RESCUE STEPS

1. **PUSH ON/OFF BUTTON**
2. **FOLLOW VOICE PROMPTS**
3. **IF INSTRUCTED PRESS "SHOCK" BUTTON**

1  **PUSH ON/OFF BUTTON**

2 

FOLLOW VOICE PROMPTS

3  **IF INSTRUCTED PRESS "SHOCK" BUTTON**

Thank you for choosing the RESCUE SAM AED.

The RESCUE SAM defibrillator is a complete acute cardiac care response system designed for basic life support (BLS) patient management protocols.

These operating instructions include information and procedures related to all features of the RESCUE SAM defibrillator. Your RESCUE SAM defibrillator may not have all of these features.

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

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

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

In this regard:

- Only persons authorized by PROGETTI S.r.l. should do the servicing of the device. You should operate this device in accordance with the instructions specified in this manual.

To ensure safety and reliability, use only parts and accessories recommended by PROGETTI S.r.l.

Important Notice

Considering the defibrillator as an emergency healthcare device, Progetti Srl recommends to submit RESCUE SAM AED to a **preventive maintenance program** (functional check and electrical safety check) annually.

For further information, please contact the technical service of Progetti Srl by mail at service@progettimedical.com or by phone +39 011 644738.

Progetti Srl shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this material.

Information in this document is subject to change without notice.

Limited Warranty

The "Limited Warranty" shipped with Progetti S.r.l. AED products serves as the sole and exclusive warranty provided by Progetti S.r.l., with respect to the products contained herein.

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1 Introduction to the *RESCUE SAM AED*

This User Manual provides information to guide trained operators in the use and maintenance of the RESCUE SAM series Semi-Automatic External Defibrillator ("AED") and its accessories. This chapter includes an overview of the AED, a discussion of when it should and should not be used, and information on required operator training.

1.1 Overview

The *RESCUE SAM* is a Semi-Automatic External Defibrillator ("AED") that is designed to be easy to use, portable and battery powered.
Voice prompts and visual indicators provide a simple interface for the operator. The *RESCUE SAM* is capable of recording event information including ECG and SHOCK/NO-SHOCK recommendations.
When connected to a patient who is unconscious and not breathing, the *RESCUE SAM* performs the following tasks:

- Prompts the operator to take necessary actions to enable analysis.
- Automatically analyzes the patient's ECG.
- Determines whether a shockable rhythm is present.
- Charges the defibrillation capacitor and arms the SHOCK button if it detects a shockable rhythm.
- Prompts the operator to press the SHOCK button when the device is ready and a shock is recommended.
- Delivers a shock once the device has determined a shock is required and the SHOCK button has been pressed.
- Repeats the process if additional shocks are required.

The *RESCUE SAM* will *NOT* shock a patient automatically; it will only advise the operator. 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 must press the SHOCK button to initiate defibrillation.

The *RESCUE SAM* uses two self-adhesive defibrillation/monitoring pads to monitor ECG signals and, if necessary, to deliver defibrillation energy to the patient. These pads (also known as electrodes) are provided in a single-use, disposable package.

The *RESCUE SAM* determines proper pad-to-patient contact by monitoring the impedance between the two pads (impedance varies with the electrical resistance of the patient's body). Visual and audio prompts inform the operator of possible problems with patient contact. Voice prompts and visual indicators communicate the status of the AED and of the patient to the operator. The *RESCUE SAM* has two operational push-button controls, one info-button ans several LED indicators.

Defibrillation energy is delivered as an impedance compensated biphasic truncated exponential waveform. The device delivers 200 Joules into a 50-ohm load when using adult pads or when using attenuated child / infant pads, 50J of defibrillation energy into a 50-ohm load. Energy delivered does not change significantly with patient impedance, although the duration of the generated waveform will vary. The RESCUE SAM is designed to deliver up to 200J of defibrillation energy through a patient impedance range of 25 – 175 ohms.

Defibrillation and AED operating power is supplied by a replaceable (non-rechargeable) lithium battery pack that provides for long standby life and low maintenance operation. Each pack is marked with an expiration date.

The *RESCUE SAM* records event documentation on its internal memory.

1.2 The RESCUE SAM AED

A. *Speaker*. The speaker projects the voice prompts when the *RESCUE SAM* is on.

B. *SHOCK button*. This button will flash when a shock is recommended - push this button to deliver the shock to the patient. This button is disabled at all other times.

C. *Instructions LEDs*. This LEDs will flash according to the voice prompts .

D. *ON/OFF button*. Push button to turn the *RESCUE SAM* on. Push again to disarm and turn the AED off.

E. *Information* button and LED. Il permet d'écouter encore le message sur l'état du système.

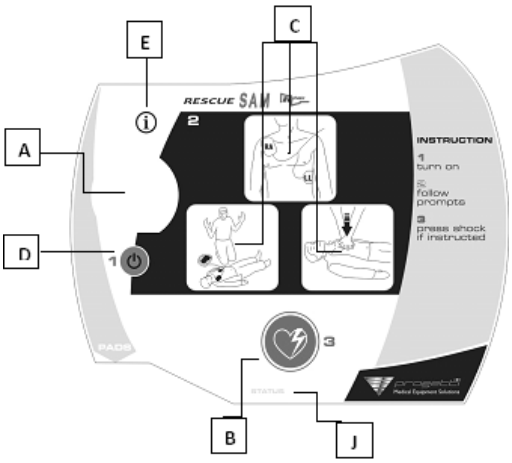
F. *Pads connector port*. Insert Patient Pads Connector into this port to connect pads to *RESCUE SAM*.

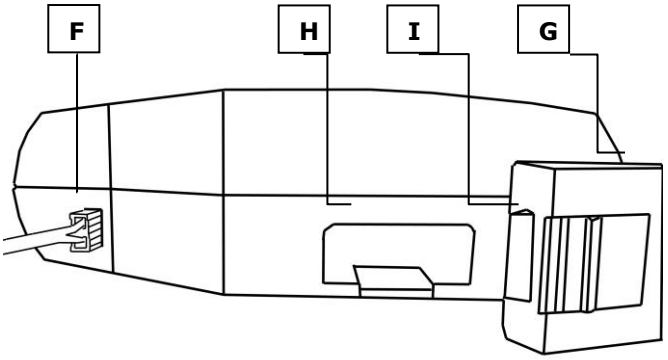
G. *Battery pack*. The battery pack provides a replaceable main power source for the *RESCUE SAM*.

H. *Battery pack opening.* Insert the battery pack firmly into this opening until the latch clicks into place.

I. *Battery pack eject* lever. This lever releases the battery pack from the *RESCUE SAM*. To remove the battery pack, push the lever and extract the battery pack from the unit.

J. *Status Indicator*. When the unit is off, this indicator blinks green to indicate the unit is fully operational and blinks red to indicate unit needs attention from the user or servicing.





1.3 Indications

The *RESCUE SAM* is indicated for use on victims of sudden cardiac arrest ("SCA") when the patient is:

- Unconscious and unresponsive.
- Not breathing.

For patients under 8 years old, use child/ infant electrode pads. Do not delay therapy to determine exact age or weight.

1.4 Contraindications

The *RESCUE SAM* should not be used if the patient shows any of the following signs:

- Conscious and/or responsive.
- Breathing.
- Has a detectable pulse.

1.5 Operator Training Requirements

In order to safely and effectively operate the *RESCUE SAM*, a person shall have met the following requirements:

- RESCUE SAM and/or defibrillation training as required by local, state, provincial, or national regulations.
- Any additional training as required by the authorizing physician.
- Thorough knowledge and understanding of the material presented in this User Manual.

2 Dangers, Warnings and Cautions

This chapter includes a list of danger, warning, and caution messages that relate to the Progetti Srl *RESCUE SAM* and its accessories. Many of these messages are repeated elsewhere in this User Manual and on the *RESCUE SAM* or accessories. The entire list is presented here for convenience.

DANGER:	Immediate hazards that will result in serious personal injury or death.
WARNING:	Conditions, hazards, or unsafe practices that may result in serious personal injury or death.
CAUTION:	Conditions, hazards, or unsafe practices that may result in minor personal injury, damage to the *RESCUE SAM*, or loss of data.

2.1 Shock, Fire Hazard, Explosion

2.1.1 Electricity

DANGER	Hazardous electrical output. This equipment is for use only by qualified personnel.

2.1.2 Battery Pack

CAUTION	Follow all battery pack labeling instructions. Do not install battery packs after the expiration date.
WARNING	Lithium battery packs are not rechargeable. Any attempt to recharge a lithium battery pack may result in fire or explosion.
WARNING	Do not immerse battery pack in water or other liquids. Immersion in fluids may result in fire or explosion.
WARNING	Do not attempt to recharge, short-circuit, puncture, or deform battery. Do not expose battery to temperatures above 50°C. Remove battery when depleted.
CAUTION	Recycle or dispose of lithium battery packs in accordance with local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

2.1.3 Usage Environment

DANGER	Possible explosion hazard if used in the presence of flammable anesthetics or concentrated oxygen.
DANGER	The *RESCUE SAM* has not been evaluated or approved for use in hazardous locations as defined in the National Electric Code standard. In compliance with IEC classification the *RESCUE SAM* is not to be used in the presence of flammable substance/air mixtures.
CAUTION	Do not immerse any portion of this product in water or other fluids. Do not allow fluids to enter the device. Avoid spilling any fluids on this device or accessories. Spilling fluids into the *RESCUE SAM* may damage it or present a fire or shock hazard. Do not autoclave or gas sterilize the *RESCUE SAM* or its accessories.
CAUTION	The *RESCUE SAM* should be stored and used only within the range of environmental conditions specified in the technical specifications.

2.1.4 Defibrillation/Shock Delivery

WARNING	Defibrillation current can cause operator or bystander injury. Do not touch the patient during defibrillation. Do not touch equipment connected to the patient or metal objects in contact with the patient during defibrillation. Disconnect other electrical equipment from the patient before defibrillating. Disconnect the *RESCUE SAM* from the patient prior to use of other defibrillators.
WARNING	Improper use can cause injury. Use the *RESCUE SAM* only as instructed in the User Manual. The *RESCUE SAM* delivers electrical energy that can potentially cause death or injury if it is used or discharged improperly. Do not discharge with defibrillation pads touching or gel surface exposed.
WARNING	Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock hazard and potential damage to that equipment.
CAUTION	Avoid contact between parts of the patient's body and conductive fluids such as water, gel, blood or saline, and metal objects, which may provide unwanted pathways for defibrillating current.

2.1.5 Maintenance

WARNING	Electrical shock hazard. Dangerous high voltages and currents are present. Do not open unit, remove covers, or attempt repair. There are no user serviceable components in the *RESCUE SAM*. Refer servicing to qualified service personnel.

2.2 Improper Device Performance

2.2.1 Usage Environment

WARNING	Radio frequency (RF) interference from RF devices such as cellular phones and two-way radios can cause improper AED operation. In accordance with IEC 801.3, a distance of 2 meters between RF devices and the *RESCUE SAM* is recommended.
CAUTION	Although the *RESCUE SAM* is designed for a wide variety of field use conditions, rough handling beyond specifications can result in damage to the unit.

2.2.2 Pads

WARNING	Use only Progetti Srl disposable self-adhesive defibrillation/monitoring pads, battery packs, and other accessories supplied by Progetti Srl or its authorized distributors. Substitution of non-Progetti Srl approved accessories may cause the device to perform improperly.
CAUTION	Follow all defibrillation pad label instructions. Use defibrillation pads prior to their expiration date. Do not re-use defibrillation pads. Discard defibrillation pads after use (in the event of suspected pad malfunction, return pads to Progetti Srl for testing).
WARNING	The defibrillation pads are intended for one time use only and must be discarded after use. Reuse can lead to potential cross infection, improper performance of the device, inadequate delivery of therapy and/or injury to the patient or operator.

2.2.3 Patient Analysis

WARNING

Aggressive or prolonged CPR to a patient with defibrillation pads attached can cause damage to the pads. Replace the defibrillation pads if they become damaged during use.

WARNING

CPR rates above the American Heart Association guidelines of 100 BPM (beats per minute) can cause incorrect or delayed diagnosis by the patient analysis system.

WARNING

Do not place adult defibrillation pads in the anterior-posterior (front-back) position. A shock or no shock decision may be inappropriately advised. The *RESCUE SAM* requires that the adult defibrillation pads be placed in the anterior-anterior (front-front) position.

WARNING

Some very low amplitude or low frequency rhythms may not be interpreted as shockable VF rhythms. Also some VT rhythms may not be interpreted as shockable rhythms.

WARNING

Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis, especially if very low amplitude or low frequency rhythms are present. During analysis and from "Shock Advised" until "Shock Delivered," patient movement and vibration must be minimized.

WARNING

In patients with cardiac pacemakers, the RESCUE SAM may have reduced sensitivity and not detect all shockable rhythms. If you know the patient has an implanted pacemaker, do not place electrodes directly over an implanted device.

2.2.4 Shock Delivery

WARNING

Do not allow defibrillation pads to touch each other, or to touch other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart.

WARNING

During defibrillation, air pockets between the skin and defibrillation pads can cause patient skin burns. To help prevent air pockets, make sure self-adhesive defibrillation pads completely adhere to the skin. Do not use dried out or expired defibrillation pads.

2.2.5 Maintenance

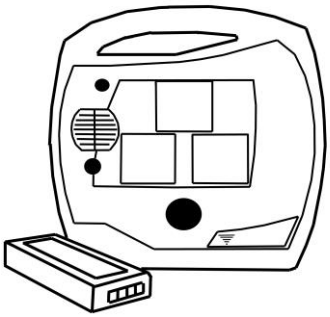
WARNING	Periodic user-initiated and automatic self-tests are designed to assess the *RESCUE SAM*'s readiness for use. However, no degree of testing can assure performance or detect abuse, damage, or a defect that occurred after the most recent test is completed.
WARNING	Use of damaged equipment or accessories may cause the device to perform improperly and/or result in injury to the patient or operator.
CAUTION	Improper maintenance can cause the *RESCUE SAM* not to function. Maintain the *RESCUE SAM* only as described in this User Manual. The AED contains no user serviceable parts – do not take the unit apart.

3 Setting up the RESCUE SAM AED

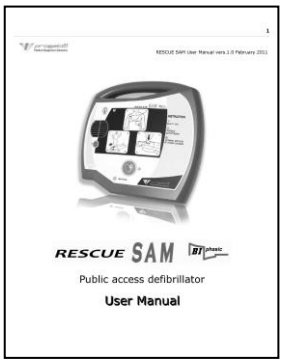
This chapter describes the steps required to make your Progetti Srl *RESCUE SAM* AED operational. The *RESCUE SAM* is designed to be stored in a "ready" state. This chapter tells you how to make the device ready, so that if and when you need it, few steps are required to begin using the device.

3.1 Overview

The following components and accessories are included with your *RESCUE SAM*. Replacement and other accessories are detailed in the "*RESCUE SAM* Accessories" section. Before getting started, identify each component and ensure that your package is complete.



RESCUE SAM and Battery pack



User Manual

Defibrillation pads

3.2 Installing and Removing the Battery Pack

The lithium battery pack provides power to the *RESCUE SAM*.

Do not install the battery pack after the expiration date printed on the label. The battery pack is non-rechargeable.

To insert the battery pack into the *RESCUE SAM*, orient the battery pack so that the label faces up. Make certain that the battery opening in the side of the AED is clean and clear of any foreign objects. Insert the battery pack into the opening in the side of the AED. Slide the pack all the way in until the latch clicks. If the pack does not slide all the way in, it is most likely inserted upside down. Once fully inserted, the battery pack surface should be flush with the side of the AED.

To remove the battery pack, push the battery release lever and pull the battery pack out.

After battery insertion the RESCUE SAM runs an automatic self test that verifies the readiness for rescue operation. With battery inserted, press the flashing red button to switch to the standby status. Upon passing the self test the status green LED will flash. If the self test does not pass the status red LED will flash.

3.3 Connecting the Pads

The *RESCUE SAM* defibrillation/monitoring pads are supplied sealed in a pouch with the connector and part of the cable exposed. This allows the pads to be stored in a pre-connected state for rapid deployment during an emergency.

CAUTION: DO NOT remove the defibrillation pads from the sealed package until the pads are to be used. The packaging should be opened only immediately prior to use, otherwise the pads may dry out and become non-functional.

Note: The *RESCUE SAM* is designed to be stored with the pads connector already installed. This simplifies the procedure for setting up and operating the device in an emergency.

First, check to ensure that the pad package has not expired. Pads past their expiration date should not be used and should be discarded.

Insert the connector end of the defibrillation pad cable into the pads connector port on the bottom-left corner of the *RESCUE SAM*. Insert pads connector firmly until it is fully seated in the unit.

CAUTION: The pads are intended for one time use only and must be discarded after use or if the package has been opened.

3.4 Storing the RESCUE SAM AED

The *RESCUE SAM* (preferably with pads attached) should be stored in environmental conditions within range of the specifications - refer to the "Environmental" section of "Technical Specifications". The unit should also be stored so that the Active Status Indicator can be readily seen.

The Status Indicator should periodically blink with a green light. If it blinks with a red light or does not blink at all, the *RESCUE SAM* needs servicing – refer to the "Checking the Status Indicator" section for more information.

Progetti Srl recommends storing your AED in an easily accessible location.

3.5 Positioning the defi pads inside the carrying bag (optional)

1. Connect the pre-connected defi pads to the defibrillator as shown in the picture below

2. Insert the pre-connected defi pads inside the carrying bag as shown in the picture

3. Close the bag cover

4 Using the RESCUE SAM AED

This chapter describes how to use the *RESCUE SAM*. The *RESCUE SAM* was designed for simple operation, allowing the operator to focus on the patient.

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

The following sections describe in detail how to use the *RESCUE SAM*. The basic steps for use are:

- Turn the *RESCUE SAM* ON by pressing the ON/OFF button.
- Connect pads to AED if not yet connected.
- Place pads on patient (follow instructions on pad package).
- Follow voice prompts.
- Press SHOCK button if instructed by the AED.

4.1 Checking RESCUE SAM Status

STATUS LED:

- **Flashing Green:** The RESCUE SAM is in standby mode and ready for a rescue operation.
- **Solid Green:** The RESCUE SAM is switched ON.
- **Flashing Red:** The RESCUE SAM has detected a system error.
- **Solid Red:** The RESCUE SAM has detected a system error during self-test. The RESCUE SAM will be inoperable.
- **Solid Blue:** The RESCUE SAM is in data base operation mode.

4.2 Turning on the RESCUE SAM AED

Press the ON/OFF button to turn the *RESCUE SAM* on. The Status LED will illuminate green anytime the AED is on. Voice prompts will guide the operator in the use of the unit. To turn the unit off, press the button again. The Status LED will indicate the state of the unit.

4.3 Preparation

4.3.1 Call for Help

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 to contact professional emergency services.
If another person is available, the user should direct that person to call for help and then continue the rescue without delay.

4.3.2 Preparing the Patient

Prepare the patient by removing any clothing from the patient's chest. Wipe away moisture from the chest if necessary (the defibrillation pads will stick better on dry skin). If necessary, shave excessive chest hair, which can prevent effective patient-electrode contact. To ensure that electrode pads fully contact the patient's skin, check that no jewelry or other objects are directly underneath where the pads will be placed.

4.3.3 Opening the Pad Package

Open the pad package by tearing along the dotted line, starting at the black arrow (follow directions on the package). Pull the protective backing from the pads and check that the pads are:

- Free from obvious signs of damage.
- Clean of excessive debris (for example, dirt if the pad was dropped).
- Not dried out, and that the gel is sticky and will adhere to the patient.
- Not expired. Do not use pads after the expiration date printed on the package.

If any of these conditions is found, use a new set of pads.

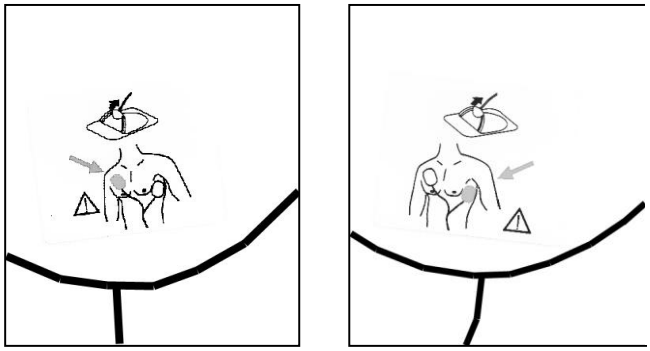
4.3.4 Connecting Defibrillation Pads to the RESCUE SAM

The RESCUE SAM is designed to be stored with the defibrillation pad connector attached to the unit, while the pads themselves remain sealed in their package. This reduces the time needed to setup and start treatment in an emergency.
The AED should be stored with the pad connector plugged into the unit. However, if pads were damaged or not properly connected, you may need to substitute a new set of pads during an emergency. The pad connector is on the bottom left corner of the AED.

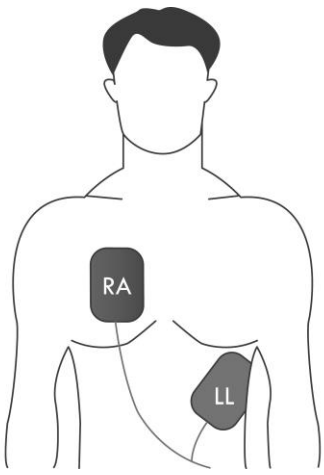
To remove an old set of pads, pull firmly on the pad connector. Do not reuse used pads. Insert the connector for the new pads as shown. The connector will only fit in one way – if the connector does not fit, rotate the connector before trying again. Insert connector firmly until it is completely seated in the unit.

4.3.5 Applying Pads to the Patient

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



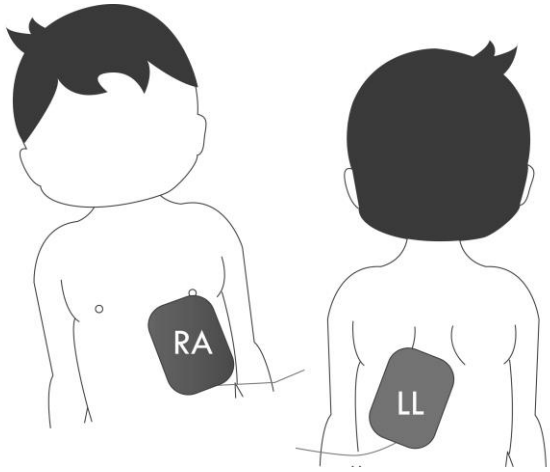
Pads position marking



Pads placement

4.3.6 Preparation of the pediatric patient

If the patient is an infant or child under the age of 8 years or weight less than 25kg (55 lbs), the device must be used with the attenuated defibrillation electrodes for children. Do not delay the procedure to define the exact weight or age.
Remove the electrodes from the package by tearing the package along the dotted line near the end of the pack. Remove the pads from the package and follow the directions and the schema for the correct placement of defibrillation electrodes placed on the packaging of the defibrillation electrodes and on the electrodes. Remove the protective coating from each electrode before placing them. Remove the coating only when the electrode is ready to be applied. Place the electrodes with the adhesive side of the patient's skin. Place the electrodes as shown in the diagram. The placement of pediatric electrodes in children under the age of 8 years is different from that of adults or children older than 8 years.
Follow the instructions in the figure shown here.



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

4.3.7 Follow RESCUE SAM AED Prompts

"Attach Pads" – This indicates that the pads are not attached to the patient or the pads connector is not plugged in. Check that the pads are properly placed and fully adhering to the patient and that there are no air bubbles between the pads and the patient. Make sure that the pads are not touching each other. If the pads are not sticking due to moisture, dry the patient. If the pads are not sticking due to excessive hair, shave or clip excessive chest hair. If the prompts continue, try replacing the pads with a new set. The "attach pads" blue LEDs will flash red during this message. If the pads are not attached within 3 minutes the RESCUE SAM will switch off automatically.

"Analyzing heart rhythm" - Once the RESCUE SAM has determined that the pads are making a good connection to the patient, the AED will start the ECG rhythm analysis. The unit analyzes the ECG signal and determines whether a shockable or non-shockable rhythm is present. While analyzing, the AED will continue to monitor the pad connections and will abort analysis if it detects any pad problems.

"Do not touch the patient" – This indicates that the RESCUE SAM is trying to analyze the patient's heart rhythm and that the operator should not touch the patient. This message will be spoken at the beginning of the analysis period and also if motion or interference has been detected. The "do not touch patient" blue LED will flash during this message.

"No shock advised" – This indicates that the RESCUE SAM has determined that a shock is not required. The unit will not charge and the SHOCK button will not be enabled. The user will be prompted to begin CPR, if needed, for a period of two minutes.

"Shock advised" – This indicates that the RESCUE SAM has determined that a shock is recommended and the unit will begin charging in anticipation of a defibrillation shock.

"Stand clear" – This indicates that the RESCUE SAM is charging and that the operator and others should stand clear of the patient. Analysis will continue during this phase and the "stand clear" blue LED will continue to flash. A tone will sound to indicate charging progress. If the unit detects a rhythm change to a non-shockable one, charging will abort and the user will be prompted to begin CPR, if needed, for a period of two minutes.

"Press the red shock button" – This indicates that the RESCUE SAM has fully charged, that the heart rhythm analysis algorithm still indicates a shock is recommended, and the unit is ready to deliver a shock. The operator should press the SHOCK button to deliver the shock. The "Shock" button will be lit red during this phase.

"No shock delivered" – This indicates that the RESCUE SAM has aborted shock mode and internally discharged. If while waiting for the shock button to be pressed, the unit detects a rhythm change to a non-shockable rhythm, the unit will cancel the shock. Also, if the shock button is not pressed within 15 seconds of the initial "press the red shock button" prompt, the unit will automatically cancel the shock.

"Begin CPR, press hard and fast in the center of the chest " – This indicates that the user should perform CPR for two minutes. The unit will not be monitoring the patient's ECG rhythm during this required two-minute CPR period. The "CPR" blue LED will flash and a timing sound will be emitted at 100 beats/minute.

5 Memory and data transfer

Rescue SAM defibrillator has an internal memory capable of recording ECG traces and events happened during the emergency phases.

5.1 How registration and memory management work

The internal defibrillator memory is able to record up to 8 sessions, every session could be long up to 60 minutes. Once the 8 session will be complete the defibrillator will replace and rewrite automatically the oldest session.

The data inside the device are kept also when the defibrillator is turned OFF.

Progetti s.r.l. company offers as optional the possibility to see the registration on a computer by an interface of data download and software management.

WARNING	RESCUE SAM defibrillator is able to record for single event 60 minutes. If the data collected exceed this limit, the following ones will be not recorded.
WARNING	RESCUE SAM overwrite the oldest event. Be sure to archive the data on a PC in order to avoid to lost past events.

5.1.1 View events

Sam Data Manager is an application software based on Windows, it is able to read the data recorded inside the RESCUE SAM, showed and manage it on the PC. The main function for Sam Data Manager are:

- The rescue staff is able by the software to rebuild a cardiac event starting from the moment when the AED is turned ON and connected to the patient until to the RESCUE SAM where turned OFF.
- It allows to medical staff to review the event in every moment.
- It allows to service point and to the manufacturer a clear and detailed reconstruction of all events and the proper use of the AED analyzing the performance of the device.
- It provides to the technicians extra parameters for the detection of faults in equipment suspected of improper operation.

WARNING	Sam Data Manager 1.0 is an application software stand-alone that could not be used when the AED is working, it is developed only to support the analysis post event of the data recorded on the internal memory.
WARNING	The recording of an event must be brought to the competent medical facility in the area to allow to examine the data.

5.2 Interface data downloads

Available from the optional accessories, Progetti S.r.l. provides for RESCUE SAM defibrillator a special adapter and related software management. This kit allows the user to download the data registered during the usage and allows to transfer this data on a personal computer for read, management and archive by the software "Sam Data Manager"

5.2.1 Module data download

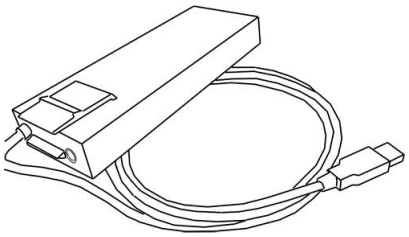


Fig. 1

RESCUE SAM defibrillator is supplied with a special adapter (Fig. 1) complete of USB cable and power adapter. This interface module allow the power supply for the defibrillator only for the data download from the internal memory of the RESCUE SAM.

5.2.2 Software for data downloads

Sam Data Manager is an application based on PC that allow to review ECG data and other parameters related to the patients and to the performance of the device after an emergency situation.

Sam Data Manager is able to be installed on different Windows platforms, Windows XP and Windows 7. The minimum requirements for the PC system and for guarantee suitable performance are the follow:

o Processor Pentium dual core o 1 Gb of RAM o 100 Mbyte hard disk free space

5.3 Functioning and Interface procedure

For the data download is sufficient to follow this simple operation:

- Insert the interface module into the RESCUE SAM without connect the USB cable to the PC
- Connect the power supply to the interface by the appropriate charger
- Wait for the RESCUE SAM led status become BLU
- Connect the USB cable to the PC
- Start the program SAM DATA MANAGER on the PC and follow the video instruction

5.4 Software download

The software RESCUE SAM – SAM DATA MANAGER is available for free download from our web site www.progettimedical.com after login in the reserved area.

6 Maintaining and Troubleshooting the RESCUE SAM AED

This chapter describes the maintenance and troubleshooting procedures for the *RESCUE SAM*. The Self-Tests that are performed by the device are described along with the frequency and nature of periodic maintenance for which the owner/operator is responsible. A troubleshooting guide is provided to help diagnose user serviceable problems.

The *RESCUE SAM* contains no user serviceable parts.

6.1 Self-Tests

Power-On Self-Tests are performed every time the unit is turned on and test the basic operation of the unit. The unit also performs daily, weekly and monthly self-tests automatically (without any intervention from the operator) to check the integrity of the unit's hardware and software. Manually initiated Self-Tests may be run to test the RESCUE SAM's systems, including the charging and shocking functions (the shock is internally dissipated, i.e. no voltage will be present at the pads) at any time by tacking off the battery pack and reinserting it.

Note: manually initiated Self-Tests will use approximately one shock's worth of energy from the battery pack and running manually initiated Self-Tests will reduce the usable capacity of the battery.

6.2 Routine Maintenance

Although the RESCUE SAM is designed to be very low maintenance, simple maintenance tasks must be performed by the owner/operator on a regular basis to ensure the unit's dependability.

Daily	Monthly	After Each Use	Action
o	o	o	**Check that the Status Indicator is flashing green**
	o	o	**Check the condition of the unit and accessories**
		o	**Replace pads**
	O		**Check pads and battery pack expiration dates**

For a greater safeguard, we suggest to the Users to make a manual Selftest at least every 3 months, pushing the Info button.

6.3 Maintenance Related Voice Prompts:

"System error " – This indicates that the *RESCUE SAM* has failed the self-test and is non-operational and needs servicing.

"Battery low" – This indicates that the battery pack capacity is low and should be replaced soon. The AED will still be able to deliver at least a minimum of four defibrillation shocks the first time this message is spoken.

6.4 Cleaning

Periodically clean the *RESCUE SAM* of any dirt or contaminants on the case and connector socket. The following are important guidelines to be adhered to when cleaning the device:

- The battery pack should be installed when cleaning the *RESCUE SAM.*
- Do not immerse the *RESCUE SAM* in fluids or allow fluids to enter the unit. Use a soft cloth to wipe the case clean.
- Do not use abrasive materials or strong solvents such as acetone or acetone based cleaning agents. The following cleaning agents are recommended for cleaning the *RESCUE SAM* case and the connector socket:
  - Soapy water
  - Ammonia based cleaners
  - Hydrogen peroxide
  - Isopropyl alcohol (70 percent solution)
  - Chlorine bleach (30 ml / liter water)
- Ensure that the connector socket is completely dry before reinstalling the pads cable

6.5 Storage

The RESCUE SAM should be placed in a readily accessible location in an orientation where the Status Indicator in the bottom center of the panel can be easily seen. In general, the unit should be stored in clean, dry and moderate temperature conditions. Make sure that the environmental conditions of the storage location are within the ranges detailed in the "Environmental" section.

6.6 Operator's Checklist

The following checklist may be used as the basis for an Operator's Checklist. The table should be copied and filled out as recommend by the schedule in the "Routine Maintenance" section. As each item is completed it should be checked off.

Progetti Srl RESCUE SAM Operator's Checklist						
Serial Number: _____ **Location:** _____						
Date:						
Check unit and accessories for damage, dirt and contamination. Clean or replace as necessary.						
Check that spare battery pack and pads available .						
Check that battery pack and pads not past expiration dates.						
Check status flashing green.						
Comments:						
Inspected by: (signature)						

6.7 Troubleshooting

The following table lists the common causes for problems, the possible cause and the possible corrective actions. Refer to the other sections of the User Manual for detailed explanations on how to implement the corrective actions. If the unit continues to be non-functional, refer the unit for servicing.

Symptom	Possible Cause	Corrective Action
Unit will not turn on	Battery pack not inserted	Insert battery pack
	Battery pack depleted or non-functional	Replace battery pack
	Unit is non-functional	Return unit for service
Unit immediately turns off	Battery pack depleted	Replace battery pack
	Unit is non-functional	Return unit for service
STATUS is solid red	Unit detected an error	Return unit for service
STATUS does not blink at all	Battery pack not inserted	Insert battery pack
	Battery pack non-functional	Replace battery pack
	Unit is non-functional	Return unit for service
Battery insertion self-test failed	Unit needs servicing	Return unit for service

6.8 Repair

The *RESCUE SAM* contains no user serviceable parts. If the unit need servicing, return to an authorized service center. Refer to "Contacts" section for contact information.

7 RESCUE SAM AED Accessories

This chapter describes the components and accessories that can be used with the Progetti Srl *RESCUE SAM*. Information on obtaining replacement components and accessories is included in the "Contacts" section.

7.1 Defibrillation/Monitoring Pads

The *RESCUE SAM* is used with Progetti Srl self-adhesive defibrillation/monitoring pads for adults or with attenuated pediatric pads for infants and children. These pads (also known as "electrodes") serve two functions:

- Allow the unit to read the patient's electrocardiograph (ECG) rhythm.
- Deliver defibrillation energy to the patient when needed.

The Progetti Srl self-adhesive defibrillation/monitoring pad assembly comes in a "leads-out" sealed package that allows the device to be stored with pads connected. When the *RESCUE SAM* is used, the operator needs only to remove the pad packaging, tear open the package and turn the device on to administer care.

7.2 Battery Packs

The Progetti Srl AED uses a lithium battery pack. The battery pack is inserted into the battery pack opening on the side of the AED and latches into place.

The battery is based on a lithium battery technology and provides the AED with a long shelf and standby life.

7.2.1 Battery Status Indicator

The Status Indicator is located on the RESCUE SAM front panel and is used to indicate battery pack status in stand-by mode. A periodically blinking green LED indicates that the battery pack status is OK and the battery pack is ready for use. A blinking red LED indicates a battery pack problem.

7.3 Recycling Information

At the end of its useful life, recycle the defibrillator and its accessories.

7.3.1 Preparation

Items should be clean and contaminant-free prior to being recycled. When recycling used disposable electrodes, follow local clinical procedures.

7.3.2 Packaging

Packaging should be recycled in accordance with local and national requirements.

8 Technical Specifications

8.1.1 Physical

Category	Specification
Size	(29 x 28 x 9 cm)
Weight	Approximately 2.2Kg with Battery pack

8.1.2 Environmental

Category		Specification
Operating / Maintenance	**Temperature**	-5 ÷ 46°C (23 ÷ 115°F)
	Humidity	5% – 95% (non-condensing)
Standby / Storage	**Temperature**	-20 ÷ 50°C (-4 ÷ 122°F)
	Humidity	5% – 95% (non-condensing)
Shock / Drop Abuse Tolerance		Meets IEC60601-1 clause 21
Sealing		IEC 60529 class IP54; Splash Proof, Dust Protected (Battery pack installed)
ESD		Meets EN 61000-4-2:2001
EMC (Emission)		EN 60601-1-2:2001+A1:2006, method EN 55011:1998 Group 1 Level B
EMC (Immunity)		EN 60601-1-2:2001+A1:2006, method EN 61000-4-3:1998 Level 3

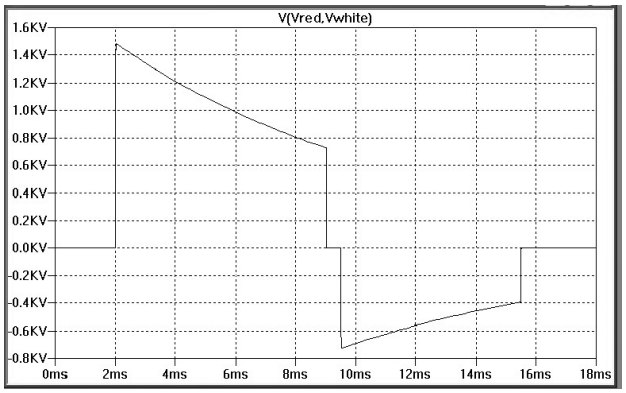
8.1.3 Defibrillator

Category	Specification
Waveform	Biphasic Truncated Exponential
Energy	200 J nominal delivered into a 50 ohm load
Charge control	Automatic by Patient Analysis System
Charge time from shock-advised	Typically <8 seconds with a fresh battery pack. Charge time may increase with used battery pack and for temperatures below 10°C.
Charge complete indication	• SHOCK button lit red. • "Press Shock button" voice prompt

Shock delivery		Shock is delivered by a single SHOCK button
Disarm	**Automatic**	If Patient Analysis System decides rhythm is no longer shockable, or within 15 seconds after Charge complete, if operator has not pressed SHOCK button.
	Manual	If operator presses the OFF/DISARM button at any time to disarm and turn off the device.

8.1.4 Waveform Specifications

The *RESCUE SAM* delivers a nominal 200J Biphasic Truncated Exponential waveform to patients with impedances ranging from 25 to 175 ohms.



The waveform is adjusted to compensate for measured patient impedance. Nominal phase times and energy delivered are shown in the tables below.

Patient Impedance (Ohms)	Phase A, Duration (msec)	Phase B, Duration (msec)	Energy Delivered (Joules)
25	6	6	200J+/-10%
50	8	6	200J+/-10%
75	8	8	200J+/-10%
100	10	8	200J+/-10%
125	10	10	200J+/-10%
150	12	10	200J+/-12%
175	12	10	200J+/-12%

8.1.5 Patient Analysis System

The *RESCUE SAM* Patient Analysis System ensures that the pad/patient impedance is within the proper range and analyzes the patient's ECG rhythm to determine whether a shock is required. In an initial ECG signal conditioning stage, ECG data are received and digital processing is done to remove baseline wander and high-frequency noise.

The ECG signal are then processed by the ECG signal analysis routines. The arrhythmia detection process determines whether or not to advise shocking the patient by examining the outputs of these analyses.

8.1.5.1 Patient Analysis System Performance

Rhythm Class	Sample Size	Performance	Specifications
Shockable Rhythm – Ventricular Fibrillation	220	>97%	Meets the IEC60601-2-4:2004 Sensitivity > 90%
Shockable Rhythm – Ventricular Tachycardia	165	>95%	Meets the IEC60601-2-4:2004 Sensitivity > 75%
Non-Shockable Rhythm – Normal Sinus Rhythm	130	99%	Meets the IEC60601-2-4:2004 Specificity >95%
Non-Shockable Rhythm – Asystole	148	100%	Meets the IEC60601-2-4:2004 Specificity > 95%
Non-Shockable Rhythm – All other non-shockable rhythms	219	>98%	Meets the IEC60601-2-4:2004 Specificity > 95%

8.1.6 Guidance and Manufacturer's Declaration - Electromagnetic Emissions and Immunity

Electromagnetic emissions

The RESCUE SAM is intended for use in the electromagnetic environment specified below. The customer or the user of the RESCUE SAM should assure that it is used in such an environment		
Emissions Test	**Compliance**	**Electromagnetic environement guidance**
RF Emissions CISPR 11	Group 1 Class B	The RESCUE SAM uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The RESCUE SAM is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	not applicable	
Voltage fluctuations IEC 61000-3-3	not applicable	

Electromagnetic immunity

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 60601-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	No other ESD requirements are necessary.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power line supply lines ±1 kV for input/output lines		Not applicable
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth		Not applicable

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should not be greater than levels characteristic of a typical location in a commercial or hospital environment.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the RESCUE SAM , including cables, than necessary. The recommended separation distance calculated from the equation applicable to the frequency of the transmitter is shown in the following table. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from 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. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RESCUE SAM is used exceeds the applicable RF compliance level above, the RESCUE SAM should be observed to verify normal operation. If abnormal performance is observed additional measures may be necessary, such as reorienting or relocating the RESCUE SAM.			

Separation Distances

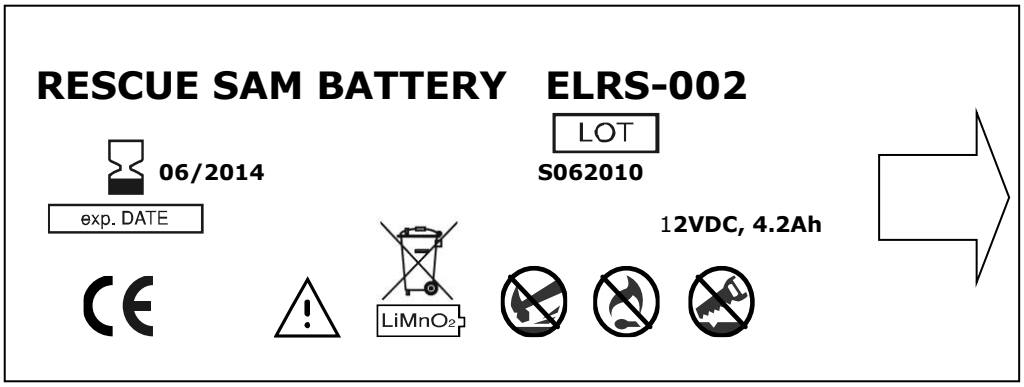
The RESCUE SAM is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RESCUE SAM can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RESCUE SAM as recommended below, according to the maximum output of the communications equipment.

Recommended separation distances between portable and mobile RF communications equipment and the RESCUE SAM				
Separation distance according to frequency of transmitter (m)				
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz outside ISM bands** **d = 1.16√P**	**150 kHz to 80 MHz inside ISM bands** **d = 1.2√P**	**80 MHz to 800 MHz** **d = 1.2√P**	**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	1.20	2.30
10	10	3.69	3.79	7.27
100	100	11.67	12.00	23.00
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1: As 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. Note 2: 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. Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

8.2 Battery pack

Category	**Specification**
Model number	ELRS-002
Battery type	12VDC, 4200 mAh, Lithium/Manganese Dioxide. Disposable, recyclable, non-rechargeable.
Capacity	A new battery typically will provide 200 shocks or 4 hours of operating time at 25°C.
Shelf-life (prior to installation)	Typically 5 years
Standby-life (after installation)	Typically 4 year

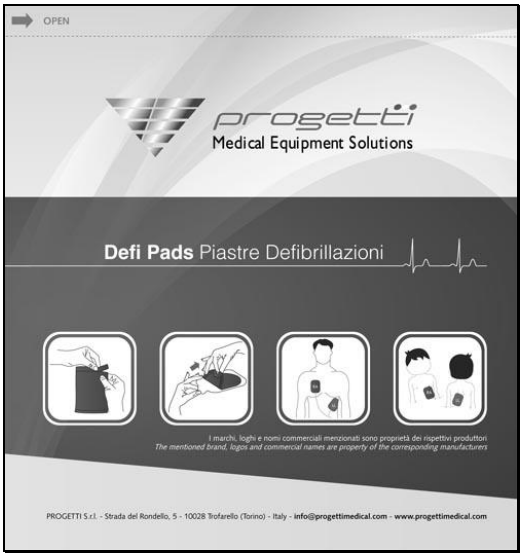
Battery label:



8.3 Self-Adhesive Defibrillation/Monitoring Pads

Use only the Pads supplied or approved by Progetti Srl.

Category	Specification	
Model number	DFBAD01PRC	
Type	Adult	
Intended use	Disposable	
Adhesion	Self-adhesive	
Active gel surface area	105 cm2 each (nominal)	
Cable/connector type	Integrated	



9 Glossary of Symbols

RESCUE SAM Defibrillator

Symbol	Description
	Power ON/OFF button
	Info button
	Status Led
	SHOCK button
	BF type, defibrillation proof equipment
	Attention: Refer to the User Manual.
	Instructions in the User Manual.
CE 0068	CE Marking
SN	Serial Number

Battery

Symbol	Description
LOT	Lot Number
 exp. DATE	Expiration date
	Do not mutilate or open the battery
	Do not expose the battery to high heat or open flames. Do not incinerate the battery.

	Do not crush the battery.
	Lithium Manganese Dioxide battery. Follow local regulations on battery disposal or recycling.
	Attention: Refer to user manual.
	CE marking

10 Contacts

PROGETTI S.r.l.

Strada del Rondello, 5
10028 TROFARELLO (TO)
ITALY

Phone: +39 011 644738
FAX: +39 011 645822
HOME PAGE: www.progettimedical.com

Department :
GENERAL INFO : info@progettimedical.com
SALES DEPARTMENT : sales@progettimedical.com
EXPORT DEPARTMENT : export@progettimedical.com
SERVICE DEPARTMENT : service@progettimedical.com
SHIPMENT : export@progettimedical.com

11 Warranty Information

ORIGINAL END USER'S LIMITED WARRANTY

COVERAGE

Progetti Srl, provides a limited warranty that the defibrillator and its associated accessories (batteries and pads), whether purchased concurrently with the defibrillator as part of a configuration or separately, shall be substantially free from defects in material and workmanship. Progetti Srl's limited warranty shall only extend to the original end user, where the original end user purchased the items from an authorized Progetti Srl, retailer. This limited warranty may not be assigned or transferred. The terms of the Limited Warranty in effect as of the date of original purchase shall apply to any warranty claims.

Length of Warranty

The defibrillator's limited warranty is for a period of five (5) years from the date of purchase. The battery's limited warranty is for a period of four (4) years from the date of purchase, but in no event shall the limited warranty period extend past the date printed on the battery. Single use accessories (disposable pads) shall have a limited warranty up to use or for a period up to the expiration date, whichever is earlier. The limited warranty for all other accessories is for a period of one (1) year from the date of purchase, or to the expiration date, whichever is earlier.

Limited Warranty Limitations

This limited warranty does not cover damage of any sort resulting from, but not limited to, accidents, improper storage, improper operation, alterations, unauthorized service, tampering, abuse, neglect, fire, flood, war. Additionally, this limited warranty does not cover damage of any sort to the defibrillator or its associated accessories resulting from the use of the defibrillator with unapproved accessories or use of the accessories with unapproved medical devices. The defibrillator and its associated accessories are not warranted to be compatible with any other medical device.

Limited Warranty Voided

The limited warranty is immediately voided if: the defibrillator or its associated accessories are serviced or repaired by any entity, including persons, not authorized by Progetti Srl, ; specified maintenance is not performed; the defibrillator is used with one, or more, unauthorized accessories; the associated accessories are used with an unauthorized defibrillator; or the defibrillator or associated accessories are not used in accordance with Progetti Srl, approved instructions.

Exclusive Remedy

At Progetti Srl's sole discretion, Progetti Srl shall have the option to repair or replace. In the event of replacement, Progetti Srl shall have the right at its sole discretion to replace the item with a new, or refurbished, same or similar item. Determination of a similar item shall be at the sole discretion of Progetti Srl. In the case of replacement, the replacement at a minimum shall reflect the prorated time remaining for the item based on the remaining limited warranty period. In no event, shall the limited warranty period of a replacement item extend past the limited warranty period of the item it is replacing.

Warranty Service

Only PROGETTI S.r.l. or its authorized representatives should service the device. If unauthorized personnel service the device during the warranty period, the warranty will become null and void.

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

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

When the need for maintenance arises:

Please contact PROGETTI S.r.l. or its authorized representatives immediately. Prepare a summary of the problems. Also include the name of model, product serial number, date of purchase, name of sales representative, customer information

Main service center:

PROGETTI S.r.l

Strada del Rondello, 5

10028 TROFARELLO (TO)

Phone:+39-011- 644738

Fax: + 39- 011- 645822

Email: service@progettimedical.com

Web site: www.progettimedical.com

Obligations and Warranty Limits

THE FOREGOING LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND REPLACES, TO THE DEGREE PERMITTED BY APPLICABLE STATE LAW, ALL OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.
NO PERSON (INCLUDING ANY AGENT, DEALER, OR REPRESENTATIVE OF PROGETTI SRL,) IS AUTHORIZED TO MAKE ANY REPRESENTATION OR WARRANTY CONCERNING THE DEFIBRILLATOR OR ITS ASSOCIATED ACCESSORIES, EXCEPT TO REFER TO THIS LIMITED WARRANTY.
THE EXCLUSIVE REMEDY WITH RESPECT TO ANY AND ALL LOSSES OR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER SHALL BE AS SPECIFIED ABOVE. PROGETTI SRL, SHALL IN NO EVENT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, EXEMPLARY DAMAGES, SPECIAL, PUNITIVE, COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR PERSONAL INJURY, EVEN IF PROGETTI SRL, HAS BEEN ADVISED OF THE POSSIBILITIES OF SUCH DAMAGES, HOWEVER OCCASIONED, WHETHER BY NEGLIGENCE OR OTHERWISE, UNLESS APPLICABLE STATE LAW DOES NOT ALLOW SUCH EXCLUSION OR LIMITATION.

WARRANTY CERTIFICATE

This device is warranted against defects in materials and workmanship.

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

This warranty does not cover any accessories.

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

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

CLIENT:_____

_____

_____

DEVICE: AED Defibrillator

Model: RESCUE SAM **SN** _____

VALIDITY starting from : _____/_____/_____

Delivery date:_____ **Invoice N°**_____ **dated**_____

Declaration of EU conformity

progetti® Medical Equipment Solutions

Doc. N. FT-RescueSAM-2.0/8.1-5.2

Rev. 5.2

DECLARATION OF EU CONFORMITY

DICHIARAZIONE DI CONFORMITA' EU

TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 AND SUBSEQUENT AMENDMENTS

AI SENSI DELLA DIRETTIVA 93/42/CEE DEL 14 GIUGNO 1993 E SUE SEGUENTI MODIFICHE

CONCERNING MEDICAL DEVICES

RELATIVA AI DISPOSITIVI MEDICI

PRODUCT *Prodotto*	**Defibrillatore Automatico Esterno (DAE)** *Automated External Defibrillator (AED)*
MODELS (**REF**) *Modelli*	**Rescue SAM**
CND CODE *Codice CND*	**Z12030599**
GMDN / UMDNS CODE *Codice GMDN / UMDNS*	**17882**
CLASS *Classe*	**II b**
MANUFACTURER *Fabbricante*	**PROGETTI S.r.l.** Strada del Rondello, 5 10028 Trofarello (TO) - ITALY
APPLIED STANDARDS *Norme applicate*	**EN 1041:2008, EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 60601-1:2006/A1:2013/A12:2014, EN 60601-1-2:2015, EN 60601-2-4:2011, EN 60601-1-6:2010/A1:2015, EN 62304:2006/A1:2015, EN 62366-1:2015, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12-1 Rev.8, MEDDEV 2.12/2 Rev.2**
SERIAL NUMBER (**SN**) *Numero di serie*	*

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

*DICHIARIAMO QUINDI CHE IL PRODOTTO SOPRA SEGNALATO SODDISFA LA TRASPOSIZIONE IN DIRITTO NAZIONALE, LE DISPOSIZIONI DELLA **DIRETTIVA 93/42/CEE** DEL CONSIGLIO DEL 14 GIUGNO 1993 RELATIVA AI DISPOSITIVI MEDICI, SECONDO I REQUISITI ESSENZIALI E LE MODIFICHE SUCCESSIVE. TUTTA LA DOCUMENTAZIONE DI SUPPORTO È DISPONIBILE PRESSO IL FABBRICANTE. INOLTRE, IL PRODOTTO È REALIZZATO IN BASE ALLA DIRETTIVA **2011/65/CEE (ROHS)** E SUCCESSIVE MODIFICHE. IL PRODOTTO IN OGGETTO È STATO REALIZZATO AI SENSI DI UN **SISTEMA DI GESTIONE DELLA QUALITÀ** SECONDO L'**ALLEGATO II** DELLA **DIRETTIVA 93/42/CEE**.*

NOTIFIED BODY *Ente Notificato*	MTIC InterCert S.r.l. (Notified Body N°**0068**) Via Moscova, 11 20017 Rho (MI) - ITALY
EC MARKING *Marcatura CE*	CE 0068
EC CERTIFICATE N° *Certificato CE n°*	**0068/QCO-DM/025-2015 Rev.03**
EXPIRE DATE OF EC CERTIFICATE *Data di scadenza del certificato CE*	**27/05/2024**
FIRST ISSUE DATE OF EC CERTIFICATE *Data di prima emissione del certificato CE*	06/05/2015
PLACE AND DATE OF ISSUE *Luogo e Data di emissione*	TROFARELLO (TO), 01/02/2021
SIGNATURE *Firma*	Dr. CESARE MANGONE MANAGEMENT REPRESENTATIVE

*IF YOU WANT RECEIVE DEDICATED DECLARATION OF CONFORMITY FOR YOUR DEVICE **SERIAL NUMBER**

*PER RICEVERE LA DICHIARAZIONE DI CONFORMITA' DEDICATA ALLO SPECIFICO **NUMERO DI SERIE***

AND/OR UPDATED ONE, PLEASE CONTACT PROGETTI S.R.L. OFFICE TO THE EMAIL info@progettimedical.com

E/O UN AGGIORNAMENTO, SI PREGA DI CONTATTARE PROGETTI S.R.L. ALL'INDIRIZZO EMAIL info@progettimedical.com

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