User Manual

External SEMI -AUTOMATIC Defibrillator

for public access

Rev.	12.4

SaverOne®

AEDs

QUICK USE GUIDE

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

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Summary

1 Introduction

1.1 Preface

Thank you for choosing the defibrillator manufactured by A.M.I. Italia S.r.l. model ***Saver One*** .
In order to use the device correctly, you must read this user manual carefully before use. The User Manual of ***Saver One*** 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 accordance with provisions

The device Saver One 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 Guarantee

The device ***SAVER ONE*** ha***s*** a guarantee of 6 (six)*years.
The non-rechargeable battery Li-$SOCl_2$ (SAV-C0903) has a guarantee of 4 (four)* years in Stand-by mode (assuming a battery activation test, daily self-tests without turning on the AED). This information refers to new batteries, fully charged at a temperature of 20°C and humidity of 45%.
* *For more information consult **Chapter 15** "Guarantee contract for defibrillators SAVER ONE"*

1.4 Exclusion of liability

The rights of liability are excluded in cases of damage to people or objects, if attributable to one of the indicated causes:
- Use of the appliance not in compliance with the provisions.
- Improper use and maintenance of the appliance.
- Use of the device and / or its accessories which show obvious or partial damage.
- Failure to comply with the instructions in the user manual concerning precautions, operation, maintenance and repair of the appliance.
- Use of non-original accessories and/or parts not approved by the manufacturer.
- Arbitrary interventions, repairs or modifications of the device.
- Arbitrary overcoming of performance limits.
- Lack of surveillance of parts subject to wear.

1.5 Indications

The ***SAVER ONE can*** only be used if the patient:
- is unconscious and...
- does not breathe and...
- shows no signs of blood circulation

1.6 Counter indications

The ***SAVER ONE cannot*** be used if the patient:
- is in a conscious state or...
- shows normal respiration or...

- shows signs of blood circulation

1.7 Version information

This user manual has a version number. The version number changes every time the manual is updated for changes made to the function of the device or to the device itself. The contents of this user manual are subject to change without notice. The information on the version of this manual is as follows.

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

1.8 Symbols in the manual

In this user manual there are several symbols that indicate the various precautions for use:

SYMBOL	INDICATION	DESCRIPTION
	**DANGER**	Indicates an immediate risk to the safety of people, which also **involves death** and damage to the device or parts thereof
	**CAUTION**	Indicates an unsafe situation or practice **involving serious personal injury** and damage to the device or parts thereof

1.9 Manufacturer contacts

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 Napoli (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

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

2 Safety instructions

For a correct use of the ***SAVER ONE defibrillator***, users must be aware of the safety factors listed below.
Please read them carefully.
The ***SAVER ONE defibrillator***, individually and in connection with its standard and optional (original) accessories, complies with the safety regulations currently in force and is in compliance 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 listed in this user manual are respected.
The following are the main precautions to be taken for the correct and safe use of the defibrillator, divided for easy consultation between hazard indications, warning indications and disposal instructions.

2.1 Indications of DANGER

- Use the ***SAVER ONE*** in accordance with the prescriptions in this user manual. Carefully read these instructions for use and in particular the safety instructions indicated in them.
- In accordance with IEC standards (section 2.4), the use of the ***SAVER ONE*** 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 the Li-$SOCl_2$ battery (SAV-C0903). Explosion risk!
- Do not allow the batteries to come into contact with an open flame. Do not expose to fire.
- Do not short circuit the battery terminals.
- In case of leakage of liquids or strange smells from the batteries, keep them away from fire to prevent any leaked electrolytes from catching fire.
- Danger of electric shock. The device generates high voltages and dangerous levels of current.
- Do not open the ***SAVER ONE,*** do not remove the panels and do not attempt to repair it. The ***SAVER ONE*** contains no components that users can repair. For repair purposes, the SAVER ONE P 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. Remove the patches and only then position the electrodes. 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 phase. Avoid any contact between:
  - parts of the patient's body
  - conductive liquids (such as gel, blood or solution of table salt)
  - metal objects in the surroundings of the patient (such as bed frame or stretching device) that represent indirect ways for the defibrillation current
- Before using the device ensure the patient's safety, if necessary move them carefully and position them in a safe place as per the AHA / ERC guidelines
- Do not immerse any part of the ***SAVER ONE,*** its parts or accessories in water or other liquids.
- Do not allow liquids to enter the ***SAVER ONE its*** parts or accessories. Avoid spilling liquid 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*** or its accessories.

2.2 Indications of CAUTION

- Avoid the formation of air bubbles between the skin and defibrillation PADs. The formation of air bubbles during defibrillation can 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 breathing normally. The ***SAVER ONE is*** equipped with a pacemaker detection system that allows ignoring the signal emitted by the latter; however, with some types of pacemakers, ***SAVER ONE*** may discourage a defibrillation shock.
  During the application of the electrodes:
  • Do not apply the electrodes directly to 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 cellular phones and two-way radios, can cause the ***SAVER ONE*** to malfunction. The ***SAVER ONE*** must be kept at least 2 meters away from these RF devices, as indicated in the standards of EN 61000- 4-3. Keep away from other therapeutic and diagnostic energy sources (eg diathermy, high-frequency surgery, magnetic tomography).
- Use the ***SAVER ONE only*** if you have achieved a BLS-D or ALS-D training course.
- Before using the device, make sure that there is no obvious damage.
- 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). Using paediatric defibrillation PADS the ***SAVER ONE automatically*** switches to paediatric mode, reducing the maximum energy available to 50J.
- Arrange the patient cables so as to reduce the possibility of wrapping or strangling the patient.
- In a domestic environment, keep the defibrillator out of the reach of children and pets.
- Do not apply the defibrillation electrodes directly on an implanted pacemaker to avoid any errors in the interpretation of the device and to avoid damage to the pacemaker through the defibrillation impulse.
- Disconnect high-voltage pulse-sensitive equipment from the patient, ie that is not defibrillator-proof, before delivering the shock.

CAUTION 

- Do not allow defibrillation electrodes to touch or come into contact with ECG electrodes, swabs, transdermal patches, etc. Failure to do so may result in creation of electric arcs and burns to the patient during defibrillation, and even current leakage.
- Position the defibrillation PADS as indicated in this user manual and indicated on the package.
- Do not use defibrillation PADs if the gel has been detached from the support or is torn, split or dry.
- If damage has been detected, do not operate the ***SAVER ONE*** 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 make false interpretations.
- Do not use defibrillation PADs if they are damaged, even partially.
- Do not touch the patient or PADs during heart rhythm analysis.
- Moving or transporting the patient during the cardiac rhythm analysis performed by the device can lead to an incorrect or not timely diagnosis. During the heart rhythm analysis phase, minimize the movements. If the device is used in an ambulance in motion, stop the vehicle and start again only after having delivered the shock.
- In order to use the ***SAVER ONE***, you 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 8-25kg).
- Before applying the defibrillation PADS, if necessary, dry the patient's chest and remove unwanted hair.
- Do not subject ***SAVER ONE***, its accessories, its parts to falls and / or strong impacts
- Do not use damaged accessories and / or parts, otherwise the device may malfunction.
- Use only original accessories and / or spare parts.
- Avoid excessively aggressive handling of the device of its accessories or parts in order to avoid possible damage. Inspect the entire system periodically.
- Carry out the sanitation operations of the device in compliance with the standards indicated in paragraph 10.3 and always make sure that the device is switched off with the battery removed and PADs disconnected.
- Defibrillation PADs are disposable, to be used only on one patient. Do not reuse defibrillation pads; discard after use and replace with a new pair.
- Defibrillation PADs are not sterile or sterilizable.
- Intense or prolonged administration of cardiopulmonary resuscitation with defibrillation electrodes applied to the patient can damage the electrodes. Replace them if they are damaged due to use or handling.
- Improper maintenance can damage the ***SAVER ONE*** or cause it to malfunction. Follow the instructions in this user manual.
- Use original non-rechargeable Li-SOCl2 (SAV-C0903) batteries from A.M.I. Italia S.r.l. before the indicated expiration date.
- Recharge the rechargeable Li-ion battery (SAV-C0011) at least once every 4 months ensure its perfect function and extend its life.
- The Li-ion rechargeable batteries ACC model (SAV-C0011) must be charged using only the SAV-C0012 battery charger from A.M.I. Italia S.r.l. otherwise the batteries could be damaged
- Remove the batteries from the device only if it has been turned off for at least 5 seconds. Otherwise the device and the battery can be seriously damaged.
- The ***SAVER ONE***, its parts and accessories are not sterile or sterilizable
- Do not expose the ***SAVER ONE***, its parts or accessories to direct light or high temperatures
- The Battery Charger (SAV-C0012) must only be used with the Meanwell power supply model GS40A15-P1J (SAV-C0014) supplied by A.M.I. Italia S.r.l. The use of different power supplies could compromise the correct functioning of the battery charger and damage the ACC rechargeable batteries (SAV-C0011)
- In order to safeguard the battery life (SAV-C0903) and guarantee automatic daily tests, after installing it, it is advisable to not remove the battery (SAV-C0903) unless it is to be replaced. The removal of the battery and the subsequent insertion involves a complete test of the AED which considerably consumes its capacity. Furthermore, if the battery is not properly attached it could be damaged.

2.3 Indications of DISPOSAL 

- The ***SAVERO ONE,*** its parts and accessories must not be disposed of with other household waste within the European community. To prevent possible damage to the environment or human health caused by incorrect waste disposal, recycle this product responsibly also to promote sustainable use of resources. To dispose of the used product, use the appropriate waste collection services or return it to the local distributor. In this way it will be possible to recycle safely for the environment

3 Description of the device

3.1 Device Information

The ***SAVER ONE*** is called PAD or Public Access Defibrillator.
The ***SAVER ONE*** is a **semi-automatic** external defibrillator, i.e. the operator must press the shock button if indicated in order to deliver the shock. Designed to automatically detect and analyse the victim's heart rate, it can deliver one or more defibrillation shock if a ventricular fibrillation or ventricular tachycardia is detected (monomorphic or polymorphic with beat ≥180). The energy is delivered by a truncated exponential biphasic (B.T.E.) electrical shock capable of self-adapting to the patient's chest impedance.
The ***SAVER ONE*** is available in two versions:

SAVER ONE 200 J (SVO-B0001) – Maximum deliverable energy 200J
SAVER ONE 360 J (SVO-B0002) – Maximum deliverable energy 360J

The ***SAVER ONE*** is an extremely compact and lightweight portable device; it can be used with two types of battery:

- **Non-rechargeable battery Li-SOCl$_2$** (SAV-C0903), which requires no maintenance, is guaranteed to operate in standby mode for 4 years or carry out a high number of shocks
- **Rechargeable battery Li-ion (SAV-C0011), recommended for those who use the defibrillator intensively**

The ***SAVER ONE*** has been designed to be used not only by medical personnel but also by lay personnel who have duly completed a training course on cardio-pulmonary resuscitation with the use of the defibrillator (BLS-D). The ***SAVER ONE*** is equipped with voice commands that instruct the rescuer in every phase of resuscitation. The device has been designed for rapid use to facilitate use by the user.
The device is built in accordance with directive 2007/47 / EC and complies with IEC/EN 60601-2-4.

The device allows the data to be recorded on an SD Memory Card so that they can be re-displayed on a PC. During the non-use phase, if battery is installed, the device carries out daily self-tests to verify its functional condition, in order to guarantee its prompt use in the moment of need. On the keyboard of the device there is a mini LCD display and a two-colour LED (red / green) through which it is possible to see 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 defibrillator*** is classified as follows:

Code **UMDNS**	11132
Code **GMDN**	47910
Code **CND**	Z12030501
Directory number **RDM**	114276 / 1535105
Code **CIVAB**	DEF01
Class of belonging according to directive **2007/47/CE**	IIb
Type of protection against electric shock	Internally powered
Type of patient isolation	BF
Degree of protection against penetration of liquids	IPx4
Degree of protection against dust penetration	IP5x
Degree of safety in the presence of a flammable anaesthetic mixture with air, oxygen or nitrous oxide	Not protected
Sterilization or disinfection method suggested by the supplier	See Paragraph 10
Mode of operation	Continuous operation

4 Description of device details

4.1 General structure of the device

Image 1

Nr.	Description
1	Compartment for PADS connector or ECG cable
2	Microphone for environmental recordings
3	Status mini display
4	Carrying handle
5	Battery compartment
6	Keyboard with buttons and light icons
7	IrDA port (service only, present only in the models with TFT display)
8	Loudspeaker

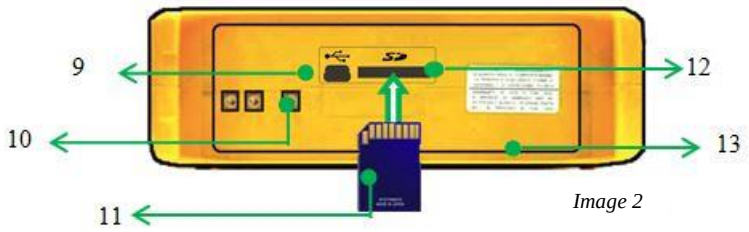


Image 2

Nr.	Description
9	USB port
10	Battery contact tabs
11	SD Memory Card insertion
12	SD Memory Card port
13	Gasket

4.2 Keys, icons and indicators

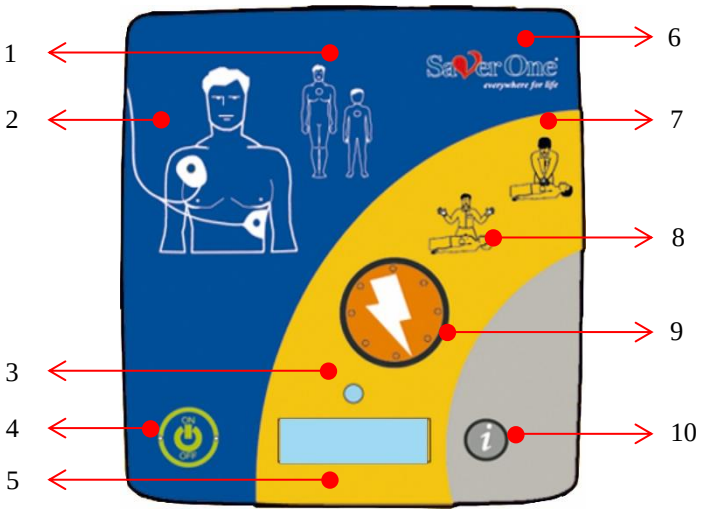
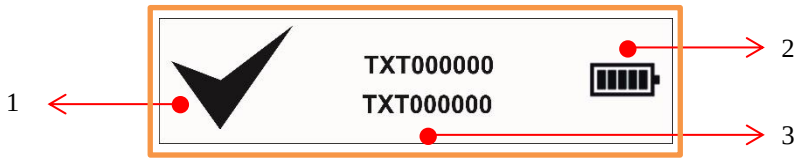


Image 3

Nr.	Function	Nr.	Function
1	**“Patient Type” Indicator** Indicates the type of mode in use: **Adult** if you insert Adult PADs **Child** if you insert paediatric PADs	6	**Product logo** Indicates the model of the device
2	**"Place PADs" Indicator** Icon equipped with LEDs indicating to position the defibrillation PADs.	7	**"CPR" Indicator** Indicates to start CPR
3	**Control LEDs** Luminous LED (red / green) allows you to check the functional status of the AED.	8	**"Do Not Touch" Indicator** Icon equipped with LEDs indicating not to touch the patient during certain operations
4	**ON / OFF button** Allows you to switch the device on or off.	9	**Shock indicator** Equipped with luminous LEDs it allows to deliver a defibrillation shock if indicated
5	**Status mini display** It allows you to check the functional status of the device	10	**"I" button** Allows in operating mode to show useful information on the device

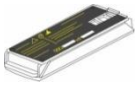
4.3 Status display



Nr.	Description
1	Device status icon
2	Remaining battery level
3	Text commands

4.4 Standard and optional accessories of the device

The ***SAVER ONE*** defibrillator comes with the following standard accessories:

Code	Image	Quantity	Description
SVO-B0001		**1 Unit** (Version 200J or 360J)	***SAVER ONE*** *200J*
SVO-B0002			***SAVER ONE*** *360J*
SAV-C0846		**1 Unit**	Adult Pads
SAV-C0903		**1 Unit**	Non-rechargeable Li-$SOCl_2$ battery
SAV-C1005-HU		**1 Unit**	User guide
SAV-C0916		**1 Unit**	Carry bag

The following are the optional ***SAVER ONE*** accessories that can be purchased separately:

Code	Image	Quantity	Description
SAV-C0011		**1 Unit**	ACC Rechargeable Li ion battery
SAV-C0012		**1 Unit**	Charger
SAV-C0013		**1 Unit**	GS40A15-P1J Power supply
SAV-C0014		1Unit *(Contains 3 units)*	N.01 Charger N.01 GS40A15-P1J Power supply N.01 Power supply cable
SAV-C0016		**1 Unit**	Children Pads
SAV-C0019		**1 Unit**	CD-ROM Saver View Express
SAV-C0907		**1 Unit**	SD Card
SAV-C0027		**1 Unit**	Memory Card reader for PC

5 Parts and accessories of the *SAVER ONE*

5.1 SAVER ONE Batteries

The ***SAVER ONE defibrillator*** can work with two different types of batteries:

- (SAV-C0903) **Non**-rechargeable Li-$SOCl_2$ battery
- (SAV-C0011) Rechargeable Li ion battery

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

The non-rechargeable battery with Li-$SOCl_2$ technology (SAV-C0903) is supplied fully charged and ready for use. The Li-$SOCl_2$ non-rechargeable battery has been designed to have a long battery life and no maintenance whatsoever.

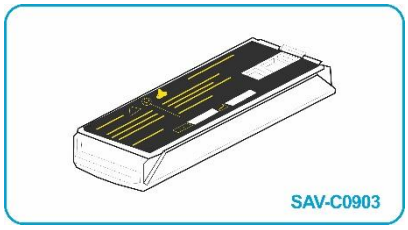


Image 4

The non-rechargeable battery of the ***SAVER ONE*** in Standby mode is guaranteed for 4 (four) years assuming a battery activation test, daily self-tests without turning on the AED. The Li-$SOCl_2$ non-rechargeable battery (SAV-C0903) is able to carry out a large number of shocks which vary according to the version:

SAVER ONE Standard 200J	300 complete rescue cycles (shocks at 200J. and CPR)
SAVER ONE Power 360J	200 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*** 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 5.1.
With a 5% battery the **SAVER ONE** allows to deliver about **14 shocks** or **40 days of stand-by**

ALARM: Remaining capacity level of Battery at **≤ 1%**
This warning will be provided both in Stand-by and in operating mode, as indicated in paragraph 5.1
With a battery at **≤ 1%** the ***SAVER ONE*** carries out about **7 shocks** or **20 days of stand-by**
In this condition the use of the device is not recommended.

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

5.1.2 Rechargeable Li ion battery (SAV-C0011)

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

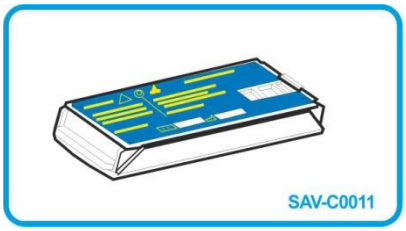


Image 5

The ACC 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 Standard 200J	typically 250 continuous shocks
SAVER ONE Power 360J	typically 160 continuous shocks

If the remaining battery level is low, the ***SAVER ONE informs*** the user via audio and visual messages.
The ***SAVER ONE*** 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 5.1.
With a 5% battery the **SAVER ONE** allows to deliver about **14 shocks** or
40 days of stand-by

ALARM: Remaining capacity level of Battery at **≤ 1%**
This warning will be provided both in Stand-by and in operating mode, as indicated in paragraph 5.1
With a battery at **≤ 1%** the ***SAVER ONE*** carries out about **7 shocks/20 days of stand-by**
In this condition, the use of the device is not recommended.

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 Suggestions for a proper maintenance of battery SAV-C0011

A.M.I Italia recommend that batteries SAV-C0011 left in a “storage stage” to be fully recharged at least every 4 months from the receipt of the goods and to be recharged regularly every 4 months when attached to the device "ready to use" , to avoid completely discharging it and to maintain maximum life expectancy of the battery. The battery pack technology and the modules offered are to ensure a long-lasting duration but they require a correct maintenance; failure to follow these requirements will result in an early deterioration of the battery, which will not be covered by warranty.

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

5.1.4 Inserting and removing the batteries

To be able to operate the ***Saver One*** the insertion of a battery is required. Below are detailed instructions for correctly installing the batteries (rechargeable or non-rechargeable) in the ***Saver One.***

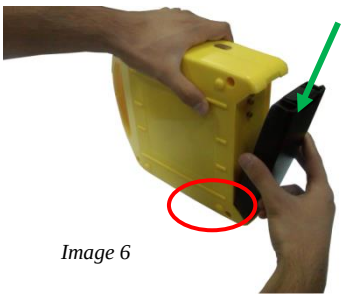


Image 6

Image 7

- Place the device on the side as shown in the figure (6)
- Hold the device firmly with your left hand as shown in figure (6)
- Insert the battery as shown in figure (6) following the direction of the arrow and matching it perfectly with the point highlighted by the circle
- Push the battery as shown in figure (7) following the direction of the arrow, until you hear a click that confirms the correct insertion

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

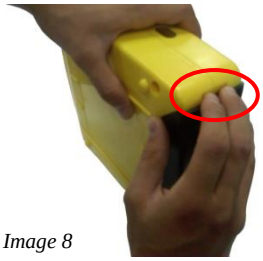


Image 8

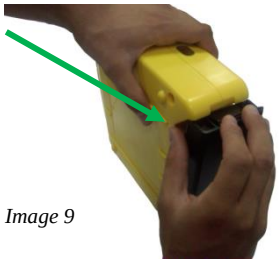


Image 9

- Position the device as shown in figure (8)
- Hold the device firmly with your left hand as shown in figure (8)
- Using two fingers of the right hand press on the battery hook highlighted by the circle in figure (8)
- At the same time pull the battery in the direction indicated by the arrow shown in figure (9)

5.2 Recharging station for rechargeable batteries

The charging station (SAV-C0014) allows you to recharge rechargeable batteries with Li-ion technology ACC model (SAV-C0011) of the ***Saver One*** . The charging station consists of the following parts:

- Charger (SAV-C0012) image (10)
- AC/DC power supply/adapter model GS40A15-P1J (SAV-C0013) image (11)
- Power cable with three-pole Italian plug (SAV-C0366) image (12)

Image 10

Image 11

Image 12

5.2.1 Structure of the battery charger

Image 13

Nr.	Description	Function
1	Charger LED	Indicates the battery charge level or the functional status of battery charger
2	Supply	Input for 12V, 5A power supply connector
3	Battery contacts	Contacts for energy exchange between charger and battery

The Battery Charger (SAV-C0012) must only be used with the AC/DC power supply/adapter supplied by A.M.I. Italia S.r.l. model GS40A15-P1J of Meanwell (SAV-C0013).
The battery charger (SAV-C0012) and the relative power supply unit (SAV-C0013) are not certified under the supervision of the IMQ notified entity, therefore they do not fall into the 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

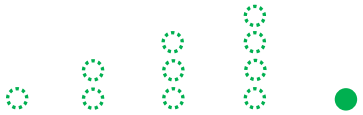
A Place the charger on a perfectly horizontal shelf and firmly attached to the floor
B Connect the power supply (SAV-C0013) to the charger and then to the power outlet
C The LED on the charger will flash green, indicating that it is ready to charge
D Insert the battery to charge into the battery charger as shown in image (14)

Image14

The recharging station allows you to recharge exclusively original ACC 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 the one indicated. The battery charger is equipped with a control LED that indicates both its functional status and the battery charge level, if inserted. The following is a table that allows identification of the control LED coding:

INDICATOR	**RED**		**GREEN**	
FIXED	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

When recharging, the battery charger control LED will flash green with a different frequency depending on the level of recharge, until the charge is fully indicated by the control LED with FIXED green light.



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

5.3 Defibrillation PADs for Adults *SAV-C0846*

The ***Saver One*** allows the use of two different defibrillation PADs depending on the patient to be treated:

- Defibrillation PADs for **Adults** model SAV-C0846
- Defibrillation PADs for C**hildren** model SAV-C0016

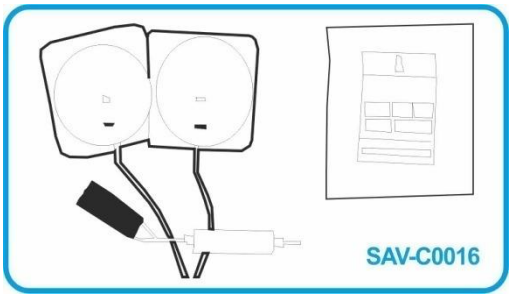
5.3.1 Defibrillation PADs for Adults *SAV-C0846*

The SAV-C0846 defibrillation PADs are pre-gelled disposable types.
They must be used on adult patients (**age> 8 years or weight> 25Kg**). Defibrillation PADs are supplied in a single sealed package with the expiration 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 presence of the cable and the PAD connector **outside the sealed package**. This solution has been adopted in order to maximally speed up the positioning of the Pads avoiding the need to insert the connector during the phases of the rescue.

The **SAV-C0846** PADs are polarized type, that is, the positioning of the electrodes **must not be reversed.**
For more information on positioning the defibrillation PADs, refer to the relevant paragraph.

5.3.2 PADs for Children *SAV-C0016*

The SAV-C0016 defibrillation PADs are pre-gelled disposable types.
They must only be used on children patients **(age <8 years or weight <25Kg**). The defibrillation PADs are supplied in a single sealed package with the expiration 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**.

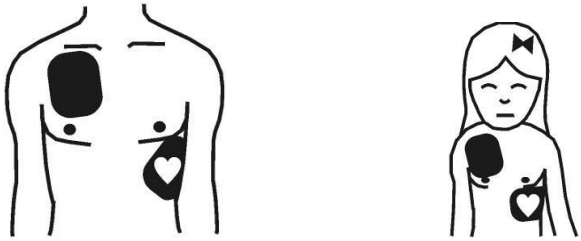


The PADs SAV-C0016 allow to deliver shocks on paediatric patients with a maximum energy level of 50J as prescribed by the international guidelines ERC/AHA 2017. The PADs SAV-C0016 are polarized type, that is, the positioning of the electrodes **must not be reversed**.
For more information on positioning the defibrillation PADs, refer to the relevant paragraph.

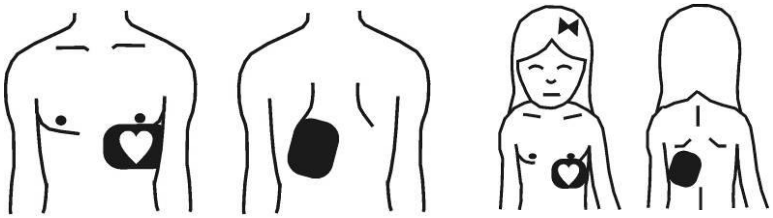
5.3.3 Positioning of defibrillation PADs

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



1 Position **Pad 1** immediately below the patient's right collarbone
2 Position **Pad 2**on the ribs on the left side of the patient under the left side of the chest

5.4 Memory Card

The ***Saver One*** 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*** 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

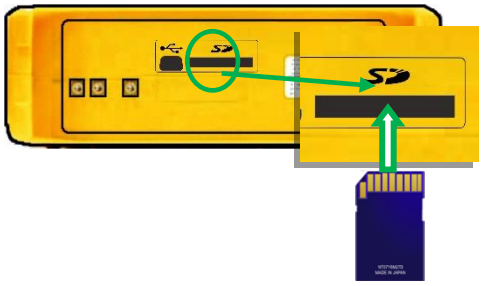


Figure 21

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*** 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.

6 Auto test

The SAVER ONE has been designed to be a totally safe device, always ready for use and able to automatically and constantly verify correct operation, minimizing maintenance operations.

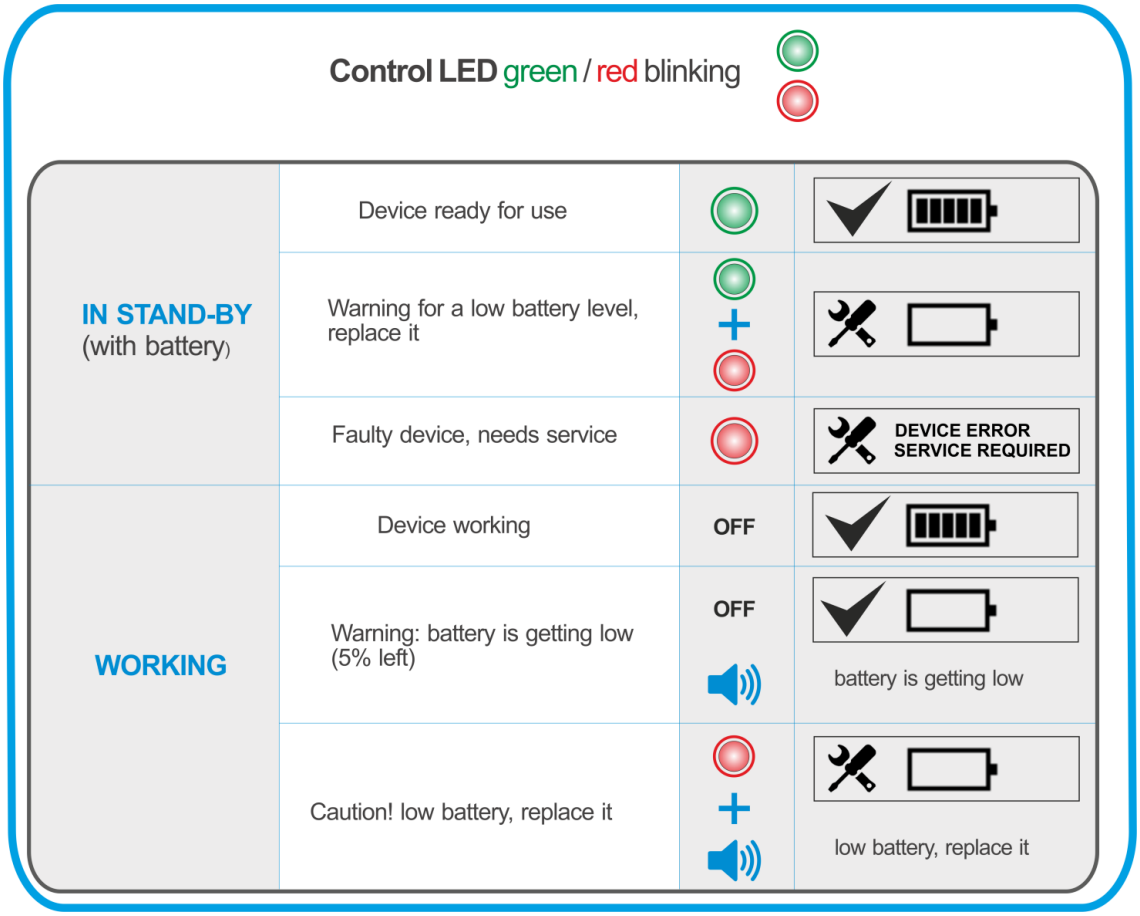
The SAVER ONE performs different types of self-tests:

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

The outcome of the control 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.

6.1 Display and control LED

Both the mini display and the control LED are positioned on the front of the ***SAVER ONE*** keyboard.
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 relative screens of the control mini display.



6.2 ACTIVATION Test

The ***SAVER ONE*** 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 control (firmware/hardware), which involves a consumption of the battery equal to a shock; therefore it is advisable, once performed, not to remove the battery from the device.
The ACTIVATION test requires a manual intervention by the operator, who must perform the following steps:

- **Insert the battery into the device**

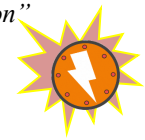
If the battery is correctly inserted, the ***SAVER ONE*** will automatically turn on emitting an acoustic signal and the power button will light up green while the control LED will turn off.

The following screens will appear on the control display:

The device will emit a voice command (audio) suggesting the operation to complete.

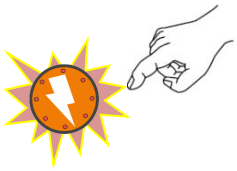
Vocal Command: *"Device test"*
"Press the flashing red button"

The shock button will light up with flashing light.



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

- **Press the shock button to start the ACTIVATION test**



If the shock button is pressed correctly, it will stop flashing and the device will start the activation test:

If no error is detected the following screen will be shown on the display:

- **Turn off the device**

If it is not to be used immediately turn off the ***SAVER ONE and*** leave the battery inserted to ensure that periodic self-diagnostic tests are performed (see Section 6.3).

***If the shock button is not pressed within the time limit indicated by the countdown, the Saver One detects an error.**
Turn the device back on and press the shock button within the time limit indicated by the countdown.
However, if the shock button has been pressed but the shock button continues to flash, the shock button is not working properly.
Turn off the device and perform the operation again; if the problem persists, contact the authorized technical assistance center.

6.3 AUTOMATIC Test

The ***SAVER ONE was*** designed to always be ready in the moment of real need.
The device is equipped with 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*** will inform the operator of the start of the automatic self-test through the mini status display:

During the test  after the test 

The automatic self-test involves a reasonable consumption of the battery.
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 using the LED and the mini-control display located on the device keyboard.
Consult the Led table and the mini-control display shown in paragraph 6.1

6.4 POWER ON Test

The SAVER ONE performs self-diagnostic tests each time it is turned on, either from the power button or by inserting the battery.
Following to the battery insertion a diagnostic test of ACTIVATION is performed. This self-test involves a fair amount of energy consumption. It is recommended, once performed, to not remove the battery from the AED.
These tests are performed in order to verify the correct operation of the device before use.
Each test is conducted automatically and lasts a few seconds.
After pressing the power button,  (or after inserting the battery) the SAVER ONE will emit an acoustic signal to confirm power-up, the control LED will be off and the following screen will be displayed:

If no error is found, the following screen will appear on the display:

From this moment the device will be ready to be used and will provide the operator with the first instructions to start the intervention.

If not to be used immediately, switch off the SAVER ONE and leave the battery inserted to ensure periodic self-testing (see Section 6.3).

7 Information button

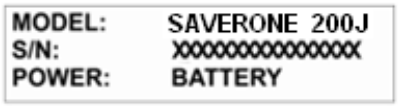
The SAVER ONE is equipped with an "***i***" button, through which the operator can view various useful information about the device in use on the LCD display.
This button can only be used when the device is switched on and is automatically disabled in the event of an ongoing emergency.
The information shown on the Display is divided into three different pages, which can be consulted by pressing the "***i***" button *n* times (*n* meaning the number of pages).
Below is a detailed description of the procedure for using this button and the information displayed:

➢ **Switch on the device**

The SAVER ONE will carry out the automatic power on test after which it will be ready for use.

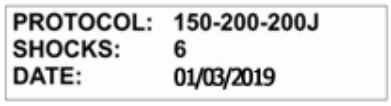
➢ **Press the "*i*" button**

1. After pressing the button the **first time** the following screen will appear with the related information:



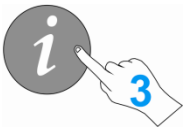
Nr.	Description
1	Device model
	Device Serial Number
2	Type of supply

2. Pressing the button for the **second time** will display the following screen with the related information:



Nr.	Description
3	Pre-set shock protocol
4	Number of shocks made
5	Current date

3. Pressing the button for the **third time** will display the following screen with the related information:



Nr.	Description
6	Change language

To change the language, press the "i" button for about 3 seconds and release it.
The user will see the following screen:

Select the desired language by pressing the "i" button. Once the desired language has been selected, press the "i" button for about 3 seconds to confirm the selection.
The selected language remains in memory and at the next restart of the device, it will be the default language.

8 Defibrillation

If you need to help a person with sudden cardiac arrest, remember to implement the sequence of actions recommended by ERC and AHA.
The ERC has established a rescue protocol to be respected during the resuscitation of a person suffering from sudden cardiac arrest. This protocol has been called the "chain of life".

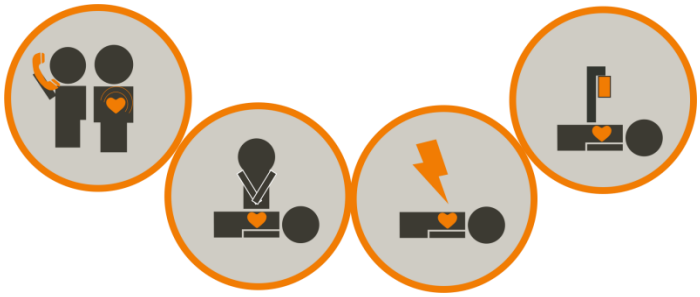


Image 18

1. Make sure the person needs help (*unconscious and not breathing and does not shows signs of blood circulation)*and call immediately your local emergency number.
2. While waiting for a defibrillator to be available, begin CPR manoeuvres immediately
3. Use the ***SAVER ONE*** defibrillator to restore normal heart rhythm
4. Continue until resuscitation of medical competence

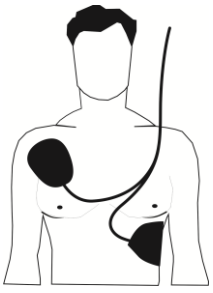
8.1 Switching on the *SAVER ONE*

The ***SAVER ONE defibrillator*** will automatically start the semi-automatic defibrillation mode every time it is turned on (default setting). Below are the procedures to follow to use the device in this mode.

Press the power button on the device 

The **SAVER ONE** will emit an acoustic signal to confirm the power on, the ON / OFF button will be lit fixed green.
The following screens will appear on the LCD display:

If the test is successful, the device will suggest the first operation to be performed by the operator using voice (audio) and visual commands (luminous icons and display text):

Voice commands	Display	Luminous Icons Keyboard
Call your local emergency number	call now the emergency service	Command Position Defibrillator PADs 
Remain calm and follow the voice instructions. If the patient is unconscious and does not breathe, remove clothing in order to apply the electrodes on the bare chest	Remove clothing to expose bare chest	
Place the electrodes firmly on the chest as shown in the figure	Place Electrodes firmly to bare chest	

8.2 Preparation of the patient

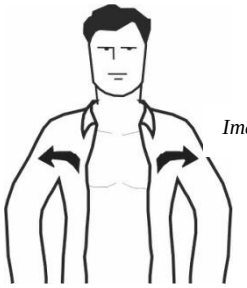


Image 19

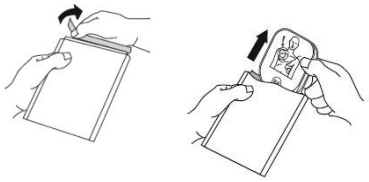
In order to correctly position the defibrillation PADs on the chest, it is necessary to carry out the following preliminary operations:

Remove clothing from the patient's chest

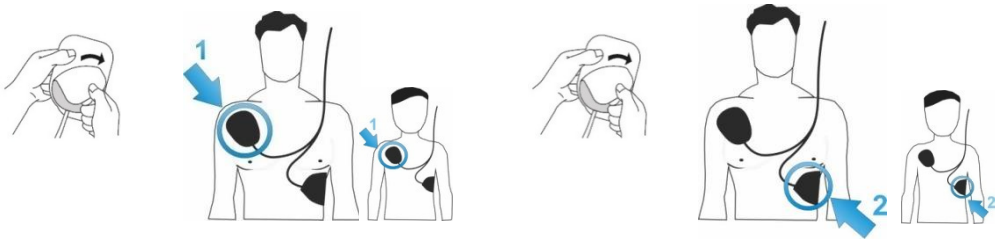
If the patient's chest has thick hair it might be necessary to shave the Pads positioning points.

8.3 Positioning the PADs

A Remove the defibrillation PADs from their packaging.



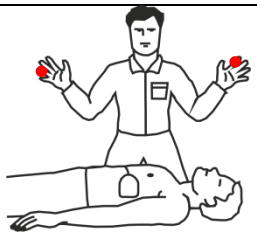
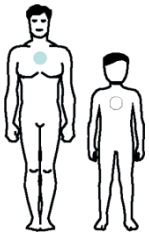
B Remove the protective film from each individual PAD and place it on the patient's chest



The defibrillation PADs are polarized type, this requires that they be positioned at the points indicated on each single PAD. If the patient is a child, use the SAV-C0016 paediatric defibrillation PADs, see the relative paragraph for more information.

8.4 Cardiac rhythm analysis

The ***SAVER ONE*** automatically analyses the patient's heart rhythm. This phase is highlighted by the following commands:

Voice commands	Display	Luminous Icons Keyboard
Do not touch the patient	Rhythm Analysis Don't touch patient	 Icon do not touch the patient on with fixed light
Cardiac rhythm analysis in progress		 Icon type of pads used (*adult / child*)

During cardiac rhythm analysis, the patient's body must not be touched and must not be subjected to vibrations or movements. The ***SAVER ONE*** 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 min. 200 µVolts

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

VT *Ventricular tachycardia*
(including ventricular flutter and polymorphic ventricular tachycardia)

Rhythm frequency min. 180 bpm and peak-to-peak amplitude min.200 µVolts

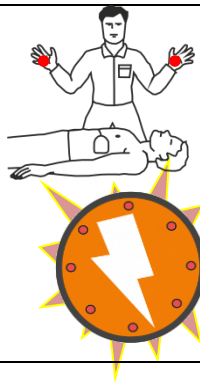
Some rhythms with very low amplitude or low frequency VT may not be interpreted as shockable.

The **SAVER ONE** 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** is able to detect and filter impulses coming from an implanted pacemaker.

8.5 Shockable rhythm

If a Ventricular Fibrillation or Tachycardia is detected, the SAVER ONE will inform the operator using the following commands:

Voice commands	Display	Icons/ Luminous buttons
Shock recommended	device is charging stay clear patient	 Do not touch the patient icon on with fixed light
Keep distance, charging		
Press the red flashing button	Press shock Button	Shock button flashing

To deliver the shock press the shock button within 15 seconds.
Before pressing the shock button move away and make sure no one is touching the patient. If, the shock button is not pressed within 15 seconds from the shock warning, the ***Saver One S1 Series*** will automatically disarm. At this phase the shock button will no longer flash and the device will inform the user through the following commands:

Voice commands	Display
Shock cancelled	SHOCK CANCELLED
Shock button was not pressed	

If, on the other hand, the shock button was pressed the ***Saver One*** will deliver the defibrillation shock. In this phase the shock button will no longer flash and the device will inform the user through the following commands:

Voice commands	Display
Shock delivered	SHOCK DELIVERED

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

Saver One S1 Series 200J: The first shock is delivered to energy of **150J** the following at **200J**
Saver One S1 Series 360J: The first shock is delivered to energy of **200J** the second at **250J** the following 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.

8.6 Change of rhythm

The SAVER ONE analyses the patient's heart rhythm continuously, during the resuscitation phase.
If the device after recommending the shock detects a change in the heart rate of the patient who no longer needs a defibrillation, it will carry out the automatic disarmament. This phase is highlighted by the following commands:

Voice commands	Display
Shock cancelled	SHOCK CANCELLED 

8.7 Non-shockable rhythm

If the ***SAVER ONE*** does not detect a VF or a VT during heart rate analysis, it will inform the operator using the following commands:

Voice commands
Shock not recommended

All rhythms other than VF and VT will be considered as non-shockable. For more information, paragraph 10.6.

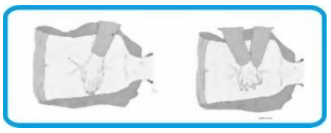
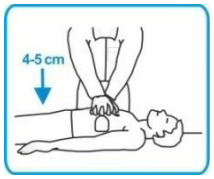
8.8 CPR

The ***SAVER ONE*** defibrillator will guide the operator to CPR (**C**ardio **P**ulmonary **R**esuscitation) in one of the following cases:

- A shockable rhythm was detected and a defibrillation shock was delivered
- A non-shockable rhythm was found
- A shockable rhythm was found but the patient's rhythm changed

The ***SAVER ONE*** will provide instant by instant instructions for performing CPR, instructing the operator on how to perform chest compressions and insufflations. According to the 2017 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.
During the phase of chest compressions, the SAVER ONE mediates a metronome which will set the rhythm to maintain in order to perform the compressions at the right time. Once the compressions have ended, you will need to perform the two breaths. These instructions are repeated throughout the CPR phase, or about 2 minutes.

The following table shows the main operations to be performed and the relative visual-text-vocal commands provided by ***SAVER ONE***

<table>
<tr><th>No.</th><th>Type of command
(SAVER ONE)</th><th>Instruction SAVER ONE</th><th>Operations to be performed</th></tr>
<tr><td rowspan="3">1</td><td>Vocal</td><td>“Begin Cardio-Pulmonary Resuscitation”</td><td rowspan="3">A. Make sure the patient is lying on a flat surface
B. Kneel beside the victim
C. Place the heel of one hand in the centre of the victim's chest
D. Place the heel of the other hand over the first one
E. Interlace the fingers of both hands and make sure that the pressure is not applied to the ribs. Do not exert any pressure on the upper portion of the abdomen or the lower portion of the sternum
  </td></tr>
<tr><td>Visual DISPLAY</td><td>  </td></tr>
<tr><td>Visual LUMINOUS ICON</td><td>  </td></tr>
<tr><td rowspan="4">2</td><td>Vocal</td><td>“Quickly compress the patient's chest”</td><td rowspan="4">F. Stand vertically on the victim's chest and, with arms extended, compress the sternum. Keeping the arms stretched, the external cardiac massage is exercised using the weight of the trunk; the oscillation movement must be from pivoting on the coxo-femoral joint
G. After each compression release all pressure from the chest without losing contact between one's hands and the sternum; repeat the manoeuvre with a frequency of 100 / min (a little less than 2 compressions per second)
H. The compression and release phase must be approximately equal in duration
  </td></tr>
<tr><td>Visual DISPLAY</td><td>  </td></tr>
<tr><td>Visual LUMINOUS ICON</td><td>  </td></tr>
<tr><td>Acoustic Signal
(BEEP)</td><td>The ***SAVER ONE*** signals with a BEEP every compression to be performed.</td></tr>
<tr><td rowspan="3">3</td><td>Vocal</td><td>“Perform two breaths”
“Exhale”
“Exhale”</td><td rowspan="3">Immediately open the air passage using the head and chin towards the back manoeuvre
 
Perform two insufflations
The rescuer inhales normally and keeping the chin lifted with two fingers, make the lips adhere around the mouth of the injured person. The contralateral hand closes the nostrils to avoid air release and keeps the head in hyperextension. Blow out the air by performing a normal expiration lasting about 1 second.
  </td></tr>
<tr><td>Visual DISPLAY</td><td>  </td></tr>
<tr><td>Visual LUMINOUS ICON</td><td>  </td></tr>
<tr><td>4</td><td colspan="2">The ***SAVER ONE*** will repeat STEP 1 to 3 for about 2 minutes</td><td>Follow the voice and text instructions of the ***SAVER ONE*** until the device stops the CPR phase (about 2 minutes)</td></tr>
</table>

9 Recording, viewing and archiving the data

The ***SAVER ONE*** 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 archiving is done automatically (cannot be deactivated by the user) both on **the internal memory** of the device and on **the memory card** when installed.

9.1 Data recording

The **internal memory** of the ***SAVER ONE*** allows the storage of up to 6 hours of environmental recordings (audio), ECG tracing, patient data (FC 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 **external memory SD Card:**

- **AED1LOG.txt** This file stores all the automatic self-tests performed by the device with its outcomes and all the **SERVICE** information. This type of file can be viewed on a PC using a simple reading program.

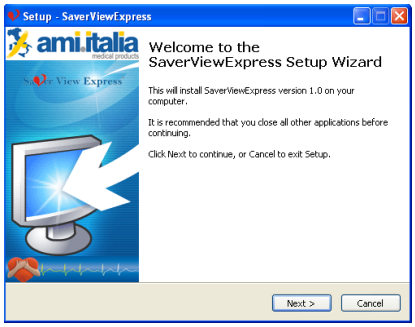
- **AEDFILE.aed** This file stores the rescue data such as: environmental recordings (audio), ECG tracing, patient data (FC and Ω) and all rescue events. This type of file can be redisplayed on a PC using the PC Saver View Express software.

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 (50 hours)
	2 GB		6.000 minutes (100 hours)
SDHC Card	4 GB		12.000 minutes (200 hours)

9.2 Archiving data on PC

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



Saver View Express®

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

10 Maintenance

The ***SAVER ONE*** defibrillator was designed to make maintenance operations as simple and autonomous as possible. In fact, thanks to the control 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 relative accessories.
Whenever it is necessary to contact the supplier for assistance during an installation, or to report anomalies, contact the supplier using the references:

Assistance request

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

10.1 After each use

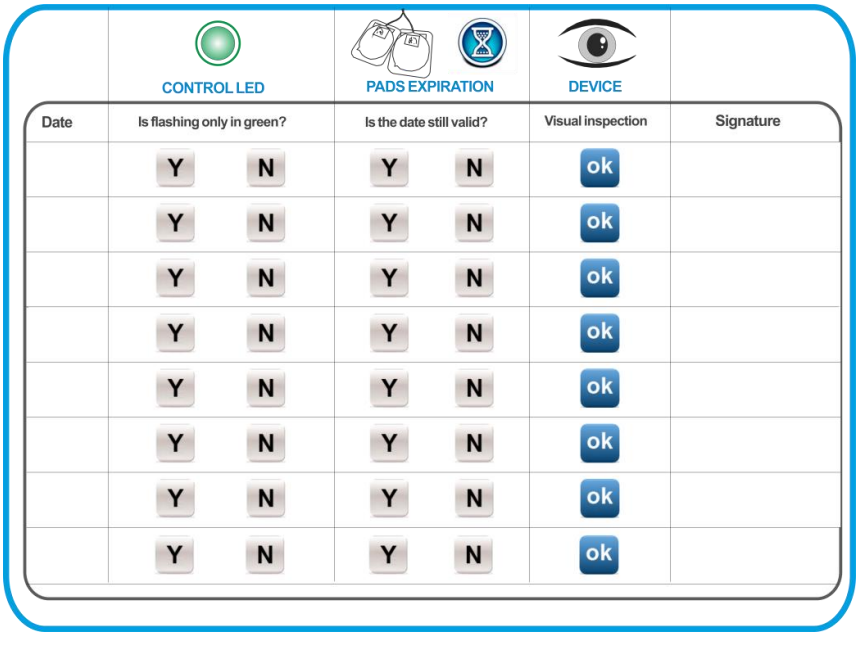
After using the ***SAVER ONE defibrillator*** it is necessary to proceed with the following operations in order to prepare the device for the next use:

1. Check the presence of the memory card and its remaining capacity (see paragraph 5.3)
2. Check that the control LED is on with flashing lighting (flashing green)
3. If they have been used, replace the PADs with a new package
4. If not used, check the expiry date of the PADs, if expired replace them with a new package

10.2 Ordinary maintenance

Thanks to the control tests carried out in total autonomy by ***SAVER ONE,*** ordinary maintenance will require a simple and quick inspection, following the operations described in the table:

Check Daily	Check Monthly	Check before use	Check after use	Action indicated
*		*	*	Check the LED and the control display.
*		*	*	Check the integrity of the device, its parts and the accessories supplied.
	*	*		Check the expiration date of the defibrillation PADs.
		*	*	Check the remaining capacity of the memory card.



10.3 Cleaning

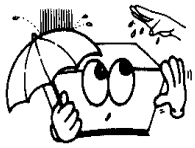
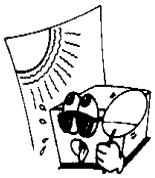
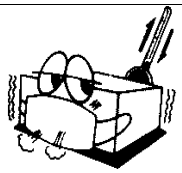
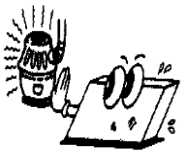
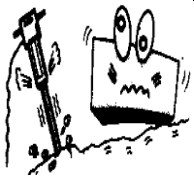
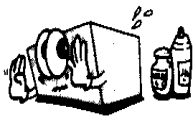
The structure of the ***SAVER ONE defibrillator***, including the connection port of the defibrillation electrodes, can be sanitized using a soft cloth dampened with one of the cleaning solutions listed below:

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

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.

10.4 Preservation

The ***SAVER ONE*** must be stored in a place where the environmental and safety conditions indicated in the table below are observed according to the temperature and humidity indicated in the chapter 12.2. If installed it is advisable to keep the device with the battery always inserted to allow it to carry out periodic self-diagnostic tests. For easy retrieval of the device in case of emergency, place it in easily accessible place and faced in a way that the control LEDs are clearly visible.

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

10.5 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 user's manual. If the failure of the unit persists, request assistance.

Symptom	LED	Mini display 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 totally discharged or faulty	Try replacing the battery. If the problem persists, call for assistance
			The device does not work	Ask for assistance
In **standby** the control LED flashes green but the mini display is off		**OFF**	The mini display is broken	Contact the assistance centre
In **standby** the control LED is off but a "V" appears on the control mini-display.	**OFF**		The control LED is broken	Contact the assistance centre
In **standby** the control LED flashes RED and a wrench appears on the control display.			During the daily self-test a critical error of the device was found	Contact a service centre and report the error code.
In **standby** the control LED flashes GREEN / RED alternately and a wrench appears on the control display.			Very low battery Level <1% The device may turn off during use. *(see the relevant paragraph)*	Replace the battery
In the **operating mode** the voice command "Low battery" is issued.	 **OFF**		Low battery. 5% battery level. It is possible to use the device but the battery level is low *(see the relevant paragraph)*	Get a new battery and replace it as soon as possible.
During normal use the voice command "Battery low, Replace"			The battery is depleted. Level <1% The device may turn off during use. *(see the relevant paragraph)*	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 communicate: "Place electrodes"	**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	Correctly position the PADs on the patient's stripped chest. If necessary, remove the hair from the chest with a razor
			PADs are not working properly	Check the integrity and expiration of the PADs, replace them if necessary
The device turns on, the mini is on but no voice command is issued	**OFF**		The device's speaker does not work	Ask for assistance

11 Technical specifications

The technical specifications of the ***SAVER ONE defibrillator***, its parts and accessories are shown below.

11.1 Physical characteristics

Category	Nominal specifications
Dimensions	26,5 x 21,5 x 7,5 cm
Weight	With battery **Li-SOCl$_2$** *(SAV-C0903)*: 1.95 Kg including Adult Pads With battery **Li-ion** *(SAV-C0011)*: 2.09 Kg + including Adult Pads

11.2 Environmental requirements

Category	Nominal specifications	
Temperature	Operational and standby: Storage and transport:	0 a 55°C (32 a 131°F) -40 a 70°C (-40 a 158°F)
Relative humidity	Operational and standby:	10% a 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 50 hPa (from>35°C to +70°C)
Atmospheric pressure	Operating conditions:	620 hPa at 1060 hPa (altitude calculated min -382 mt and max 3955 mt)
Operating functional 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 the inoperative conditions, let the device stabilize at the operating conditions for at least 2 hours, before the normal use.
Tolerance to impacts and falls	Complies with IEC/EN 60601-1clause 21 (mechanical forces)	
Sealing system	Complies with IEC/EN 60529 class IP54 standards; anti-spray, dustproof (with battery installed)	
ESD (electrostatic shock)	Complies with IEC/EN 61000-4-2:2002 (3), Security level 4	
EMC emissions / immunity	See chapter 12	

11.3 Reference regulations

Regulations and Directives	DIRECTIVE 2007/47/CE IEC/EN 60601-1 IEC/EN 60601-1-2 IEC/EN 60601-1-4 IEC/EN 60601-1-6 IEC/EN 60601-1-8 IEC/EN 60601-1-11 IEC/EN 60601-1-12 IEC/EN 60601-2-4 IEC/EN 60086-4 IEC/EN 60529

11.4 Alarms table

Priority	Cause	Visual signal
HIGH	Device ready to deliver the shock	LED Shock Icon flashing
HIGH	Low battery (<1% capacity)	Control LED flashing

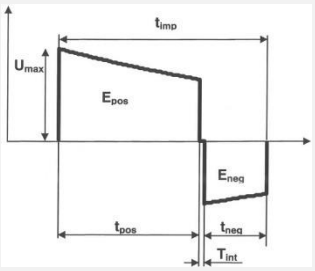
11.5 Controls and indicators

Category	Nominal specifications
Buttons	ON / OFF button (device switching on and off) "i" button INFORMATION
Visual Indicators	• Mini display LCD control of device status • Device status control LED (bicolour RED / GREEN) • LED to place defibrillation PADs (2 LED Red) • LED do not touch patient (2 LED Red) • LED it is possible to touch patient (1 LED Red) • LED adult patient (1 LED Green) • LED paediatric patient (1 LED Green) • LED ON/OFF button (2 LED Green) • LED shock indicator AUTO (8 LED Red)
Sound Indicators	Multilingual voices for instructions during use of the device Acoustic signals of warnings and dangers
Speaker	Pre-set Volume (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	Recording automatically activated when device is switched on

11.6 Data memory

Category	Nominal specifications	
Internal Memory Capacity	6 hours of environmental audio recording, ECG tracing and events	
External memory (optional)	External SD / SDHC memory cards up to 8GB	
Archived data	**AED1LOG.txt**	Daily self-tests, Errors found, Device usage data, Device information
	AEDFILE.aed	Rescue events, voices and environmental noises, ECG tracing of rescue, Vital parameters of the patient analysed and detected by the SAVER ONE
Data display	Via PC Saver View Express software (Microsoft Windows compatible)	

11.7 Defibrillator

Category	Nominal specifications	
Waveform  	**Biphasic Truncated Exponential (BTE)** The waveform parameters are automatically adjusted according to the patient's impedance. In the graph on the left t_{pos} represents the duration of phase 1 (ms), **t_{neg}** represents the duration of phase 2 (ms), **t_{int}** is the delay between phases, **U_{max}**indicates the peak voltage, **t_{imp}**is the final voltage. In order to compensate for variations in the patient's impedance, the duration of each phase of the waveform is dynamically adjusted based on the charge delivered, as indicated in the paragraph following.	
Energy delivered (max) (Adults)	***Version 200J:*** ***Version 360J:***	200J nominal 350J nominal
Shock protocol (Adults)	***Version 200J:*** ***Version 360J:***	Incremental: ***First***: 150J – ***Subsequent***: 200J Incremental: ***First***: 200J – ***Second***: 250J – ***Subsequent***: 350J
Energy delivered (max) (Children)	***Version 200J:*** ***Version 360J:***	50 J nominal (when using defibrillation PADs SAV-C0016)
Shock protocol (Children)	***Version 200J:*** ***Version 360J:***	Fixed: ***First and Subsequent***: 50J
Charge control	Automatic through patient analysis system	
Charge time (from the shock notice)	***Version 200J:*** ***Version 360J:***	≤ 9 sec (according to IEC/EN 60601-2-) ≤ 15 sec (according to IEC/EN 60601-2)
Charge time (from the beginning of the analysis)	***Version 200J:*** ***Version 360J:***	≤ 15 sec (according to IEC/EN 60601-2) ≤ 21 sec (according to IEC/EN 60601-2)
Indication charge completed	• SHOCK Icon flashing • Voice Command “The shock will be delivered in 5 seconds”, then starts one beep per second	
Shock delivery	The shock is delivered automatically, after the 5 seconds	
Disarmament	***Automatic:*** ***Manual:***	• If the patient's analysis system considers the rhythm no longer shockable, or • If defibrillation PADs have been removed from the patient or disconnected from the unit. • If the operator presses the OFF / DEACTIVATE button at any time to deactivate or switch off the appliance.
Shock detection vector	Through the defibrillation PADs (Lead II)	
Isolation of the patient	Type BF	

11.8 Efficiency of delivered energy

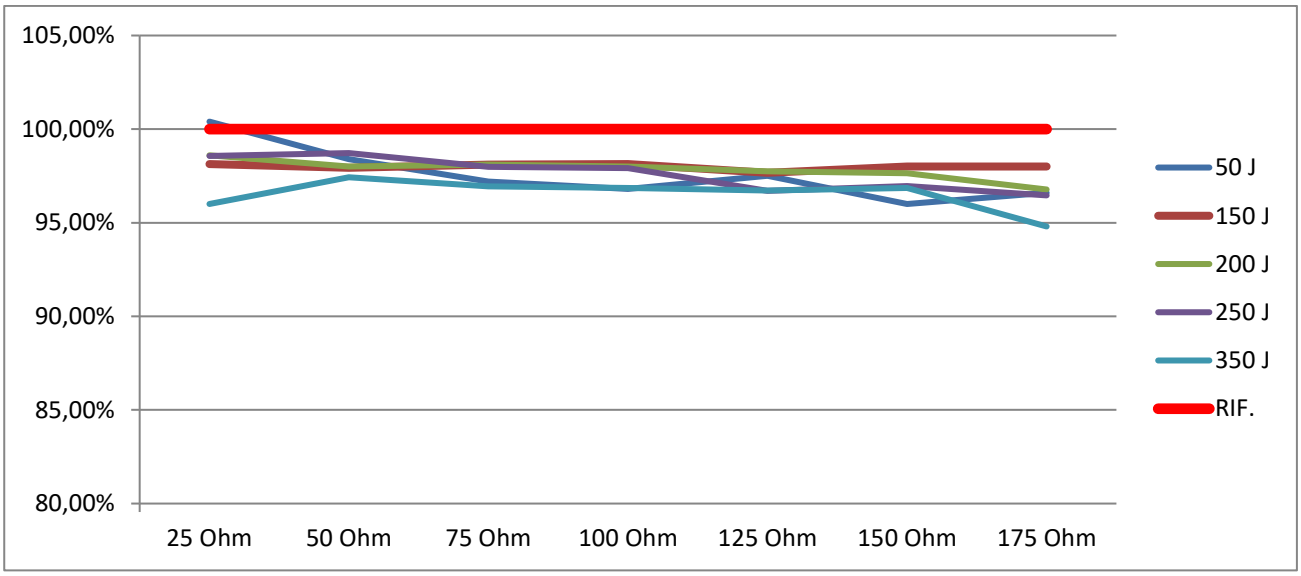
Impedance	Shock of 50 J (Paediatric)				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Set Energy (J)	
25 Ohm	6,8	3,3	18,6	50	**50,2**
50 Ohm	7,2	3	12,3	50	**49,2**
75 Ohm	7,4	2,8	9,6	50	**48,6**
100 Ohm	7,5	2,7	8,1	50	**48,4**
125 Ohm	7,6	2,6	7,1	50	**48,75**
150 Ohm	7,7	2,5	6,4	50	**48**
175 Ohm	7,7	2,4	5,8	50	**48,3**

Impedance	Shock of 150 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Set Energy (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	Shock of 200 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Set Energy (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	Shock of 250 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Set Energy (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	Shock of 350 J				Energy delivered (Joules)
	T_{pos} (ms)	T_{neg} (ms)	U_{max} (A)	Set Energy (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**



Efficiency of the energy supplied graph

11.9 Patient analysis system

Category	Nominal specifications
Function	Determines the patient's impedance and evaluates the ECG rhythm and signal quality to determine whether the shock delivery is appropriate.
Impedance range	20 - 200 Ω
ECG analysis time	≥4 seconds (with new fully charged battery) respecting IEC/EN 60601-2-4
Sensibility	97% Respects the guidelines IEC/EN 60601-2-4
Specificity	99% Respects the guidelines IEC/EN 60601-2-4
Shockable rhythms	If used on a patient who has the characteristics listed in the usage criteria, the ***SAVER ONE*** 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 cardiac rhythm frequency min. 180 bpm and peak-to-peak amplitude at least 200µVolts (including ventricular flutter and polymorphic ventricular tachycardia)
Non-shockable rhythms	The ***SAVER ONE*** is designed to not recommend shocks with all other rhythms, including: normal sinusoidal rhythm, moderate ventricular fibrillation (<200 µVolts), some slow ventricular tachycardia and asystoles.

11.10 ECG Analysis Function

ECG rhythm	Dimension Test sample	Objective	Detected value
Shockable rhythm Ventricular Fibrillation (VF)	500	Sensibility > 90%	98%
Shockable rhythm Ventricular Tachycardia (VT, bpm>140)	600	Sensibility > 75%	92%
Non-shockable rhythm Normal sinusal rhythm	1500	Specificity > 99%	100%
Non-shockable rhythm Asystole	30	Specificity > 95%	100%
Untreatable rhythm generic AF, SVT, PVC	30	Specificity > 95%	100%
Positive predictive values			97.1%
False positives			4.1%

11.11 Non rechargeable battery

Category	Nominal specifications	
REF (Model)	SAV-C0903	
Type	Li-$SOCl_2$ (lithium-thionyl chloride) disposable, non-rechargeable	
Voltage - Capacity	28,8 VDC – 3500 mAh	
Performance*	***Standard 200J***	300 cycles of complete rescues (shocks at 200J. and CPR)
	Power 360J	200 cycles of complete rescues (shocks at 360J. and CPR)
	ECG analysis	35 continuous hours
Duration in Standby* ***(installed battery)***	4 years if installed in the AED, assuming an activation test, daily self-tests without turning on the AED	

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

11.12 Rechargeable battery

Category	Nominal specifications	
REF (Model)	SAV-C0011	
Type	Li ion (lithium ions) Rechargeable	
Voltage- Capacity	21,6 VDC - 2100 mAh	
Performance*	***Standard 200J***	250 continuous shocks
	Power 360J	160 continuous shocks
	ECG analysis	21 continuous hours
Charging time*	≤ 2,5 hours with charging station SAV-C0012	
Shelf Life*	2 years or 300 charge/shock cycles (*the one that occurs first)*	

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

11.13 Internal back-up battery

Category	Nominal specifications
Type	Battery Coin Cell (LiMnO2)
Purpose	Maintaining configuration data (date / time, etc.)
Voltage	3 VDC
Duration	Maintains data for 3 years (without external battery) Maintains data for 6 years (with external battery inserted within 12 months)

11.14 Rechargeable battery charger

Category	Nominal specifications	
REF (Model)	SAV-C0012	
Charge control	LED multicolour red green (see relevant paragraph)	
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

11.15 Defibrillation PADs

Category	ADULTS	CHILDREN
REF (Model)	SAV-C0846	SAV-C0016
Series	*Cable and connector outside to the envelope*	*Cable , connector and PADs into the envelope*)
Patient range	Adults age **>8 years** or weight > **25Kg**	Children age **< 8 years** or weight < **25Kg**
Intended use	Disposable	
No. of shocks tolerated	50 shocks at 360J	
Support material	Medical FOAM, thickness 1 mm	
Conductive gel	Low impedance conductive adhesive gel	
Total area (*for pad*)	136 cm ²	75 cm ²
Active area (*for pad*)	94 cm ²	40 cm ²
Conductive material	Metal foil	
Connection	Anti-shock safety connector	
Cable length	120 cm (normally)	

11.16 Timing of Shock cycles

Charging time performance in accordance with 60601-2-4 (201.101)	Specific	Result
The maximum time between the beginning of the ECG rhythm analysis and the completion of the charge at maximum energy	< 30 seconds	OK
The maximum time from turn on to completion of the charge at maximum energy	< 40 seconds	OK

12 Compliance with electromagnetic emission standards

The following paragraphs will specify the compliance with electromagnetic emission standards:

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

12.1 Guidelines and manufacturer's declaration - Electromagnetic emissions

The ***SAVER ONE*** was designed to be used in electromagnetic environments with features listed below. The customer or the user of the ***SAVER ONE 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. Therefore, its RF emissions are very low and are unlikely to interfere with nearby electronic equipment.
RF Emissions CISPR 11	Class B	The **AED** can be used in any building, including those for residential use and those directly connected to the public low-voltage power supply network that supplies residential buildings.
Harmonic Emissions **IEC/EN 61000-3-2**	Not applicable	
Voltage fluctuations / flicker **IEC/EN 61000-3-3**	Not applicable	

12.2 Guidelines and manufacturer's declaration - Electromagnetic immunity

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

Immunity test	Test level IEC/EN 60601-1	Compliance level	Electromagnetic environment - Guidelines
Electrostatic shock (ESD) **IEC/EN 61000-4-2**	±6 kV contact	±6 kV contact	Floors must be wood, concrete or ceramic tiles. If the floors are covered with synthetic material, the relative humidity must be at least 30%.
	±8 kV air	±8 kV air	
Fast transients / bursts **IEC/EN 61000-4-4**	±2 kV by electricity networks	Not applicable	
	±1 kV by input / output networks	±1 kV by input / output networks	
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	Compliance 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 no higher than those of stations located in typical heavy industrial applications, power plants and control rooms of high voltage substations.
Note: U_T is the main AC current before the test level is applied			
RF conducted	3 Vrms	Not applicable	
IEC/EN 61000-4-6	from 150 kHz to 80 MHz outside of ranges ISM[a] 10 Vrms from 150 kHz to 80 MHz inside the ranges ISM[a]	Not applicable	
RF radiated **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 communications equipment in use and any part of the AED, including cables, must never be less than the recommended separation distance calculated based on the equation applicable to the transmitter 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 transmitter's maximum output power range in watts (W) according to the transmitter manufacturer's data and d is the recommended distance in meters (m) [b]. The field strengths of fixed radiofrequency transmitters, as determined by an investigation in electromagnetic sites,[c]should be less than the compliance level in each frequency range.[d] Interference may occur near the devices marked with this symbol.

NOTE 1	From 80 MHz to 800 MHz, the higher frequency range applies.
NOTE 1	These guidelines may not apply in all situations. Electromagnetic propagation is influenced by absorption and reflection from structures, objects and people.
a	The ISM bands (industrial, scientific and medical) between 150 kHz and 80 MHz are from 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 levels of compliance in the ISM bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are designed to reduce the possibility of interference in the event that portable and mobile communication devices are inadvertently approached to the area where the patient is found. 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 ranges.
c	It is not possible to accurately predict theoretically the field strengths of fixed transmitters, such as base stations for radio (cellular / cordless) telephones and mobile radios, amateur radio, AM and FM radio and TV. To assess the electromagnetic environment with fixed RF transmitters, consider conducting an electromagnetic site survey. If the power of the fields measured in the location in which the AED is used exceeds the specific RF compliance level mentioned above, it will be necessary to monitor the AED to verify its correct functioning. If operating anomalies are observed, it may be necessary to take corrective measures, for example by moving or reorienting the AED.
d	Over the frequency range between 150 kHz and 80 MHz, field strengths must be less than 1 V / m.

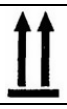
12.3 Recommended separation distance between portable and mobile RF communication equipment and SAVER ONE device

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

Maximum transmitter power output rate W	**Separation distance according to the transmitter 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 GHz** $d = 2.3\sqrt{P}$
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 rated at a maximum power not listed above, the separation distance "*d*" in meters (m) can be determined using the equation applicable to the transmitter frequency, where P represents the maximum power produced by the watt transmitter (W) according to the transmitter manufacturer.				
NOTE 1:	At 80 MHz and 800 MHz, the separation distance applied is that used for high frequency ranges.			
NOTE 2:	The ISM frequency bands (for industrial, scientific and medical applications) between 150 kHz and 80 MHz are 6,765 MHz up to 6,795 MHz; 13,553 MHz up to 13,567 MHz; 26,957 MHz up to27,283 MHz and 40,66 MHz up to40,70 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 range from 80 MHz to 2.5 GHz to decrease the possibility that a Mobile / portable equipment may interfere if inadvertently brought into the patient's area.			
NOTE 4:	These guidelines may not be applicable in all situations. Electromagnetic diffusion is influenced by the absorption and reflection of structures, objects and people.			

13 Simbology

	ILCOR Universal Symbols for AED
	High Voltage Electrical Hazard
	General Notices: Refer to the consultation of accompanying documents before using the appliance
	Type BF, Defibrillation-proof Equipment
	Do not expose to high temperatures or flames
	Do not recharge
	Do not open
	Do not destroy or damage it
	Do not use it in puddles of water
	Read the User Manual
	Battery recycling
	Follow local waste regulations
	Fragile
	Store in a dry place
	Do not expose to direct sunlight
	Risk of electric shock do not open
	Type CF applied part

	IMQ brand
	CE mark with identification number
IP54	Degree of protection of the appliance against dust and water (including battery)
SN	Serial Number
	Manufacturing date
LOT	Lot Number (LOT)
	Expiration date
REF	Model identifier
	Manufacturer Name
	Absence of latex
	Single use, do not reuse
	Not Sterile
	External directions on the box
	This side up
	Temperature Limits
	Only stack up to 6 cartons in height

14 Certifications

14.1 EC 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; 10AO00009; 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 cosign

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 | www.imq.it

14.2 IMQ Brand

IMQ S.p.A. - Società con Socio Unico
I-20138 Milano - via Quintiliano, 43
tel. 0250731 (r.a.) - fax 0250991500
e-mail: info@imq.it - www.imq.it

Rea Milano 1595884
Registro Imprese Milano 12898410159
C.F./P.I. 12898410159
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.

15 SAVER ONE Defibrillator Warranty

1 Warranty Restriction

A.M.I. Italia S.r.l guarantees the original purchasers that its SAVER ONE 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 considered to be the final user of the product purchased. This limited warranty is granted only to the original purchaser of the SAVER ONE defibrillator of A.M.I. Italia S.r.l and is not transferable or assignable to third parties.

The SAVER ONE defibrillators are as follows:

SAVER ONE Semi-Automatic (code SVO-B0001/ SVO-B0002)

SAVER ONE Automatic (code SVO-B0847/SVO-B0848)

SAVER ONE D (code SVD-B0004 / SVD-B0005)

SAVER ONE P(code SVP-B0006 / SVP-B0007)

2 Duration

A.M.I. Italia S.r.l guarantees the original purchaser of SAVER ONE defibrillators, starting from the date of dispatch* of the warranty validation form (to A.M.I. Italia S.r.l) or starting from 30 (thirty) days from the date of shipment from A.M.I. Italia S.r.l, the one that occurs chronologically first; defibrillators have a typical life expectancy of about 10 years. The guarantee offered by A.M.I. Italia S.r.l covers a period equal to:

- **AED SAVER ONE** have a six (6) year warranty
- **Non-rechargeable batteries Li-$SOCl_2$** (SAV-C0903) if installed in the AED and in Standby mode they 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 S / C (45 %)
- **Rechargeable batteries Li-Ion** (SAV-C0011) are guaranteed for two (2) years from the date of production only if the temperature conditions (temperature 20 ° C) and humidity (45%) are met and if they are recharged at least one (1) time every four (4) months
- **The disposable pads** guaranteed until their expiration 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 still be valid*

3 Procedure

Please complete (in its entirety) the limited warranty validation form and send it by post (Registered letter A / R) to A.M.I. Italia S.r.l. The date shown on the A / R recommendation will prevail. You will find the Warranty validation form attached to the user manual or inside the original packaging of the SAVER ONE defibrillator. In the event that a defect covered by this warranty is found, the original purchaser must contact the reference retailer or an authorized A.M.I. Italia S.r.l.

A.M.I. Italia S.r.l reserves the exclusive right to repair or replace the product.

4 Exclusions

This warranty does not cover non-conformities subsequent to purchase, such as those caused by accidents, modifications, negligence, incorrect use or abuse, non-compliance with procedures or hazards, or warnings or cautions described in the user manual; failure to perform a reasonable and adequate maintenance, incorrect installation, replacement of parts and accessories that do not comply with the specifications provided by AMI Italia Srl, any modifications made to the device and in general all subsequent non-conformities deriving from failure to comply with the provisions contained in the user manual.

This warranty does not cover, as it does not constitute cases of original non-conformity, the normal wear and tear of components subject to decay during use such as buttons, LEDs and battery contacts. This warranty will also be automatically invalidated 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 DAE is removed;
- in case the commercial name of the product or manufacturer is covered, modified or cancelled

Finally, this warranty does not apply to used SAVER ONEAEDs sold, in which case the warranty must be offered by the reseller of the used product with the exclusion of any liability, even indirect, borne by A.M.I. Italia S.r.l

5 Damage

Except as explicitly provided in this warranty, A.M.I. Italia S.r.l. WILL NOT BE LIABLE FOR ANY INCIDENTAL OR INDIRECT DAMAGES ARISING FROM THE USE OF THE SAVER ONEDEFIBRILLATOR OR CLAIMS IN VIRTU OF THIS AGREEMENT, WETHER THE CLAIM REFERS TO THIS AGREEMENT, TO ILLEGAL OR OTHERWISE. The warranty statements mentioned are exclusive and replace any other remedy. Some states do not allow the exclusion or limitation of incidental or indirect damages, so the above limitation or exclusion may not be relevant.

6 Waiver

ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE AND ALL IMPLIED WARRANTIES ARISING OUT OF NEGOTIATIONS, USE OR BUSINESS CONSUMPTIONS, BY STATUTE OR OTHERWISE ARE STRICTLY LIMITED TO THE TERMS OF THIS WRITTEN WARRANTY. This warranty will be your sole and exclusive buyer's remedy for this purchase. In the event of an alleged violation of any guarantee or legal action brought by the original purchaser for alleged negligence or other unlawful conduct by A.M.I. Italia S.r.l, the sole and exclusive remedy of the original purchaser will be constituted by the repair or replacement of the resulting defective materials, based on what was previously established. No retailer or agent or employee of A.M.I. Italia S.r.l is authorized to make changes, extensions or additions to this warranty.

7 Territorial limit

This warranty is valid for products purchased in one of the countries of the European Union or in the countries in which the EU laws and regulations apply.

8 Warning

Install, use and maintain SAVER ONE defibrillators by A.M.I. Italia Srl in absolute compliance with the instructions contained in the user manual

9 Other rights

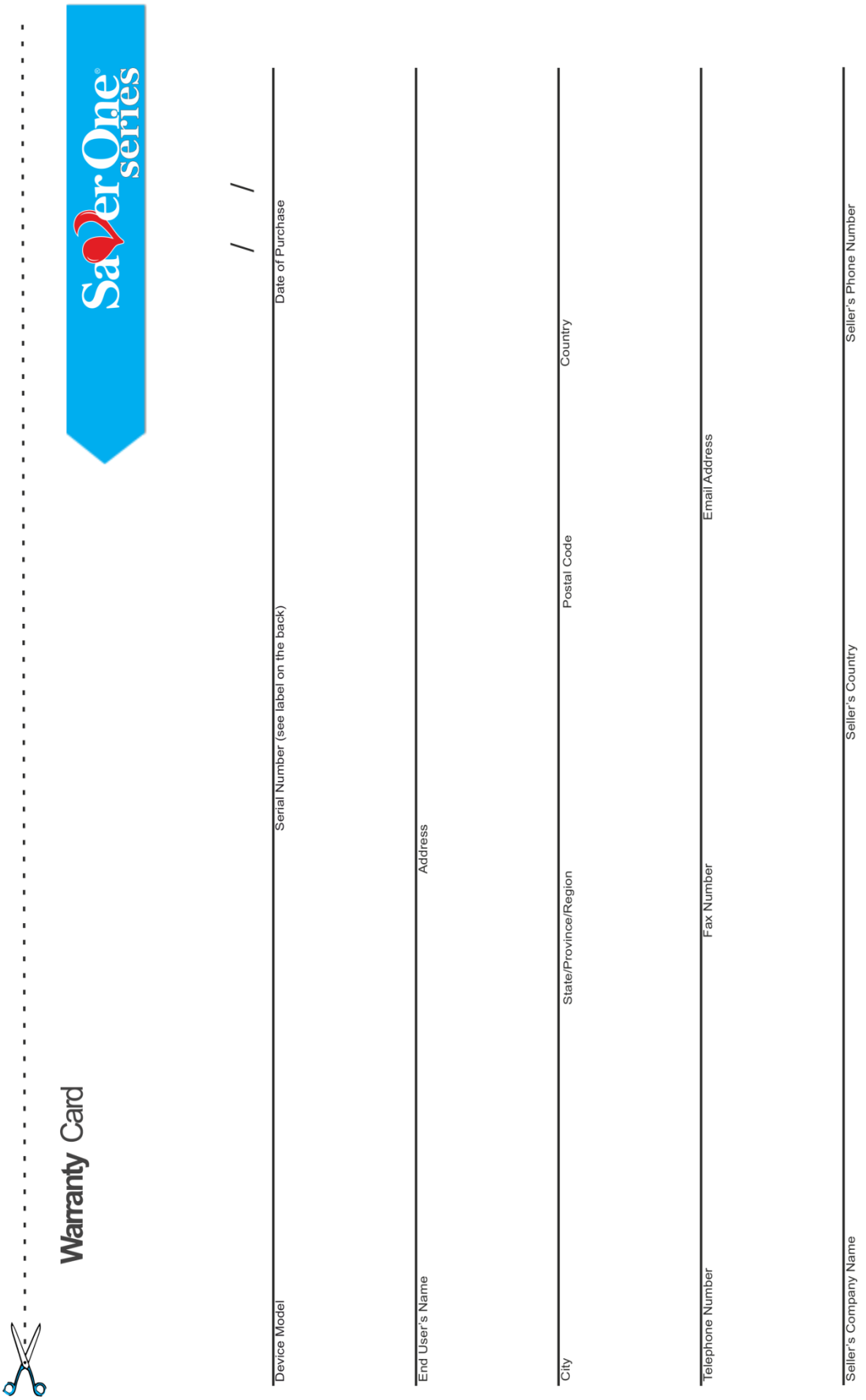
This limited warranty guarantees the original purchaser specific legal rights; any other rights may vary depending on the state of belonging.

10 Applicable law

Any dispute relating to this agreement or arising from the use of SAVER ONE series defibrillators by A.M.I. Italia S.r.l. will be governed by Italian law, at the Court of Naples, Italy.

16 Product registration

In order to guarantee a correct and rapid traceability of the product sold, we ask you to complete the form below and send it by fax or registered letter to A.M.I. Italia S.r.l.



SaverOne®

AEDs

AMI ITALIA
MEDICAL PRODUCT

IMQ