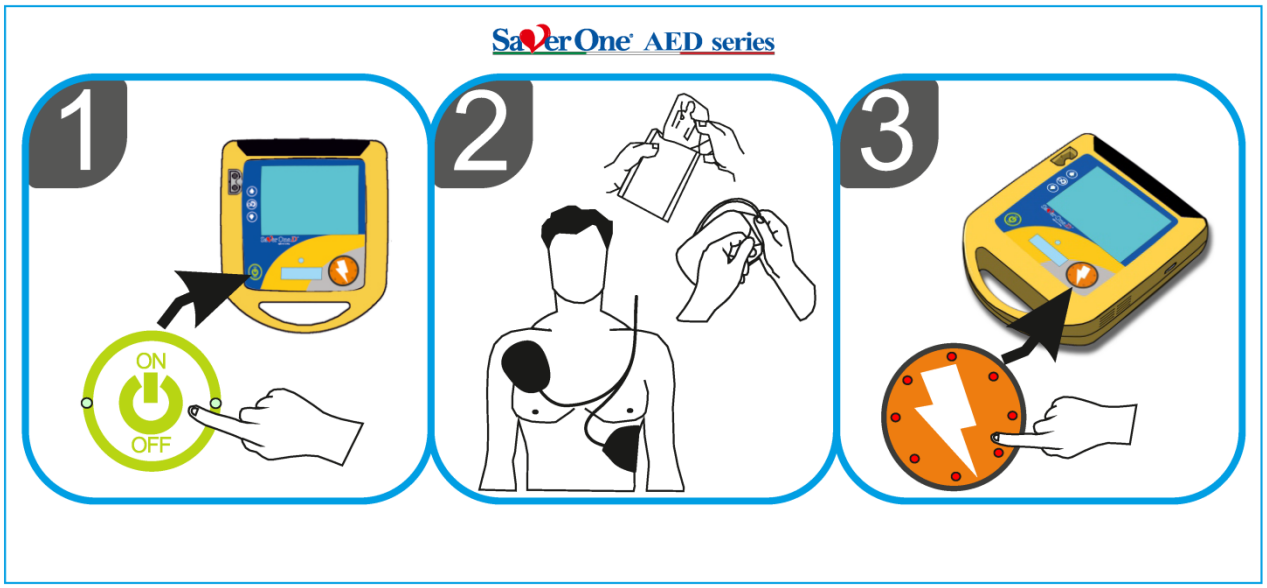
USER MANUAL
EXTERNAL SEMIAUTOMATIC DEFIBRILLATOR
WITH DISPLAY

SAVER ONE D

Rev. 12.4

AEDs

QUICK START GUIDE



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Printed in Italy

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1 INTRODUCTION

1.1 PREAMBLE

Thank you for choosing the defibrillator manufactured by A.M.I. Italia S.r.l. model ***Saver One D***.
In order to use the device correctly, you must read this user manual carefully before use. The User Manual of ***Saver One D*** contains the instructions for its use in compliance with its function and purpose. For error-free operation and to achieve the right performance, it is fundamental to comply with the requirements of this user manual, to guarantee the safety of the patient, of the rescuer and of any third parties. As an integral part of the defibrillator, this manual must always be kept close to the product so that it can be easily referenced in case of need.
Note: In order to guarantee the correct and fast traceability of the product and to receive information regarding all implemented updates, the user is required to register the device at the appropriate section of the AMI ITALIA website, www.amiitalia.com.

1.2 USE IN CONFORMITY WITH THE PROVISIONS

The device ***Saver One D*** can be used exclusively if the conditions indicated in this user manual are complied with. Any use that differs from that required is understood to be non-compliant with the provisions and may cause damage to people and/or property. In that case A.M.I. Italia S.r.l. hereby disclaims all liability.

1.3 WARRANTY

The device ***Saver One D*** has a guarantee of 6 (six)* years.
The SAV-C0903 and SAV-C0904 non-rechargeable batteries are guaranteed for 4 (four)* years in stand-by mode (assuming one activation test, daily self-tests and no AED power-up). This information refers to new batteries, that are fully charged and stored at a temperature of 20°C and 45% humidity.

* *For more information refer to **Chapter 16** "Saver One Series defibrillators warranty"*

1.4 DISCLAIMER OF LIABILITY

The rights of liability are excluded in cases of damage to people or property, if attributable to one of the indicated causes:

- Use of the appliance not in compliance with the provisions.
- Inadequate use and maintenance of the appliance.
- Using the device and/or its accessories when they are visibly or partially damaged.
- Failure to comply with the instructions in the user manual concerning precautions, operation, maintenance and repair of the appliance.
- Using non-original accessories and spare parts and/or of accessories and spare parts that are not approved by the manufacturer.
- Performing arbitrary operations, repairs or modifications of the device.
- Arbitrarily exceeding the performance limits.
- Failing to supervise the parts that are subject to wear and tear.

1.5 INSTRUCTIONS

The ***Saver One D*** can only be used if the patient:

- is unconscious
- is not breathing and...
- has no heartbeat

1.6 COUNTERINDICATIONS

The ***Saver One D*** cannot be used if the patient

- is conscious or..
- is breathing normally or..
- has a heartbeat

1.7 INFORMATION ON THE VERSION

This user manual has a version number. The version number changes every time the manual is updated for changes made to the operation of the device or to the device itself. The contents of this user manual shall be subject to amendment without advance notice. The information on the version of this manual is as follows.

Version number: 12.4
Issue date: 06/04/2021

1.8 SYMBOLS USED IN THE MANUAL

This user manual uses various symbols that indicate the various precautions for use:

SYMBOL	INDICATION	DESCRIPTION
	**HAZARD**	**Indicates an immediate risk to the safety of people, which also involves death and damage to the device or parts thereof**
	**WARNING**	**Indicates an unsafe situation or practice which leads to serious injury to persons and damage to the device or parts thereof**

1.9 CONTACT DETAILS OF THE MANUFACTURER

You can contact our company at the following addresses:

A.M.I. Italia S.r.l.

REGISTERED OFFICE
Via G. Porzio Centro Direzionale Isola G/2
80143 Naples (NA) Italy

PRODUCTION SITE ITALY - PRODUCTION, LABORATORIES, OFFICES
Via Cupa Reginella, 15/A
80010 Quarto (NA) Italy
Phone: +39 081 806 34 75 - Fax: 39 081 876 47 69

PRODUCTION SITE HUNGARY - PRODUCTION, LABORATORIES, OFFICES
A.M.I. International KFT
Kőzúzó u. 5/A
2000 Szentendre (Hungary)
Phone: +36 26 302.210

Request for assistance

email: *info@amiitalia.com*
Tel.: +39 081 806 05 74
Website: www.amiitalia.com

2 SAFETY INSTRUCTIONS

For correct use of the ***Saver One D*** defibrillator, users must be aware of the safety factors listed below.
We recommend that you read them carefully.
The ***Saver One D*** defibrillator, individually and in connection with its standard and optional (original) accessories, complies with the safety regulations currently in force and with the provisions of the directives on medical products.
The appliance and its accessories are to be considered safe in the case of application according to the provisions and if the descriptions and indications in this user manual are complied with.
The following are the main precautions to be taken for the correct and safe use of the defibrillator, broken down for ease of referencing into hazard statements, warning statements and disposal instructions.

2.1 HAZARD STATEMENTS

- Use the ***Saver One D*** in accordance with the requirements of this user manual. Carefully read these instructions for use and in particular the safety instructions indicated therein.
- In accordance with IEC/EN standards (section 3.2), the use of the ***Saver One D*** device or its accessories in the presence of flammable substances (petrol or similar) or in an atmosphere enriched with oxygen or flammable gases/vapours is not allowed.
- Do not recharge SAV-C0903 and SAV-C0904 disposable batteries. Explosion hazard!
- Avoid contact of the batteries with naked flames. Do not expose to fire.
- Do not cause a short-circuit of the battery terminals.
- In case of leakage of fluids or strange odours from the batteries, keep them away from fire to prevent the possible combustion of leaking electrolytes.
- Shock hazard. The device generates high voltage and hazardous current levels. Do not open the ***Saver One D***, do not remove the panels and do not attempt to repair it. The ***Saver One D*** contains no components that users can repair. For repair purposes, the ***Saver One D*** must be sent to an authorized technical service centre.
- Do not apply the electrodes to the patient's chest if nitro-glycerine patches are present. Only place the electrodes once you have removed the plasters. Otherwise there is a risk of causing an explosion.
- Do not touch the patient and prevent third parties from coming into contact with the patient during the defibrillation shock. Avoid all contact between:
  - parts of the patient's body
  - conducting liquids (such as gel, blood, or saline solution)
  - metal objects near the patient (such as bed frame or stretching device) that are indirect routes for the defibrillation current.
- Before using the device ensure the patient's safety, if necessary move them carefully and put them in a safe place as per the international guidelines AHA/ERC.
- Do not immerse any part of the ***Saver One D***, its parts or accessories in water or other liquids.
- Do not allow liquids to enter the ***Saver One D***, its parts or accessories. Avoid pouring liquids on the device and its accessories. Failure to do so may cause damage or cause a risk of fire or electric shock. Do not sterilize the ***Saver One D*** or its accessories.

2.2 WARNINGS

- Avoid the formation of air bubbles between the skin and the defibrillation pads. The formation of air bubbles during defibrillation may cause severe burns to the patient's epidermis. To avoid the formation of air bubbles, make sure that the electrodes fully adhere to the skin. Do not use electrodes whose gel has dried; check the expiration date before use.
- Do not delay treatment in patients with an implanted pacemaker and perform a defibrillation attempt if the patient has lost consciousness and is not breathing or not breathing normally. The **Saver One D** is equipped with a pacemaker detection system that ignores the signal it emits; however, with some types of pacemakers, the **Saver One D** may advise against a defibrillation shock.
  During the application of the electrodes:
  • Do not apply the electrodes directly on an implanted device.
  • Apply the electrodes at least 2.54 cm (1 inch) from any implanted device.
- RF (radio frequency) interference, caused by devices such as mobile phones and two-way radios, can cause the **Saver One D** to malfunction. The **Saver One D** must be kept at least 2 metres away from these RF devices, as indicated in the standards IEC/EN 61000-4-3. Keep at sufficient distance from other therapeutic and diagnostic sources of energy (e.g. diathermy, high-frequency surgery, magnetic tomography).
- Use the **Saver One D** only if you have passed a BLS-D or ALS-D training course.
- Before using the device, make sure that it is not obviously damaged.

- The infrared interface emits optically invisible radiation. The emission diode complies with IEC/EN 60825-1 Class 1 "Eye Save".
- Do not use Paediatric Defibrillation PADs (SAV-C0016) on adult patients (older than 8 years and weighing more than 25kg). When using Paediatric Defibrillation PADs the **Saver One D** (Ref: **SVD-B0004, SVD-B0005**) automatically switches to paediatric mode, reducing the maximum deliverable energy to 50J.
- Do not use SAV-C0599 universal Face to Face defibrillation PADs in paediatric mode on adult patients (older than 8 years and weighing more than 25kg). By setting "paediatric mode" in the menu, **Saver One D** (Ref. **SVD-B0004-U, SVD-B0004-U-Q, SVD-B0005-U, SVD-B0005-U-Q**) switches to paediatric mode, reducing the maximum deliverable energy to 50J.
- Place the patient cables so as to reduce the possibility of entangling or strangling the patient.
- In a domestic environment, keep the defibrillator away from the reach of children and pets.
- Do not apply the defibrillation electrodes directly on an implanted pacemaker to avoid any reading errors by the device and to avoid damage to the pacemaker through the defibrillation pulse.
- Disconnect the patient from equipment that is sensitive to high voltage pulses, or equipment that is not defibrillator-proof, before delivering the shock.

WARNING

- Do not allow the defibrillation electrodes to touch or to come into contact with ECG electrodes, pads, transdermal plasters, etc. Otherwise, the formation of electric arcs and burns to the patient could be caused during defibrillation, the current may even be dispersed.
- Place the defibrillation pads as indicated in this user manual and on the packaging.
- Do not use the defibrillation PADs if the gel has detached from the support or if it appears torn, detached or dry
- If damage has been observed, do not operate the **Saver One D** under any circumstances.
- Before using the device, remove metal objects from the patient's body (including necklaces or bracelets, etc.)
- Do not use defibrillation pads other than those supplied by the manufacturer. Otherwise, the defibrillator may perform false interpretations.
- Do not use the defibrillation pads if they are damaged, even partly.
- Do not use defibrillation PADs if the expiry date has been exceeded.
- When applying the ECG SAV-C0017 cable make sure it is not in contact with any conductive element. Ensure that all ECG electrodes are properly secured to the patient.
- Do not touch the patient or PADs during heart rhythm analysis.
- Moving or transporting the patient during the analysis of the heartbeat by the device may lead to a wrong or untimely diagnosis. Reduce movements to a minimum while the heartbeat is being analysed. If the device is used in a moving ambulance, stop the vehicle and only start driving after the shock has been delivered.
- In order to use the **Saver One D**, one must have completed a training course for basic or advanced cardio-pulmonary resuscitation with the use of a defibrillator (BLS-D or ALS-D course).
- Avoid the use of adult defibrillation PADs (SAV-C0846) on children (ages 1-8 years or weighing 8-25kg), in this case the **Saver One D** (Ref. **SVD-B0004, SVD-B0005**) does not automatically reduce the maximum energy that can be delivered to 50J and may, therefore, become hazardous for the paediatric patient.
- Avoid using the universal Face to Face SAV-C0599 defibrillation PADs in adult mode on children (aged 1-8 or weighing 8-25 kg). In fact, in adult mode the ***Saver One D*** (Ref. **SVD-B0004-U, SVD-B0004-U-Q, SVD-B0005-U, SVD-B0005-U-Q**) does not automatically reduce the maximum deliverable energy to 50J and therefore can become potentially dangerous for the paediatric patient, therefore set the paediatric mode correctly from the menu when needed.
- If needed, before applying the defibrillation PADs dry the patient's chest and remove excess hair
- Do not allow **Saver One D**, its accessories, its parts to be dropped and/or subjected to hard impacts.
- Do not use damaged accessories and/or parts; otherwise, the device may be caused to malfunction.
- Use solely original accessories and/or spare parts.
- Avoid handling the device, its accessories or its parts too aggressively to avoid possible damage. Inspect the entire system regularly.
- Sanitise the device in compliance with the regulations indicated in paragraph 10.3 and always make sure that the device is switched off with the battery removed and PADs disconnected.
- The defibrillation pads are single-use, to be used on just one patient. Do not reuse the defibrillation pads; throw them away after use and replace them with a new pair.
- Defibrillation PADs are not sterile or sterilisable.
- The intense or prolonged administration of cardiopulmonary resuscitation with the defibrillation electrodes applied to the patient can damage the electrodes. Replace them if they are damaged due to use or handling.
- Inadequate maintenance may damage the **Saver One D** or cause it to malfunction. Comply with what is described in this User Manual.
- Use non-rechargeable batteries SAV-C0903 and SAV-C0904 before the indicated expiry date.
- Recharge the rechargeable Li-ion battery model (SAV-C0011) at least once every 4 months to ensure its perfect

operation and extend its life.

- Rechargeable Li-ion batteries model (SAV-C0011) must only be charged using charger model CBACCS1 (SAV-C0012) by A.M.I. Italia S.r.l. otherwise the batteries may be damaged.
- Remove the batteries from the device only if it has been off for at least 5 seconds. Otherwise the device and the battery can be seriously damaged.
- **Saver One D**, its parts and accessories are non-sterile and non-sterilisable.
- Do not expose the **Saver One D**, its parts or accessories to direct light or high temperatures.
  - The Battery Charger CBACCS1 (SAV-C0012) must only be used with the Meanwell power supply model GS40A15-P1J SAV-C0013) supplied by A.M.I. Italia S.r.l. The use of different power supplies might undermine the correct operation of the battery charger and damage the rechargeable batteries model (SAV-C0011)
  - In order to protect the battery life (SAV-C0903 /SAV-C0904) and guarantee automatic daily tests, after installing it, it is advisable not to remove the battery from the device unless it is to be replaced.

  The removal of the battery from the device and its subsequent insertion, involves a complete self-test of the AED which implies non-negligible consumption of the battery itself. Furthermore, if the battery is not properly attached it could be damaged.
  - All products, product data and specifications are subject to modification to improve their reliability, functionality, design or other aspects.

2.3 WARNINGS FOR USE IN ECG MONITORING

- The monitoring mode based on the use of the screen, for the purpose of identifying an ECG rhythm, is an important aid for the specific use of the device itself, i.e. the detection of a shockable rhythm leading to the subsequent decision to release a therapeutic shock. The monitoring mode is intended for those environments or rescue conditions where experienced operators, or under specialized medical supervision, may have the benefit of evaluating patients with a high risk of a cardiac event that can be life threatening. By switching defibrillator operation from the analysis mode to the monitoring mode, the device continues to analyse the patient's ECG and, if a potentially shockable rhythm is detected, the operator can return to defibrillation mode and prepare to administer the shock. In any case, do not use the device in "ECG Monitoring" mode in environments such as operating rooms or intensive care units and consequently with medical equipment typical of such environments (such as an electrosurgical unit). Moreover, for the intended use, the device does not guarantee completely suitable display performance in patients with pacemakers.
- Use the device only with accessories (patient cables, electrodes, adhesive clips) supplied by AMI Italia following the instructions in this manual for their application.
- Take care not to let the conductive parts of the electrodes come into contact with other conductive parts, including the earth.
- As a precaution, if there is a defibrillator connected to the patient that may deliver a defibrillation shock, avoid touching the patient while undergoing ECG Monitoring and, to ensure the necessary protection, use only accessories (patient cables, electrodes, adhesive clips) supplied by AMI Italia and listed in this manual.
- In patients with pacemakers, the heart rate reading might count pacemaker pulses even in the event of cardiac arrest or some arrhythmias. In this case, do not rely completely on alarms related to the counting of beats. Continuously monitor patients with pacemakers and follow the instructions in this manual regarding the pacemaker pulse rejection capabilities of this device.
- In patients with pacemakers, the values displayed by the device may not be sufficiently accurate. In this case, these should not be used to draw medical conclusions.
- The device is able to recognise and manage T waves appropriately up to a maximum width of 1 mV.
- To monitor whether the electrodes have been applied to the patient, the device injects a sinusoidal current of Ipp = 0.5mA and f = 25.2 KHz.
- The frequency of the QRS complexes is calculated by making the arithmetic average over 3 consecutive intervals (4 QRS complexes) and the value shown on the display is updated every second.
- Delays in monitoring mode alarm condition determination are limited to within 5 seconds, except for LOW FREQUENCY and ASYSTOLE alarms where the alarm delay remains within 10 seconds. In this case, in lower limit conditions (30bpm), 2 seconds elapse between two consecutive beats, and since the QRS detection algorithm requires 4 complexes, the time required to detect an LF alarm condition is longer than 6 seconds. For the ASYSTOLE warning, having to exclude first that it is not an LF condition and then confirm that it is ASYSTOLE, the warning time is longer than the previous one by about 2 seconds (about 8 seconds).
- The device takes less than 3 seconds to switch from the indication of 80 bpm to 120 bpm and vice versa.
- The device takes less than 3 seconds to switch from the indication of 80 bpm to 40 bpm and vice versa.
- For the two waveforms of fast ventricular tachycardia: 195 bpm @ Vpp=2mV, 1mV, 4mV and 206 bpm@ Vpp=1mV, 0.5mV, 2mV, the device signals the alarm condition within 5 seconds.
- In the event of an alarm, the sound emitted is composed of at least 4 different frequencies so that it can be heard even by people who have partially impaired hearing. Icons and descriptions of the detected alarm status are shown on the display simultaneously.
- The device guarantees 35 hours of continuous monitoring with a new, fully charged battery.

2.4 INSTRUCTIONS FOR DISPOSAL 

- The Saver One D, its parts and accessories must not be disposed of with other household waste within the European community. To prevent possible harm to the environment or to persons' health caused by incorrect disposal of waste, recycle this product responsibly, also to promote a sustainable use of resources. In order to discard the used product, go to the appropriate waste collection centre or take it to the area distributor. The product can therefore be recycled safely for the environment.

3 DEVICE DESCRIPTION

3.1 DEVICE INFORMATION

The ***Saver One D*** is called **AED** or **A**utomatic **E**xternal **D**efibrillator equipped with TFT display and mini-LCD.
The device was designed to be used by lay personnel as well as by healthcare personnel who have duly attended and passed a BLSD course according to international guidelines AHA/ERC.
Designed to automatically detect and analyse the victim's heartbeat, it is able to deliver one or more defibrillation shocks if it detects a ventricular defibrillation or a ventricular tachycardia (monomorphic or polymorphic with >180 beats). The energy is supplied by a biphasic truncated exponential (BTE) electrical shock able to adapt to the patient's thoracic impedance.
The ***Saver One D*** is available in the following versions:

Saver One D 200J (**SVD-B0004**) – Maximum deliverable energy 200J Standard opt.
Saver One D 360J (**SVD-B0005**) – Max. deliverable energy 360J Standard opt.
Saver One D 200J (SVD-B0004-U) - Max. deliverable energy 200J Univer. Face To Face PADs opt.
Saver One D 360J (SVD-B0005-U) – Max. deliverable energy 360J Univer. Face To Face PADs opt.
Saver One D 200J (**SVD-B0004-Q**) – Maximum deliverable energy 200J Q-CPR opt.
Saver One D 360J (SVD-B0005-Q) – Maximum deliverable energy 360J Q-CPR opt.
Saver One D 200J (SVD-B0004-U-Q) – Max. deliverable energy 200J Univer. Face To Face PADs and Q-CPR opt.
Saver One D 360J (SVD-B0005-U-Q) – Max. deliverable energy 360J Univer. Face To Face PADs and Q-CPR opt.

It can be used with the following battery types:

- **SAV-C0903 - Non-rechargeable battery** - it requires no maintenance, is guaranteed to operate in standby mode for 4 years or carry out a high number of shocks
- **SAV-C0904 - Non-rechargeable battery** - it requires no maintenance, is guaranteed to operate in standby mode for 4 years or carry out a high number of shocks
- **SAV-C0011 - Rechargeable battery** - recommended for intensive defibrillator use

The device is equipped with a large 5.7-inch LCD **colour** display that shows all the information relating to the treatment and its functional status. Furthermore, the ***Saver One D*** has a mode that allows the patient's ECG monitoring to be performed using a special 2-pole ECG cable (SAV-C0017) with detection of 1 lead (II) or directly from the PADs.

The device allows the rescue data to be recorded on an SD Memory Card so that they can be displayed on a PC or printed directly on the Martel MCP7830 printer (*optional function*). During non-use, if the battery is installed, the device carries out daily self-tests to check its functional condition, in order to guarantee its prompt use when needed. On the keyboard of the device there is a mini-LCD display and a two-colour LED (red/green) to view the outcome of the functional tests and to know the functional status of the device even if switched off (stand-by mode).

3.2 CLASSIFICATIONS

The ***Saver One D*** defibrillator is classified as follows:

UMDNS code	11132
GMDN code	47910
CND code	Z12030501
RDM [(It.) Medical Device Register] number	238278 / 1535710
CIVAB [Biomedical Equipment Information and Assessment Centre] code	DEF01
Class in accordance with Directive **2007/47/EC**	IIb
Type of protection from electric shock	Powered Internally
Type of patient insulation	BF CF (only for ECG cable)
Protection rating against penetration by liquids	IPx4
Protection rating against penetration by dust	IP5x
Degree of safety in the presence of inflammable anaesthetic mixtures with air, oxygen or nitrous oxide	Not protected
Sterilisation or disinfection method suggested by the supplier	See Paragraph 11.3
Operation mode	Continuous operation

4 DESCRIPTION OF DEVICE DETAILS

4.1 GENERAL STRUCTURE OF THE DEVICE

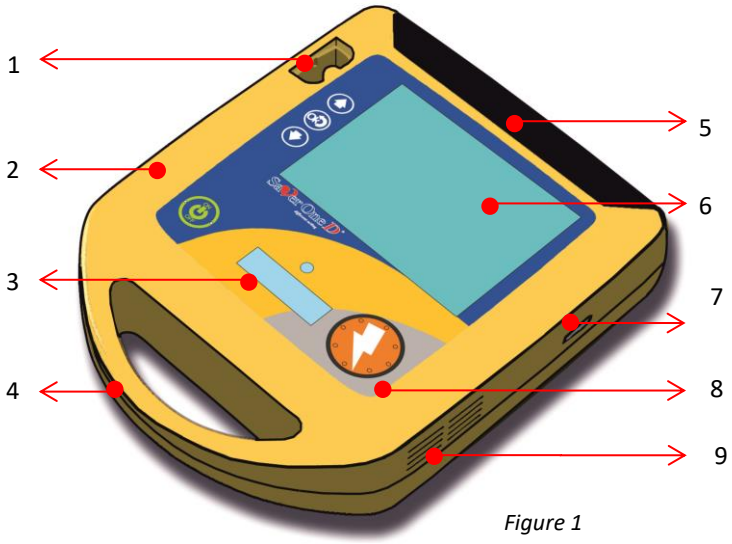


Figure 1

No.	Description
1	Compartment for PADS connector or ECG cable
2	Microphone for environmental recordings
3	Mini status display
4	Carry handle
5	Battery (removable)
6	TFT colour display
7	IrDA port (service only)
8	Keypad with buttons
9	Speaker

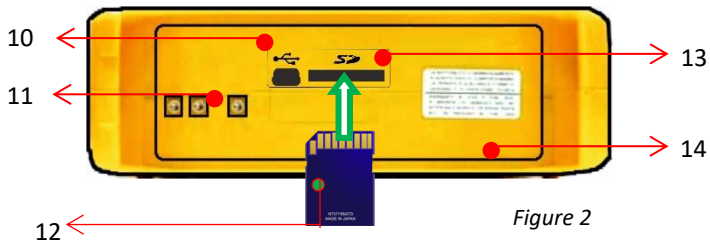


Figure 2

No.	Description
10	USB port
11	Battery contact tabs
12	SD Card port
13	SD Memory Card port
14	Gasket

4.2 KEYS, ICONS AND INDICATORS

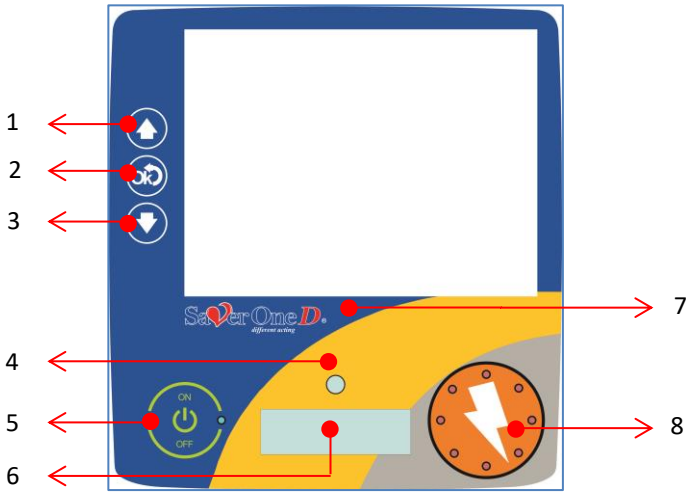


Figure 3

No.	Function	No.	Function
1	**UP navigation key** To scroll up the menu	**5**	**ON/OFF button** To switch the device on or off
2	**Navigation key ENTER** To enter the menu and confirm the selection made	**6**	**Mini status display** To check the functional status of the device
3	**DOWN navigation key** To scroll down the menu	**7**	**Product logo** Indicates the device model
4	**Control LEDs** LED (red/green) to check the functional status of the device	**8**	**Shock button** Fitted with LEDs to deliver a defibrillation shock if indicated

4.3 MINI STATUS DISPLAY

The mini display is designed to inform the user about the functional status of the device and its battery even when the device is switched off (stand-by mode).

No.	Description
1	Functional status of the device
2	Remaining battery level

4.4 TFT COLOUR DISPLAY

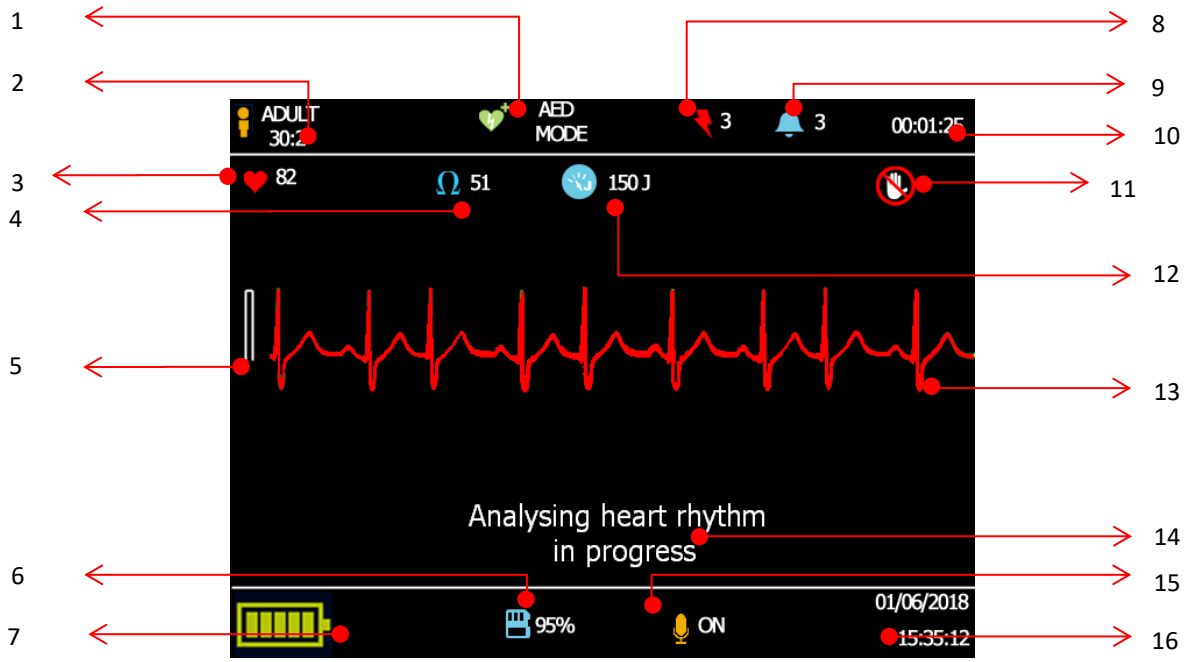
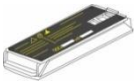
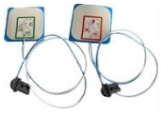


Figure 4

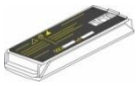
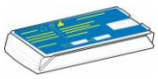
No.	Description			No.	Description
1	Indicates the OPERATIVE mode			9	Indicates the number of VFs and/or VTs detected by the device
	AED: Semi-automatic Defibrillation		**AED MODE**		
	MONITORING: ECG Monitoring		**ECG**		
2	Indicates the type of patient to be treated and Compression/Insufflation Ratio: **Adult 30:2** **Paediatric 30:2**			10	Indicates the duration of the rescue
3	Indicates the patient's heart rate			11	Indicates not to touch the patient in certain operations
4	Indicates the patient's measured thoracic impedance			12	Energy charged and subsequently delivered
5	Reference bar			13	ECG track of the patient
6	Indicates the residual space on the SD Card memory			14	Text prompt that instructs on the operation to be performed
7	Indicates the remaining battery level			15	Indicates whether the recording microphone is active
8	Indicates the number of shocks administered			16	Indicates current date and time

4.5 STANDARD AND OPTIONAL ACCESSORIES OF THE DEVICE

The ***Saver One D*** defibrillator comes with the following standard accessories:

Code	Image	Quantity	Description
SVD-B0004 **SVD-B0004-U** **SVD-B0004-Q** **SVD-B0004-U-Q**		**1 Unit** (Version 200J or 360J)	***Saver One D** 200J*
SVD-B0005 **SVD-B0005-U** **SVD-B0005-Q** **SVD-B0005-U-Q**			***Saver One D** 360J*
SAV-C0846		**1 Unit**	Pre-connected Adult PADs for standard models only **(without -U option)**
SAV-C0904		**1 Unit**	Non-rechargeable battery Li-MnO_2
SAV-C0916		**1 Unit**	Carry case
SAV-C1005-HU		**1 Unit**	User Guide
SAV-C0599		**1 Unit**	Pre-connected Universal Face to Face PADs (only for models **with -U option)**
SMT-C14034		**1 Unit**	Q-CPR sensor (only for models **with -Q option**)

The following are the optional ***Saver One D*** accessories that can be purchased separately:

Code	Image	Quantity	Description
SAV-C0903		**1 Unit**	Non-rechargeable battery Li-$SOCl_2$
SAV-C0011		**1 Unit**	Rechargeable Li ion battery
SAV-C0012		**1 Unit**	CBACCS1 Charger
SAV-C0013		**1 Unit**	GS40A15-P1J Power supply
SAV-C0014		**1Unit** *(Contains 3 items)*	01 CBACCS1 Charger 01 GS40A15-P1J Power supply 01 Power supply cable
SAV-C0016		**1 Unit**	Children PADs for standard models only **(without -U option)**
SAV-C0017		**1 Unit**	2-way ECG cable
SAV-C0019		**1 Unit**	CD-ROM Saver View Express
SAV-C0907		**1 Unit**	SD Card
SAV-C1070		**1 Unit**	Thermal printer MARTEL MCP7830
SAV-C0027		**1 Unit**	Memory Card reader for PC

5 PARTS AND ACCESSORIES OF THE *SAVER ONE D*

5.1 BATTERIES

The ***Saver One D*** defibrillator can work with the following different types of batteries:

- SAV-C0903 - Non-rechargeable battery
- SAV-C0904- Non-rechargeable battery
- SAV-C0011 - Rechargeable battery

For AED models Saver One D and Saver One P, considering the higher consumption due to the presence of the TFT display, AMI ITALIA recommends the use of the rechargeable battery SAV-C0011 (combined to the charging station SAV-C0014) rather than the disposable batteries SAV-C0903/SAV-C0904.

5.1.1 Non-rechargeable battery SAV-C0903 (Li-$SOCl_2$) and SAV-C0904 (Li-MnO_2)

The non-rechargeable batteries (SAV-C0903, based on Li-$SOCl_2$ technology, or SAV-C0904, based on Li-MnO_2 technology) are supplied fully charged and ready for use. They have been designed for long autonomy and require no maintenance.

Figure 5

Both ***Saver One D*** non-rechargeable battery types in standby mode have an estimated life of 4 (four) years assuming a battery activation test, daily self-tests and no AED power-up. Both are capable of a high number of discharges, which varies depending on the version of the device:

Saver One D *Standard 200J*	250 complete rescue cycles (shocks at 200J. and CPR)
Saver One D *Power 360J*	160 complete rescue cycles (shocks at 360J. and CPR)

If the remaining battery level is low, the ***Saver One*** informs the user via audio and visual messages.
The ***Saver One D*** will give a **low** battery warning when the level is ≤**5% (WARNING)** and a **very low** battery warning when the level is ≤ **1% (ALARM).**

WARNING: Remaining capacity level of Battery equal or less than **5%**.
This notice will only be provided in Operating mode as indicated in paragraph 7.1.
With a 5% battery the ***Saver One D*** makes it possible to administer about **14 shocks** or **40 days of stand-by**

ALARM: Remaining capacity level of Battery equal or less than **1%**.
This warning will be issued both in Stand-by and in operating mode, as indicated in paragraph 7.1.
With a battery at ≤ **1%** the ***Saver One*** carries out about **7 shocks** or **20 days of stand-by**
In this condition it is not recommended to use the device: replace the battery.

!!ATTENTION!!
In order to protect the battery life (*SAV-C0903 /SAV-C0904*) and guarantee automatic daily tests, after installing it, it is advisable not to remove the battery from the device unless it is to be replaced.
The removal of the battery from the device and its subsequent insertion, involves a complete self-test of the AED which implies a non-negligible consumption of the battery capacity.
Furthermore, if the battery is not properly attached it could be damaged.

5.1.2 Rechargeable SAV-C0011 battery (Li ion)

The rechargeable battery with Li-ion technology (SAV-C0011) of the ***Saver One D*** is suitable for intensive defibrillator use. Being rechargeable, it allows operators to reduce management costs and guarantee a greater number of interventions.

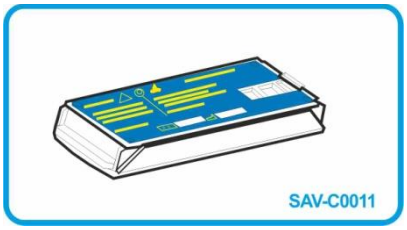


Figure 6

The rechargeable battery of the ***Saver One*** can be recharged using only the dedicated charger (SAV-C0012) with relative accessories supplied by A.M.I. Italia S.r.l. The battery allows you to carry out a high number of shocks which varies according to the version of the Saver One in your possession:

Saver One D *Standard 200J*	typically 200 continuous shocks
Saver One D *Power 360J*	typically 110 continuous shocks

If the remaining battery level is low, the ***Saver One D*** informs the user via audio and visual messages.
The ***Saver One D*** will give a **low** battery warning when the level is ≤**5% (WARNING)** and a **very low** battery warning when the level is ≤ **1% (ALARM)**

WARNING: Residual battery level equal to or lower than **5%**.
This notice will only be provided in Operating mode as indicated in paragraph 7.1.
With a 5% battery the ***Saver One D*** makes it possible to administer about **14 shocks** or **40 days of stand-by**

ALARM: Residual battery level equal to or lower than **1%**
This warning will be issued both in stand-by and in operating mode, as indicated in paragraph 7.1.
With a **1%** battery the ***Saver One D*** makes it possible to administer about **7 shocks/20 days of stand-by.** In this condition it is not recommended to use the device: replace the battery.

It is advisable to replace these batteries every 2 years or after having made a number of recharges greater than **300** (the event that occurs first).

5.1.3 Recommendations for proper maintenance of battery SAV-C0011

A.M.I Italia recommends that SAV-C0011 batteries left in a “storage stage” be fully recharged at least every 4 months from the receipt of the goods and recharged regularly every 4 months when attached to the "ready to use" device, to prevent them from being completely depleted and to maintain maximum battery life. The battery pack technology and the modules offered are designed to ensure a long service life but they require proper maintenance; failure to comply with these requirements will result in early deterioration of the battery, which will not be covered by warranty.

For warranty replacement consideration, batteries are to be returned to the original distributor/dealer.

5.1.4 Insertion and removal of the batteries

To be able to operate, a battery must be inserted in the ***Saver One D***. Below are detailed instructions for correctly installing the batteries (rechargeable or non-rechargeable) in the ***Saver One D***.

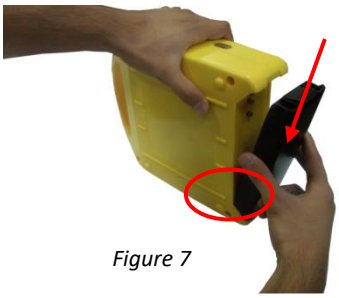


Figure 7

Figure 8

- Place the device on the side as shown in the figure (7)
- Hold the device firmly with your left hand as shown in figure (7)
- Insert the battery as shown in figure (7) following the direction of the arrow and matching it perfectly with the point highlighted by the circle
- Push the battery as shown in figure (8) following the direction of the arrow, until you hear it click, which means it has been properly inserted

Follow the instructions below to **remove** the battery from the device:

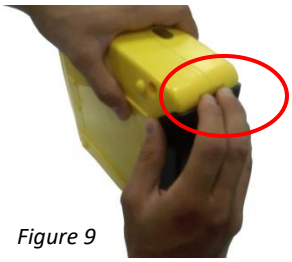


Figure 9

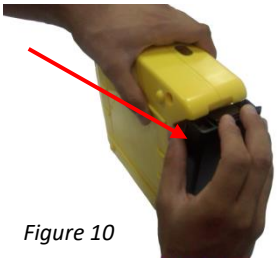


Figure 10

- Position the device as shown in figure (9)
- Hold the device firmly with your left hand as shown in figure (9)
- Using two fingers of the right hand press on the battery hook highlighted by the circle in figure (9)
- At the same time pull the battery in the direction indicated by the arrow shown in figure (10)

5.2 RECHARGING STATION FOR RECHARGEABLE BATTERIES

The charging station (SAV-C0014) recharges rechargeable batteries with Li-ion technology model (SAV-C0011) of the ***Saver One D***. The charging station consists of the following parts:

- Charger (SAV-C0012) figure (11)
- AC/DC power supply unit/adapter model GS40A15-P1J (SAV-C0013) figure (12)
- Power cable with three-pole Italian plug (SAV-C0366) figure (13)

Figure 11

Figure 12

Figure 13

5.2.1 Structure of the battery charger

Figure 14

No.	Description	Function
1	Charger LED	Indicates the battery charge level or the functional status of battery charger
2	Power supply	Input for 12V, 5A power supply connector
3	Battery contacts	Contacts for energy exchange between charger and batt ery

The Battery charger (SAV-C0012) must only be used with the AC/DC power supply unit/adapter supplied by A.M.I. Italia S.r.l. model GS40A15-P1J from Meanwell (SAV-C0013).
The battery charger (SAV-C0012) and the related power supply unit (SAV-C0013) are not certified under supervision of the IMQ notified body, therefore they do not fall under EC certificate no.1104/MDD. Furthermore, these devices do not have the IMQ mark, therefore they are not indicated in the IMQ certificate no. CA10.00185.

5.2.2 Recharge procedure

A Place the charger on a perfectly horizontal surface that is firmly supported by the floor
B Connect the power supply unit (SAV-C0013) to the charger and then to the power outlet
C The LED on the charger will flash green, indicating that it is ready to charge
D Insert the battery to be charged into the battery charger as shown in figure (15)

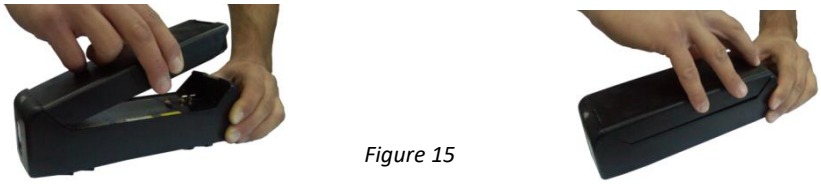


Figure 15

The recharging station recharges exclusively original rechargeable Li ion batteries (SAV-C0011) of A.M.I. Italia S.r.l.. The charging time of around 2.5 hours may increase in the case of batteries that have undergone recharging cycles higher than indicated. The CBACCS1 battery charger is equipped with a control LED that indicates both its functional status and the battery charge level, if inserted. The following table identifies the control LED indications:

INDICATOR	**RED**		**GREEN**	
STEADY	Battery not working		Battery charge completed	
FLASHING	**Battery inserted**	Faulty battery charger	**Battery inserted**	Battery charging
	Battery not inserted		**Battery not inserted**	Battery charger waiting for battery insertion

While recharging, the battery charger control LED will flash green with a different frequency depending on the recharge level, until fully charged, indicated by the control LED with STEADY green light.

Charge level	**0%**	**25%**	**50%**	**75%**	**100%**
Number of consecutive flashes	**1**	**2**	**3**	**4**	**Steady**

5.3 DEFIBRILLATION PADS

The ***Saver One D*** allows the following defibrillation PADs to be used, depending on the patient to be treated and the device model:

- **Adult** defibrillation PADs model SAV-C0846 (only for models **SVD-B0004 and SVD-B0005**)
- **Child** defibrillation PADs model SAV-C0016 (only for models **SVD-B0004 and SVD-B0005**)
- Universal Face to Face defibrillation PADs **for adult/pediatric (age >1 year)** model SAV-C0599 (only for models with patient selection **SVD-B0004 -U, SVD-B0004 -U-Q, SVD-B0005-U, SVD-B0005-U-Q**)

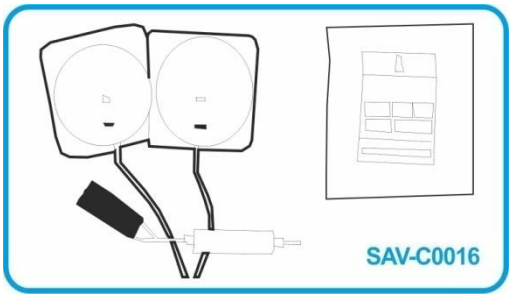
5.3.1 Adult defibrillation PADs *SAV-C0846*

The SAV-C0846 defibrillation PADs are pre-gelled and disposable.
They must be used on adult patients **(age> 8 years or weight> 25Kg).** The defibrillation PADs are supplied in a single sealed package showing the expiry date (typically 30 months). On the expiry date, the PADs must be replaced even if not used.
The **SAV-C0846** PADs are characterized by the cable and the PAD connector outside **the sealed package**. This solution has been adopted in order to further speed up the placement of the PADs avoiding the need to insert the connector during the rescue.

For more information on placing the defibrillation PADs, refer to the relevant paragraph

5.3.2 PADs for Children *SAV-C0016*

The SAV-C0016 defibrillation PADs are pre-gelled and disposable.
They must only be used on paediatric patients **(age <8 years or weight <25Kg)**. The defibrillation PADs are supplied in a single sealed package showing the expiry date (typically 30 months). On the expiry date the PADs must be replaced even if not used.
The cable, connector and PAD adapter are **inside the sealed package**.



The SAV-C0016 PADs make it possible to deliver shocks on paediatric patients with a maximum energy level of 50J as prescribed by the international guidelines.
For more information on placing the defibrillation PADs, refer to the relevant paragraph

5.3.3 Face-to-Face *SAV-C0599* universal defibrillation pads

Face-to-Face universal defibrillation PADs are pre-gelled and disposable.
They must be used in adult/paediatric patients **(age >1 year)**. The defibrillation PADs are supplied in a single sealed package showing the expiry date (typically 24 months). On the expiry date, the
PADs must be replaced even if not used.
The **SAV-C0599** PADs are characterized by the cable and the PAD connector outside **the sealed package**. This solution has been adopted in order to further speed up the placement of the PADs avoiding the need to insert the connector during the rescue.
When the connector is inserted into the appropriate compartment, at each self-test the defibrillator, if compatible with them (see paragraph 5.2), will check the status of the SAV-C0599 PADs and a warning will be given on the expiry date (see paragraph 7.1).
NOTE: For SAV-C0599 pads, after the expiry date shown on the packaging, it is recommended to replace them, regardless of the warning issued by the connected defibrillator.

For more information on placing the defibrillation PADs, refer to the relevant paragraph.

5.3.4 Universal Face-to-Face SAV-C0599 Defibrillation PADs Management

The SAV-C0599 defibrillation PADs are managed by the models that provide for patient selection (see paragraph 6.1) with the aid of the display: after the device is switched on, the display immediately shows the screen in which the operator is asked to select adult or paediatric patient, using the menu navigation keys, which are designated separately for the two types of patients for greater safety. Once the desired choice has been made, press the button to confirm the selection.

- ARROW UP → ADULT
- ARROW DOWN → CHILD

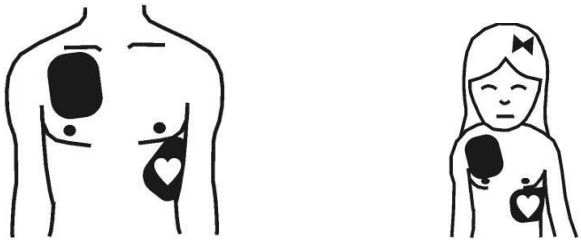
With the SAV-C0599 Universal PADs, the following discharges can be delivered after patient selection:

- Adults: energy up to 200J (SVD-B0004-U, SVD-B0004-U-Q), up to 360J (SVD-B0005-U, SVD-B0005-U-Q)
- Children: maximum energy of 50J (on all compatible models see section 5.3).

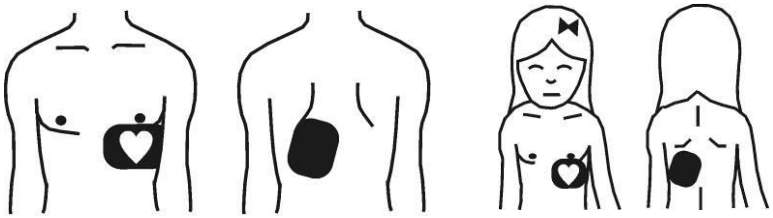
5.3.5 Placement of the defibrillation pads

The correct placement of the PADs is essential for an efficient analysis of the patient's heart rhythm and for the consequent delivery of the shock (if necessary).
For the placement and polarity of the electrodes of each type of pad, always refer to the instructions on the packaging and in the instruction manual of the PADs.

- Emergency defibrillation
- Cardioversion
- Stimulation
- Monitoring (provides a Lead II track)



- Emergency defibrillation
- Cardioversion
- Stimulation
- Monitoring



5.4 Q-CPR SENSOR

The Saver One D (Ref: **SVD-B0004-Q, SVD-B0004-U-Q, SVD-B0005-Q, SVD-B0005-U-Q**) makes it possible to provide feedback on proper execution of cardiac massage thanks to the proprietary AMI Italia external accessory module (figure 17) to perform CPR Quality (Q-CPR) to be interposed between the rescuer's hands and the patient's chest.

This external module is able to monitor the quality of the CPR being performed, measuring its depth and frequency, and to provide this information via Bluetooth to the defibrillator, which will then indicate to the rescuer whether or not the massage performed meets the indications of the international AHA/ERC resuscitation guidelines, by means of a graphic bar shown on the display (as reference for the depth of the compressions) and by an acoustic signal (as reference for the rhythm of the compressions).

For the external accessory module for Q-CPR (Ref. SMT-C14034), in conjunction with compatible defibrillator models, please refer to the appropriate manual.

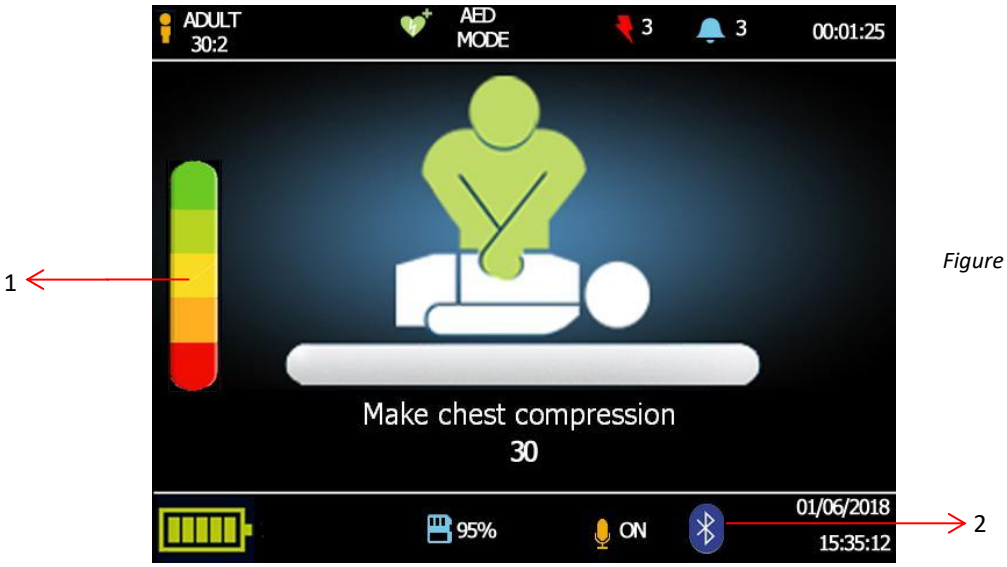


Figure 16

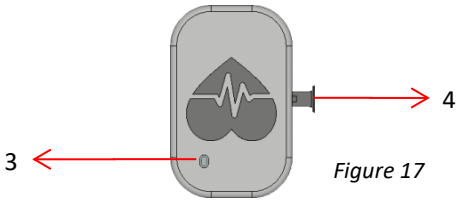


Figure 17

No.	Image	Function
1	CPR Quality Bar	Displays depth of cardiac massage: red insufficient or excessive depth, orange and yellow intermediate levels, green adequate depth
2	Blue-Tooth Icon	Indicates that the external Q-CPR module is connected to the defibrillator
3	LED (on external Q-CPR module)	LED flashing: indicates that the Q-CPR module is on but not connected to the defibrillator. LED steady on: indicates that the Q-CPR module is connected to the defibrillator.
4	Power on lever (on external Q-CPR module)	Power on lever on the Q-CPR module: by pushing this lever in, the module turns on; by pulling the lever out, the module turns off (in this case, make sure that the LED (3) is off).

5.5 2-POLE ECG CABLE SAV-C0017

The SAV-C0017 ECG cable is fitted with two clip terminals for disposable pre-gelled electrodes (*optional*).
The ECG cable can read the patient's lead II to show the ECG trace on the ***Saver One D display.*** The SAV-C0017 ECG cable can only be used if the ***Saver One D is set*** in "ECG MONITORING" operating mode (see Chapter 9).
The ECG SAV-C0017 cable is classified as type CF

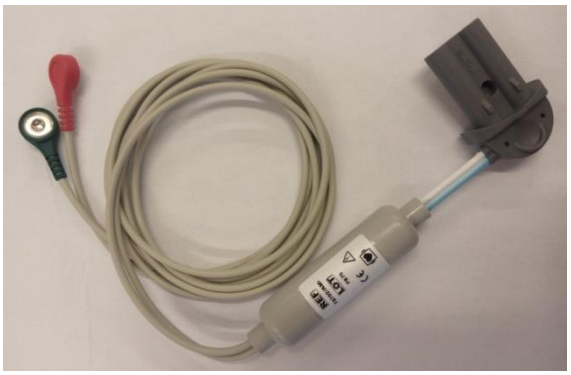
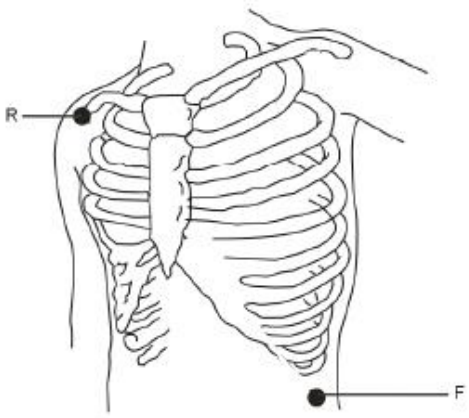


Figure 18

5.5.1 Placement of the electrodes

The SAV-C0017 ECG cable electrodes must be placed as shown in figure (17):



International coding (European IEC/EN)	
Code (IEC/EN)	Colour (IEC/EN)
R	**RED**
F	**GREEN**

Figure 19

Electrode R: near the right shoulder, directly below the clavicle.
Electrode F: on the left side of the hypogastrium.

5.6 MEMORY CARD

The ***Saver One D*** can record data on the external **memory card** as well as on the **internal memory**.
Supported memory cards are ***SD/SDHC*** cards with capacities up to 8GB

Figure 20

To install a Memory Card in the ***Saver One D*** follow this procedure:

- **A.** The Memory Card must be inserted before attaching the battery
- **B.** Place the device on a firm, stable horizontal surface as shown in the figure

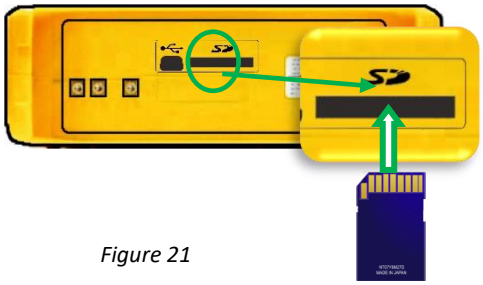


Figure 21

- **C.** Insert the Memory Card with the contacts facing upwards as shown in the figure and push it until it is completely inserted

The data recorded directly on the internal memory of the Saver ONE can be downloaded via the **USB port** on the back of the device (*figure 21*).
The USB cable to be used must be a **mini USB 2.0** (USB/Mini USB connection)

Figure 22

To connect the mini-USB cable to the ***Saver One D*** follow this procedure:

- **A.** Detach the battery and insert the Mini USB terminal of the cable in the appropriate compartment on the Saver ONE
- **B.** Connect the USB terminal of the cable to a Personal Computer
- **C.** Use the PC Saver View Express software

!!ATTENTION!!
The USB is a service port used for device configuration purposes (for the exclusive use of personnel authorized by AMI) or for downloading recorded data stored internally.
The functions related to the USB port are enabled and accessible only when the device is turned off.

5.7 MARTEL MCP7830 THERMAL PRINTER (*SAV-C1070*)

The ***Saver One D*** defibrillator can print the ECG trace and patient data using the external thermal printer model ***Martel MCP7830*** (SAV-C1070).
The communication between printer and defibrillator is wireless thanks to the IrDA port of the ***Saver One D*** (located on the left side of the defibrillator) and that of the printer.
The ***Martel MCP7830*** printer is supplied with the following accessories:

- Rechargeable NiMH battery
- AC/DC battery charger
- PC interface cable
- Thermal paper roll (57mm, 30Ø)

All information on the thermal printer can be found in the specific user manual of Martel MCP7830.

Before using the printer, carefully read the user manual attached to it; pay particular attention to the Precautions and Warnings section.

To print the events, a memory card must be installed in the ***Saver One D***. Otherwise the defibrillator will not enable printing

5.7.1 Printer structure

Figure 23

No.	Description
1	Compartment for thermal paper roll
2	Power button
3	IrDA Port
4	Power LED - Communication LED - Error LED
	PC communication port (bottom side)
	DC connector (bottom side)

6 SAVER ONE D SELECTION MENU

The ***Saver One D*** menu allows you to make multiple selections and settings and to view useful information about the device and the rescue. All the settings that can be selected to use the device to its full potential will be described in detail in the next paragraphs.

6.1 MAIN MENU

Press the ON/OFF button to turn on the device
When the device is turned on, the model name and operating status of the device will be shown on the display:

Figure 24

Figure 25

After that, for models with universal pads only (-U option), the following image will appear:

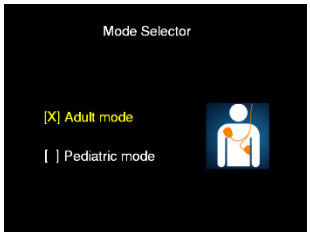
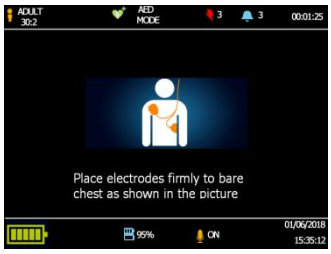


Figure 26

Figure 27

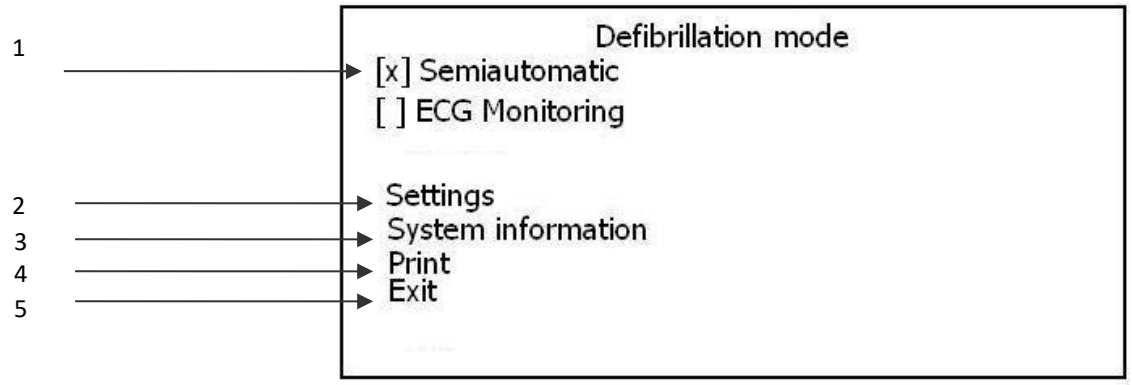
from which the operator will have to select the "patient mode" between adult or paediatric by means of the "UP" and "DOWN" arrows on the keypad and confirm the choice by pressing the "ENTER" button (figure 27).

At this point, in all models, the device will show the following:



To access the settings menu, press the ENTER key as shown in figure (29).

After pressing the ENTER key, the following screen will be shown on the ***Saver One D*** display:

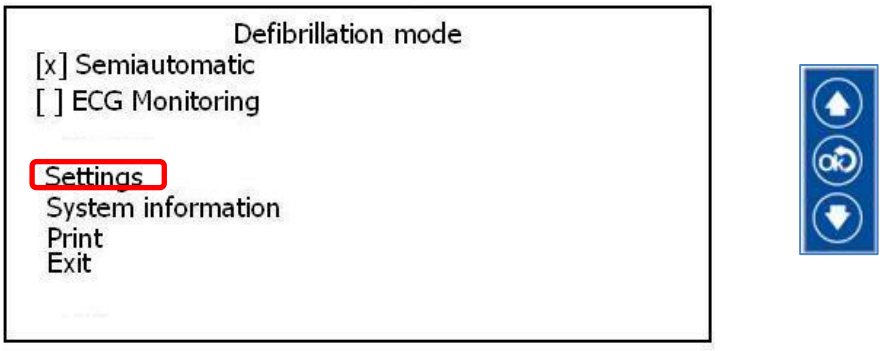


Below is a description of the messages that appear on the display:

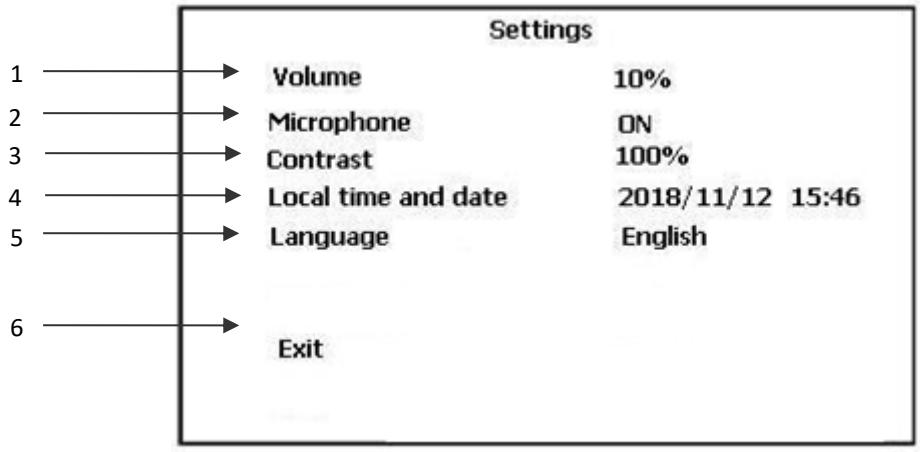
No.	Image	Function
1	[x] Semiautomatic [ ] ECG Monitoring	To select the desired operating mode.
2	**Settings**	To access the settings submenu
3	**System information**	To access the device information submenu
4	**Print**	To access the print submenu *(only if using Martel MCP7830 printer)*
5	**Exit**	To go back to the main screen

6.2 SETTINGS MENU

Enter the *MAIN* menu and using the navigation keys on the defibrillator keypad, select the *SETTINGS* item and press the enter key.



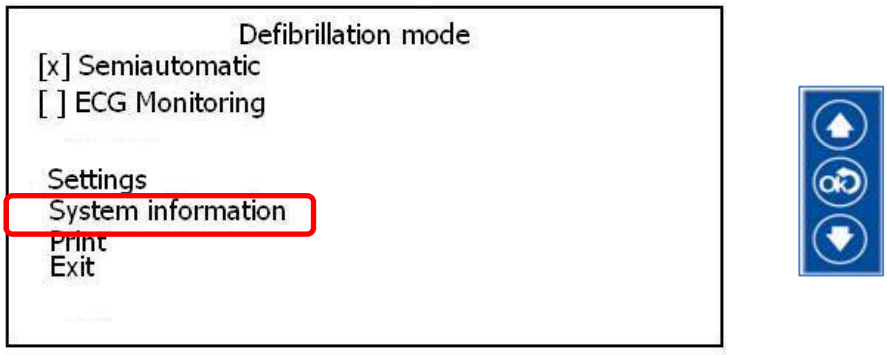
After pressing the ENTER key, the following screen will be shown on the ***Saver One D*** display:



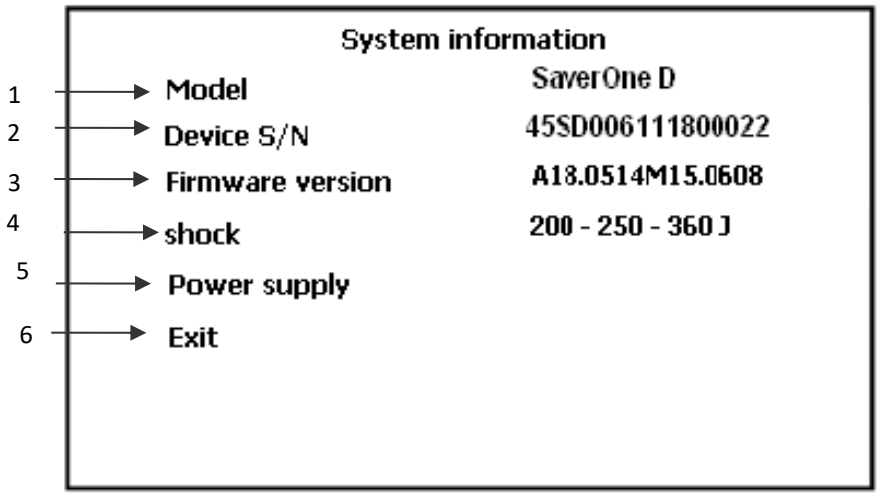
No.	Image	Function	Possible variations
1	Volume	To increase or decrease the sound level (voice + acoustic signals)	**10% - 100%**
2	Microphone	To enable or disable the microphone for recording environmental events on the Memory Card	**ON - OFF**
3	Contrast	To change the contrast level of the display	**0% - 100%**
4	Local time and date	To change the local date and time	**dd/m/year - hh:mm**
5	Language	To change the language selected for voice and text prompts (*default 1 language, up to 5 selectable languages on request*)	**English**
6	Exit	To exit the Settings menu and return to the main operating screen	

6.3 SYSTEM INFORMATION MENU

Enter the *MAIN* menu and use the navigation keys on the defibrillator keyboard to select the *SYSTEM INFORMATION* item and press the ENTER key.



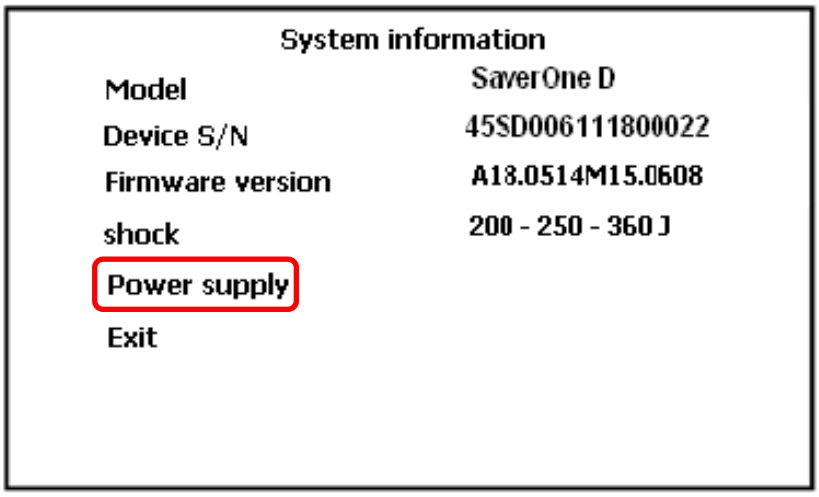
After pressing the ENTER key, the following screen will be shown on the ***Saver One D*** display:



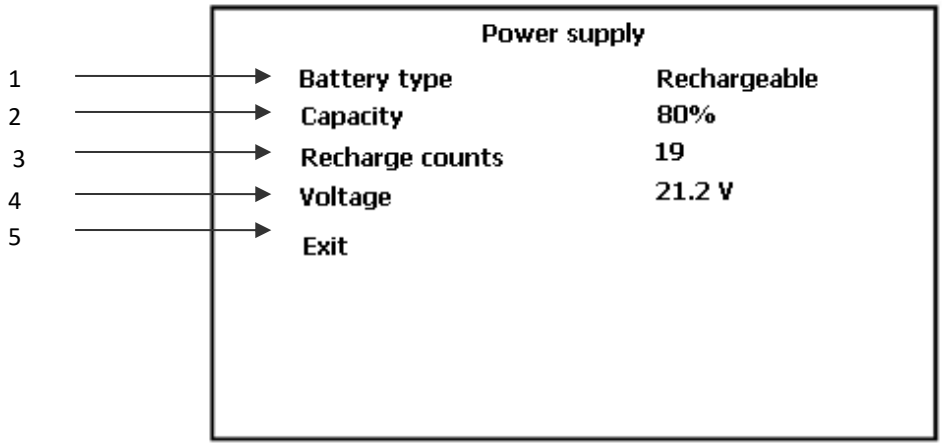
No.	Image	Function	Possible variations
1	Model	Indicates the device model	**Saver One D**
2	Device Serial No.	Reference number for service	
3	Firmware version	Indicates the software version installed on the device	**Axx.xxxxMxx.xxxx**
4	Shock	Indicates the shock protocol used	
5	Power supply	To access to the power supply sub-menu	
6	Esc	To exit the Settings menu and return to the main operating screen	

6.3.1 Power supply Sub menu

Enter the *SYSTEM INFORMATION* menu and use the navigation keys on the defibrillator keypad to select the item *POWER SUPPLY* and press the ENTER key.



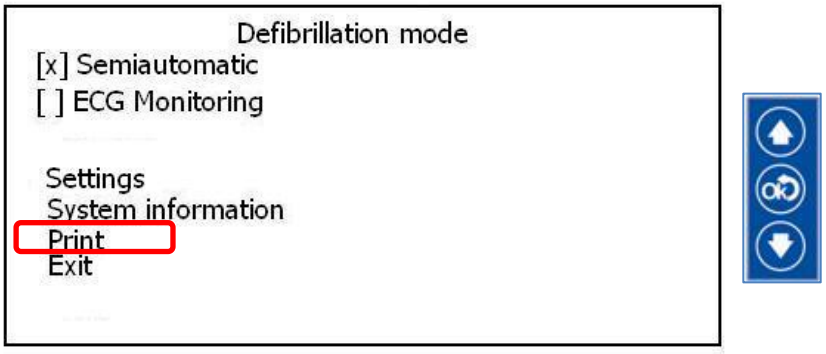
After pressing the ENTER key the following screen will appear on the display:



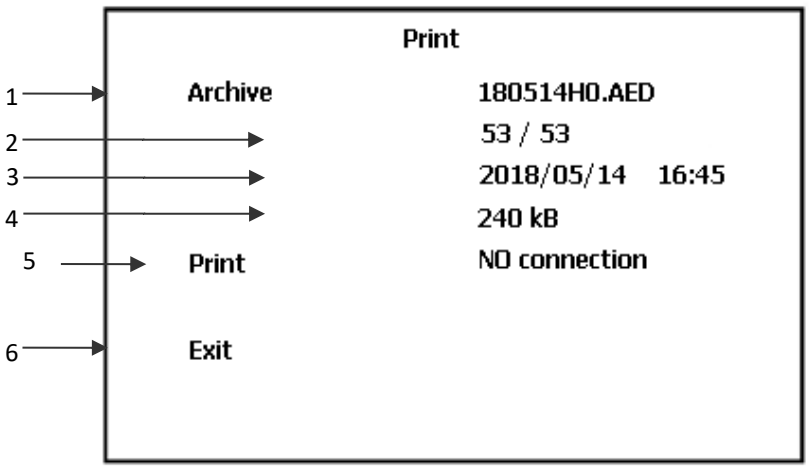
No.	Image	Function	Possible variations
1	Type	Indicates the type of battery installed	Non-rechargeable / Rechargeable
2	Capacity	Indicates the remaining battery capacity	**0 – 100%**
3	No. of recharges	Indicates how many times the rechargeable battery has been recharged ***Note: This item is only displayed when the rechargeable battery is inserted***	**0 - XX**
4	Voltage	Indicates battery voltage	**xx.xV**
5	Output	To exit the Settings menu and return to the main operating screen	

6.4 PRINT MENU

Enter the *MAIN* menu and use the navigation keys on the defibrillator keypad to select the *PRINT* item and press the ENTER key.



After pressing the ENTER key the following screen will appear on the display:



No.	Image	Function	Possible variations
1	Archive	To select rescue events recorded on memory card	**YYMMDDxx.AED**
2	1/3	Indicates the selected rescue and the total amount of recorded rescues	**1/X**
3	2020/02/14 13:23	Indicates the date and time of the selected rescue	**dd/m/year - hh:mm**
4	41 kB	Indicates the size of the file	**XX KB**
5	Print	Indicates whether the external printer is connected or not	**Ready** **No connection**
6	Output	To exit the Settings menu and return to the main operating screen	

7 SELF-TEST

The ***Saver One D*** has been designed to be a totally safe device, always ready for use and able to automatically and constantly check correct operation, reducing maintenance operations to the minimum.

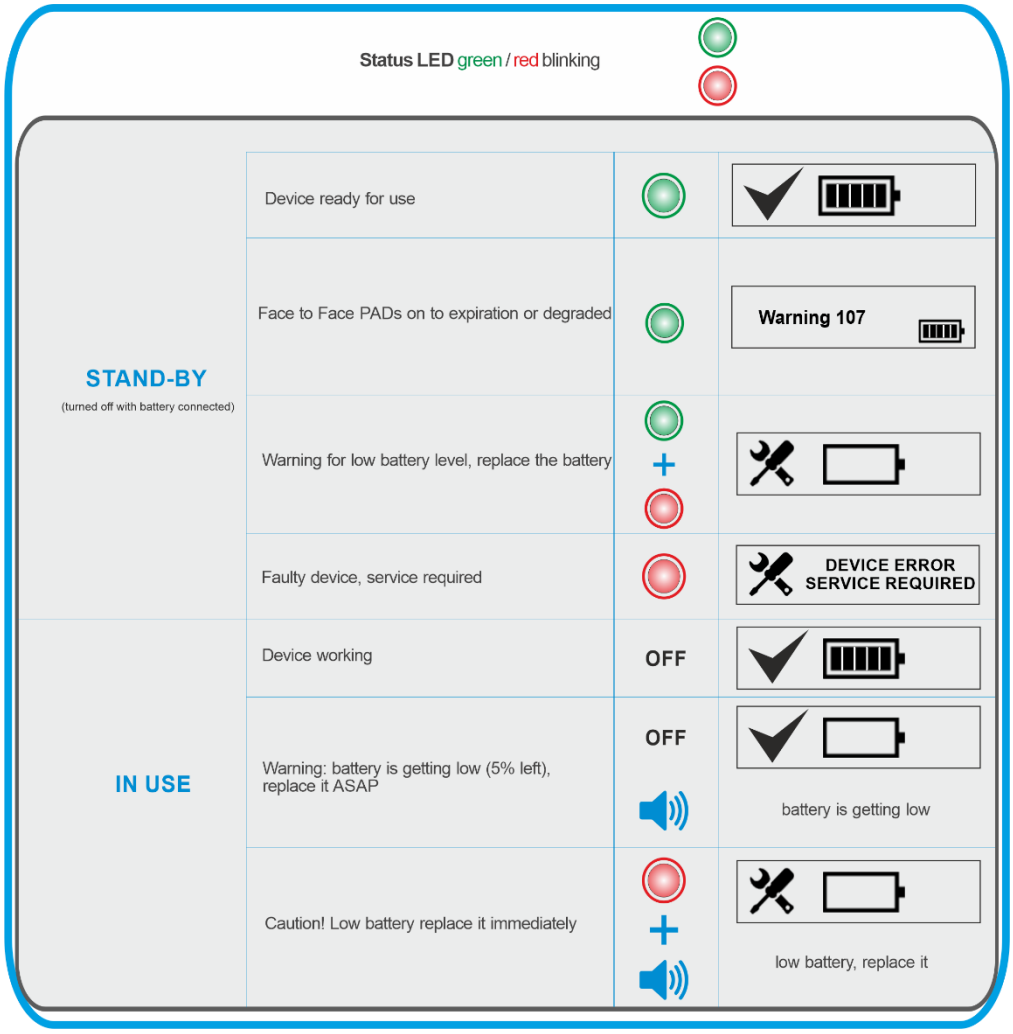
The ***Saver One D*** performs different types of self-tests:

- ***Activation*** **:** Every time a battery is inserted in the device
- ***Automatically*** **:** During Stand-by mode with daily/monthly/half-yearly intervals
- ***Switch-on*** **:** When the device is switched on

The outcome of the test can be viewed via a two-colour LED (green/red) and the LCD mini-display.
The mini-display and the control LED let you know at any time, even when the device is switched off (stand-by mode), the functional status of the device and its battery.

7.1 LED AND MINI STATUS DISPLAY

Both the mini display and the control LED are located on the front of the Saver One D keypad.
Based on the different colour of the control LED and the information shown on the display, the operator can independently determine the functional status of the defibrillator and its battery.
The following table shows the flashing code of the control LED and the related screens of the mini status display.

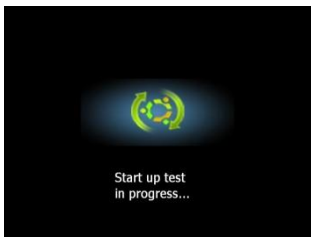


7.2 ACTIVATION TEST

The Saver One D performs functional tests only if the battery is installed.
Each time a battery is inserted, the device will perform a diagnostic ACTIVATION test.
During this test the device performs a complete check (firmware/hardware), which involves battery use equal to a shock; therefore it is advisable, once performed, not to remove the battery from the device.
The ACTIVATION test requires action by the operator, who must perform the following operations:

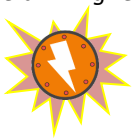
- **Insert the battery in the device**

If the battery is correctly inserted, the ***Saver One D*** will automatically turn on emitting an acoustic signal and the power button will light up green while the control LED will turn off.



The following screens will appear on the colour TFT display:
The device will issue a voice prompt (audio): *"Device test"*
"Push the blinking red button"

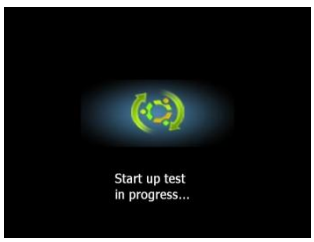
The shock button will start blinking.

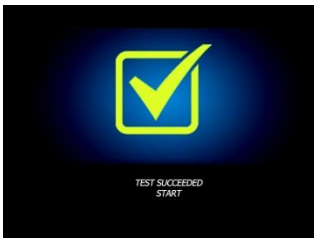


The operator will have a maximum of 60 seconds* to push the shock button.

- **Push the shock button to launch the ACTIVATION test**

If the shock button is pressed correctly, it will stop blinking and the device will start the activation test.
The following screens will appear on the colour TFT display:





- **Switch off the device**

If it does not need to be used immediately, switch off the ***Saver One D*** and leave the battery inserted to ensure periodic self-testing (see Paragraph 7.3)

* *If the shock button is not pressed within the time limit indicated by the countdown, the **Saver One D** detects an error.*
Switch the device back on and press the shock button within the time limit indicated by the countdown.
If, on the other hand, the shock button has been pressed but the shock button continues blinking it means that the shock button does not work properly. Turn off the device and perform the operation again; if the problem persists, contact the authorized technical support centre.

7.3 AUTOMATIC TEST

The ***Saver One D*** has been designed to always be ready at the time of real need.
The device has a mode, called stand-by, in which when the device is switched off (with battery installed) it performs diagnostic tests **automatically** on a daily basis.
The automatic self-test does not require any manual operation by the operator and takes a few seconds.
The ***Saver One D*** will inform the operator of the start of the automatic self-test through the mini status Display:

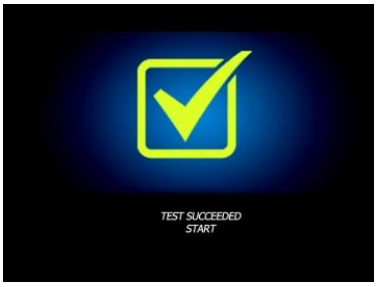
During self-test 

After self-test (battery level) 

The automatic self-test involves a certain battery use.
Since a daily test with complete analysis would lead to excessive battery consumption, three levels of automatic tests have been set: **basic** (daily), **in-depth** (monthly), **complete** (half-yearly).
The result of the automatic self-test can be verified with the LED and the mini-control display located on the device keypad.
Refer to the tables for LED and status mini- display shown in paragraph 7.1.

7.4 ON TEST

The ***Saver One D*** performs self-diagnostic tests each time it is turned on.
This test is performed in order to check the proper operation of the device before use.
The test is conducted automatically and lasts a few seconds.
After pressing the power button, the ***Saver One D*** will emit an acoustic  signal to confirm power-up, the control LED will be off and the following screen appears on the colour display:



The device is now ready for use and will provide the operator with the first instructions to start the intervention.

If it does not need to be used immediately, switch off the ***Saver One D*** and leave the battery inserted to ensure periodic self-testing.

8 DEFIBRILLATION

If it is necessary to rescue a person suffering from Sudden Cardiac Arrest, please remember to follow the sequence of actions recommended by the international guidelines AHA/ERC.
These establish a rescue protocol to be respected during resuscitation of a person suffering from sudden cardiac arrest. This protocol has been called the "chain of life".

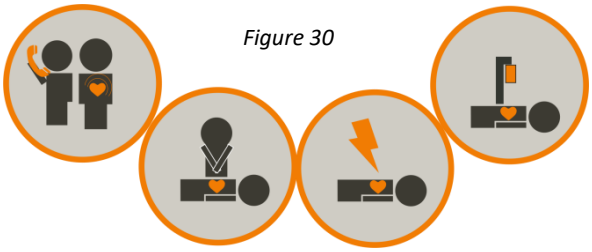


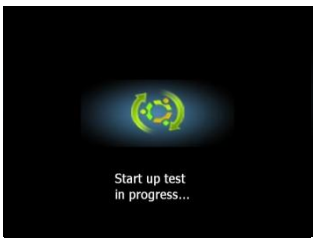
Figure 30

1. Make sure the person is in need of rescue *(is unconscious, not breathing, has no heartbeat)* and call the emergency number immediately.
2. While waiting for a defibrillator to be available, begin CPR manoeuvres immediately
3. Use the ***Saver One D*** defibrillator to restore normal heart rhythm
4. Continue until resuscitation under medical responsibility

8.1 SWITCHING ON THE *SAVER ONE D*

The ***Saver One D*** defibrillator will automatically start the semi-automatic defibrillation mode every time it is turned on (default setting). The procedures to follow to use the device in this mode are set out below.

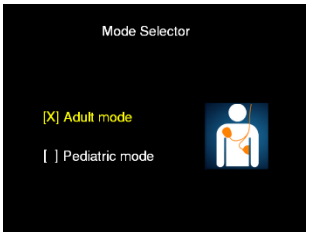
Push the device's on button 
The ***Saver One D*** will emit an acoustic signal to confirm switching on; the ON/OFF button will be lit steady green. The following screens will be shown in sequence on the colour display:



If the test is successful, the device will continue to the next steps.

8.2 ADULT AND PAEDIATRIC MODE

For models using universal defibrillation pads SAV-C0599 only (Ref. **SVD-B0004-U, SVD-B0004-U-Q, SVD-B0005-U, SVD-B0005-U-Q),** a screen will appear in which the operator will be asked to select the "patient mode" between adult and paediatric using the "UP" and "DOWN" arrows on the keypad. To confirm your selection, press the "ENTER" button.



8.3 REMOVE CLOTHES

If the initial test is successful, and after patient selection (in models with -U option) the device will suggest the first sequence of operations to be performed by means of voice (audio) and visual (colour display) prompts, as shown in the following table:

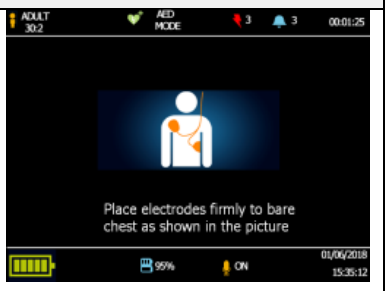
Voice prompts	Text
Place the emergency call	Call the emergency number.
Keep calm and follow the voice instructions	Keep calm and follow the voice instructions

The ***Saver One D*** advises the operator on how to ascertain the patient's condition, before correctly placing the defibrillation PADs on the patient. This information is highlighted through voice prompts (audio messages) and visual prompts (colour display), as shown in the table below:

Voice prompts	Text
If the patient is unconscious and does not breathe, remove their clothes to apply the electrodes on their bare chest.	Remove Patient's clothing

8.4 PLACEMENT OF THE DEFIBRILLATION PADS

At this point, for all models, the device will advise the operator on how to correctly place the defibrillation PADs on the patient. This information is provided through voice prompts (audio messages) and visual prompts (colour display), as shown in the table below:

Voice prompts	Text	...Display
Place the electrodes firmly on bare chest as shown in the picture	Place the electrodes on the patient's chest	

Refer to paragraph 5.3 for more information on defibrillation PADs and their application.

8.5 HEARTBEAT ANALYSIS

If the defibrillation PADs have been correctly applied and the connector is inserted in the appropriate compartment, the ***Saver One D*** automatically analyses the heart rhythm of the patient. This information is highlighted by voice (audio) and visual (colour display) prompts, as shown in the following table:

Voice prompts	Text	Video Display
Do not touch the patient.	Heartbeat analysis … in progress ..	
Heartbeat analysis		

During the heartbeat analysis, the patient's body must not be touched and it must not be subject to vibrations or movements. The **Saver One D** analysis software was designed to recommend defibrillation shock treatment only if the patient is suffering from the following arrhythmias:

VF Ventricular Fibrillation

Peak-to-peak amplitude of min. 200 µVolts

Some rhythms with very low amplitude or low frequency VF may not be interpreted as shockable.

VT Ventricular Tachycardia

Rhythm frequency min. 180 bpm and peak-to-peak amplitude min. 200 µVolts (including ventricular flutter and polymorphic ventricular tachycardia)

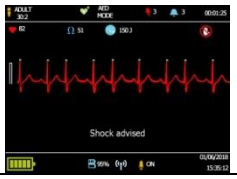
Some rhythms with very low amplitude or low frequency VT may not be interpreted as shockable.

The **Saver One D** detects both noise artefacts in the ECG, caused, for example, by patient movement, defibrillation electrode adjustment, and electronic disturbances from external sources. In these cases the analysis is delayed or interrupted.

The **Saver One D** is able to detect and filter impulses coming from an implanted pacemaker

8.6 SHOCKABLE RHYTHM

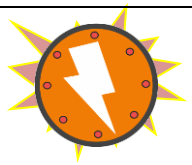
If the ***Saver One D*** after analysing the patient's heart rhythm recognises a VF or TV. This information is highlighted by voice (audio) and visual (colour display) prompts, as shown in the following table:

Voice prompts	Text	Video Display
Shock Recommended	Shock recommended	

Then it automatically performs the charging phase. This information is highlighted by voice (audio) and visual (colour display) prompts, as shown in the following table:

Voice prompts	Text	Video Display
Do not touch the patient	Charging … in progress ..	
Charging		

The progress of the device charge is indicated by the charging bar
Once the charging phase is completed, the ***Saver One D*** is ready to administer the shock. This information is highlighted by voice (audio) and visual (colour display) prompts, shown in the table; in addition, the shock button light will blink

Voice prompts	Text	Video Display
Stay clear from patient	Press shock button	
Push the blinking red button		
		

Before pressing the shock button, move away and make sure that no one is touching the patient.
To shock, press the shock button within 15 seconds.
If the shock button is not pressed within 15 seconds of the shock alert, the ***Saver One D*** will automatically disarm. This information is highlighted by voice (audio) and visual (colour display) prompts, as shown in the following table:

Voice prompts	Text
The shock button was not pushed	Shock button not pressed Shock Cancelled
Shock Cancelled	

If the shock button is pressed, the ***Saver One D*** will perform the defibrillation shock. This information is highlighted by voice (audio) and visual (colour display) prompts, shown in the table; in addition the shock button will stop flashing.

Voice prompts	Text
Shock Delivered	Shock Delivered
You can now touch the patient	

The ***Saver One D*** performs the shock using the BTE (Biphasic Truncated Exponential) waveform with auto compensation of the patient's thoracic impedance. The ***Saver One D*** shock protocol is incremental, i.e. the energy delivered to the patient varies incrementally based on the number of shocks performed:

Saver One D 200J: The first shock is administered at **150J** energy the following ones at **200J**
Saver One D 360J: The first shock is carried out at an energy of **200J** the second at **250J** the subsequent ones at **360J**

The detected impedance value must be between 20 and 200 Ohm; if a value outside this range is detected, it is required to position the PADs.
The shock protocol is pre-set, cannot be modified by the user and is reset at each power up. It can only be modified by A.M.I. Italia S.r l. at the express request of the customer and endorsed by a competent body.

8.7 NON-SHOCKABLE RHYTHM

If the ***Saver One D*** does not detect a VF or VT during the heart rhythm analysis. This information is highlighted by voice (audio) and visual (colour display) prompts, as shown in the following table:

Voice prompts	Text	Video Display
Shock NOT recommended	Shock NOT recommended	

All rhythms other than VT and VF will be assessed as non-shockable. For more information, please see paragraphs 12.10 and 12.11.

8.8 CHANGE OF RHYTHM

The ***Saver One D*** is designed to analyse the patient's heart rhythm continuously, moment by moment.
If, after recommending the shock, the device detects a sudden change in the heart rate of the patient who no longer needs defibrillation, it will disarm automatically. This information is highlighted by voice (audio) and visual (colour display) prompts, as shown in the following table:

Voice prompts	Text
Shock Cancelled, rhythm changed	Shock Cancelled, rhythm changed

8.9 CPR

The ***Saver One D*** defibrillator will guide the operator through CPR (**C**ardio **P**ulmonary **R**esuscitation) in one of the following cases:

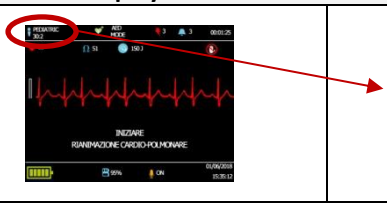
- A shockable rhythm has been detected and a defibrillation shock has been delivered
- A non-shockable rhythm has been detected
- A shockable rhythm has been detected but the shock button has not been pushed
- A shockable rhythm has been detected but the patient's rhythm has changed

This information is highlighted by voice (audio) and visual (colour display) prompts, shown in the table

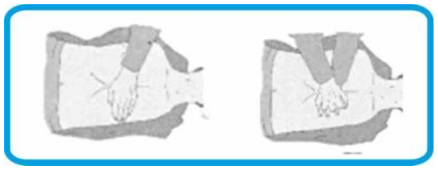
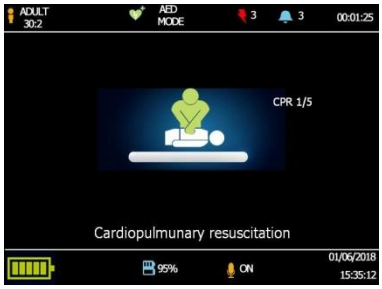
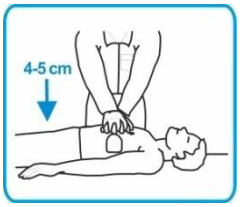
Voice prompts	Text	…Display
Start cardiopulmonary resuscitation	Start cardiopulmonary resuscitation	
Perform 5 cycles of 30 compressions followed by 2 breaths		

The ***Saver One D*** will provide instructions for performing CPR instant by instant, instructing the operator on how to perform chest compressions and insufflations. According to the international AHA/ERC guidelines, the duration of cardio-pulmonary resuscitation is about 2 minutes.

If resuscitation is carried out by a single operator, the compressions/insufflations ratio must be **30/2** for 2 minutes (5 cycles) for both adult and child patients.

	…Display	
Ratio **30/2** for about 2 minutes (5 cycles)		

The following table shows the main operations to be performed and the related visual-text-vocal prompts provided by ***Saver One D***

<table>
<tr><th>No.</th><th>Type of prompt (Saver D)</th><th>Saver One D Instruction</th><th>Operations to be performed</th></tr>
<tr><td rowspan="2">1</td><td>Voice/Text</td><td>“Start Cardio-Pulmonary Resuscitation”</td><td rowspan="2">A. Check that the patient is on a firm surface
B. Kneel at the victim’s side
C. Place the heel of one hand on the centre of the victim’s chest
D. Place the heel of the other hand on top of the first
E. Link the fingers of both hands and make sure that the pressure is not applied to the ribs. Do not apply any pressure on the upper part of the abdomen or on the lower part of the sternum
  </td></tr>
<tr><td>Visual</td><td> 
</td></tr>
<tr><td rowspan="3">2</td><td>Voice/Text</td><td>“Quickly press on the patient’s chest”</td><td rowspan="3">F. Place yourself vertically to the victim’s chest and, with arms extended, press the sternum. Keeping the arms extended, perform external cardiac massage by using the weight of the torso; the oscillating movement must be centred around the hip joint
G. After each compression, release all pressure on the chest without losing contact between your hands and the sternum; repeat the manoeuvre with a frequency of 100/min (a little fewer than 2 compressions per second)
H. The compression and release phase must be approximately equal in duration
 
</td></tr>
<tr><td>Visual</td><td> 
</td></tr>
<tr><td>Acoustic Signal (BEEP)</td><td>The Saver One D marks the compressions to be performed with a BEEP.</td></tr>
<tr><td rowspan="2">3</td><td>Voice/Text</td><td>“Perform two insufflations”</td><td rowspan="2">Open immediately the air passage by tilting the head and the chin backwards
 
Perform two insufflations
The rescuer inhales normally and, while holding the patient’s chin up with two fingers, places their lips around the mouth of the victim. The opposite hand closes the nostrils to keep the air from coming out and keeps the head hyper-extended. Air is blown in breathing normally for about 1 second
 
</td></tr>
<tr><td>Visual</td><td> 
</td></tr>
<tr><td>4</td><td colspan="2">The Saver One D will repeat STEP 1 to 3 for about 2 minutes</td><td>Follow the voice and text instructions of the Saver One D until the device stops the CPR phase (about 2 minutes)</td></tr>
</table>

9 ECG MONITORING

The ***Saver One D*** defibrillator can also be used to monitor the patient's ECG tracing. The "ECG Monitoring" mode allows the operator to monitor the patient's cardiac rhythm in total safety by disabling automatic defibrillation (in order to perform defibrillation, exit the current mode and select semi-automatic defibrillation).
The ECG trace of the patient in this mode can be read with the help of two different accessories:

- **Using the defibrillation PADs**
- **Using the 2-pole ECG cable SAV-C0017**

The ***Saver One D*** allows you to view one single ECG channel by analysing lead II.
The use of this mode is indicated for medical personnel; to access it, you can optionally request to enter a special security password (see the following paragraphs for more information).

	In this mode the defibrillator does not allow charging and does not allow defibrillation.
	This mode is intended for exclusive use by specialized medical personnel. The password must only be used by medical personnel. In monitoring mode, the internal capacitor is not intended to store any energy and is always discharged, therefore this operating mode is extremely safe

9.1 ACTIVATION OF ECG MONITORING MODE

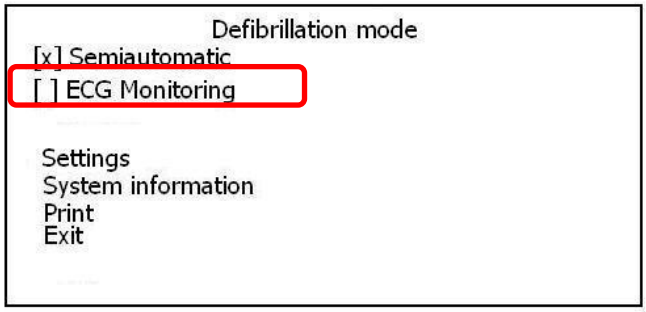
After switching it on, the ***Saver One D*** will automatically start the semiautomatic defibrillation mode. In order to start the ECG Monitoring mode, you must enter the menu and select the new mode.

1 Enter the main menu by pressing the enter key on the device keypad as shown in figure 31

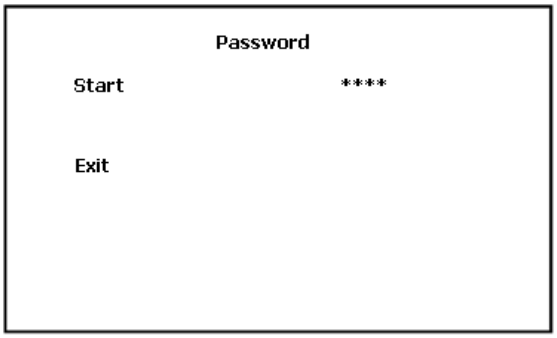
For more information on the ***Saver One D*** menu, refer to the relevant paragraph.

Figure 31

2 In the menu, select "ECG Monitoring"



3 If the password entry request has been set up, the following screen will be displayed when accessing the mode:



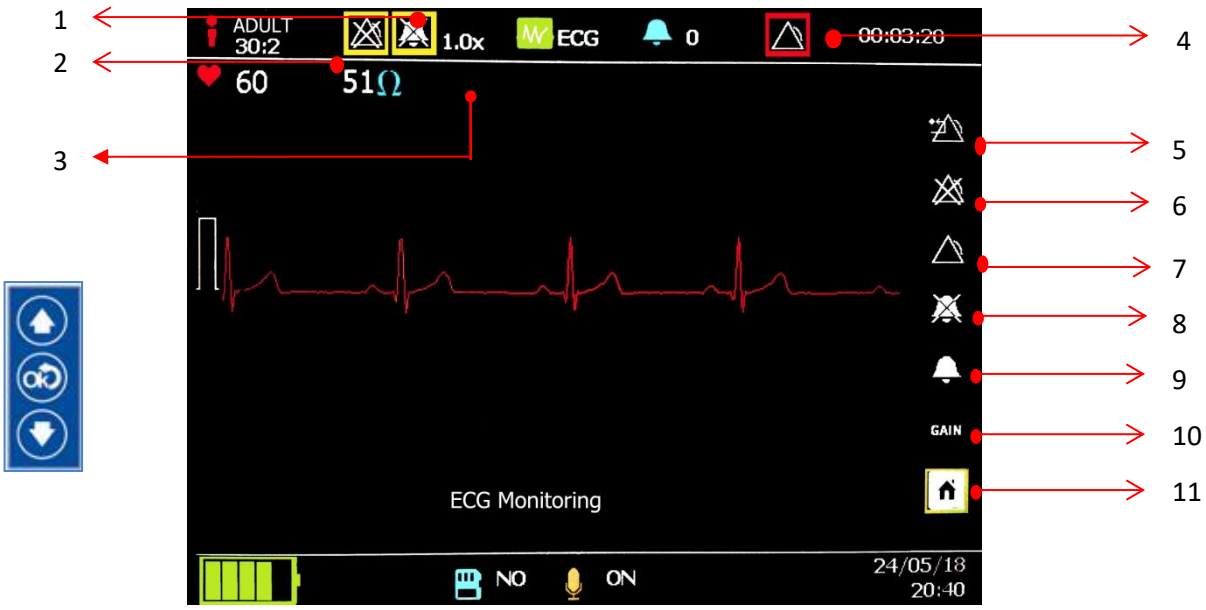
At this point you need to enter the security password. This safeguard (optionally configurable at the Customer's request) can be used to avoid random selection errors by personnel not authorised to use this mode. The password must only be used by medical personnel.
This password consists of a sequence of 4 characters (the arrows and on the defibrillator keypad) must be entered in the following order:

MANUAL Defibrillation Mode Password			
			
UP	**DOWN**	**UP**	**DOWN**

Enter the password following the sequence above. As you enter the sequence, the dashes next to "Enter password" will turn into asterisks. Once the sequence is completed, the ECG Monitoring mode will automatically start.

9.2 DESCRIPTION OF ECG MONITORING FEATURE

Once the ECG Monitoring mode has been selected, an icon-based MENU is shown on the right side of the display to manage the functions provided in this mode. In addition, other icons relating to events and/or statuses that appear during use of the Monitoring mode can appear on the upper part of the display.



No.	Description	No.	Description
1	Status of "Inhibition of acoustic alarm signals"	7	"Enable alarm detection" button
2	Status of "Alarm detection inhibition"	8	"Pause acoustic alarm signals" button
3	Gain in amplitude of the ECG signal ratio	9	"Enable alarm acoustic signal" button
4	"Alarm detection" event	10	"ECG amplitude gain setting" button
5	"Alarm Reset" button	11	"Exit Monitoring Mode" button
6	"Pause alarm detection" button		

The icon-based MENU on the right of the Display is used to manage the Monitoring mode functions. The selected icon is highlighted by a yellow box around it; to move along the MENU, use the and buttons. To press the selected button use the button.

In particular:

- Pressing button 5 resets the alarms;
- Pressing button 6 disables alarm detection for 30 seconds. This status is highlighted by icon 2 displayed.
- Pressing button 7 will force enabling alarm detection. This status is highlighted by the absence of icon 2.
- Pressing button 8 disables the acoustic alarm signal for 30 seconds. This status is highlighted by icon 1 displayed. In this state the alarms continue to be detected but only generate visual signals (Icon 4 displayed).
- Pressing key 9 enables acoustic alarm signaling. This status is highlighted by the absence of icon 1;
- Press button 10 to enter the submenu for selecting the gain value in amplitude of the ECG signal. This status is highlighted by a thicker box around button 10. While in this status, the and buttons are used to select the desired gain.

  Once chosen, press the button again to return to the main icon MENU.
- Press button 11 to exit the Monitoring mode and go back to the main MENU.

The physiological alarms detected are:

Code	Displayed message	Description	Priority	Alarm signalling delay (max)
1	Cardiac Low frequency	Detection of a slow sinus rhythm	HIGH	< 10 sec *
2	Asystole	Detection of an absent sinus rhythm	HIGH	< 10 sec *
3	Fibrillation Detected	Detection of ventricular fibrillation. In this case the patient should undergo a defibrillation shock	HIGH	< 5 sec
4	Tachycardia Detected	Detection of fast ventricular tachycardia. In this case the patient should undergo a defibrillation shock	HIGH	< 5 sec
5	Cardiac High frequency	Detection of an accelerated sinus rhythm. In this case the patient should NOT undergo a defibrillation shock	HIGH	< 5 sec

* See warning section for the use of the monitoring mode

The technical alarms detected are:

Code	Displayed message	Description	Priority	Alarm signalling delay (max)
1	Patient lost	Absence of patient detection	HIGH	< 5 sec
2	ECG saturation	Non-operational device condition due to saturation of the ECG amplifier stage	HIGH	< 5 sec

10 RECORDING, PRINTING AND STORING RESCUE DATA

The ***Saver One D*** defibrillator is able to record and store both the **SERVICE data** of the device and the **complete data of the rescue operations** carried out. Data recording and storing is carried out automatically (cannot be disabled by the user) both on the **internal memory** of the device and on the **memory card** when installed (with the exception of recording voices and environmental noise). The operator can also print the data recorded directly from the device thanks to the use of the portable thermal printer Martel MCP7830 (SAV-C1070) or the PC Saver View Express software.

10.1 DATA RECORDING

The **internal memory** of the ***Saver One*** makes it possible to store up to 6 hours of environmental recordings (audio), ECG tracing, patient data (HR and Ω) and all rescue events. The stored data can be viewed on a PC using the PC Saver View Express software (SAV-C0019).
Two types of files are stored on the **SD Card external memory**:

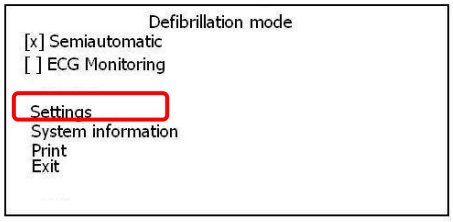
- **AED1LOG.txt** This file stores all the automatic self-tests performed by the device with their outcomes and all the **SERVICE** information. This type of file can be viewed on a PC via a simple reading program
- **AEDFILE.aed** This file stores the rescue data such as: environmental recordings (audio), ECG tracing, patient data (HR and Ω) and all rescue events. This type of file can be viewed again on a PC using the PC Saver View Express software.

The number and duration of recordings depend on the capacity of the memory card, below is an example:

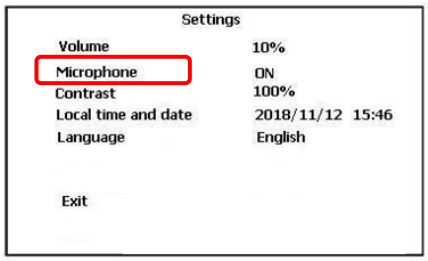
Type	Capacity	Stored Data	
SD Card	512 MB	Sounds, Events, Parameters, ECG. Service (AED1LOG + AEDFILE)	1,500 minutes (25 hours)
	1 GB		3,000 minutes (50hours)
	2 GB		6,000 minutes (100 hours)
SDHC Card	4 GB		12,000 minutes (200 hours)

The recording of voices and environmental noise of the rescue (audio) can be activated or deactivated. This procedure is possible by activating or deactivating the device's microphone from the settings menu:

1 Turn on the device and enter the settings menu



2 Select the microphone item and set as desired



ON Active microphone
Saver One D makes environmental recordings

OFF Microphone disabled
Saver One D does not make environmental recordings

10.2 PRINTING OF RESCUE DATA

The ***Saver One D*** defibrillator allows you to print data stored in the memory directly from the device by using the portable thermal printer model Martel MCP7830 (SAV-C1070).
Rescue data can only be printed if the data has been previously stored on the memory card.
To proceed with data printing, the operator must perform the following operations:

1 Install the printer (***Saver One D*** >> MCP7830 communication)
2 Select the data to be printed (print data search)
3 Proceed with printing

10.2.1 Martel MCP7830 Printer Installation

For more information on the ***Martel MCP7830*** (SAV-C1070) portable printer, refer to its user manual

1 Preparation for printing

- Make sure the printer battery is charged and working
- Insert the paper roll
- Position the printer so that its IrDA port is in line with that of the ***Saver One D***

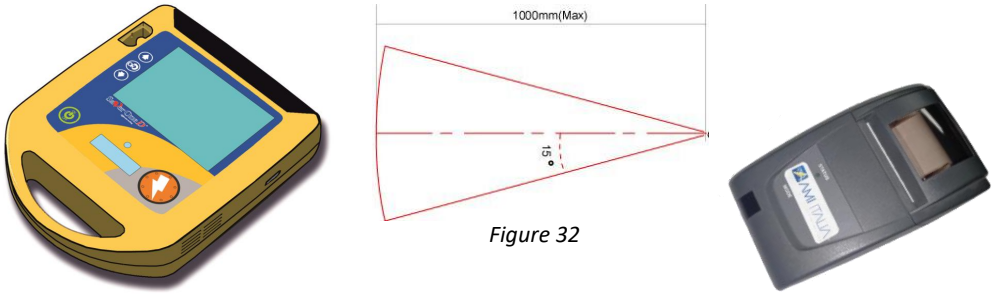


Figure 32

2 Turn on the Martel MCP7830 printer

The three LEDs will blink asynchronously and the first LED will turn on with steady green light to confirm that the printer has switched on.

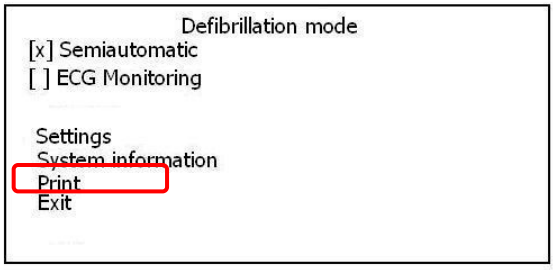
2 Turn on the Saver One D

When turned on, the ***Saver One D*** will automatically detect the printer and be ready to print the stored data.
The correct connection of the printer will be displayed in the settings menu in the print section.

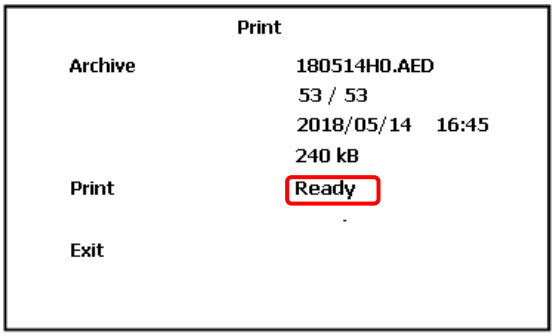
10.2.2 Selection of the data to be printed

After interfacing the printer with the ***Saver One D*** defibrillator, the operator must select the data and start printing. Printing of the data will only be possible if the device is not in operating mode (PADs placed on patient). To be able to select the various rescues to be printed, the operator must follow the procedure below:

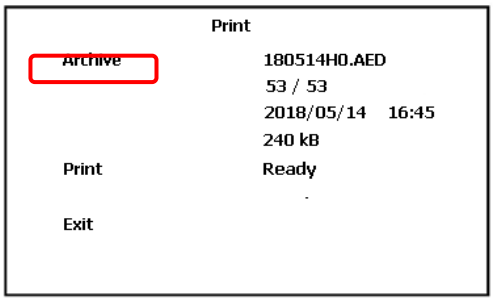
1 Enter the ***Saver One D*** menu and select the PRINT item

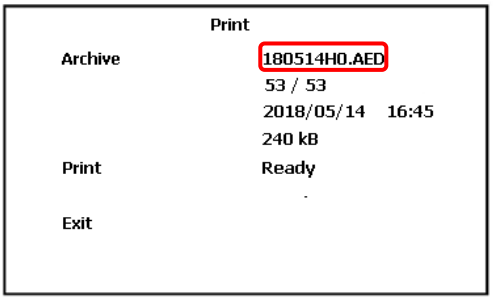


2 Make sure the ***Saver One D*** defibrillator has correctly detected the printer



If the ***Saver One D*** does not detect the printer, the message "No connection" will be displayed.
In the print menu select the ARCHIVE item and select the rescue data to print

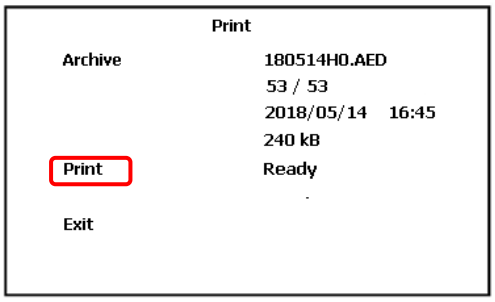




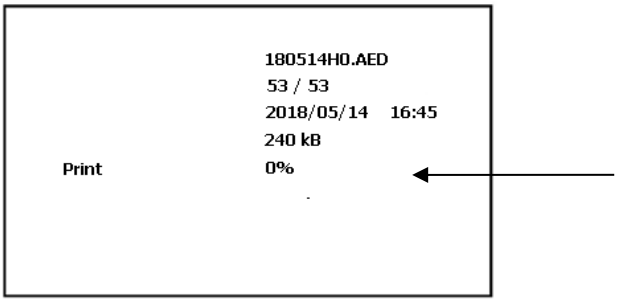
Each individual file with the .AED extension corresponds to the data recording of one individual rescue. The file can be identified by the information shown directly below its name (rescue date and start time)
For more information on the print menu see the relevant paragraph

10.2.3 Printing

From the print menu, after selecting the desired file, select PRINT to start printing



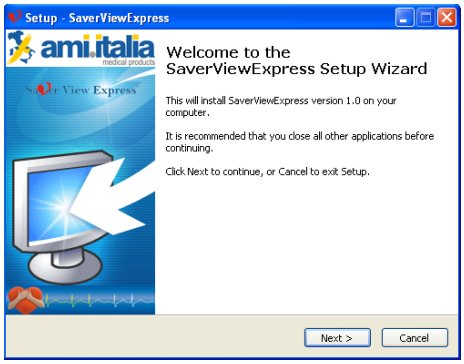
The following screen will be displayed, in which the operator can check the print progress



If the operator wishes to interrupt the printing procedure, they must select PRINT again and confirm; printing will be interrupted and you will automatically go back to the previous menu.
The print slip contains all the rescue events, the data relating to the device and the ECG tracing of the patient. It will also be possible to note down some personal data relating to the patient and the name of the resuscitator.

10.3 STORAGE OF DATA ON A PC

The rescue data recorded by the ***Saver One D*** defibrillator can be stored, analysed and printed from a Personal Computer using the Saver View Express management software.



Saver View Express®

Figure 33

For more details on the PC Saver View Express software, please consult the related user manual.

11 MAINTENANCE

The ***Saver One D*** defibrillator was designed to make maintenance operations as simple and autonomous as possible. In fact, thanks to the tests carried out in total autonomy by the device, it is not necessary to perform any extraordinary maintenance, but only routine maintenance which consists of a frequent visual check of the LED and the control display, together with a visual inspection of the relevant accessories.
Should it be necessary to contact the supplier for assistance during an installation, or to report anomalies, use the following information:

Request for assistance
email: info@amiitalia.com
Tel.: +39 081 806 05 74
Website: **www.amiitalia.com**

11.1 AFTER EACH USE

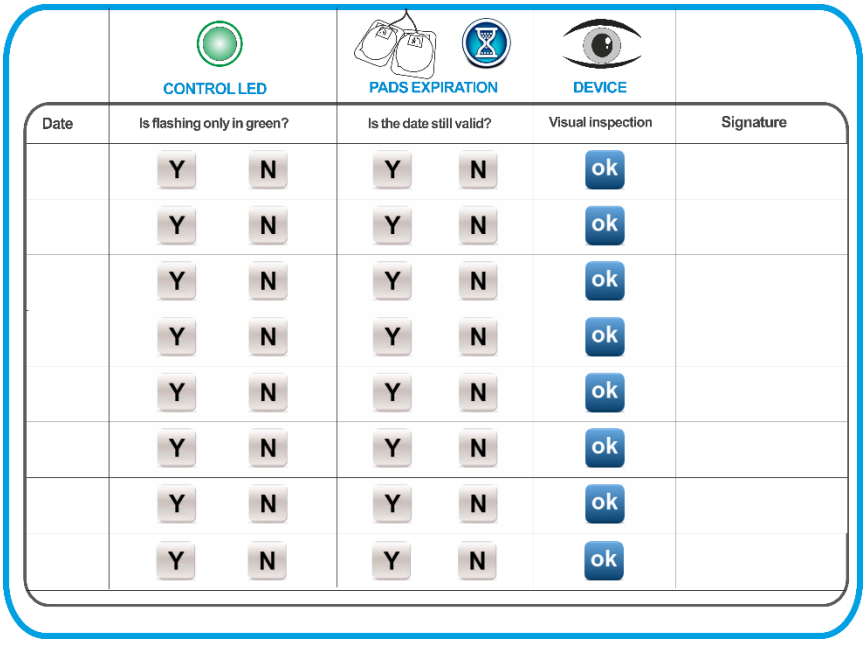
After using the ***Saver One D*** defibrillator, the following operations must be performed in order to prepare the device for the next use:

1 Check for the memory card and its remaining capacity.
2 Check that the control LED is on and blinking (blinking green)
4 If they have been used, replace the PADs with a new package
5 If not used, check the expiry date of the PADs, if expired replace them with a new package

11.2 SCHEDULED MAINTENANCE

Thanks to the tests carried out in total autonomy by ***Saver One D,*** routine maintenance will require a simple and quick inspection, following the operations described in the table:

Daily Check	Monthly Check	Check before use	Check after use	Action
*		*	*	Check the LED and the control display. See the relevant paragraph 7.1 and 11.5
*		*	*	Check the integrity of the device, its parts and accessories supplied.
	*	*		Check the expiry date of the defibrillation PADs
		*	*	Check the residual capacity of the memory card



11.3 CLEANING

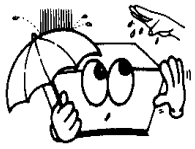
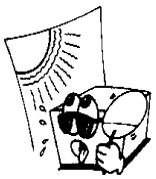
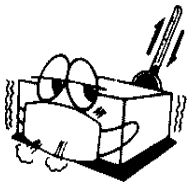
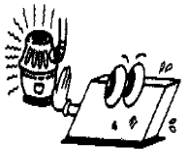
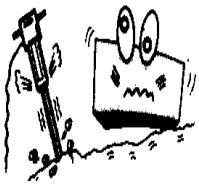
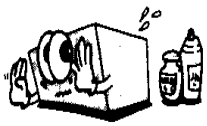
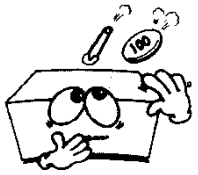
The structure of the ***Saver One D*** defibrillator, including the connection port of the defibrillation electrodes, can be sanitized using a soft cloth dampened with one of the cleaning solutions listed below:

a) Isopropyl alcohol (70% solution)
b) Soapy water
c) Bleach (30 ml per litre of water)
d) Detergents containing ammonia
e) Detergents containing glutaraldehyde
f) Hydrogen peroxide

Do not immerse the Saver One in any liquid
Do not use abrasive materials or detergents, strong solvents, such as acetone or acetone-based detergents, and enzymatic detergents.
Do not sterilize the Saver One or its accessories

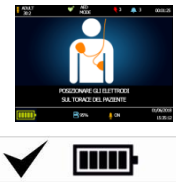
11.4 STORAGE

The ***Saver One D*** must be stored in a place where the environmental and safety conditions indicated in the table below are complied with, according to the temperature and humidity indicated in chapter 12.2. The device must be stored with battery always inserted, to perform periodic self-testing. For easy retrieval of the device in case of emergency, place it in easily accessible places and so that the control LEDs and mini-LCD are clearly visible.

	Do not use, install or store the ***Saver One D*** in conditions of temperature or humidity that exceed the ranges indicated in this user manual.		Do not install or store the ***Saver One D*** in areas directly exposed to sunlight
	Do not install or store the ***Saver One D*** in areas subject to sudden changes in temperature or humidity		Do not install or store the ***Saver One D*** near heat sources
	Do not use, install or store the ***Saver One D*** in places subject to strong vibrations		Do not use, install or store the ***Saver One D*** in environments with high concentrations of flammable or anaesthetic gases
	Do not install or store the ***Saver One D*** in areas with a high concentration of dust		The ***Saver One D*** must be opened for maintenance only by A.M.I. Italia srl or personnel authorised thereby.

11.5 TROUBLESHOOTING GUIDE

The following table lists the symptoms, the possible causes and the possible corrective actions of the problems that may arise. For more information on the implementation of corrective actions, refer to the other sections of the operator's manual. If the failure of the unit persists, request assistance.

Symptom	LED	Mini display and Colour TFT	Possible cause	Corrective action
Device with battery installed does not switch on, the LED and the control display are both off	**OFF**	**OFF**	The battery is completely empty or faulty	Replace the battery. If the problem persists, contact technical support
			The device is not working	Please contact technical support
In **standby** the control LED flashes green but the mini display is off		**OFF**	The mini display is broken	Contact a support centre
In **standby** the control LED is off but a "V" appears on the control mini-display.	**OFF**		The control LED is broken	Contact a support centre
In **standby** the control LED flashes RED and a wrench appears on the control display			A critical error of the device was found during the daily self-test.	Contact a support centre and report the error code.
In **standby** the control LED flashes GREEN/RED alternately and a wrench appears on the control display			Battery empty Level <1% The device could switch off during use. *(please see paragraph 5.1)*	Replace the battery
In the **operating mode** the voice prompt "Low battery" is provided	 **OFF**		Battery low. Battery level 5%. It is possible to use the device but the battery level is low *(see the relevant paragraph)*	Purchase a new battery and replace it as soon as possible.
During normal use the voice prompt "Battery low, Replace" is issued			The battery is empty. Level <1% The device could switch off during use. *(please see paragraph 5.1)*	Avoid using the device if possible. Replace the battery
With the device turned on and after placing the PADs on the patient, the device continues to prompt: "Place the Pads"	**OFF**		The PADs connector has not been inserted correctly or it has been removed	Insert the PADs connector in the appropriate compartment
			The Pads have been placed incorrectly	Please place the Pads correctly on the patient's naked chest. If needed, remove chest hair with a razor
			The Pads are faulty	Please control that the Pads are intact and their expiry date; replace them, if needed
When inserting the battery the **Activation test** requires you to press the shock button to start the test. The button is pressed but the test does not start. For about 60 seconds the AED requires to press the button and then it turns off automatically, signalling "Error xx" on the mini-LCD.	**OFF**	 	The shock button does not work properly	Try switching off the device and repeating the test. If the problem persists, contact technical support
The device turns on, the mini display and the TFT are on but no voice prompt is issued	**OFF**		The device's speaker is not working	Please contact technical support

12 TECHNICAL SPECIFICATIONS

The technical specifications of the ***Saver One D*** defibrillator, its parts and accessories are shown below.

12.1 PHYSICAL CHARACTERISTICS

Category	Rated specifications	
Dimensions	26.5 x 21.5 x 7.5 cm	
Weight	with *SAV-C0903/SAV-C0904* battery:	1.99 Kg + Adult PADs (2.08 Kg)
	with battery *SAV-C0011*:	2.04 Kg + Adult PADs (2.13 Kg)

12.2 ENVIRONMENTAL REQUIREMENTS

Category	Rated specifications	
Temperature	Operational and stand-by:	0°C a 55°C (32°F a 131°F)
	Storage and transport:	-40°C to 70°C (-40°F to 158°F)
Relative humidity	Operational and stand-by:	10% to 95% (without condensation)
	Storage and transport:	without humidity control (from -40°C to +5°C) up to 90% (from + 5°C to +35°C) with water vapour up to 50hPa (from >35°C to +70°C)
Atmospheric pressure	Operating conditions:	620 hPa at 1060 hPa (calculated altitude min -382 and max 3955 m)
Operating conditions	Normal use:	Keep the AED device within the operating and standby ranges (not the storage and transport ranges) so that the device is ready for use. When starting from non-operational conditions, let the device stabilize at the operating conditions for at least 2 hours, before normal use.
IrDA Port	Free of biological risks. Compliant with IEC/EN 62471 (2006) “photobiological safety of lamps and lamp systems” exempt.	
Tolerance to shocks and falls	Compliant with standards IEC/EN 60601-1 clause 21 (mechanical forces)	
Sealing system	Compliant with standards IEC/EN 60529: class IP54; anti-spray, dustproof (with battery installed)	
ESD (electrostatic discharge)	It complies with standards IEC/EN 61000-4-2	
EMC emissions/immunity	See chapter 13	

12.3 REGULATORY FRAMEWORK

Regulations and Directives	DIRECTIVE 2007/47/EC IEC/EN 60601-1 IEC/EN 60601-1-2 IEC/EN 60601-1-4 IEC/EN 60601-1-6 IEC/EN60601-1-8 IEC/EN 60601-1-11 IEC/EN 60601-1-12 IEC/EN 60601-2-4 IEC/EN 60086-4 IEC/EN 60529 DIRECTIVE 2014/53/EU - RED IEC/EN 60601-2-27 except points 202.6.2.101, 201.12.1.101.12.13, 208.6.6.2.101, not executed because the device is not intended for use in environments such as operating theatres or intensive care units (see section warnings for use of monitoring mode)

12.4 TECHNICAL ALARMS TABLE

Priority	Cause	Visual signal	Operating mode
HIGH	Device ready to administer shock	Blinking LED button	Defibrillator
HIGH	Battery empty (capacity < 1%)	Blinking control LED	Defibrillator / Monitoring

12.5 PHYSIOLOGICAL ALARMS TABLE (ONLY IN MONITORING MODE)

Priority	Cause	Visual signal	Operating mode
HIGH	Cardiac Low frequency	Alarm icon and cause indication	Monitoring
HIGH	Asystole	Alarm icon and cause indication	Monitoring
HIGH	Fibrillation Detected	Alarm icon and cause indication	Monitoring
HIGH	Tachycardia Detected	Alarm icon and cause indication	Monitoring
HIGH	Cardiac High frequency	Alarm icon and cause indication	Monitoring

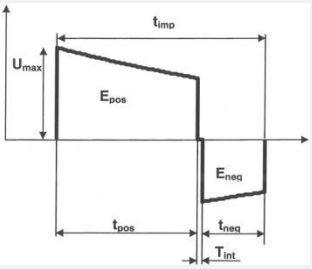
12.6 CONTROLS AND INDICATORS

Category	Rated specifications
Buttons	ON / OFF button (device switch-on and off) 3 Navigation Buttons UP, ENTER, DOWN Shock button (to deliver the defibrillation shock)
Visual Indicators	• Mini LCD Display for device status • LED for device status (two colour RED/GREEN) • ON/OFF button LED (2 green LEDs) • Shock LED button (8 red LEDs)
Audio Indicators	Multilingual voices for instructions during use of the device Warning and hazard acoustic signals
Speaker	Adjustable volume 20-100% (Emissions in compliance with IEC/EN 60601-2-4 point 6.1) Min. Variation 20% max 100% (60 dBA to 80 dBA ± 3 dBA)
Microphone	ON/OFF setting from menu for recording voices and environmental noise

12.7 DATA STORAGE

Category	Rated specifications	
Internal memory	**Storage capacity:** up to 6 hours of "continuous" environmental audio, ECG tracing and events (in circular buffer mode)	
External memory (optional)	**Type and size:** Memory Card SD/SDHC / recommended up to 8GB	
Stored data	**AED1LOG.txt**	Daily self-tests, Errors detected, Device use data, Device information
	AEDFILE.aed	Rescue data, Environmental voices and sounds, Rescue ECG trace, Vital parameters of the patient analysed and read by the ***Saver One D S1 Series***
Data display	Through PC Saver View Express Software (Microsoft Windows compatible)	

12.8 DEFIBRILLATOR

Category	Rated specifications	
Waveform 	**Biphasic Truncated Exponential (BTE)** The waveform parameters are regulated automatically depending on the patient's autonomy. In the graph on the left, t_{pos} represents the duration of phase 1 (ms), $\mathbf{t}_{neg}$ represents the duration of phase 2 (ms), $\mathbf{t}_{int}$ is the delay between the phases, $\mathbf{U}_{max}$ indicates the peak voltage, $\mathbf{t}_{imp}$ is the end voltage. In order to compensate for variations in patient impedance, the duration of each phase of the waveform is regulated dynamically based on the shock delivered, as indicated in the following paragraph.	
Energy delivered (max) (Adults)	***Version 200J:***	200J nominal
	Version 360J:	350J nominal
Shock protocol (Adults)	***Version 200J:***	Incremental: ***First*****:** 150J – ***Subsequent***: 200J
	Version 360J:	Incremental: ***First*****:** 200J - ***Second***: 250J – ***Subsequent***:350J
Energy delivered (max) (Children)	***Version 200J:***	50J nominal
	Version 360J:	(when using defibrillation PADs SAV-C0016)
Shock protocol (Children)	***Version 200J:***	Fixed: ***First and subsequent*****:** 50J
	Version 360J:	
Charging control	Automatic through a patient analysis system	
Charge time (from shock warning)	***Version 200J:***	≤ 9 sec (according to IEC/EN60601-2-4) (150J with new fully charged battery)
	Version 360J:	≤ 15 sec (according to IEC/EN60601-2-4) (360J with new fully charged battery)
Charge time (from the start of the analysis)	***Version 200J:***	≤ 15 sec (according to IEC/EN60601-2-4) (150J with new fully charged battery)
	Version 360J:	≤ 21 sec (according to IEC/EN60601-2-4) (360J with new fully charged battery)
Indication of full charge	• The SHOCK button is blinking • Voice prompt "Press red flashing button"	
Delivery of the shock	The shock is delivered by a single SHOCK button	
Disarming	***Automatic:***	• If the patient analysis system considers the rhythm to be no longer shockable, or • If the operator has not pushed the SHOCK button within 15 seconds from completion of the charge, or • If the defibrillation PADs have been removed from the patient or disconnected from the unit.
	Manual:	• If the operator pushes the OFF/DEACTIVATION button, at any time, to deactivate or switch off the device.
Shock detection vector	Through the defibrillation pads (Lead II)	
Patient insulation	Type BF	

12.9 EFFICIENCY OF THE ENERGY DELIVERED

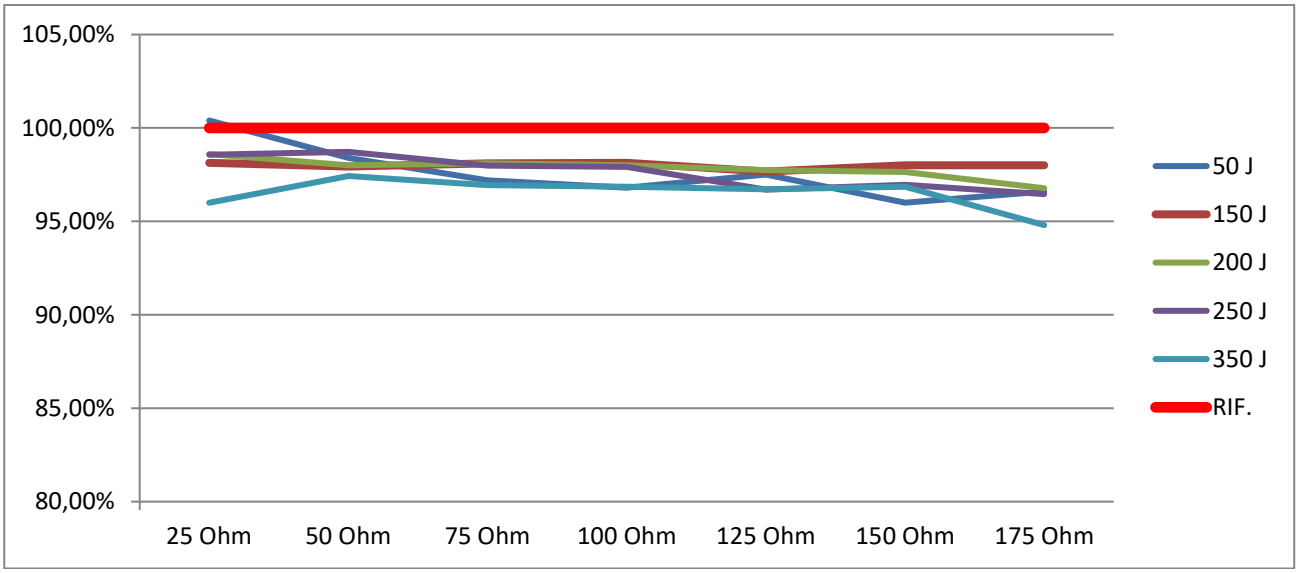
Impedance	Shocks at 50 J (Paediatric)				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Energy set (J)	
25 Ohm	6.8	3.3	18.6	50	**50.2**
50 Ohm	7.2	3	12.3	50	**49.2**
75 Ohm	7.4	2.8	9.6	50	**48.6**
100 Ohm	7.5	2.7	8.1	50	**48.4**
125 Ohm	7.6	2.6	7.1	50	**48.75**
150 Ohm	7.7	2.5	6.4	50	**48**
175 Ohm	7.7	2.4	5.8	50	**48.3**

Impedance	Shocks at 150 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Energy set (J)	
25 Ohm	4.6	5.6	43.8	150	**147.2**
50 Ohm	6.2	4	24.9	150	**146.9**
75 Ohm	6.8	3.3	18.4	150	**147.15**
100 Ohm	7.2	3	15	150	**147.2**
125 Ohm	7.4	2.8	13	150	**146.5**
150 Ohm	7.5	2.7	11.5	150	**147**
175 Ohm	7.6	2.6	10.4	150	**147**

Impedance	Shocks at 200 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Energy set (J)	
25 Ohm	4.6	5.6	57.6	200	**197.2**
50 Ohm	6.1	4	28.8	200	**196**
75 Ohm	6.8	3.3	15.9	200	**196.2**
100 Ohm	7.2	3	17.3	200	**196**
125 Ohm	7.4	2.8	14.9	200	**195.5**
150 Ohm	7.5	2.7	13.2	200	**195.3**
175 Ohm	8.5	3	11.4	200	**193.55**

Impedance	Shocks at 250 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Energy set (J)	
25 Ohm	4.6	5.6	56.6	250	**246.4**
50 Ohm	6.2	4	32.3	250	**246.8**
75 Ohm	6.8	3.3	23.7	250	**244.95**
100 Ohm	7.2	3	19.4	250	**244.8**
125 Ohm	8.4	3.4	15.8	250	**241.75**
150 Ohm	10	4	13.3	250	**242.4**
175 Ohm	11.5	4.6	11.4	250	**241.15**

Impedance	Shocks at 350 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Energy set (J)	
25 Ohm	4.9	9.4	65.2	350	**336**
50 Ohm	7.2	6	36.6	350	**341**
75 Ohm	9.5	6.9	25.4	350	**339.3**
100 Ohm	12	8.2	19.4	350	**339**
125 Ohm	14.4	9.5	15.8	350	**338.5**
150 Ohm	16.9	10.9	13.3	350	**339**
175 Ohm	18.9	11.5	11.4	350	**331.8**



Delivered energy efficiency graph

12.10 PATIENT ANALYSIS SYSTEM

Category	Rated specifications
Function	It determines patient impedance and assesses the ECG rhythm and the quality of the signal, to determine whether administering the shock is appropriate or not.
Impedance range	20 - 200 Ω
ECG analysis time	≥4 seconds (with new fully charged battery) in compliance with IEC/EN 60601-2-4
Sensitivity	97% Complies with IEC/EN60601-2-4 guidelines
Specificity	99% Complies with IEC/EN60601-2-4 guidelines
Shockable rhythms	If used on a patient with the characteristics listed in the use criteria, the ***Saver D*** defibrillator is designed to recommend a defibrillating shock when it detects the right impedance and when the following situations occur: ***Ventricular Fibrillation*** peak-to-peak amplitude at least 200µVolts ***Ventricular tachycardia*** with heartbeat frequency min. 180 bpm and peak-to-peak amplitude at least 200µVolts (including ventricular flutters and polymorphic Ventricular tachycardia)
Non-shockable rhythms	The ***Saver D*** is designed to not recommend shocks with all other rhythms, including: normal sinusoidal rhythm, moderate ventricular fibrillation (<200 µVolts), some slow ventricular tachycardias and asystoles.

12.11 ECG ANALYSIS OPERATION

ECG rhythm	Dimension Test sample	Objective	Value detected
Rhythm to be defibrillated Ventricular Fibrillation (VF)	500	Sensitivity > 90%	98%
Rhythm to be defibrillated Ventricular Tachycardia (VT, bpm >140)	600	Sensitivity > 75%	92%
Rhythm not to be defibrillated Normal sinus rhythm	1500	Specificity > 99%	100%
Rhythm not to be defibrillated Asystole	30	Specificity > 95%	100%
Non-treatable rhythm Generic AF, SVT, PVC	30	Specificity > 95%	100%
Positive predictive values			97.1%
False positives			4.1%

12.12 ECG MONITORING

Category	Rated specifications
Type of protection	**BF** with defibrillation PADs **CF** only with SAV-C0017 cable
Intended use	The ECG Monitoring function is intended to be used in situations where the patient is always followed by an operator and is never left alone
Bandwidth	0.5 at 40Hz (default) with defibrillation PADs or ECG cable SAV-C0017
Lead ECG	Lead II
ECG Amplitude Range	10 mm/mV
Heart Rate Range	30 – 200 bpm
Heart Rate Resolution	1 bpm
Heart Rate Alarm (*)	Threshold MIN = 30 bpm; Threshold MAX 120 bpm

(*) The alarm thresholds are set by the Manufacturer and cannot be changed locally. On request it is possible to have different threshold values

12.13 DISPLAY

Category	Rated specifications
Type	**Colour TFT** with LED backlight
Visible area	5.7" (diagonal) - 112 x 80 mm
Resolution	640 x 480 pixels
ECG tracing displayed	1 (Lead II)
ECG tracing speed	25 mm/sec (default)
Information shown on Display	• Patient's heart rate (bpm) • Patient thoracic impedance (Ω) • VF or VT detected (numeric value) • Shocks delivered (numeric value) • Textual prompts on operations to be performed (text) • Graphical images on operations to be performed (graphic icons) • Active technical and physiological alarms (graphic icons) • Operational mode • Set energy level (J) • Charge duration (graphic incremental bar) • Treatment duration (hh/mm/sec) • Battery level (incremental bar graph) • Local date and time (dd/month/year - hh/mm/sec)

12.14 NON-RECHARGEABLE BATTERY

Category	Rated specifications	
REF (Model)	SAV-C0903	SAV-C0904
Type	Li-$SOCl_2$ (Lithium-thionyl chloride) disposable, non-rechargeable	Li-MnO_2 (Lithium ions and Manganese dioxide) disposable, non-rechargeable
Voltage - Capacity	25.2 VDC – 3500 mAh	24 VDC – 3000 mAh
Performance *	***Version 200J*** 250 continuous shocks with new fully charged battery ***Version 360J*** 160 continuous shocks with new fully charged battery	
	Monitoring ECG monitoring duration 24 hours continuously	
Duration in Standby* *(battery installed)*	4 years if installed in the AED, assuming an activation test, daily self-tests without turning on the AED	

***New and fully charged battery stored at a constant temperature of 20°C and relative humidity of 45% without condensation**

12.15 RECHARGEABLE BATTERY

Category	Rated specifications
REF (Model)	SAV-C0011
Type	Li ion (lithium ions) Rechargeable
Voltage - Capacity	21.6 VDC – 2100 mAh
Performance*	***Version 200J*** 200 continuous shocks with new fully charged battery ***Version 360J*** 110 continuous shocks with new fully charged battery
	ECG Monitoring ECG monitoring duration 14 hours continuously
Charge time*	≤ 2.5 hours with new batteries and charging station SAV-C0012
Shelf Life*	2 years or 300 charge/shock cycles (*whichever occurs first*)

***New and fully charged battery stored at a constant temperature of 20°C and relative humidity of 45% without condensation**

12.16 INTERNAL BACK-UP BATTERY

Category	Rated specifications
Type	Battery Coin Cell (LiMnO2)
Purpose	Preserving configuration data (date/time, etc.)
Voltage - Capacity	3 VDC – 1000mAh
Duration	Maintains data for 3 years (without external battery) Maintains data for 6 years (with external battery inserted within 12 months)

12.17 BATTERY CHARGER

Category	Rated specifications	
REF (Model)	SAV-C0012	
Charge control	Multicolour red green LED	
Power supply	***Input***	15Vdc-2.67A / 12Vdc-5.5A
	Output	26VDC - 1.5A
	Absorption	40W / 66W
AC/DC Adapter	***Model***	MeanWell GS40A15-P1J
	Identification code	SAV-C0013
	Input	100-240VAC – 50/60Hz – 1.5A
	Output	15V – 2.67A
	Absorption	40W

12.18 THERMAL PRINTER

Category	Rated specifications
Model	Martel MCP7830
Identification code	SAV-C1070
Type	Thermal, Dot matrix
Dimensions	85.5 x150x55mm
Weight	400g approx. (including battery and paper)
Power supply	Rechargeable battery 4.8 V DC/1600 mAh (4 x cell AA Ni-MH)
Autonomy	1 hour continuous printing
Charge duration	4 hours
Print speed	80 mm/sec
Resolution	203dpi, 8dots/mm
Paper type	Thermal paper (57mm, 30Ø)

12.19 DEFIBRILLATION PADS

Category	ADULTS	CHILDREN	Universal Face to Face
REF (Model)	SAV-C0846	SAV-C0016	SAV-C0599
Series	Cable and connector external to the bag	Cable, connector and PADs inside packaging	Cable and connector external to the bag
Patient range	Adult age **>8 years** or weight **> 25Kg**	Child age **< 8 years** or weight **< 25Kg**	**Adult/Paediatric** (age>**1 year**)
Intended use	Disposable		
Number of shocks tolerated	50 shocks at 360J		
Support material	Medical FOAM, thickness 1 mm		
Conducting gel	Adhesive low-impedance conducting gel		
Total surface *(per pad)*	136 cm ²	75 cm ²	136 cm²
Active area *(per pad)*	94 cm ²	40 cm ²	94 cm ²
Conducting material	Metal foil		
Connection	Safety shock-proof connector		
Cable length	120 cm (standard)		

12.20 ECG CABLE

Category	Rated specifications
Code	SAV-C0017
Type	Single cable with connector and terminals
Intended use	Reusable
Terminals	2 poles with CLIP terminals (button)
Coding	International IEC/EN
Model	CF

12.21 CHARGE TIME

Charging time performance in accordance with IEC/EN 60601-2-4 (201.101)	Requirement
The maximum time between the beginning of the ECG rhythm analysis and the completion of the charge at maximum energy	< 30 seconds
The maximum time from switch-on to completion of charging at maximum energy	< 40 seconds

12.22 BLUETOOTH MODULE

Category	Rated specifications
Frequency	2400.00 (MHz); 2440.00(MHz); 2485.00(MHz)
Performance	• Compatibility with external accessory module for Q-CPR (REF.SMT-C14034) • Internal 115200 baud Serial Port

13 COMPLIANCE WITH ELECTROMAGNETIC EMISSION STANDARDS

The following paragraphs specify compliance with the electromagnetic emission standards:

- Guidelines and manufacturer declaration - Electromagnetic emissions
- Guidelines and manufacturer declaration - Electromagnetic immunity
- Recommended distances between portable and mobile radiofrequency communication equipment and the AED

13.1 GUIDELINES AND MANUFACTURER DECLARATION - ELECTROMAGNETIC EMISSIONS

The **Saver ONE D** was designed to be used in electromagnetic environments with features listed below. The customer or the user of the **Saver ONE D** must ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - Guidelines
RF emissions CISPR 11	Group 1	The **AED** uses RF energy only for its internal operation. Its RF emissions are, therefore, very low and it is improbable that they may interfere with electronic devices nearby.
RF emissions CISPR 11	Class B	The **AED** can be used in any building, including residential buildings and buildings directly connected to the public low-voltage electricity network that supplies residential buildings.
Harmonic Emissions **IEC 61000-3-2**	Not applicable	
Voltage fluctuations/flickers **IEC 61000-3-3**	Not applicable	

13.2 GUIDELINES AND MANUFACTURER DECLARATION - ELECTROMAGNETIC IMMUNITY

The **Saver ONE D** was designed to be used in electromagnetic environments with features listed below. The customer or the user of the **Saver ONE D** must ensure that it is used in such an environment.

Immunity test	Test level IEC/EN 60601-1	Conformity Level	Electromagnetic environment Guidelines
Electrostatic discharge (ESD) **IEC/EN 61000-4-2**	±6 kV contact	±6 kV contact	The floors must be made of wood, cement or ceramic bricks. If the floors are covered by synthetic materials, the relative humidity must be at least 30%.
	±8 kV air	±8 kV air	
Fast transients/burst **IEC/EN 61000-4-4**	±2 kV for electricity networks	Not applicable	
	±1 kV for I/O networks	±1 kV for I/O lines	
IEC/EN 61000-4-11	5% U_T (95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 seconds	Not applicable	

Immunity test	Test level IEC/EN 60601-1	Conformity Level	Electromagnetic environment Guidelines
Supply frequency (magnetic field) 50/60 Hz **IEC/EN 61000-4-8**	3 A/m	80 A/m	Power frequency magnetic fields must be at levels that do not exceed those of stations located in typical heavy industry applications, power plants and control rooms of high-voltage substations.
Note: U_T is the alternating network current before the application of the test level			
Conducted RF	3 Vrms	Not applicable	
IEC/EN 61000-4-6	from 150 kHz to 80 MHz outside the ISM[a] bands 10 Vrms from 150 kHz to 80 MHz inside the ISM[a] bands	Not applicable	
Radiated RF **IEC/EN 61000-4-3**	10 V/m from 80 MHz to 2.5 GHz	10 V/m	The distance between portable and mobile RF communication devices in use and any part of the AED, including cables, must never be shorter than the recommended separation distance calculated based on the equation that applies to the transmitter's frequency. **Recommended separation distance** $d = 1.2\sqrt{P}$ from 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ from 800 MHZ to 2.5 GHz where P is the maximum output power of the transmitter in watt (W) in accordance with the data of the transmitter's manufacturer and d is the recommended distance in metres (m)[b]. The field strengths of fixed radiofrequency transmitters, as determined by an investigation in electromagnetic sites,[c] should be lower than the conformity level in all frequency ranges.[d] Interference may occur near devices marked with this symbol. 

NOTE 1	The higher frequency interval applies at 80 MHz and 800 MHz
NOTE 1	These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people
a	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; from 13.553 MHz to 13.567 MHz; from 26.957 MHz to 27.283 MHz; and from 40.66 to 40.70 MHz.
b	The compliance levels in the ISM bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are there to reduce the possibility of interference in case the portable and mobile communication devices are accidentally placed near the area where the patient is. For this reason, an additional factor of 10/3 is added to the calculation of the recommended separation distance for transmitters whose frequencies fall within these intervals.
c	It is not possible to predict with precision on a theoretical level the field strength of fixed transmitters, such as base stations for radiotelephones (mobile/cordless telephones) and wireless phones, amateur radios, AM and FM transmitters, and TVs. In order to assess the electromagnetic environment with fixed RF transmitters, please take into account the possibility of performing an electromagnetic analysis of the site. If the field strength measured at the site where the AED is used exceeds the specific RF compliance level as per above, it will be necessary to keep an eye on the AED, to check that it is working properly. If operating anomalies are observed, it may be necessary to adopt corrective actions, for example by moving or turning the AED.
d	Other than the frequency interval between 150 kHz and 80 MHz, the field strengths must be lower than 1 V/m.

13.3 RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENT AND THE SAVER ONE DEVICE

The **Saver ONE D** must be used in an electromagnetic environment in which radiated RF interference is controlled. The customer or the operator of the **Saver ONE D** can help prevent electromagnetic interference by maintaining the minimum distances recommended below, between the portable and mobile RF communications equipment (transmitters) and the **Saver ONE D**, based on the maximum output power of the communication devices.

Maximum Rate of transmitter power emission W	**Separation distance in accordance with the transmitter's frequency m**			
	From 150kHz to 80 MHz outside the ISM bands $d = 1.2\sqrt{P}$	**From 150kHz to 80 MHz inside the ISM bands** $d = 1.2\sqrt{P}$	**From 80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**From 800 MHz to 2.5 Hz** $d = 2.3\sqrt{P}$
0.01	0.12 m	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.38 m	0.38 m	0.73 m
1	1.12 m	1.2 m	1.2 m	2.3 m
10	3.7 m	3.8 m	3.8 m	7.3 m
100	12 m	12 m	12 m	23 m
For transmitters whose estimated maximum power is not listed above, the separation distance *"d"* in metres (m) can be determined using the equation that applies to the transmitter's frequency, where P represents the maximum power produced by the transmitter in watt (W) in accordance with the transmitter's manufacturer.				
NOTE 1:	At 80 MHz and 800 MHz, the separation distance applied is the one used for high frequency intervals.			
NOTE 2:	The ISM frequency bands (for industrial, scientific and medical application) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 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 the calculation of the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency interval from 80 MHz to 2.5 GHz to reduce the possibility that portable/mobile equipment can interfere, if accidentally brought into the patient's area.			
NOTE 4:	These guidelines may not be applicable to all situations. Electromagnetic diffusion is affected by absorption and reflected from structures, objects and people.			

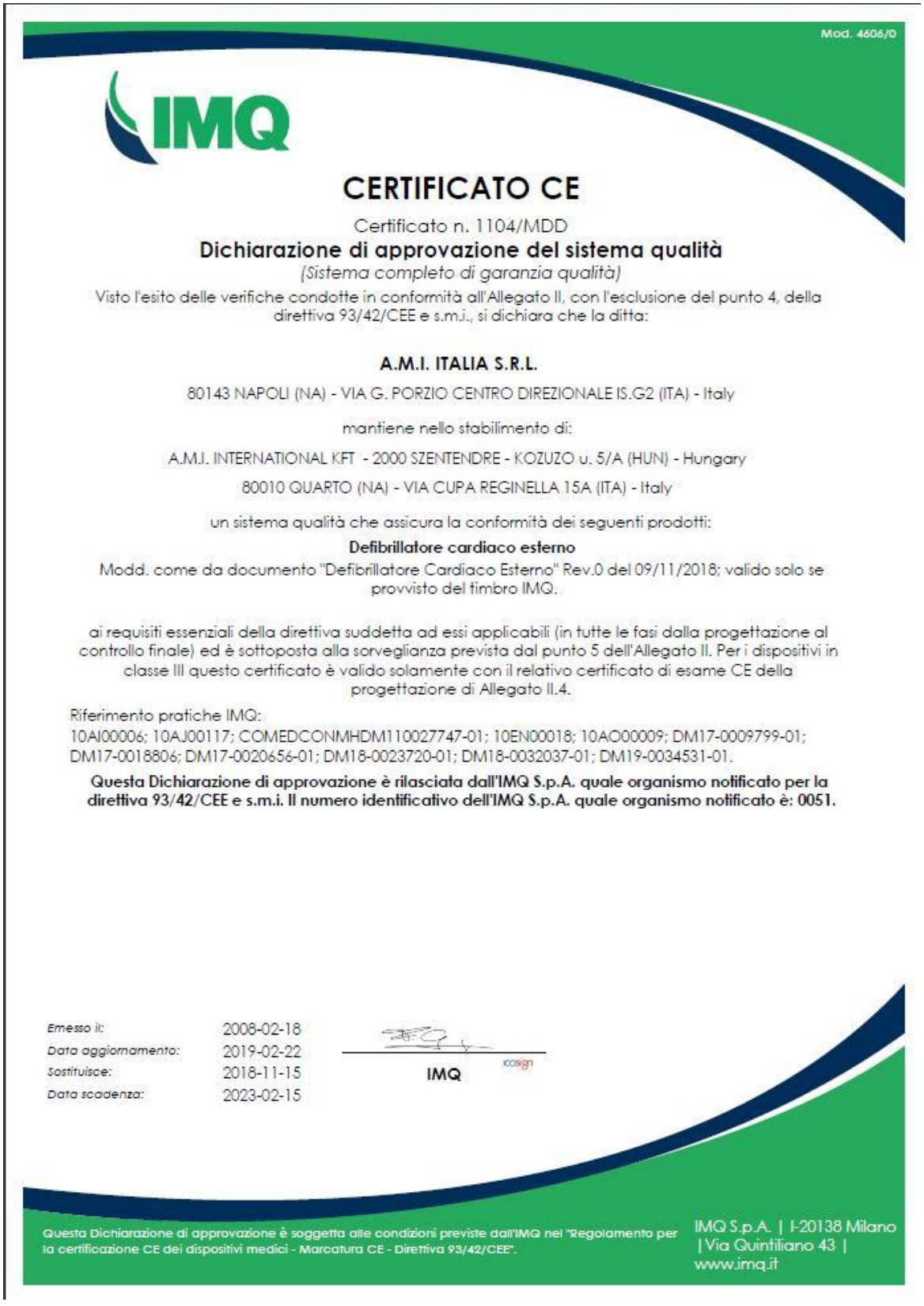
14 SYMBOLS

	Universal ILCOR symbols for AEDs
	Hazard High Electrical Voltage
	General Warnings: Please refer to the accompanying documents before using the device
	Type BF, Defibrillation-proof device
	Do not expose to high temperatures or flames
	Do not recharge
	Do Not Open
	Do not destroy or damage
	Do not use in water puddles
	Read the User Manual
	Battery Recycling
	Please comply with the local regulatory framework on waste
	Fragile
	Keep in a dry place
	Do not expose to direct sunlight
	Shock hazard do not open
	CF-type applied part

	IMQ Mark
	CE marking with identification number
IP54	Level of Protection of the device against dust and water (including the battery)
SN	Serial Number
	Manufacture Date
LOT	Lot Number (LOT)
	Expiry Date
REF	Model identification number
	Manufacturer Name
	Latex-Free
	Single-use, do not reuse
	Non Sterile
	External instructions of the box
	This Side Up
	Temperature Limits
	Do not stack in piles of more than 6 boxes

15 CERTIFICATIONS

15.1 CE CERTIFICATE



Mod. 4606/0

IMQ

CERTIFICATO CE

Certificato n. 1104/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

A.M.I. ITALIA S.R.L.

80143 NAPOLI (NA) - VIA G. PORZIO CENTRO DIREZIONALE IS.G2 (ITA) - Italy

mantiene nello stabilimento di:

A.M.I. INTERNATIONAL KFT - 2000 SZENTENDRE - KOZUZO u. 5/A (HUN) - Hungary

80010 QUARTO (NA) - VIA CUPA REGINELLA 15A (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Defibrillatore cardiaco esterno

Modd. come da documento "Defibrillatore Cardiaco Esterno" Rev.0 del 09/11/2018; valido solo se provvisto del timbro IMQ.

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
10AI00006; 10AJ00117; COMEDCONMHDM110027747-01; 10EN00018; 10AC00009; DM17-0009799-01; DM17-0018806; DM17-0020656-01; DM18-0023720-01; DM18-0032037-01; DM19-0034531-01.

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2008-02-18
Data aggiornamento:	2019-02-22
Sostituisce:	2018-11-15
Data scadenza:	2023-02-15

IMQ

Questa Dichiarazione di approvazione è soggetta alle condizioni previste dall'IMQ nel "Regolamento per la certificazione CE dei dispositivi medici - Marcatura CE - Direttiva 93/42/CEE".

IMQ S.p.A. | I-20138 Milano | Via Quintiliano 43 | www.imq.it

Mod. 4606/0

IMQ

EC CERTIFICATE

Certificate No 1104/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

A.M.I. ITALIA S.R.L.

80143 NAPOLI (NA) - VIA G. PORZIO CENTRO DIREZIONALE IS.G2 (ITA) - Italy

manages in the factory of:

A.M.I. INTERNATIONAL KFT - 2000 SZENTENDRE - KOZUZO u. 5/A (HUN) - Hungary

80010 QUARTO (NA) - VIA CUPA REGINELLA 15A (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

External cardiac defibrillator

Type ref. as to Document "Defibrillatore Cardiaco Esterno" Rev.0 dated 2018/11/09; valid only if provided with IMQ mark.

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:
10AI00006; 10AJ00117; COMEDCONMHDM110027747-01; 10EN00018; 10AO00009; DM17-0009799-01; DM17-0018806; DM17-0020656-01; DM18-0023720-01; DM18-0032037-01; DM19-0034531-01.

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2008-02-18
Updated:	2019-02-22
Substitution Date:	2018-11-15
Expiry Date:	2023-02-15

IMQ

This Approval Certificate is subjected to the provisions laid down in the "IMQ regulation for the certification of Medical Devices - CE Marking - Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

IMQ S.p.A. | I-20138 Milano
| Via Quintiliano 43 |
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15.2 IMQ MARK

IMQ S.p.A. - Società con Socio Unico
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Rea Milano 1595884
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Capitale Sociale € 4.000.000

CA10.00185
SN.I000XN

PID:
10010024
CID:
CN.I0005Y

Certificato di approvazione

Approval certificate

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

PRD N° 005B

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

IMQ, ente di certificazione accreditato, autorizza la ditta

IMQ, accredited certification body, grants to

A.M.I. ITALIA S.R.L.
VIA G. PORZIO CENTRO DIREZIONALE IS.G2
80143 NAPOLI NA
IT - Italy

all'uso del marchio

the licence to use the mark

IMQ

Il presente certificato è soggetto alle condizioni previste nel Regolamento "MARCHI IMQ - Regolamento per la certificazione di prodotti" ed è relativo ai prodotti descritti nell'Allegato al presente certificato.

This certificate is subjected to the conditions foreseen by Rules "IMQ MARKS - RULES for product certification" and is relevant to the products listed in the annex to this certificate.

per i seguenti prodotti

Defibrillatori cardiaci esterni (Modd.: SAVER ONE; SAVER ONE D; SAVER ONE P; GEO SAVER; GEO SAVER D; GEO SAVER P)

for the following products

External cardiac defibrillators (Models: SAVER ONE; SAVER ONE D; SAVER ONE P; GEO SAVER; GEO SAVER D; GEO SAVER P)

Emesso il / Issued on ***2008-09-25***
Aggiornato il / Updated on ***2019-03-04***
Sostituisce / Replaces ***2014-03-18***

IMQ S.p.A.

16 SAVER ONE SERIES DEFIBRILLATOR WARRANTY

1 Restriction of the Warranty
A.M.I. Italia S.r.l guarantees the original purchasers that its Saver One series defibrillators and related accessories and batteries are free from any material or manufacturing defect according to the terms and conditions of this restrictive warranty. The original purchaser is understood to be the end user of the product purchased. This limited warranty is granted only to the original purchaser of the Saver One defibrillator series. of A.M.I. Italia S.r.l and is not transferable or assignable to third parties.
The Saver One Series defibrillators are as follows:
Saver ONE Semi-Automatic no LCD (code SVO-B0918 or SVO-B0919)
Saver ONE Semi-Automatic (code SVO-B0001 or SVO-B0002)
Saver ONE Automatic (code SVO-B0847 or SVO-B0848)
Saver ONE D (code SVD-B0004 or SVD-B0005, code SVD-B0004-U or SVD-B0005-U, code SVD-B0004-Q or SVD-B0005-Q, code SVD-B0004-U-Q or SVD-B0005-U-Q)
Saver ONE P (code SVP-B0006 or SVP-B0007, code SVP-B0006-U or SVP-B0007-U, code SVP-B0006-Q or SVP-B0007-Q, code SVP-B0006-U-Q or SVP-B0007-U-Q)

2 Term
A.M.I. Italia S.r.l guarantees the original purchaser of its Saver ONE series defibrillators, from the date on which the warranty validation form is sent* (to A.M.I. Italia S.r.l) or as from 30 (thirty) days from the date of shipment from the warehouses of A.M.I. Italia srl, the one that occurs chronologically first shall be valid; defibrillators have a typical service life expectancy of about 10 years. The warranty offered by A.M.I. Italia Srl covers a period of:
- **AEDs Saver ONE Series** have a six (6) year warranty.
- **Non-rechargeable batteries Li- SOCl2** (SAV-C0903) and **Li-MnO2** (SAV-C0904) if installed in the AED and in Standby mode are guaranteed for 4 (four) years assuming a battery activation test, daily self-tests, without the AED being switched on at the following environmental conditions temperature (20°C) and humidity WO/C (45%)
- **Rechargeable batteries Li-Ion** (SAV-C0011) are guaranteed for two (2) years from the date of production only if the temperature (20°C) and humidity (45%) conditions are met and if they are recharged at least one (1) time every four (4) months
- The **disposable PADs** are guaranteed until their expiry date.
- All **other accessories** are guaranteed for six (6) months starting 30 days after the original shipping date from our warehouse.
**The date shown on the registered letter with return receipt will however be valid*

3 Procedure
Please complete (in its entirety) the limited warranty validation form and send it by post (Registered letter with return receipt) to A.M.I. Italia Srl. The date shown on the Registered letter with return receipt shall prevail. You will find the Warranty validation form attached to the user manual or inside the original packaging of the Saver ONE series defibrillator. In the event that a defect covered by this warranty is found, the original purchaser must contact the Dealer of reference or an authorized A.M.I. Italia Srl support centre.
A.M.I. Italia S.r.l reserves at its discretion the exclusive right to repair or replace the product.

4 Exclusions
This warranty shall not cover instances of non-compliance subsequently to the purchase, such as those caused by accidents, modifications, misuse, non compliance with the procedures or hazards or warnings or cautions described in the user manual, failure to perform reasonable and adequate maintenance, incorrect installation, replacement of parts and accessories that does not comply with the specifications provided by A.M.I. Italia S.r.l, any modifications to the device, and, in general, all subsequent instances of non-compliance deriving from failure to comply with the requirements contained in the user manual.

This warranty shall not cover - as it does not constitute a case of original non-conformity - the normal wear and tear of components subject to degradation during use, such as Buttons, LEDs and battery contacts. Furthermore, this warranty will be automatically declared invalid in one of the following cases:
- if the Saver ONE AED series serial number is modified, deleted, rendered illegible or otherwise tampered with;

- if the warranty seal (opening of the device) on the Saver ONE series AED is removed;
- in case the trade name of the product or manufacturer is covered, modified or deleted
Lastly, this warranty shall not be valid for the Saver ONE AEDs that were sold used; in such case, the warranty must be offered by the reseller of the used product with exclusion of all liability, also indirect, of A.M.I. Italia S.r.l

5 Damage
Unless expressly laid down by this warranty. A.M.I. Italia S.r.l. SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR INDIRECT DAMAGE DERIVING FROM THE USE OF THE SAVER ONE SERIES DEFIBRILLATOR OR CLAIMS BY VIRTUE OF THIS AGREEMENT, WHETHER THE CLAIM REFERS TO THIS CONTRACT, TO AN OFFENCE OR OTHER. The warranty declarations mentioned shall be exclusive and shall prevail over almost all other remedies. Certain countries do not allow the exclusion or limitation of incidental and indirect damage, for which the aforementioned limitation or exclusion may not apply.

6 Waiver
ANY IMPLICIT GUARANTEES OF MARKETABILITY OR SUITABILITY FOR A SPECIFIC USE AND ALL IMPLICIT GUARANTEES DERIVING FROM NEGOTIATIONS, COMMERCIAL USE OR CUSTOMS, STATUTORY OR OTHER, SHALL BE STRICTLY LIMITED TO THE TERMS OF THIS WRITTEN WARRANTY. This warranty will constitute the sole and exclusive remedy of the buyer in relation to this purchase. In case of a presumed violation of any warranty or legal action by the original buyer for presumed negligence or other unlawful behavior by A.M.I. Italia Srl, the sole and exclusive remedy of the original buyer will consist in the repair or replacement of the materials found to be defective, based on what has been laid down previously. No dealer or agent or employee of A.M.I. Italia S.r.l. shall be authorized to amend, extend or expand this warranty.

7 Territorial limits
This warranty shall be valid for products purchased in one of the Countries of the European Union or in countries where the rules and laws of the EU apply.

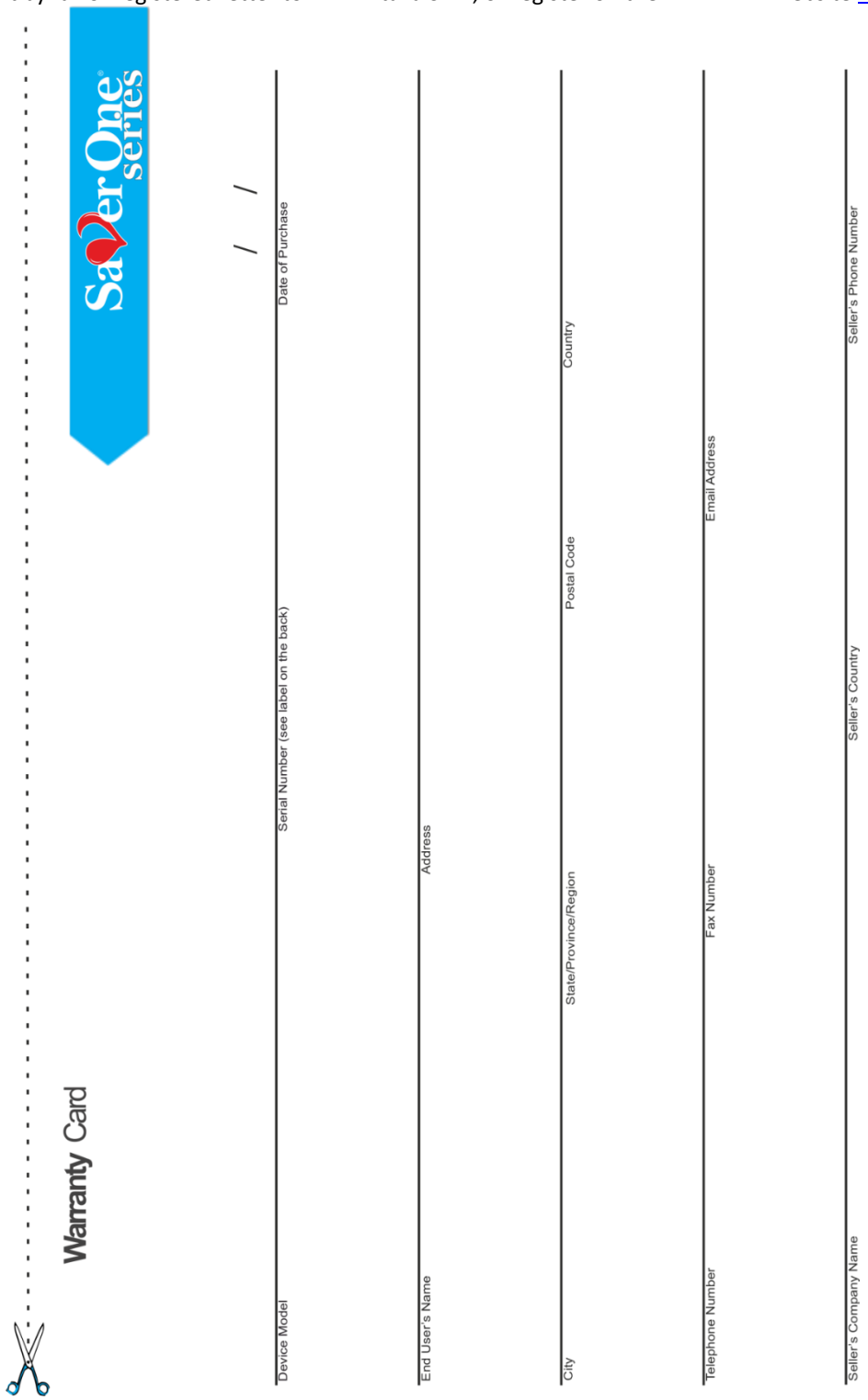
8 Warning
Install, use and perform maintenance on the Saver ONE series defibrillators of A.M.I. Italia S.r.l. in strict compliance with the instructions contained in the user manual

9 Other rights
This limited warranty guarantees specific legal rights to the original buyer; any other rights may vary depending on the country where they live.

10 Jurisdiction
Any dispute relating to this agreement or arising from the use of the Saver ONE series defibrillators of A.M.I. Italia Srl shall be governed by Italian law, before the Courts of Naples, Italy

17 PRODUCT REGISTRATION

In order to guarantee correct and rapid traceability of the product sold, we kindly ask you to complete the form below and send it by fax or registered letter to A.M.I. Italia S.r.l., or register on the AMIITALIA website www.amiitalia.com



SAVER ONE D

AEDs

AMI ITALIA
MEDICAL PRODUCT

IMQ