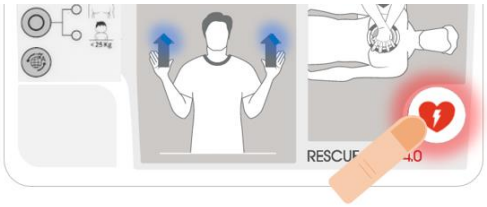
ADULT PATIENT: the device automatically charges 200 J nominal defibrillation energy.

PAEDIATRIC PATIENT: the device automatically charges 50 J nominal defibrillation energy.

NOTE: the defibrillation energy values may vary if the device includes an incremental energy release protocol (optional). In this case, it delivers a sequence of shocks with increasing defibrillation energy. The default incremental protocols are:

- Adult patients: 2 shocks - 175 J, 200 J OR 3 shocks – 150 J, 175 J, 200 J.
- Paediatric patients: 2 shocks – 50 J, 75 J OR 3 shocks – 50 J, 70 J, 90 J.

Before delivering the following shocks (second, third), the AED prompts the user to perform CPR. After the CPR, it analyses the patient's heart rhythm again and, if it detects a shockable rhythm, it charges again increasing the energy.



4.A.2. **"*Press the red shock button*."**

Meaning: the AED has fully charged, the heart rhythm analysis algorithm still indicates that a shock is recommended, and the unit is ready to deliver a shock. The red SHOCK button is lit and red and a high-frequency acoustic sound (beep) indicates that the device is fully charged and ready to deliver the defibrillation energy to the patient. The user should press the SHOCK button to deliver the shock.

If the red shock button is pressed within 15 seconds, the AED delivers the defibrillation energy to the patient and the "***Shock delivered***" voice prompt is reproduced.

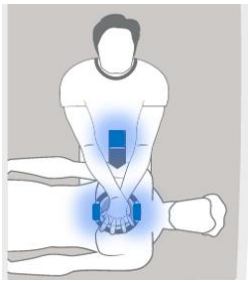
If the red shock button is not pressed within 15 seconds OR the AED detects a change in the patient's heart rhythm from a shockable to a non-shockable one while charging the defibrillation energy or while waiting for the shock button to be pressed, the device will abort the shock. The defibrillation energy is discharged automatically inside the AED (internal discharge) and the shock button is disabled. The ***"No shock delivered***" voice prompt is reproduced.

In both cases, the AED continues by reproducing the voice prompt: ***"It is now safe to touch the patient".***

MANUAL DISARM PROCEDURE:

Defibrillator disarm is the safe discharge of defibrillation energy into the defibrillator itself.

If a shock is not deemed necessary anymore by the user, but the AED has already started to charge the defibrillation energy, the user can disarm manually the AED by pressing the ON/OFF button for at least 4 seconds after the "shock advised" voice prompt. The defibrillator turns off, reproducing the "no shock delivered, powering down" voice prompt and the energy is discharged internally.



4.A.3 ***"Start CPR. Place heel of one hand on centre 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."***

Meaning: the user should perform cardiopulmonary resuscitation (CPR) for 2 minutes. The AED will NOT monitor the patient's heart rhythm during this period.

The blue LED corresponding to the "perform CPR" message will continue to flash and a beep is reproduced with a frequency of 100 bpm to help the operator perform the CPR with an adequate compression rate.

A frequency of 100 compressions/minute and a compression depth within 5–6 cm for 2 minutes is recommended.[3]

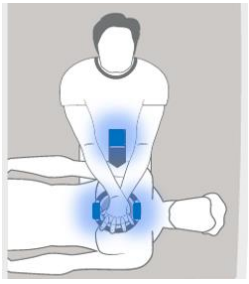
➔ **Once the CPR is over, the AED repeats the steps starting from point 4.1.**

NOTE: the voice prompts explaining how to perform the CPR (i.e. *"Place heel of one hand on centre 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."*) are reproduced only when the AED guides the operator to perform the cardiac massage for the first time. If the entire defibrillation procedure is repeated and the AED prompts the operator to perform the CPR again, it reproduces only the *"Start CPR"* voice prompt followed by the metronome sound (beep).

CASE B – NON-SHOCKABLE RHYTHM

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

Meaning: the AED has determined that no shock is necessary. The device will not charge and the SHOCK button will not be enabled.



4.B.2 ***"Start CPR. Place heel of one hand on centre 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."***

Meaning: the user should perform cardiopulmonary resuscitation (CPR) for 2 minutes. The AED will NOT be monitoring the patient's heart rhythm during this period.

The blue LED corresponding to the "perform CPR" message will continue to flash and a beep is reproduced with a frequency of 100 bpm to help the operator perform the CPR with an adequate compression rate.

A frequency of 100 compressions/minute and a compression depth within 5–6 cm for 2 minutes is recommended.[4]

➔ **Once the CPR is over, the AED repeats the steps starting from point 4.1.**

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

NOTE: the voice prompts explaining how to perform the CPR (i.e. *"Place heel of one hand on centre 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."*) are reproduced only when the AED guides the operator to perform the cardiac massage for the first time. If the entire defibrillation procedure is repeated and the AED prompts the operator to perform the CPR again, it reproduces only the *"Start CPR"* voice prompt followed by the metronome sound (beep).

Regardless of the training, all responders should perform efficient chest compressions because the more effective the CPR is, the better it is for the patient.

Rescue SAM 4.0 indicates when the user should start with the compressions and the rhythm they should adopt through an audible signal (beep). However, it does not provide feedback on how the user is performing CPR.

For this reason, the Manufacturer recommends using *Chest-eR®* to ensure a high-quality CPR performance. *Chest-eR®* is a medical device intended to be used during the CPR procedure to:

- improve the cardiac massage **quality** by providing feedback to the user;
- improve the cardiac massage **safety** for both the user and the patient.

For more information, please contact the Manufacturer at info@progettimedical.com.

5

After using Rescue SAM 4.0, press the ON/OFF button for **4 seconds** to turn off the device. The ***"Powering down"*** voice prompt is reproduced and the device turns off.

6

Detach the disposable multifunction electrodes from the patient's chest.

7

Disconnect the disposable multifunction electrodes **connector** by firmly pulling it out from the port on the top right corner of the AED.

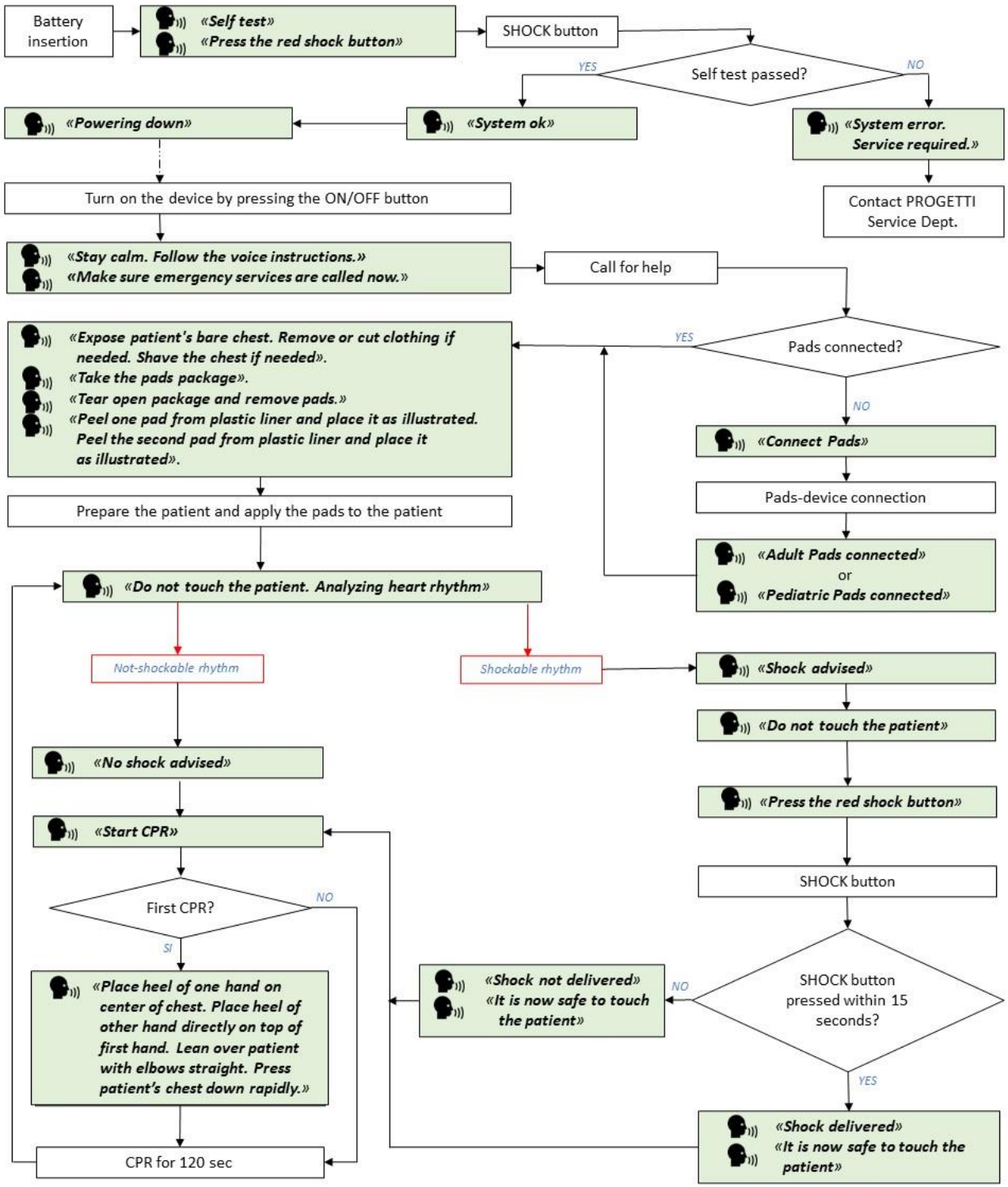
Dispose of the used multifunction electrodes according to the local policy and applicable laws. Please to not dispose of them in general waste to avoid contamination and biological hazards.

8

Inform the relevant people that Rescue SAM 4.0 and its accessories were used, so that an operator can put the device back into service by cleaning it and connecting a new pair of disposable multifunction electrodes to it. If necessary, they will also replace the battery with a new one.

5.1 SUMMARY OF DEVICE OPERATION

The following flowchart summarizes how Rescue SAM 4.0 works. Each green box contains a voice prompt reproduced by the device during the rescue.



A description of the voice prompts is given in the table below.

NOTE: voice prompts are available in one language (standard). The second/third language is available upon the Customer's request (optional). The user can switch from one language to the other by pressing the language selection button located on the device's front panel.

"***Self Test.***"	The device is performing the self-test to verify its proper functioning.
"***Press the red shock button.***"	The operator should press the SHOCK button to deliver the defibrillation energy to the patient. The SHOCK button is illuminated red during this step.
"***System error. Service required.***"	The self-test failed. It is then necessary to contact the manufacturer's technical assistance department for technical support.
"***System ok.***"	The device has passed the self-test. It is fully operative and ready for use.
"***Powering down.***"	The device is shutting down.
"Stay *calm. Follow the voice instructions."* ***"Make sure emergency services are called now."***	The device prompts the user to keep calm and listen to the voice prompts reproduced. It is recommended to call for help because the first step in a rescue should always be contacting professional emergency services. If someone else is available, the user should send them to call for help and continue the rescue without delay.
"*Connect Pads.*"	The disposable multifunction electrodes are not connected to the device. Please connect them.
"*Adult Pads connected*" Or **"*Paediatric Pads connected*"**	The device indicates that the disposable multifunction electrodes have been correctly connected to the device. If the user connected the disposable multifunction electrodes for BOTH adult AND paediatric patients, the ADULT patient is selected as default.
"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 prompts the user to prepare the patient before applying the disposable multifunction electrodes. Ensure to apply the electrodes as illustrated on the electrodes themselves and their sealed package. Verify the correct position of the electrodes, their adequate adherence to the patient's skin, and the absence of air bubbles between the electrodes and the patient's skin. Ensure that the electrodes do not touch each other. If the electrodes do not adhere due to sweat or moisture, wipe them away with a cloth. If the electrodes do not adhere due to excessive hair, shave it or cut it off. If this voice prompt continues, try replacing the electrodes with a new set.

 ***"Do not touch the patient"***	The operator shall NOT touch the patient.
 ***"Analysing heart rhythm."***	The AED has started the analysis of the ECG signal (electrocardiogram) to determine whether a shockable or non-shockable rhythm is present. During the analysis, the device will continue to monitor the electrodes' proper connection to the main unit and the patient and it will stop the analysis if problems arise. Do NOT touch the patient during this step.
 ***"No shock advised."***	The device has determined that a defibrillation shock is not required. The unit will NOT charge the defibrillation energy and the SHOCK button will NOT be enabled. The user will then be advised to begin cardiopulmonary resuscitation (CPR) for 2 minutes.
 ***"Shock advised."***	The device has determined that a shock is recommended. The unit will start charging the energy preparing for the defibrillation shock. The SHOCK button will be enabled. The operator and other people should stand clear of the patient. Analysis will continue during this phase and the blue LED corresponding to the "stand clear" message will continue to flash. An ascending sound is reproduced continuously while the device is charging the energy.
 ***"No shock delivered."***	The device aborted the shock and discharged internally. The internal discharge may occur if a change in the patient's heart rhythm occurs, i.e. from shockable to non-shockable, or if the user does NOT press the SHOCK button within 15 seconds after the initial "*Press the red shock button*" voice prompt.
 ***"Shock delivered."***	The device has delivered the defibrillation energy correctly to the patient.
 ***"It is now safe to touch the patient."***	The device indicates that the user can now touch the patient safely.
 ***"Start CPR."*** ***"Place heel of one hand on centre 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 user should perform cardiopulmonary resuscitation (CPR) for 2 minutes (120 seconds). An acoustic signal (beep) indicates the correct rhythm that the user shall keep during the CPR to make it effective. The recommended frequency is 100 compressions per minute.
 ***"Battery low."***	The battery capacity is low and should be replaced soon. The battery charge left equals 15% when the voice prompt is reproduced for the first time.

6. MEMORY AND DATA TRANSFER

Rescue SAM 4.0 is equipped with an 8-Gb internal memory where it records:

- the patient's electrocardiogram (ECG signal),
- information related to the rescue (date and time, number of shocks delivered, etc.),
- environmental noise that occurred close to the AED during the rescue.

Each record starts when the device is turned on and lasts until it is turned off. The device can record and store several events for a total length of approximately 150 hours, including environmental noise.

Once the internal memory is full, the device will not record the events anymore. It will not replace or rewrite automatically the oldest recorded event. Therefore, please ensure to transfer and save the data on a computer to avoid filling the internal memory of the device and missing event recordings.

NOTE: environmental audio recording complies with the applicable privacy regulations and it is enabled by default. It can be disabled upon the customer's request.

6.1 EVENTS VIEW

PROGETTI S.r.l. offers the possibility to see the events recorded by the AED on a computer through a data download and management software: *PG Data Manager.* This software is available on the PROGETTI's website, www.progettimedical.com.

PG Data Manager is a Windows-based software that can read the data recorded and stored in Rescue SAM 4.0, allowing the user to access and manage them and providing useful insights into the device's performance during an emergency. It also allows the user to:

- recreate the cardiac event, starting when the AED was turned on and connected to the patient until it was turned off;
- review the recorded events in every moment;
- reconstruct clearly and in detail each recorded event and each time that the device was used, allowing the analysis of its performance.

In case of errors or faults, *PG Data Manager* allows authorized technicians to access the recording(s) to identify anomalies and the potential cause of the suspected inadequate operation.

PG Data Manager is a stand-alone software application that cannot be used when the AED is working. It was developed only to support the post-event data analysis. Thus, the device cannot be used for rescue or emergency operations when it is connected to the computer for data download.

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

(1) Pentium dual-core processor;
(2) 1 Gb RAM;
(3) 100 Mb of free hard disk space.

Upon the customer's request, PROGETTI S.r.l. can provide the data download cable (optional) to connect the AED to a computer. The cable is equipped with a USB-A port for computer connection and a micro-B USB port for AED connection.

NOTE: software updates can be performed by the manufacturer and its authorized technicians. The user may perform minor software upgrades ONLY after receiving authorization from the manufacturer.

NOTE: please be informed that during the process of downloading the data stored in the device, this data will be transferred and sent to a secure server, where it will be stored for 7 years. This data will not be disclosed to third parties and does not contain any personal data. It will not be used in any way whatsoever, unless explicitly requested by the competent authorities, except for use in anonymous form for purely clinical and/or statistical study purposes, in full compliance with current privacy and data protection regulations.

6.2 DATA DOWNLOAD PROCEDURE

To download the recorded data to a computer, please follow these simple steps:

1. install the *PG Data Manager* on a computer;
2. disconnect the disposable multifunction electrodes from the AED if they are still connected to it;
3. plug the micro-B USB connector of the data download cable into the corresponding port located on the right side of the AED;
4. plug the USB-A connector of the data download cable into a USB port of the computer;
5. ensure that all the LED instructions are turned on to confirm that the device is connected to the computer properly;
6. transfer the data recorded on the AED by downloading and saving them on the computer;
7. launch the *PG Data Manager* software on the computer to access, read and manage these data.

NOTE: do not use the data download cable inappropriately to avoid damages to the AED and/or the computer.

7. STORAGE AND MAINTENANCE

7.1 STORAGE

Rescue SAM 4.0 should be stored in an easy-to-access place. It should be positioned so that the status indicator (LED), located on the mid-left side of the front panel, can be easily viewed.

In general, Rescue SAM 4.0 should be stored in a clean, dry environment at moderate temperature. It should be kept away from sunlight and handled with care.

Ensure that the environmental conditions of the storage location comply with those specified in par. 8.2 "*Technical Specifications – environmental conditions*".

7.2 CLEANING

The manufacturer recommends cleaning the Rescue SAM 4.0 AED periodically and after each use. The user should remove any dirt, contaminants or other debris from the case and the electrodes' connector port.

Please follow these instructions to clean the device properly and effectively:

- The Rescue SAM 4.0 battery pack should be installed while cleaning the device.
- Do NOT immerse Rescue SAM 4.0 or any of its parts and accessories in any liquid. Do NOT allow liquids to get into the unit. Use a soft cloth to clean the case to avoid abrasion and damage.
- 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 4.0 case and its electrodes' connector port. They can also be used for cleaning the Rescue SM 4.0 bag.
    - Soap and water;
    - Ammonia-based products;
    - Isopropyl alcohol (70% solution);
    - Bleach (30 ml/litre of water).
- Ensure that the electrodes' port compartment is completely dry before reconnecting the disposable multifunction electrodes to the AED.

WARNING: Do NOT reuse the AED and/or its accessories if they are damaged, lose integrity, or show signs of wear. Use of damaged or deteriorated devices and/or accessories may cause malfunction of the device itself and/or result in injury to the patient or operator.

CAUTION: The AED and its accessories are NOT sterile. They are NOT intended to be sterilized before use. Do NOT sterilize the AED and its accessories.

7.3 MAINTENANCE

PROGETTI S.r.l. recommends an electrical safety and functional check at least ONCE a year as part of preventive maintenance.

WARNING: Rescue SAM 4.0 does NOT contain any user-repairable parts. Only technicians authorized by the manufacturer can perform preventive and corrective maintenance on Rescue SAM 4.0.

Please, contact the manufacturer's technical assistance department for assistance and technical support at service@progettimedical.com.

Although Rescue SAM 4.0 is designed to require little maintenance, some simple routine maintenance activities shall be performed regularly by a designated person to ensure the expected safety and performance of the device during an emergency.

The table below lists a sequence of actions that the manufacturer recommends together with their frequency as part of the maintenance routine of Rescue SAM 4.0 to ensure its reliability.

EVERY DAY	EVERY MONTH	AFTER EACH USE	ACTION
✓	✓	✓	Check that the status indicator (LED) is flashing and green.
	✓	✓	Check the condition of the device, its battery and its accessories.
		✓	• Replace the disposable multifunction electrodes. • Check the battery charge left by verifying that the status indicator (LED) is green and flashing.
	✓		• Check the expiry date of the disposable multifunction electrodes. • Check the battery expiry date.
		✓	Run a self-test (refer to the following paragraph for more information).

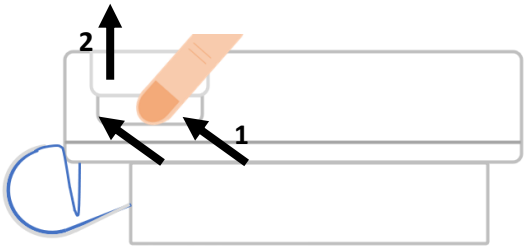
7.3.1 MANUAL SELF-TEST

The manual self-test is intended to assess the proper functionality of the AED. It requires the operator's action and it starts every time the battery is inserted in its compartment.

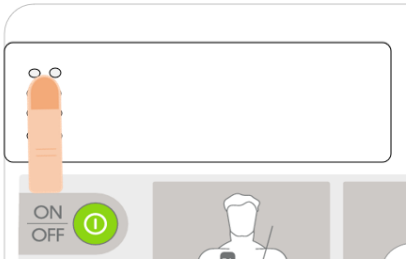
For a greater safeguard, the manufacturer recommends performing a manual self-test at least once every 3 months.

To perform the self-test, please proceed as follows:

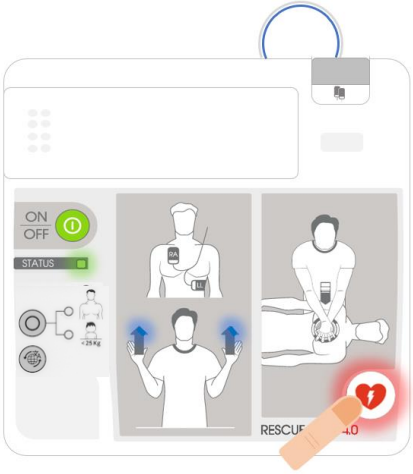
1. Remove the battery from its housing located on the top left corner of the medical device by pressing the BATTERY UNLOCK BUTTON under the battery itself (1) and lifting the left side of the battery (2).



2. Wait at least 5 seconds;
3. Reinsert the battery by placing its right side in the battery housing and pressing it until it is locked in place.



4. Once the battery is inserted correctly, the AED turns on: the status indicator will light up in solid green and the "do not touch the patient" LED instructions will be blue and flashing.
5. Please follow the voice prompts to proceed with the self-test:
    a. **"Self-test. Press the red shock button.":** press the red SHOCK button located on the bottom right corner of the AED to continue the test.



b. The device makes a rising sound. Wait for the test to be completed.

c. If the AED passes the self-test, it reproduces the "**System ok. Powering down.”** voice prompts and enters the standby mode: **the status indicator will be flashing and GREEN.**

   Rescue SAM 4.0 has passed the self-test and is now ready for use.

d. If the AED does NOT pass the self-test, it reproduces the "**System Error. Service required**" voice prompt and all the LED instructions will be blue and flashing. Then, the device reproduces the **“Powering down”** voice prompt and enters the standby mode. **The status indicator will be flashing and RED.**

   Rescue SAM 4.0 has NOT passed the self-test and it is NOT ready for use (non-operational). Please contact the manufacturer's technical assistance department for support.

NOTE: manual self-tests use a certain amount of energy from the batteries. Thus, running a manual test reduces the energy capacity of the batteries and the charge left.

7.3.2 AUTOMATIC SELF-TESTS

The unit performs a monthly automatic self-test (no operator's action required) to verify the integrity of the unit's components, both hardware and software, and their proper functionality.

The device also performs an automatic self-test every time the user presses the ON/OFF button and turns it on. In this case, the device tests its system and basic operations.

7.3.3 CHECKLIST

The following checklist may be used as a starting point for an Operator's Checklist aimed at documenting the periodic checks carried out on the device and recording the results of each test. The table should NOT be intended as an exhaustive list: new checks can be added according to the user's needs.

The table should be copied and filled out as recommended by the schedule in the par. 7.3 *"Maintenance"*. As each item is completed, it should be checked off.

AED CHECKLIST **REF: RESCUE SAM 4.0**				
Serial number (SN)				
Place				
Date	**DD-MM-YYYY**			
STATUS INDICATOR (LED) FLASHING AND GREEN	✔			
MAIN UNIT AND ACCESSORIES ARE CLEAN AND INTACT (NOT DAMAGED)	✔			
SPARE MULTIFUNCTION ELECTRODES AVAILABLE	✔			
MULTIFUNCTION ELECTRODES CONNECTED TO AED AND STILL VALID (NOT EXPIRED)	✔			
DISPOSABLE MULTIFUNCTION ELECTRODES CABLE NOT DAMAGED AND STILL INTACT	✔			
BATTERY STILL VALID (NOT EXPIRED)	✔			
Additional check [Please specify]	✔			
NOTES				
VERIFIER'S SIGNATURE				
Inspected by: [Signature]				

7.3.4 TROUBLESHOOTING

The following table lists some common problems that may arise during the use of Rescue SAM 4.0. The table also describes the possible cause(s) and action(s) required to solve the problem and restore the device functionality.

NOTE Rescue SAM 4.0 does not contain any user-repairable parts. If the unit needs to be repaired, please refer to the manufacturer or an authorized technical support centre.

To send the device for repair, please contact the manufacturer's technical assistance department by sending an e-mail to service@progettimedical.com.

Refer to chapter 9 "*Manufacturer's Contacts*" for further contact information.

PROBLEM	POSSIBLE CAUSE	ACTION NEEDED
The device does NOT turn on	The battery is not inserted.	Insert the battery according to the instructions included in this User Manual.
	The battery is not functioning.	Replace the battery according to the instructions included in this User Manual.
	The main unit is not working.	Please contact the manufacturer's technical assistance department.
The device switches off suddenly	The battery is depleted.	Replace the battery according to the instructions included in this User Manual.
	The main unit is not working.	Please contact the manufacturer's technical assistance department.
AED turned ON and status indicator LED RED and flashing	Battery at a critical level (almost depleted, ≤ 5% of charge left).	Replace the battery according to the instructions included in this User Manual.
AED turned ON and status indicator LED solid RED	The unit detected a fault.	Please contact the manufacturer's technical assistance department.
The status indicator LED is RED (blinking or solid)	The unit detected a fault.	Please contact the manufacturer's technical assistance department.
	Battery at a critical level (almost depleted, ≤ 5% of charge left).	Replace the battery according to the instructions included in this User Manual.
The status indicator LED is turned off	The battery is not inserted.	Insert the battery according to the instructions included in this User Manual.
	The battery is completely depleted.	Replace the battery according to the instructions included in this User Manual.
	The main unit is not working.	Please contact the manufacturer's technical assistance department.
Self-test failed	The unit detected a fault.	Please contact the manufacturer's technical assistance department.

7.4 DISPOSAL AND RECYCLING

At the end of the AED expected service life (7 years), dispose of the device according to the local applicable laws.

Rescue SAM 4.0 and its accessories are classified as electrical or electronic equipment, according to European Directive 2012/19/EU. Thus, the manufacturer recommends NOT disposing of Rescue SAM 4.0 and its electrical/electronic accessories in municipal waste. They shall be recycled appropriately as waste from electric and electronic equipment (WEEE).

The battery must be disposed of at a dedicated collection point; if the battery is not completely discharged, there is a danger of electrical short-circuiting. In this case, insulate the electrical contacts with insulating tape before disposal.

Items should be clean and contaminant-free before being disposed of. When disposing of used disposable electrodes, follow local clinical procedures to avoid cross-contamination.

8. TECHNICAL SPECIFICATIONS

8.1 GENERAL CHARACTERISTICS

DIMENSIONS	250 x 260 x 80 mm
WEIGHT	Approx. 2.2 kg, with the battery and the electrodes connected
INGRESS PROTECTION	IP55
NUMBER OF LANGUAGES	Standard: 1 language Optional: 1 or 2 additional languages
SOFTWARE	It is contained in the internal flash memory of the CPU and it is essential for the device control and proper functioning. The software cannot be selected because it is unique and it is uploaded into the device during its production. The user cannot access or modify the software. Class C as per EN 62304:2006+A1:2015
INTERNAL MEMORY CAPACITY	8 Gb
EVENT RECORDING	Approx. 150 hours, including environmental noise recording
DATA DOWNLOAD SOFTWARE	*PG DATA MANAGER*

8.2 ENVIRONMENTAL CONDITIONS

OPERATIVE CONDITIONS	TEMPERATURE	0 – 50°C
	HUMIDITY	20% – 80% (*non-condensing*)
	ATMOSPHERIC PRESSURE	80 – 101 kPa
STAND-BY MODE (without disposable multifunction electrodes)	TEMPERATURE	-20 – 50°C
	HUMIDITY	5% – 95% (*non-condensing*)
	ATMOSPHERIC PRESSURE	80 – 101 kPa
STAND-BY MODE (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 DISPOSABLE MULTIFUNCTION ELECTRODES

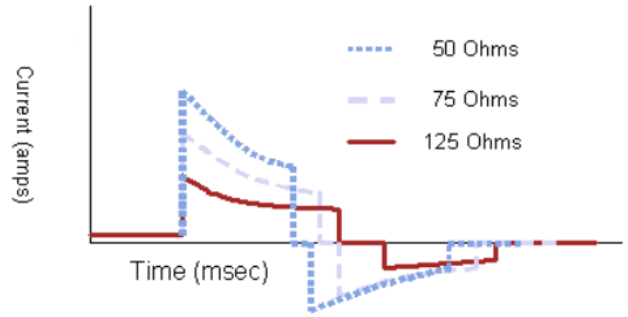
	DISPOSABLE MULTIFUNCTION ELECTRODES FOR BOTH ADULT AND PAEDIATRIC PATIENTS	DISPOSABLE MULTIFUNCTION ELECTRODES FOR ADULTS	DISPOSABLE MULTIFUNCTION ELECTRODES FOR PAEDIATRIC PATIENTS
PRODUCT CODE	**REF: RS4-DFB01PRC** 	**REF: RS4-DFBAD01PRC** 	**REF: RS4-DFBPED01PRC** 
PATIENT CLASS	For adult patients (≥ 8 years old and ≥ 25 kg) AND paediatric patients (< 8 years old and < 25 kg). Patient's type selection button on the front panel of the device.	For adult patients (≥ 8 years old and ≥ 25 kg).	For paediatric patients (< 8 years old and < 25 kg).
REUSABLE/SINGLE USE	Single-use, disposable		
ADHESION TYPE	Self-adhesive		
ACTIVE GEL SURFACE	94 cm^2 each (nominal)	94 cm^2 each (nominal)	40 cm^2 each (nominal)
MATERIAL	Low impedance conductive adhesive gel; metal sheet; medical foam. Latex-free and phthalates-free.		
CABLE/CONNECTOR	Integrated; both exposed (out of the sealed package to allow connection of the electrodes to the AED – pre-connected status).		
CABLE LENGTH	120 cm		
TYPE OF APPLIED PART	BF		
STORAGE TEMPERATURE RANGE	5°C – 35°C		
OPERATING TEMPERATURE RANGE	0°C – 50°C		
STORAGE HUMIDITY RANGE	20% – 80% (non-condensing)		
EXPIRY DATE	See the label (if the package is not opened or damaged)		
PACKAGE	1 pair of electrodes per sealed pouch		

8.4 BATTERY

MODEL (REF)	DFBSAM4.0RS4B
TYPE	12V_{DC}, 4.2Ah, $LiMnO_2$, non-rechargeable
DEFIBRILLATION CAPACITY	250 shocks at 200 J at 25°C
ESTIMATED DURATION DURING CONTINUOUS USE	10 hours of continuous functioning, i.e. shockable rhythm recognition and defibrillation with a 50-ohm load at 25°C
EXPIRY DATE	5 years
ESTIMATED DURATION IN STANDBY MODE	5 years after the insertion into the main unit
BATTERY LEVEL	The battery charge left changes according to the colours of the status indicator: • GREEN: battery sufficiently charged; • YELLOW: battery low (15%); • RED: battery critically low (5%). Refer to par. 2.2.2 for further details.

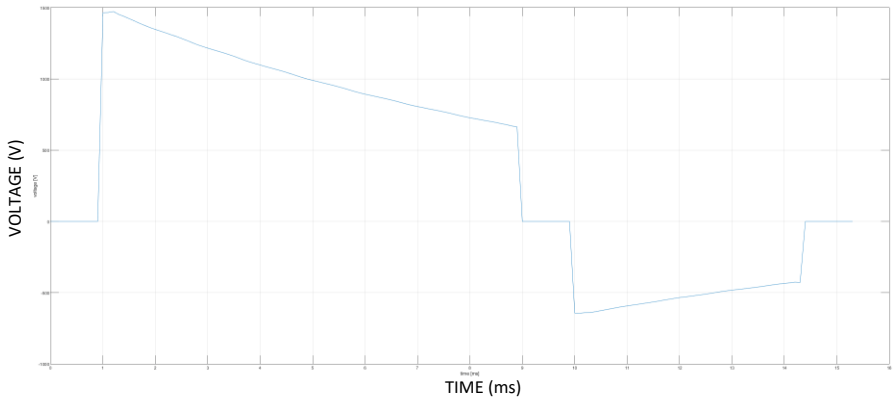
8.5 DEFIBRILLATION

OPERATING PROCEDURE	Semi-automated external defibrillation for adult and paediatric use
DEFIBRILLATION ENERGY	Standard configuration: ADULT PATIENT: 200 J (nominal); PAEDIATRIC PATIENT: 50 J (nominal). Optional configuration: incremental protocol (the AED releases a sequence of shocks with increasing defibrillation energy). The defibrillation energy values and the number of shocks may vary according to the customer's request. Default protocols: ADULT PATIENT: 2 shocks – 175 J, 200 J (nominal) OR 3 shocks – 150 J, 175 J, 200 J (nominal) PAEDIATRIC PATIENT: 2 shocks - 50 J, 75 J (nominal) OR 3 shocks – 50 J, 70 J, 90 J (nominal)
IMPEDANCE RANGE	25–200 Ω
ENERGY CHARGING TIME	≤ 4 s for 200 J with a brand-new fully charged battery. ≤ 3 s for 50 J with a brand-new fully charged battery. The charging time may increase with used batteries.

	The device partially charges the capacitor during the patient's heart rhythm analysis (ECG signal analysis) before determining whether a shock is required (pre-charge).
INDICATION OF CHARGE COMPLETED	• SHOCK button enabled and lit up RED. • "*Press the red shock button*" voice prompt reproduction. • High-pitch tones reproduced in rapid succession.
SHOCK RELEASE	The SHOCK button shall be pressed. The AED does NOT release the defibrillation energy autonomously. The user's action is required to release the energy to the patient.
INDICATION OF SHOCK DELIVERED	• The SHOCK button is disabled and not lit up anymore. • "*Shock delivered*" voice prompt reproduction.
DEFIBRILLATION PULSE WAVEFORM	Biphasic truncated exponential (BTE) waveform compensated by measuring patient impedance and variable shock duration. As soon as the patient's impedance (Rp) changes, the shock duration also changes, guaranteeing that the same amount of energy is always released (area under the curve). 
ACCURACY OF DEFIBRILLATION ENERGY RELEASED	± 10%
AUTOMATIC DISARM PROCEDURE	Once the AED has charged the defibrillation energy, the disarm will occur AUTOMATICALLY: • if the rhythm is no longer shockable OR • if the user has NOT pressed the SHOCK button within 15 seconds after the energy charge has been completed.
MANUAL DISARM PROCEDURE	Once the AED has charged the defibrillation energy, BUT the user deems that the defibrillation is NOT necessary anymore, they can press the ON/OFF button for 4 seconds to turn off the AED. The AED will discharge any residual energy internally.
BLS-D PROTOCOL	Audible signals (beep, high-pitch tones), voice prompts and LED indicators guide the user through the protocol.

8.5.1 WAVEFORM CHARACTERISTICS

The diagram shows a biphasic truncated exponential waveform released by the AED as an example. The waveform is adjusted to compensate for the patient's measured impedance. Its length and amplitude vary according to the defibrillation energy value and the measured impedance.



The following table shows how the shock duration varies according to the patient's impedance measured. Generally, the higher the impedance, the more time is needed to provide the expected amount of defibrillation energy to the patient.

Patient impedance [Ω]	Positive phase duration [ms]	Negative phase duration [ms]	Voltage [V]
25	8	4	1438
50	8	4	1498
75	8	4	1595
100	8	4	1702
125	9	5	1747
150	11	5	1747
175	13	6	1748
200	14	7	1748

8.6 ECG ACQUISITION

BAND	0.25 - 60 Hz
CMRR	120 dB
INPUT IMPEDANCE	500 kΩ
SAMPLING FREQUENCY	1200 sample/s
FILTERING	Filters aimed at improving the signal removing power interference and baseline oscillation.
HEART RATE RANGE	30 – 300 bpm

8.7 ECG ANALYSIS

The ECG analysis system constitutes an integral part of the software that controls the AED and its proper functioning. It is intended to analyse the patient's heart rhythm (ECG signal) to determine whether a shock is required to resuscitate the patient (shockable or non-shockable rhythm).

The ECG signal is processed by the ECG signal analysis system that acquires the ECG signal through the disposable multifunction electrodes, filters it and determines whether an arrhythmia is present and a shock should be recommended.

The software that performs this analysis is class C software as per EN 62304 since any incorrect operation could pose serious risks to the patient and/or the operator.

The characteristics of the patient's ECG analysis system are shown in the following table.

TYPE OF RHYTHM	DECLARED PERFORMANCE	REQUIREMENT (EN 60601-2-4)
NON-SHOCKABLE RHYTHM		
Sinus rhythm (normal)	SPECIFICITY: **100%**	SPECIFICITY: **> 95%**
Supraventricular arrhythmia	SPECIFICITY: **99.96%**	SPECIFICITY: **> 95%**
Asystole	SPECIFICITY: **100%**	SPECIFICITY: **> 95%**
All other non-shockable rhythms	SPECIFICITY: **100%**	SPECIFICITY: **> 95%**
COMBINED RHYTHM		
Combination of non-shockable rhythms & shockable rhythms	• SENSITIVITY: **97.35%** • SPECIFICITY: **99.997%**	• SENSITIVITY: **> 90%** for recognising VF • SENSITIVITY: **> 75%** for recognising VT • SPECIFICITY: **> 95%**

8.8 CE MARKING AND APPLIED STANDARDS

The device bears the CE marking and it belongs to the risk class IIb according to the Medical Device Directive (MDD) 93/42/EEC.

EN 60601-1:2006+A1:2012+A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-2-4:2011+A1:2019	Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices
EN 60601-1-6:2010+A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN ISO 62304:2006+A1:2015	Medical device software - Software life-cycle processes
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer

8.9 ELECTROMAGNETIC EMISSIONS

RESCUE SAM 4.0 is designed to be used 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 4.0 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 4.0 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]		

8.10 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
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 4.0, 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 4.0 is used exceeds the above RF compliance level, Rescue SAM 4.0 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 4.0.

8.11 SEPARATION DISTANCES

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

Recommended distances between RF communications equipment and Rescue SAM 4.0				
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

Note 1: For transmitters whose maximum output power is 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 technical specifications of the transmitter declared by its 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 4.0 and it is responsible for placing it on the market.

The following table lists the manufacturer's contacts the user can refer to for any communication and information/clarification request.

ADDRESS	Strada del Rondello, 5 - 10028 TROFARELLO (TO), ITALY
WEBSITE	**www.progettimedical.com**
PHONE	+39 011 644738
GENERAL INFORMATION	info@progettimedical.com
SALES DEPT.	sales@progettimedical.com
TECHNICAL ASSISTANCE DEPT.	service@progettimedical.com
QUALITY & REGULATORY AFFAIRS DEPT.	quality@progettimedical.com

10. WARRANTY INFORMATION

10.1 COVERAGE

PROGETTI S.r.l. provides a limited warranty that the defibrillator and its accessories, whether purchased together with the defibrillator (as part of a configuration) or separately, shall be substantially free from defects in material and workmanship. PROGETTI S.r.l. limited warranty refers only to the original consumer who purchased the items from the manufacturer or one of its authorized distributors.

This limited warranty shall not be entrusted or transferred. The terms of the limited warranty in effect as of the date of original purchase shall apply to any warranty claims.

10.2 DURATION

The limited warranty covers the defibrillator for at least two (2) years from the purchase date, except in special cases agreed with the customer. The limited warranty also covers the AED's battery, spare parts, and accessories, including consumables. In this case, the warranty is six (6) months from the purchase date. Single-use accessories (disposable multifunction electrodes) shall have a limited warranty up to use or for six (6) months from the purchase date, whichever is earlier. In no event shall the limited warranty period extend past the date printed on the item, be it the battery, a spare part or an accessory, including consumables.

10.3 LIMITATIONS

This limited warranty does not cover damage of any kind resulting from but is 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.

10.4 VOID WARRANTY

The limited warranty will be cancelled immediately if:

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

10.5 EXCLUSIVE REMEDY

At its sole discretion, PROGETTI S.r.l. shall have the right to repair or replace the Automated External Defibrillator (AED) Rescue SAM 4.0. In the event of repair, PROGETTI S.r.l. will have the right, at its sole discretion, to repair the part with a new, repaired, 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. In the event of replacement, PROGETTI S.r.l. shall also have the right at its sole discretion to replace the item with a new, identical or similar item. Determination of a similar item shall be at the sole discretion of PROGETTI S.r.l. Under no circumstances shall the limited warranty period of a replacement item extend past the limited warranty period of the item it is replacing.

10.6 WARRANTED TECHNICAL SUPPORT

Only PROGETTI S.r.l., its authorized distributors or its authorized service centres 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 or defects 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., its authorized distributors or its authorized service centres immediately. Prepare a summary of the problems and include the device model's name as well as its serial number, purchasing date, dealer's name, and your (customer's) details.

PROGETTI's technical assistance dept.:

PROGETTI S.r.l.

Strada del Rondello, 5
10028, Trofarello (TO)
ITALY

Phone: +39 011 644738
Email: service@progettimedical.com
Website: www.progettimedical.com

10.7 OBLIGATIONS AND WARRANTY LIMITS

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 Automated External Defibrillator (AED) Rescue SAM 4.0 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.

10.8 WARRANTY CERTIFICATE

PROGETTI S.r.l.	
RESCUE SAM 4.0 - 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, according to the instructions included in this user manual, has been damaged by accident or misuse or 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 discretion, to replace parts and components free of charge and under warranty in its laboratories.	
CUSTOMER	…… ……
RESCUE SAM 4.0	SN: ……
Validity (warranty starting date)	……. / …….. / ……..
Date of delivery	……. / …….. / ……..
Invoice No.	……
Invoice date	……. / …….. / ……..

11. EU DECLARATION OF CONFORMITY

progetti® Medical Equipment Solutions

Doc. N. FT-RescueSAM4.0-0.3/8.1_4.0-0.5
Rev. 0.5

Pag.1/1

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 4.0***
INTENDED USE *DESTINAZIONE D'USO*	Automated external cardiac defibrillation *Defibrillazione cardiaca esterna 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, EN ISO 20417:2021, 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 *MARCATURA CE*	CE 0068
N° EC CERTIFICATE (ref. Dir.93/42/eec *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*	**31/12/2027** (according to Reg. (EU) 2023/607) (ai sensi del Reg. (UE) 2023/607)
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 and subsequent amendments**.
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 e successive modifiche**.*
*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), **31/05/2024**
SIGNATURE *FIRMA*	Dr. CESARE MANGONE PRESIDENT & PRRC

PROGETTI S.r.l.
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