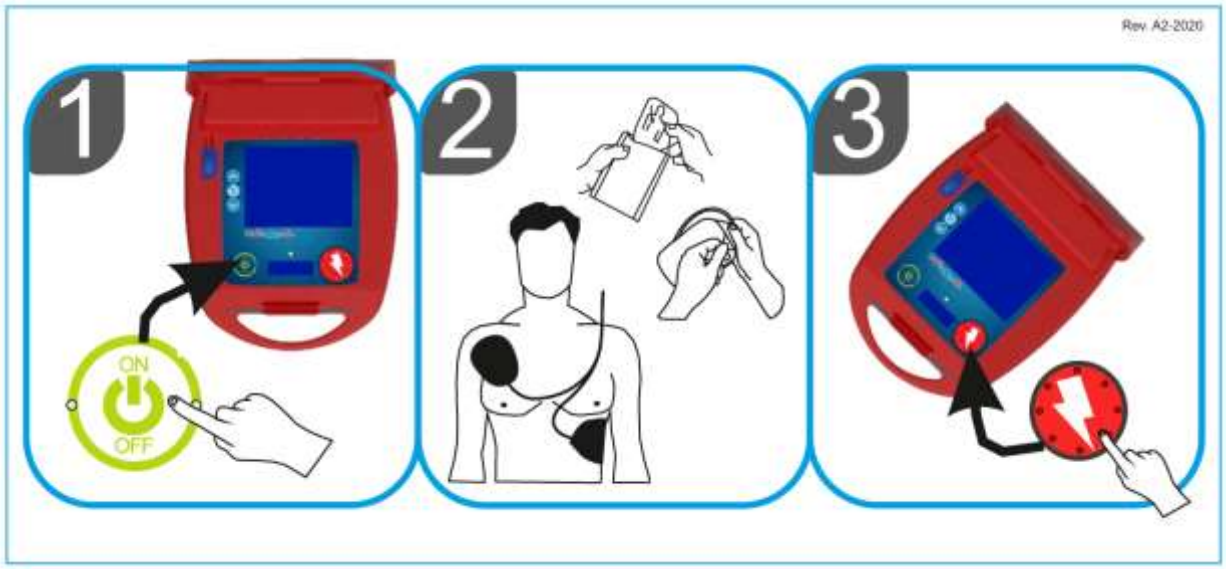
User Manual
**E**xternal **Semiautomatic D**efibrillator
with Display

| Rev. | 4.2 |
|---|---|

SaVer One® D
S1 series

AEDs

# *QUICK USE GUIDE*



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

Via Cupa Reginella, 15/a - 80010 Quarto (NA) Italy
Tel. +39 081 806 34 75 Fax +39 081 876 47 69

e-mail info@amiitalia.com http://www.amiitalia.com

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# Summary

# 1 Introduction

## 1.1 Preface

Thank you for having chosen the defibrillator of A.M.I Italia S.r.l. model ***Saver One D S1 Series***.
So that you can correctly use the device it is necessary, before usage, to carefully read this user manual. The User Manual of ***Saver One D S1 Series*** contains the instructions for its use in compliance with its function and purpose. For a function free of error and to achieve the right benefits, it is fundamental to respect the prescriptions indicated in this user manual, to guarantee the safety of the patient, of the rescuer and of any third parties. This manual is an integral part of the defibrillator and must always be kept together with the device, so that it can be easily accessible if necessary.

## 1.2 Use in accordance with provisions

The device ***Saver One D S1 Series*** can be used exclusively if the conditions indicated in the user manual are respected. Any use not as prescribed is considered not in accordance with the provisions and can cause damage to people or objects. In such cases A.M.I. Italia S.r.l declines all responsibility.

## 1.3 Guarantee

The device ***Saver One D S1 Series*** has a guarantee of 6 (six)* years.
The non-rechargeable battery Li-$SOCl_2$ (SAV-C1032) 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 16** "Saver One S1 Series defibrillators warranty"*

## 1.4 Exclusion from 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 D S1 Series*** 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 D S1 Series*** 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: 4.2
Issuing date: 01/09/2020

## 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
**Tel.:** +39 081 806 05 74
**Website:** **www.amiitalia.com**

# 2 Safety instructions

For a correct use of the ***Saver One D S1 Series*** defibrillator, users must be aware of the safety factors listed below.
**Please read them carefully.**
The ***Saver One D S1 Series*** 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 D S1 Series*** 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 D S1 Series*** 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-C1032). 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 D S1 Series***, do not remove the panels and do not attempt to repair it. The ***Saver One D S1 Series*** contains no components that users can repair. For repair purposes, the ***Saver One D S1 Series*** must be sent to an authorized technical service center.
- 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 2017 guidelines
- Do not immerse any part of the ***Saver One D S1 Series***, its parts or accessories in water or other liquids.
- Do not allow liquids to enter the ***Saver One D S1 Series*** 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 D S1 Series*** 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 D S1 Series*** is equipped with a pacemaker detection system that allows ignoring the signal emitted by the latter; however, with some types of pacemakers, ***Saver One D S1 Series*** 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 D S1 Series*** to malfunction. The ***Saver One D S1 Series*** 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 D S1 Series*** 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 D S1 Series*** 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 D S1 Series*** 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 use defibrillation PADs if the expiration date has been exceeded.
- When applying the ECG cable SAV-C0017 make sure it is not in contact with any conductor element. Verify that all ECG electrodes are properly secured to the patient
- Do not touch the patient or PADs during heart rhythm analysis.
- Moving or transporting the patient during the 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 D S1 Series***, 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 D S1 Series***, 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.
- Recharge the rechargeable Li-ion battery (SAV-C1033) at least once every 4 months ensure its perfect function and extend its life.
- The Li-ion rechargeable batteries ACC model (SAV-C1033) must be charged using only the (SAV-C1035) 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 D S1 Series***, its parts and accessories are not sterile or sterilizable
- Do not expose the ***Saver One D S1 Series***, its parts or accessories to direct light or high temperatures
- The Battery Charger (SAV-C1035) must only be used with the Meanwell power supply model GS40A15-P1J (SAV-C1037) 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-C1033)
- In order to safeguard the battery life (SAV-C1032) and guarantee automatic daily tests, after installing it, it is advisable to not remove the battery (SAV-C1032) 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 Cautions for use in ECG Monitoring

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

## 2.4 Indications of DISPOSAL 

- The ***Saver One D S1 Series***, 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 D S1 Series*** is called **AED** or **A**utomatic **E**xternal **D**efibrillator equipped with TFT display and mini LCD.
The device was designed to be used by lay personnel as well as by healthcare personnel who have duly achieved and passed a BLSD course according to international guidelines.
Designed to automatically detect and analyse the victim's heart rhythm, it is able to deliver one or more defibrillation shocks if ventricular fibrillation or ventricular tachycardia (monomorphic or polymorphic with beat> 180) is detected.
The energy is supplied by an exponential truncated biphasic electrical shock (B.T.E.) able to adapt to the patient's thoracic impedance.
The **Saver One D S1 Series** is available in two versions:

**Saver One D S1 Series 200J** (**S1D-B0984**) – Maximum deliverable energy of 200J
**Saver One D S1 Series 360J** (**S1D-B0985**) – Maximum deliverable energy of 360J

It can be used with two types of batteries:

- **Non-rechargeable battery Li-SOCl$_2$** (SAV-C1032), which requires no maintenance, is guaranteed to operate in standby mode for 4 years or carry out a high number of shocks
- **ACC Rechargeable battery Li-ion** (SAV-C1033), recommended for those who use the defibrillator intensively

The device is equipped with a large 5.7-inch LCD **colour** display that allows you to view all information relating to the treatment and its functional status. Furthermore, the ***Saver One D S1 Series*** is equipped with a mode that allows the patient's ECG monitoring to be performed using a special 2-pole ECG cable (SAV-C0017) with detection of 1 lead (II) or directly from the Pads.

The device allows the data to be recorded on an SD Memory Card so that they can be re-displayed on a PC or printed directly on the ***Martel MCP7830*** printer (*optional function*). During the non-use phase the device, if installed, the battery 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 D S1 Series*** defibrillator is classified as follows:

| | |
|---|---|
| Code **UMDNS** | 11132 |
| Code **GMDN** | 47910 |
| Code **CND** | Z12030501 |
| Directory number **RDM** | 1793094 / 1793095 |
| 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<br>CF (only for ECG cables) |
| Degree of protection against penetration of liquids | IPx6 |
| 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 11.3 |
| Mode of operation | Continuous operation |

# 4 Description of device details

## 4.1 General Structure of the device

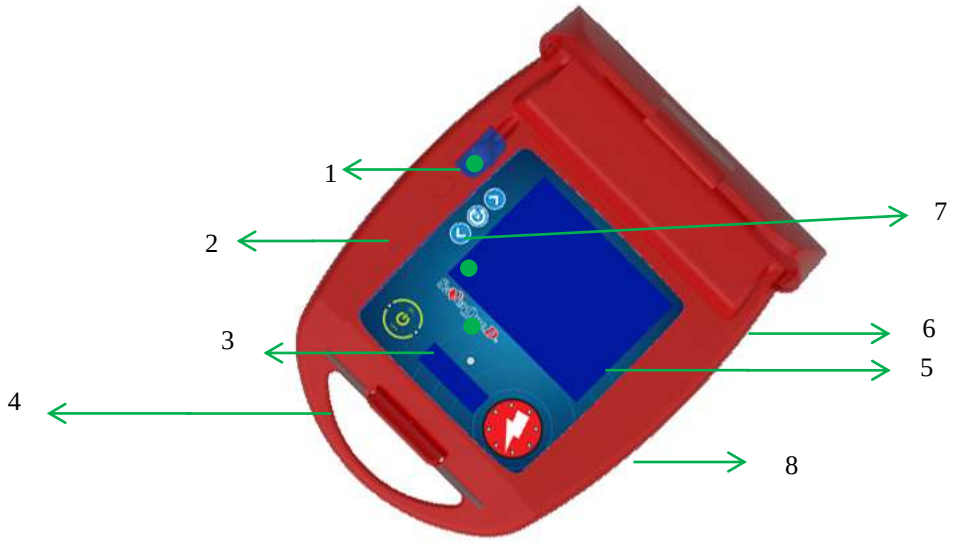



*Image 1*

| Nr. | Description |
|---|---|
| **1** | Compartment for PADS connector or ECG cable |
| **2** | Microphone for environmental recordings |
| **3** | Status mini display |
| **4** | Carrying handle |
| **5** | TFT colour display |
| **6** | IrDA port (service only) |
| **7** | Keyboard with buttons |
| **8** | Loud speaker |

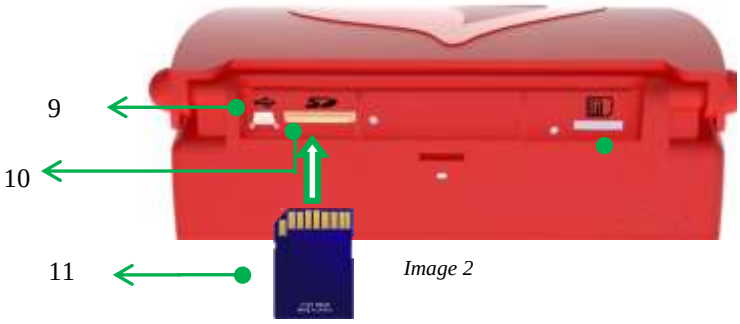



*Image 2*

| Nr. | Description |
|---|---|
| **9** | USB port |
| **10** | Compartment for SD Memory Card |
| **11** | SD card insertion |
| **12** | Saver One D S1 Series battery compartment |

## 4.2 Keys, icons and indicators

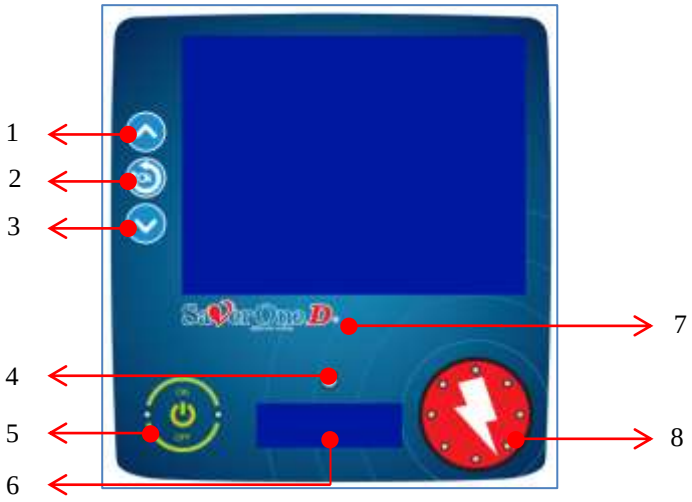
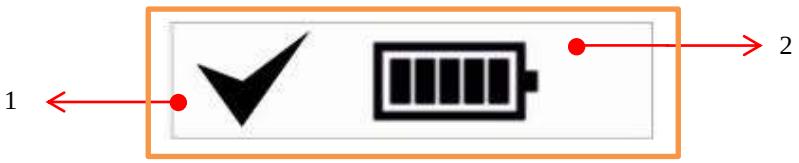



*Image 3*

| Nr. | Function | Nr. | Function |
|---|---|---|---|
| **1** | **Navigation key UP**<br>Allows you to scroll up the menu | **5** | **ON / OFF button**<br>Allows you to switch the device on or off |
| **2** | **Navigation key ENTER**<br>Allows you to enter the menu and confirm the selection you made | **6** | **Status mini display**<br>It allows you to check the functional status of the device |
| **3** | **Navigation key DOWN**<br>Allows you to scroll down the menu | **7** | **Product logo**<br>Indicates the model of the device |
| **4** | **Control LEDs**<br>Luminous LED (red / green) allows you to check the functional status of the device | **8** | **Shock button**<br>Equipped with luminous LEDs it allows to deliver a defibrillation shock if indicated |

## 4.3 Status mini display

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




| Nr. | Description |
|---|---|
| **1** | Functional status of the device |
| **2** | Remaining battery level |

## 4.4 TFT colour display

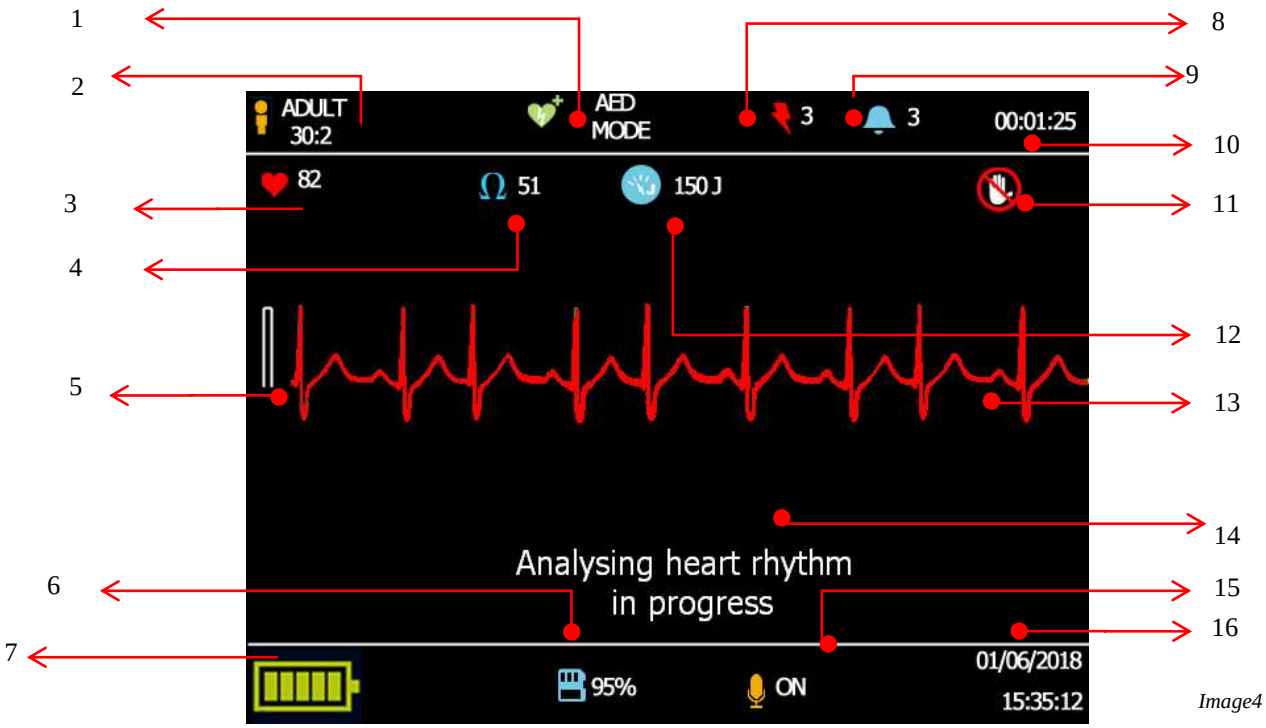



*Image4*

| Nr. | Description | Nr. | Description |
|---|---|---|---|
| **1** | Indicates the OPERATIVE mode:<br>**AED**: Semiautomatic defibrillation<br>**MONITORING**:<br>ECG monitoring | **9** | Indicates the number of VFs and / or VTs detected by the device |
| **2** | Indicates the type of patient to be treated and Ratio Compressions/Insufflations:<br>**Adult 30:2**<br>**Paediatric 30:2** *(requires children pads)* | **10** | Indicates the duration of the rescue |
| **3** | Indicates the patient's heart rate | **11** | Indicates not to touch the patient in certain operations |
| **4** | Indicates the patient's thoracic impedance detected | **12** | Energy in charge and subsequently delivered |
| **5** | Progressive charging bar | **13** | ECG track of the patient |
| **6** | Indicates the remaining level of the SD Memory Card | **14** | Text command that instructs the operation to be performed |
| **7** | Indicates the remaining battery level | **15** | Indicates whether the recording microphone is active |
| **8** | Indicates the number of shocks made | **16** | Indicates current date and time |

## 4.5 Standard and optional accessories of the device

The ***Saver One D S1 Series*** defibrillator comes with the following standard accessories:

| Code | Image | Quantity | Description |
|---|---|---|---|
| **S1D-B0984** |  | **1 Unit**<br>(Version 200J or 360J) | ***Saver One D S1 Series*** *200J* |
| **S1D-B0985** | | | ***Saver One D S1 Series*** *360J* |
| **SAV-C0846** |  | **1 Unit** | Adult Pads |
| **SAV-C1032** |  | **1 Unit** | Non-rechargeable<br>Li-SOCl2 battery |
| **SAV-C1076** |  | **1 Unit** | User guide |

The following are the optional ***Saver One D S1 Series*** accessories that can be purchased separately:

| Code | Image | Quantity | Description |
|---|---|---|---|
| **SAV-C1033** |  | **1 Unit** | ACC Rechargeable Li ion battery |
| **SAV-C1035** |  | **1 Unit** | Charger |
| **SAV-C1037** |  | **1 Unit** | GS40A15-P1J Power supply |
| **SAV-C1034** |  | **1Unit**<br>*(Contains 3 units)* | N.01 Charger<br>N.01 GS40A15-P1J Power supply<br>N.01 Power supply cable |
| **SAV-C0016** |  | **1 Unit** | Children Pads |
| **SAV-C0017** |  | **1 Unit** | 2-way ECG cable |
| **SAV-C0019** |  | **1 Unit** | CD-ROM Saver View Express |
| **SAV-C0906** |  | **1 Unit** | SD Card |
| **SAV-C1070** |  | **1 Unit** | Thermal printer MARTEL MCP7830 |
| **SAV-C0027** |  | **1 Unit** | Memory Card reader for PC |

# 5 Parts and accessories of the *Saver One D S1 Series*

## 5.1 Batteries Saver One D S1 Series

The ***Saver One D S1 Series*** defibrillator can work with two different types of batteries:

- (SAV-C1032) Non-rechargeable Li-$SOCl_2$ battery
- (SAV-C1033) ACC Rechargeable Li ion battery

For AED models Saver One D S1 Series and Saver One P S1 Series , considering the higher consumption due to the presence of the TFT display, AMI ITALIA recommends the use of the rechargeable battery SAV-C1033 (combined to the charging station SAV-C1034) rather than the disposable battery SAV-C1032

### 5.1.1 Non-rechargeable Li-$SOCl_2$ battery (SAV-C1032)

The non-rechargeable battery with Li-$SOCl_2$ technology (SAV-C1032) 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.

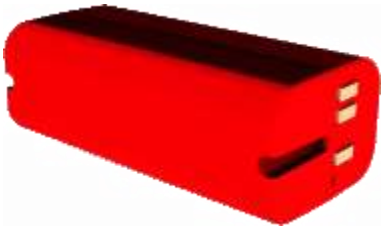


*Image 5*

The non-rechargeable battery of the ***Saver One D S1 Series*** in Standby mode is guaranteed for 4 (four) years*[1] assuming a battery activation test, daily self-tests without turning on the AED. The Li-$SOCl_2$ non-rechargeable battery (SAV-C1032) is able to carry out a large number of shocks which vary according to the version:

| | |
|---|---|
| ***Saver One D S1 Series Standard 200J*** | 250 complete rescue cycles (shocks at 200J. and CPR)*[1] |
| ***Saver One D S1 Series Power 360J*** | 160 complete rescue cycles (shocks at 360J. and CPR)*[1] |

*[1]New and fully charged battery, constant temperature at 20°C and relative humidity without condensation 45%

If the remaining battery level is low, the ***Saver One D S1 Series*** informs the user via audio and visual messages.
The ***Saver One D S1 Series*** 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 D S1 Series*** allows to shock about **14 shocks** or
**40 days of stand-by***[2]

**ALARM:** Remaining capacity level of Battery at **≤ 1%**
This warning will be provided both in Stand-by and in operating mode, as indicated in the paragraph
With a battery at **≤ 1%** the ***Saver One D S1 Series*** carries out about **7 shocks** or
**20 days of stand-by***[2]
In this condition the use of the device is not recommended.

*[2], Constant temperature at 20°C and relative humidity without condensation 45%

**!!ATTENTION!!**
**In order to protect the battery life (*SAV-C1032*) and guarantee automatic daily tests, after installing it, it is advisable not to remove the battery (*SAV-C1032*) 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.**

### 5.1.2 Rechargeable Li ion battery (SAV-C1033)

The rechargeable battery with Li-ion technology (SAV-C1033) of the ***Saver One D S1 Series*** 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 6*

The ACC rechargeable battery of the ***Saver One D S1 Series*** can be recharged using only the dedicated charger (SAV-C1035) 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 D S1 Series*** in your possession:

| | |
|---|---|
| ***Saver One D S1 Series Standard 200J*** | typically 200 continuous shocks *[1] |
| ***Saver One D S1 Series Power 360J*** | typically 110 continuous shocks *[1] |

*[1] New and fully charged battery, constant temperature at 20°C and relative humidity without condensation 45%

If the remaining battery level is low, the ***Saver One D S1 Series*** informs the user via audio and visual messages.
The ***Saver One D S1 Series*** 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 D S1 Series*** allows to shock about **14 shocks** or
**40 days of stand-by***[2]

**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 D S1 Series*** carries out about **7 shocks/20 days of stand-by***[2]
In this condition the use of the device is not recommended.

*[2], Constant temperature at 20°C and relative humidity without condensation 45%

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-C1033

A.M.I Italia recommend that batteries SAV-C1033 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 D S1 Series*** the insertion of a battery is required. Below are detailed instructions for correctly installing the batteries (rechargeable or non-rechargeable) in the ***Saver One D S1 Series.***

*Image 7*

*Image 8*

*Image 9*

- Position the appliance on its side as shown in image (7)
- Remove the cover of the battery compartment as shown in image (7)
- Insert the battery as shown in image (8)
- Push the battery as shown in image (8) positioning it at the bottom of the special compartment
- Close the battery compartment cover as shown in image (9)

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

*Image 10*

*Image 11*

- Position the device as shown in image (10)
- Pull the clamps to extract the battery as shown in image (11)

## 5.2 Recharging station for rechargeable batteries

The charging station (SAV-C1034) allows you to recharge rechargeable batteries with Li-ion technology ACC model (SAV-C1033) of the ***Saver One D S1 Series***. The charging station consists of the following parts:

- Charger (SAV-C1035) image (12)
- AC/DC power supply/adapter model GS40A15-P1J (SAV-C1037) image (13)
- Power cable with three-pole Italian plug (SAV-C0366) image (14)

*Image 12*

*Image 13*

*Image 14*

### 5.2.1 Structure of the battery charger


*Image 15*

| 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-C1035) 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-C1037).
The battery charger (SAV-C1035) and the relative power supply unit (SAV-C1037) 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-C1037) to the charger and then to the power outlet
**C** The LED on the charger will flash green, indicating that it is ready to charge
**D** Insert the battery to be charged into the battery charger as shown in image (15)

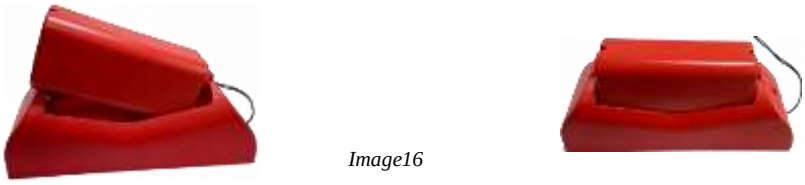
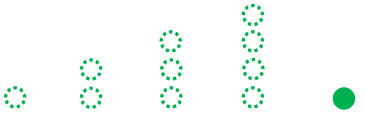


*Image16*

The recharging station allows you to recharge exclusively original ACC rechargeable Li ion batteries (SAV-C1033) 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 PADs for defibrillation

The ***Saver One D S1 Series*** 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

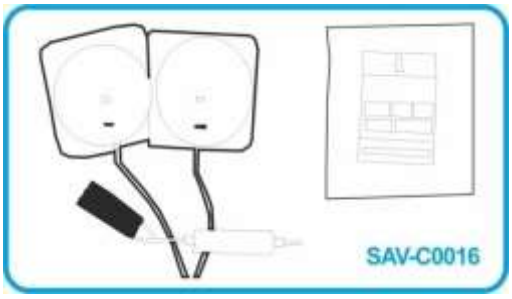
### *5.3.1* Defibrillation PADs for Adults *SAV-C0846*

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.

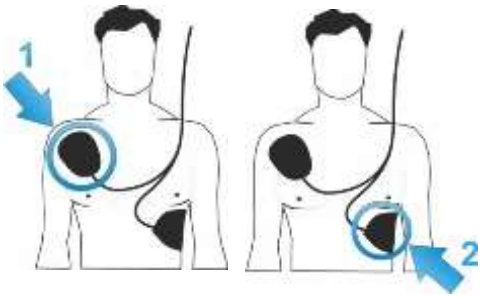
### 5.3.3 Positioning of defibrillation PADs

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).

Always refer to the instructions given both on the packaging of the PADs and directly on each individual pad.

The PADs of the ***Saver One D S1 Series*** are polarized type, do not reverse the positioning of each single pad.

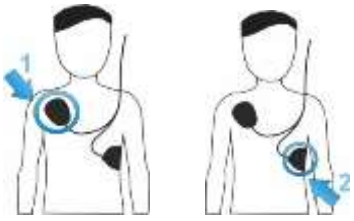

**>8 years or >25 kg**
SAV-C0846




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


**1÷8 years or <25 kg**
SAV-C0016




1 Position **Pad 1** immediately below the patient's right collarbone

2 Place **Pad 2** on the ribs on the left side of the patient under the left side of the chest

## 5.4 2-pole ECG cable SAV-C0017

The SAV-C0017 ECG cable is equipped with two clip terminals for single-use pre-gelled electrodes (*optional*).
The ECG cable is able to carry out the detection of the patient's derivation II and the relative display of the ECG tracking on the ***Saver One D S1 Series*** display. The SAV-C0017 ECG cable can only be used if ***the Saver One D S1 Series*** is set in "ECG MONITORING" operating mode (see Chapter 9).
The ECG SAV-C0017 cable is classified as type CF

*Image 17*

## 5.5 Positioning of the electrodes

The SAV-C0017 ECG cable electrodes must be positioned as shown in image (22):

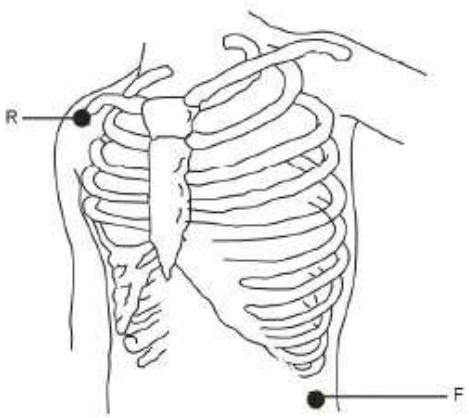



*Image 18*

| International coding (European IEC) | |
|---|---|
| Code (IEC) | Color (IEC) |
| **R** | **RED** |
| **F** | **GREEN** |

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

## 5.6 Memory Card

The ***Saver One D S1 Series*** allows the recording of data on the **internal memory** as well as on the **external memory card**.
Supported memory cards are **SD/SDHC** cards with capacities up to 8GB


*Image 19*

To install a **Memory Card** in the ***Saver One D S1 Series*** follow this procedure:

- **A.** The memory card must be inserted before attaching the battery
- **B.** Place the device on a firm, stable horizontal shelf as shown in the image

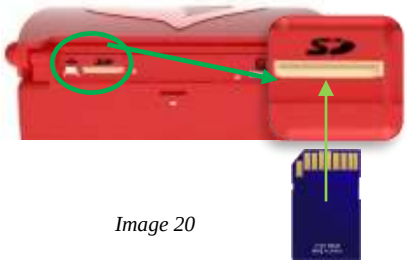


*Image 20*

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

The data recorded directly on the internal memory of the ***Saver One D S1 Series*** can be downloaded via the **USB port** on the back of the device (image 20).
The USB cable to be used must be a **mini USB 2.0** (USB / Mini USB connection)

To connect the mini USB cable to the ***Saver One D S1 Series*** follow this procedure:

- **A.** Detach the battery and insert the Mini USB terminal of the cable in the appropriate compartment on the Saver One D S1 Series
- **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.**

**WARNING: When the device is switched on, and especially when a patient is connected to it, it is recommended:**

**- do not use the USB port**
**- do not touch the USB port**
**- remove the USB cable, if inserted in the USB port, before starting the device**

## 5.7 Martel MCP7830 thermal printer *(SAV-C1070)*

The ***Saver One D S1 Series*** defibrillator can print the ECG tracing and patient data using the external thermal printer model ***Martel MCP7830*** (SAV-C1070).
The communication between printer and defibrillator is wireless thanks to the use of the IrDA port of the ***Saver One D S1 Series*** (located on the left side of the defibrillator) and that of the printer.
The ***Martel MCP7830*** printer is supplied with the following accessories:

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

All information on the thermal printer can be found in the specific user manual of **Martel MCP7830**.
Before using the printer, carefully read the user manual attached to it; pay particular attention to the Precautions and Warnings section.

To print the events, a memory card must be installed in the ***Saver One D S1 Series***. Otherwise the defibrillator will not allow printing.

### 5.7.1 Printer structure


*Image 21*

| Nr. | Description |
|---|---|
| 1 | Compartment for thermal paper roll |
| 2 | Power button |
| 3 | IrDA port |
| 4 | Power LED - Communication LED - Error LED |
| | PC communication port ( bottom side) |
| | DC connector (bottom side) |

# 6 *Saver One D S1 Series* selection menu

The ***Saver One D S1 Series*** menu allows you to make multiple selections, settings and view useful information about the device and the rescue. In the next paragraphs all the settings that can be selected to use the device to its full potential will be described in detail.

## 6.1 Main Menu

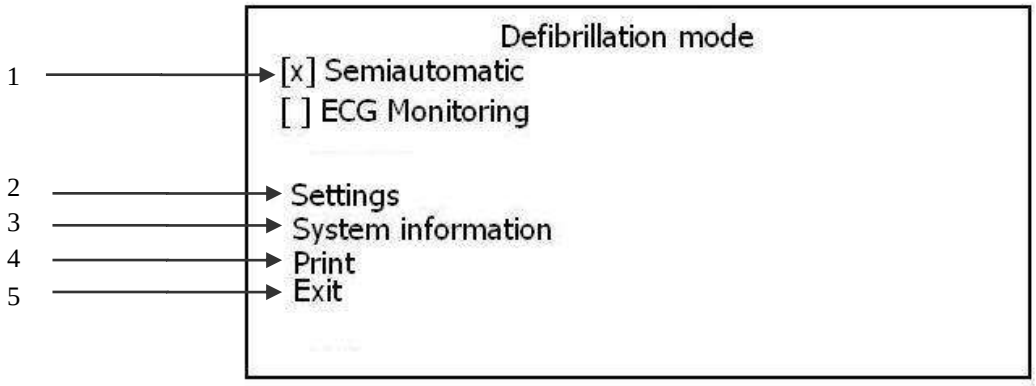
Press the ON/OFF button to turn on the device.
When the device is turned on, the model name and operating status of the device will be shown on the display


*Image 22*


*Image 23*

*Image 24*

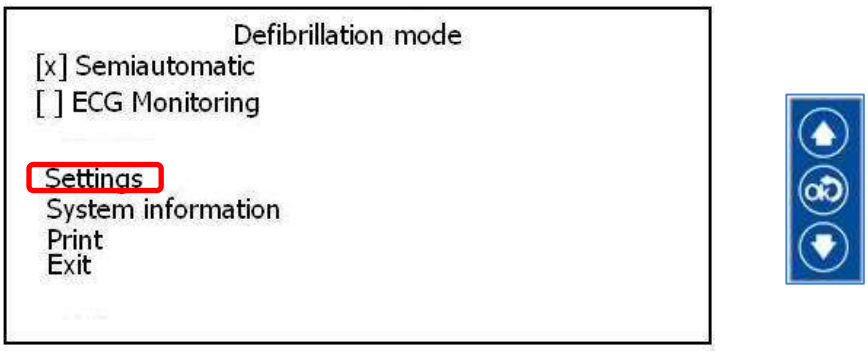
To access the settings menu, press the ENTER key as shown in image (24).
After pressing the ENTER key, the following screen will be shown on the ***Saver One D S1 Series*** display:



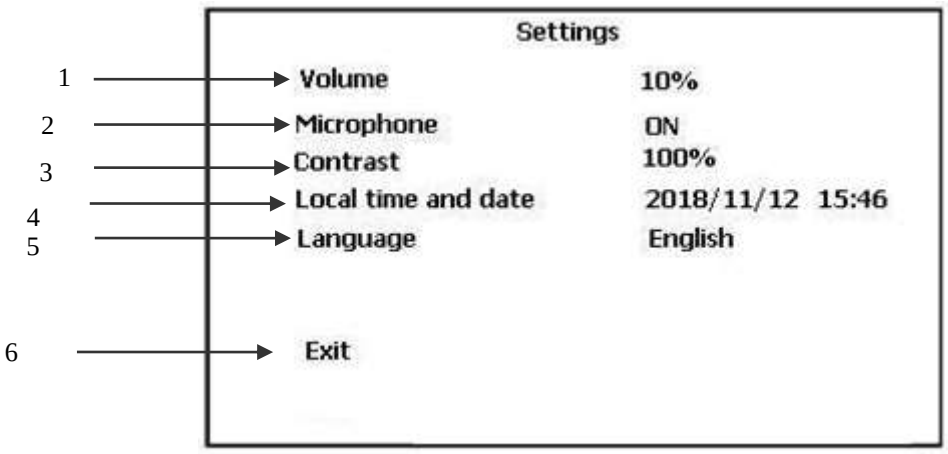

| Nr. | Image | Function |
|---|---|---|
| 1 | [x] Semiautomatic<br>[ ] ECG Monitoring | Allows you to select the desired operating mode:<br><br>**Semiautomatic Defibrillation**<br>**ECG Monitoring** |
| 2 | **Settings** | Allows access to the settings submenu |
| 3 | **System information** | Allows access to the device information submenu |
| 4 | **Print** | Allows access to the print submenu<br>*(only if using Martel MCP7830 printer)* |
| 5 | **Exit** | Allows you to return to the main screen |

## 6.2 Settings Menu

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



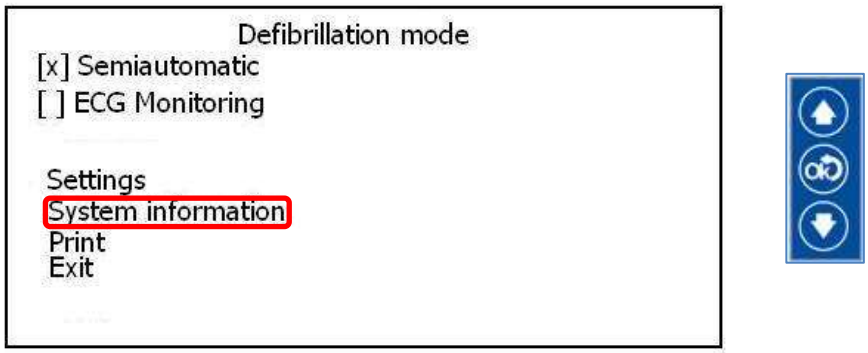

After pressing the ENTER key, the following screen will be shown on the ***Saver One D S1 Series*** display:



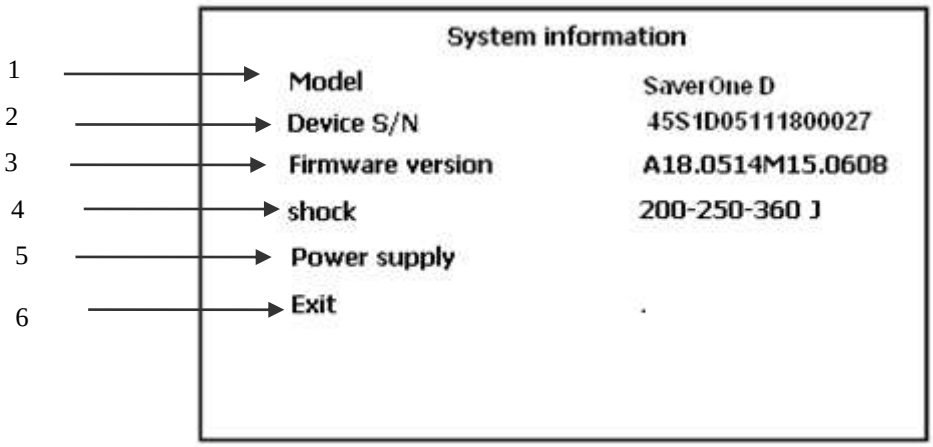

| Nr. | Image | Function | Possible variations |
|---|---|---|---|
| 1 | Volume | Allows you to increase or decrease the sound level (voice + acoustic signals) | **10% - 100%** |
| 2 | Microphone | Allows the activation or deactivation of the microphone for recording on the Memory Card of environmental events | **ON - OFF** |
| 3 | Contrast | Allows you to change the contrast level of the display | **0% - 100%** |
| 4 | Local time and date | Allows you to change the local date and time | **y/m/d - hh:mm** |
| 5 | Language | Allows you to change the language selected for voice and text commands *(default 1 language, up to 5 selectable languages on request)* | **English** |
| 6 | Exit | Allows you to exit the Settings menu and return to the main operating screen | |

## 6.3 System information Menu

Enter the *MAIN* menu and using the navigation keys on the defibrillator keyboard, select the *SYSTEM INFORMATION* item and press the enter key.



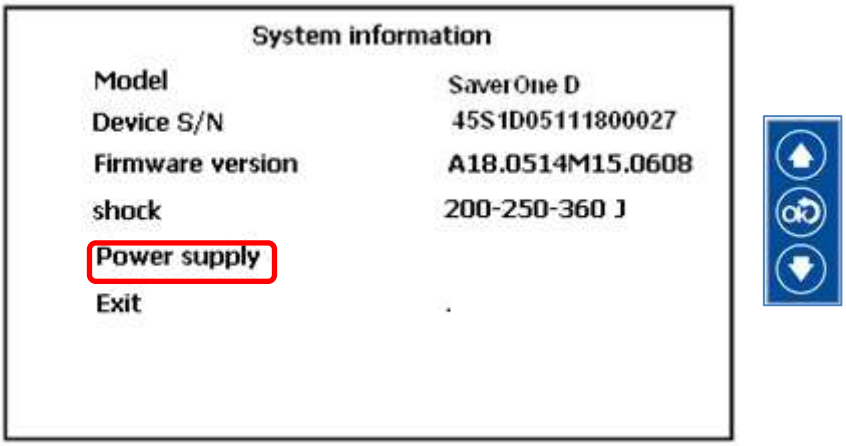

After pressing the ENTER key, the following screen will be shown on the ***Saver One D S1 Series*** display:



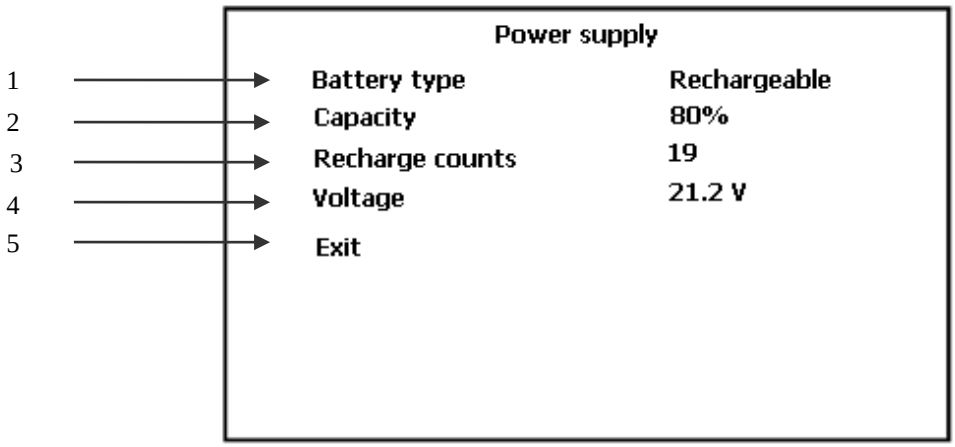

| Nr. | Image | Function | Possible variations |
|---|---|---|---|
| 1 | Model | Indicates the model of the device | **Saver One D** |
| 2 | Device Serial No. | Reference number for service | **00S1D00000000000** |
| 3 | Firmware version | Indicates the software version installed on the device | **A00.0000M00.0000** |
| 4 | Shock | Indicates the shock protocol used | |
| 5 | Power Supply | Allows access to the power sub-menu | |
| 6 | Exit | Allows you to exit the Settings menu and return to the main operating screen | |

### 6.3.1 Power Supply Submenu

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



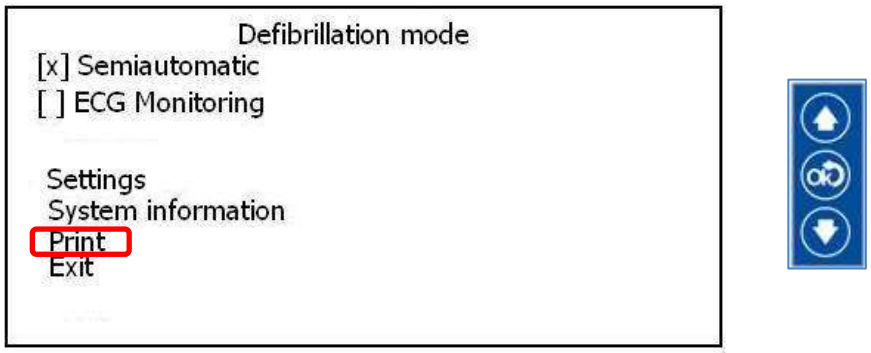

After pressing the ENTER key, the following screen will be shown on the ***Saver One D S1 Series*** display:



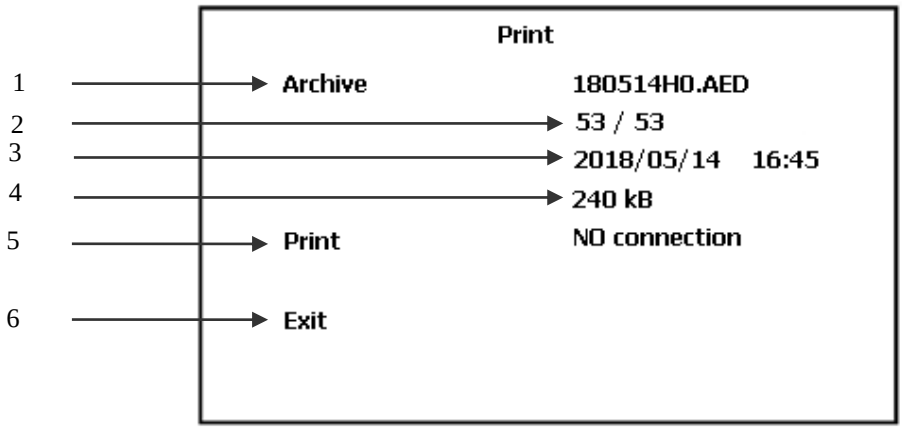

| Nr. | Image | Function | Possible variations |
|---|---|---|---|
| 1 | Type | Indicates the type of battery installed | Disposable **(Li-SOCl2 )**<br>Rechargeable **(Li-ion)** |
| 2 | Capacity | Indicates the remaining battery capacity | **0 – 100%** |
| 3 | Recharge No. | ******This item is only diplayed if the rechargeable ACC battery is inserted***<br>Indicates how many times the rechargeable battery has been recharged | **0 - XX** |
| 4 | Voltage | Indicates battery voltage | **00V** |
| 5 | Exit | Allows you to exit the Settings menu and return to the main operating screen | |

## 6.4 Print Menu

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




After pressing the ENTER key, the following screen will be shown on the ***Saver One D S1 Series*** display:




| Nr. | Image | Function | Possible variations |
|---|---|---|---|
| 1 | Archive | Allows you to select rescue events recorded on memory card | **000000L0.AED** |
| 2 | 53/53 | Indicates the selected rescue and the total amount of recorded rescues | **1/X** |
| 3 | 2018/05/14 16:45 | Indicates the date and time of the selected rescue | **y/m/d - hh:mm** |
| 4 | 240kB | Indicates the size of the file | **XX KB/MB** |
| 5 | Print | Indicates whether the external printer is connected or disconnected | **Ready**<br>**No connection** |
| 6 | Exit | Allows you to exit the Settings menu and return to the main operating screen | |

# 7 Auto test

The Saver One D S1 Series 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.

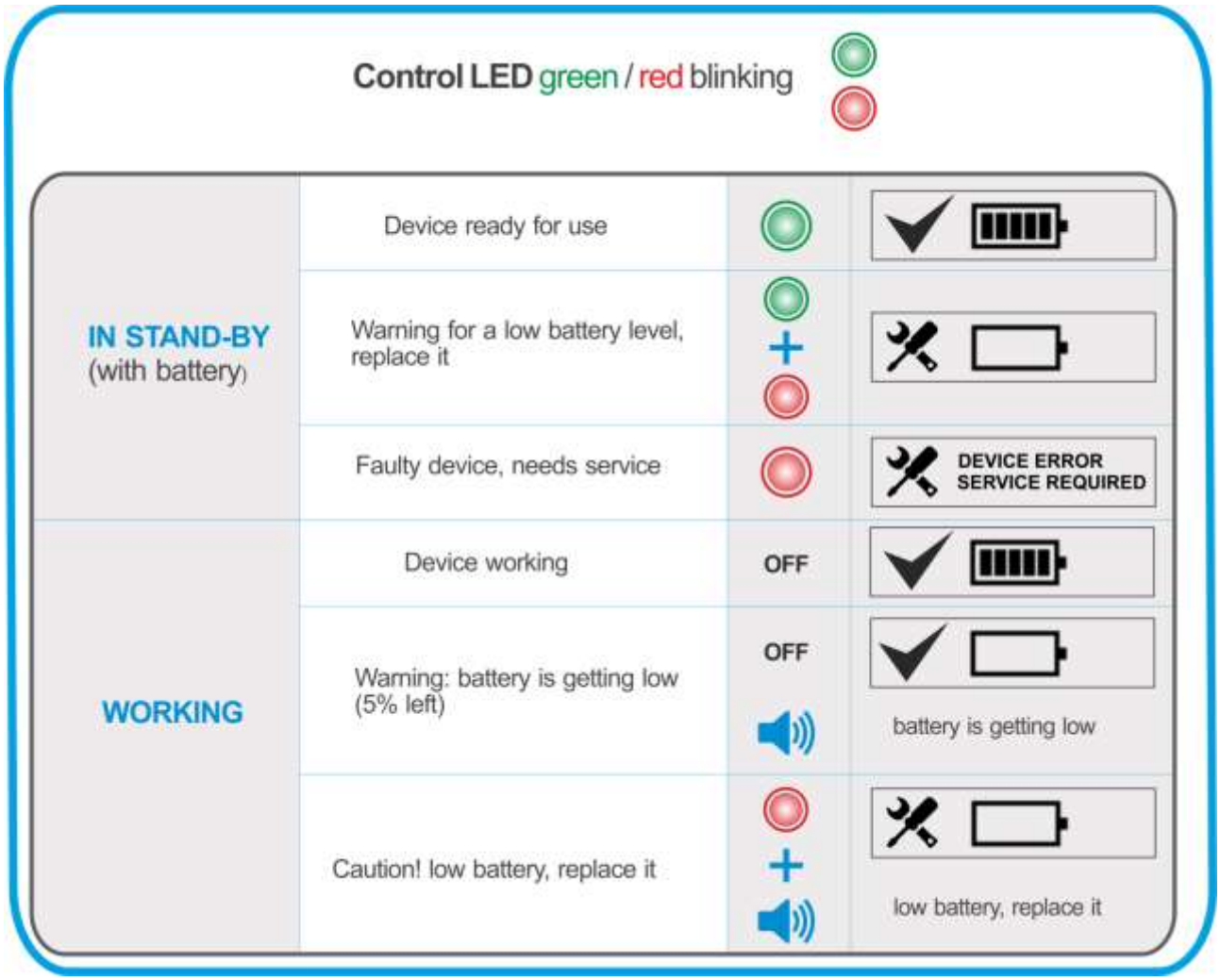
The Saver One D S1 Series performs different types of self-tests:

- ***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.

## 7.1 Control LED and mini display

Both the mini display and the control LED are positioned on the front of the ***Saver One D S1 Series*** 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.



## 7.2 ACTIVATION test

The ***Saver One D S1 Series*** 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 D S1 Series*** will automatically turn on emitting an acoustic signal and the power button will light up green while the control LED will turn off.
The following screens will appear on the colour TFT display:



The device will issue a voice command (audio): *"Testing device"*
*"Press shock 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.
The following screens will appear on the colour TFT display:


- **Turn off the device**

If it is not to be used immediately turn off the ***Saver One D S1 Series*** and leave the battery inserted to ensure that periodic self-diagnostic tests are performed (see Paragraph 7.3)

* *If the shock button is not pressed within the time limit indicated by the countdown, the **Saver One D S1 Series** detects an error.*
*Switch the device back on and press the shock button within the time limit indicated by the countdown.*
*If, on the other hand, the shock button has been pressed but the shock button continues to flash it means that the shock button does not work properly.*
*Turn off the device and perform the operation again; if the problem persists, contact the authorized technical assistance center.*

## 7.3 AUTOMATIC test

The ***Saver One D S1 Series*** has been 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 D S1 Series*** will inform the operator of the start of the automatic self-test through the mini status display:

During self 


after self-test (level of battery) 

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 tables for Led and status mini- display shown in paragraphs 4.2.

## 7.4 POWER ON Test

The ***Saver One D S1 Series*** performs self-diagnostic tests each time it is turned on.
This test is performed in order to verify the proper function of the device before use.
The test is conducted automatically and lasts a few seconds.
After pressing the power button  the ***Saver One D S1 Series*** will emit an acoustic signal to confirm power-up, the control LED will be off and the following screen will be displayed on the colour display:



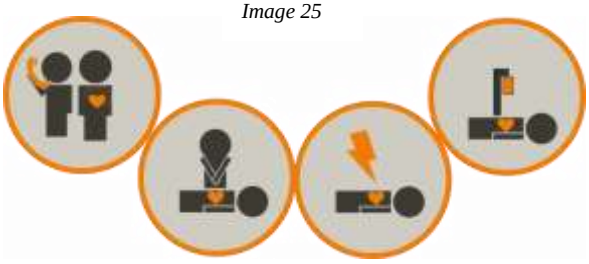
From this moment the device will be ready for use and will provide the operator with the first instructions to start the intervention.

If not to be used immediately, switch off the Saver ***Saver One D S1 Series*** and leave the battery inserted to ensure periodic self-testing (see Section 7.3).

# 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 2017.
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 25*



1. Make sure the person needs help (is unconscious, does not breathe and shows no signs of blood circulation) and call local emergency number immediately
2. While waiting for a defibrillator to be available, begin CPR manoeuvres immediately
3. Use the ***Saver One D S1 Series*** defibrillator to restore normal heart rhythm
4. Continue this until resuscitation of medical competence

## 8.1 Switching on the *Saver One D S1 Series*

The ***Saver One D S1 Series*** 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 D S1 Series*** will emit an acoustic signal to confirm the ignition; the ON/OFF button will be lit fixed green. On the colour display the following screens will be shown in sequence:



If the test is successful, the device will suggest the first sequence of operations to be performed through voice (audio) and visual (colour display) commands, as shown in the following table:

| Voice commands | Text |
|---|---|
| Make the emergency call | Call Emergency Medical Services |
| Stay calm and follow the voice instructions | Stay calm and follow the voice instructions |

## 8.2 Remove clothes

The Saver One D S1 Series suggests to the operator -before correctly positioning the defibrillation PADs on the patient- how to ascertain the patient's condition. This information is highlighted by voice commands (audio messages) and visual commands (colour display), as shown in the table below:

| Voice commands | Text |
|---|---|
| If the patient is unconscious and does not breathe, remove their clothes to expose bare chest and apply electrodes | Remove clothing expose bare chest |

## 8.3 Positioning of defibrillation PADs

The ***Saver One D S1 Series*** suggests to the user the operations to be carried out to correctly position the defibrillation PADs to the patient. This information is highlighted by voice (audio) and visual (colour display) commands, as shown in the following table:

| Voice commands | Text | Video Display |
|---|---|---|
| Place the two electrodes firmly to bare chest as shown in the picture | Place electrodes firmly to bare chest as shown in the picture |  |
| | |  <br>**ONLY IF PEDIATRIC PADS CONNECTOR SAV-C0016 IS INSERTED** |

Consult the relative paragraph for more information on defibrillation PADs and their application.

## 8.4 Cardiac rhythm analysis

If the defibrillation PADs have been correctly applied and the connector is inserted in the appropriate compartment, the ***Saver One D S1 Series*** automatically analyses the heart rhythm of the patient. This information is highlighted by voice (audio) and visual (colour display) commands, as shown in the following table:

| Voice commands | Text | Video Display |
|---|---|---|
| Do not touch the patient | Cardiac rhythm analysis … in progress.. |  |
| Cardiac rhythm analysis | | |

During cardiac rhythm analysis the patient's body must not be touched and must not be subjected to vibrations or movements. The ***Saver One D S1 Series*** 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 D S1 Series*** detects both noise artefacts in the ECG, caused, for example, by patient movement, defibrillation electrode adjustment, and electronic disturbances from external sources. In these cases the analysis is delayed or interrupted.

The ***Saver One D S1 Series*** is able to detect and filter impulses coming from an implanted pacemaker.

## 8.5 Shockable rhythm

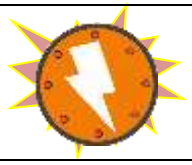
If the ***Saver One D S1 Series*** after having analysed the patient's heart rhythm recognizes a VF or VT. This information is highlighted by voice (audio) and visual (colour display) commands, as shown in the following table:

| Voice commands | Text | Video Display |
|---|---|---|
| Shock recommended | Shock recommended |  |

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

| Voice commands | Text | Video Display |
|---|---|---|
| Do not touch the patient | Charging in progress<br>… in progress .. |  |
| Charging | | |

The progress of the charge of the device is indicated by the loading bar.
Once the charging phase is over, the ***Saver One D S1 Series*** is ready to shock. This information is highlighted by voice (audio) and visual (colour display) commands, shown in the table; in addition, the shock button will flash with light.

| Voice commands | Text | Video Display |
|---|---|---|
| Move away from the patient | Press the shock button |  |
| Press the flashing red button | | |
|  | | |

Before pressing the shock button, move away and make sure that no one is touching the patient.
To shock, press the shock button within 15 seconds
If the shock button is not pressed within 15 seconds of the shock notice, the ***Saver One D S1 Series*** will automatically disarm. This information is highlighted by voice (audio) and visual (colour display) commands, as shown in the following table:

| Voice commands | Text |
|---|---|
| Shock button not pressed | Shock button not pressed<br>Shock cancelled |
| Shock cancelled | |

If the shock button is pressed, the ***Saver One D S1 Series*** will perform the defibrillation shock. This information is highlighted by voice (audio) and visual (colour display) commands, shown in the table; in addition the shock button will stop flashing.

| Voice commands | Text |
|---|---|
| Shock delivered | Shock delivered |
| You can now touch the patient | |

The ***Saver One D S1 Series*** performs the shock using the BTE (Biphasic Truncated Exponential) waveform with auto compensation of the patient's thoracic impedance. The ***Saver One D S1 Series*** shock protocol is incremental, ie the energy delivered to the patient varies incrementally based on the number of shocks performed:

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

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

## 8.6 Non-shockable rhythm

If the ***Saver One D S1 Series*** does not detect a VF or a VT during cardiac rhythm analysis, this information is highlighted by voice (audio) and visual (colour display) commands, as shown in the following table:

| Voice commands | Text | Video Display |
|---|---|---|
| Shock NOT recommended | Shock NOT recommended |  |

All rhythms other than VF and VT will be considered as non-shockable. For more information, paragraph 12.10.

## 8.7 Change of rhythm

The ***Saver One D S1 Series*** is designed to analyse the patient's heart rhythm continuously, moment by moment.
If the device after recommending the shock detects a sudden change in the heart rate of the patient who no longer needs a defibrillation, it will carry out the automatic disarmament. This information is highlighted by voice (audio) and visual (colour display) commands, as shown in the following table:

| Voice commands | Text |
|---|---|
| Shock Cancelled, rhythm changed | Shock Cancelled, rhythm changed |

## 8.8 CPR

The ***Saver One D S1 Series*** defibrillator will guide the operator to CPR (**C**ardio **P**ulmonary **R**esuscitation) in one of the following cases:

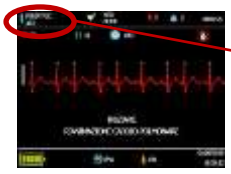
- A shockable rhythm was detected and a defibrillation shock was delivered
- A non-shockable rhythm was found
- A shockable rhythm was found but the shock button was not pressed
- A shockable rhythm was found but the patient's rhythm changed

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

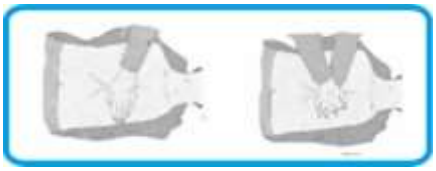
| Voice commands | Text | Video Display |
|---|---|---|
| Begin cardiopulmonary resuscitation | Begin cardiopulmonary resuscitation |  |
| Perform 5 cycles of 30 compressions followed by 2 breaths | | |

The ***Saver One D S1 Series*** 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.

The compressions/insufflations ratio must be **30/2** for 2 minutes (5 cycles) for both adult and child patients.

| Video Display | | |
|---|---|---|
| ratio **30/2** for 2 minutes (5 cycles) |  |  |

The following table shows the main operations to be performed and the relative visual-text-vocal commands provided by ***Saver One D S1 Series.***

<table>
<tr><th>No.</th><th>Type of command<br>(Saver One D S1 Series)</th><th>Instruction<br>Saver One D S1 Series</th><th>Operations to be performed</th></tr>
<tr><td rowspan="2">1</td><td>Voice / Text</td><td>“Begin Cardio-Pulmonary Resuscitation”</td><td rowspan="2">A. Check that the patient is on a rigid surface<br>B. Kneel beside the victim<br>C. Place the heel of one hand in the center of the victim's chest<br>D. Place the heel of the other hand over the first one<br>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<br>  </td></tr>
<tr><td>Visual</td><td> 
</td></tr>
<tr><td rowspan="3">2</td><td>Voice / Text</td><td>“Quickly compress the patient's chest”</td><td rowspan="3">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<br>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)<br>H. The compression and release phase must be approximately equal in duration<br> 
</td></tr>
<tr><td>Visual</td><td> 
</td></tr>
<tr><td>Acoustic signal (BEEP)</td><td>The Saver One D S1 Series signals with a BEEP every compression to be performed.</td></tr>
<tr><td rowspan="2">3</td><td>Voice / Text</td><td>“Perform two breaths”</td><td rowspan="2">Immediately open the air passage using the head and chin towards the back manoeuvre<br>  <br>Perform two insufflations<br>The rescuer inhales normally and, keeping the chin lifted with two fingers, makes 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.<br>  </td></tr>
<tr><td>Visual</td><td> 
</td></tr>
<tr><td>4</td><td colspan="2">The Saver One D S1 Series will repeat STEP 1 to 3 for about 2 minutes</td><td>Follow the voice and text instructions of the Saver One D S1 Series until the device stops the CPR phase (about 2 minutes)</td></tr>
</table>

# 9 ECG monitoring

The ***Saver One D S1 Series*** defibrillator can also be used to monitor the patient's ECG tracing. The "ECG Monitoring" mode allows the operator to monitor the patient's cardiac rhythm in total safety by disabling automatic defibrillation (in order to perform defibrillation, exit the current mode and select semi-automatic defibrillation).
The detection of the ECG trace of the patient in this mode can be done with the help of two different accessories:

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

The ***Saver One D S1 Series*** allows you to view one single ECG channel by analysing the derivation II. Since the use of this mode is indicated to specialized medical personnel, in order to be started, it can optionally require the insertion of a security password (see the following paragraphs for more information).

| | |
|---|---|
| | In this mode the defibrillator does not automatically analyse the ECG tracing, does not allow the charging phase, does not allow defibrillation. |
| | This mode is intended for exclusive use by specialized medical personnel. The password must only be used by medical personnel.<br><br>In monitoring mode, it is expected that the internal capacitor does not store any energy and it is always discharged, so this operating mode is extremely safe. |

## 9.1 Activation of ECG Monitoring mode

After switching it on, the ***Saver One D S1 Series*** will automatically start the semiautomatic defibrillation mode. In order to start the ECG Monitoring mode you should enter the menu and select the new mode.

**1** Enter the main menu by pressing the enter key on the device keyboard as shown in image (39)

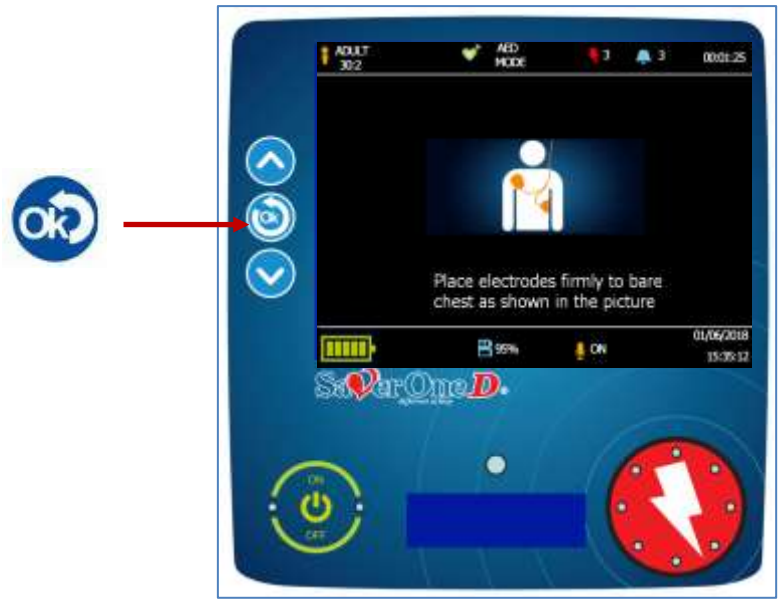
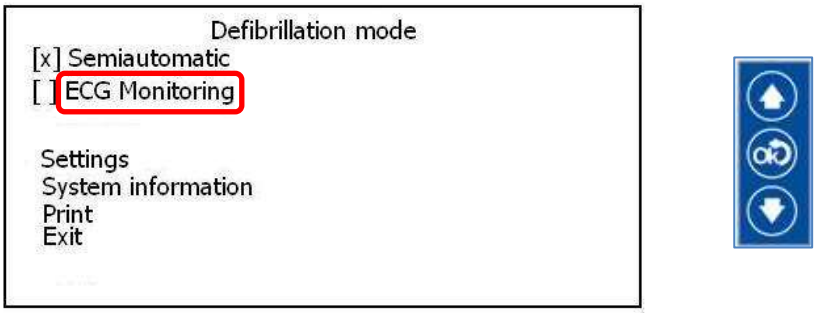


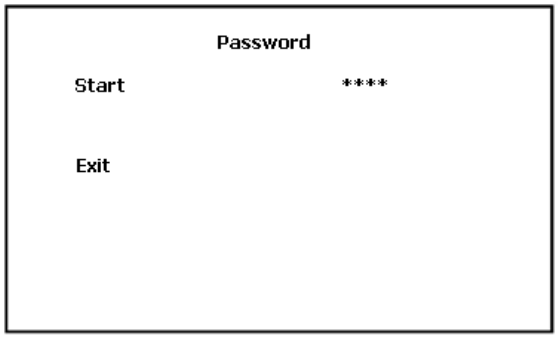

*Image 26*

For more information on the ***Saver One D S1 Series*** menu, consult the relevant paragraph.

**2** From the menu select the "ECG Monitoring" item




**3** If the password entry request has been configured, the following screen will be displayed when accessing one of the two modes:




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

| MANUAL Defibrillation Mode Password | | | |
|---|---|---|---|
| ▲ | ▼ | ▲ | ▼ |
| **UP** | **DOWN** | **UP** | **DOWN** |

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

## 9.2 Description of ECG Monitoring feature

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


| Nr. | Description | Nr. | Description |
|---|---|---|---|
| 1 | Status of "Inhibition of acoustic alarm signals" | 7 | "Enable alarm detection" button |
| 2 | Status of "Alarm detection inhibition" | 8 | "Pause acoustic alarm signals" button |
| 3 | Gain in amplitude of the ECG signal ratio | 9 | "Enable alarm acoustic signal" button |
| 4 | "Alarm detection" event | 10 | "ECG amplitude gain setting" button |
| 5 | "Alarm Reset" button | 11 | "Exit Monitoring Mode" button |
| 6 | "Pause alarm detection" button | | |

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

In particular:

- Pressing button 5 resets the alarms;
- Pressing button 6 disables alarm detection for 30 seconds. This status is highlighted by the presence of the icon 2 in display;
- Pressing key 7 will force enable the detection of alarms. This status is highlighted by the absence of the icon 2;
- Pressing button 8 disables the acoustic alarm signalling for 30 seconds. This status is highlighted by the presence of the icon 1 in display. In this state the alarms continue to be detected but only generate visual signals (Icon 4 displayed).
- Pressing key 9 enables the acoustic alarm signalling. This status is highlighted by the absence of icon 1;
- Pressing key 10 enters the submenu for selecting the gain value in amplitude of the ECG signal. This state is highlighted by the presence of a more marked box around the key 10. Standing in this state, the  and  keys are used to select the desired gain. Once chosen, press the button  again to return to the main icon MENU.
- Pressing button 11 exits the Monitoring mode and returns to the main MENU.

The physiological alarms detected are:

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

* see warning section for the use of the monitoring mode

The technical alarms detected are:

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

# 10 Recording, printing and archiving of rescue data

The ***Saver One D S1 Series*** 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 (with the exception of the recording of voices and environmental noise). The operator can also print the data recorded directly from the device thanks to the use of the portable thermal printer Martel MCP7830 (SAV-1070) or thanks to the PC Saver View Express software.

## 10.1 Data recording

The **internal memory** of the ***Saver One D S1 Series*** 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 **SD Card external memory:**

- **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.

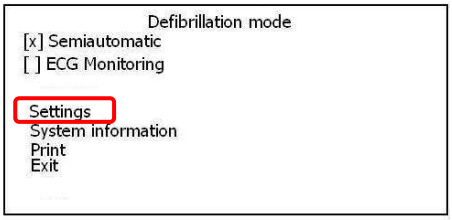
- **AEDFILE.aed** This file stores the rescue data such as: environmental recordings (audio), ECG tracing, patient data (FC and Ω) and all rescue events. This type of file can be redisplayed on a PC using the PC Saver View Express software.

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

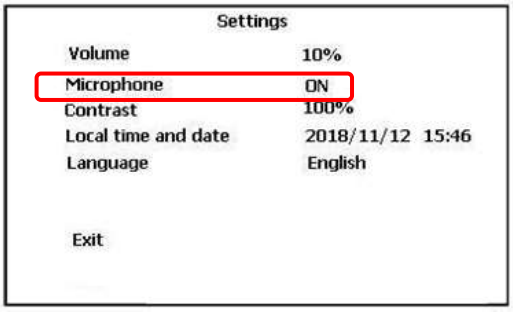
| Type | Capacity | Stored Data | |
|---|---|---|---|
| **SD Card** | **512 MB** | Sounds, Events, Parameters, ECG. Service (AED1LOG + AEDFILE) | 1.500 minutes (25hours) |
| | **1 GB** | | 3.000minutes(50hours) |
| | **2 GB** | | 6.000 minutes(100 hours) |
| **SDHC Card** | **4 GB** | | 12.000 minutes(200 hours) |

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

1 Turn on the device and enter the settings menu




2 Select the microphone item and set the desired setting




**ON** ***Saver One D S1 Series*** makes environmental recordings

**OFF** Microphone disabled:
***Saver One D S1 Series*** does not make environmental records

## 10.2 Printing of rescue data

The ***Saver One D S1 Series*** defibrillator allows you to print data stored in the memory directly from the device by using the portable thermal printer model Martel MCP7830 (SAV-C1070).
Rescue data can only be printed if the data has been previously stored on the memory card.
To proceed with data printing, the operator will have to perform the following operations:

1 Install the printer (***Saver One D S1 Series*** communication >> Martel MCP7830 )
2 Select the data to be printed (print data search)
3 Proceed with printing

### 10.2.1 Martel MCP7830 Printer Installation

For more information on the Martel MCP7830 (SAV-C1070) portable printer, consult its user manual.

**1 Preparation for printing**

- Make sure the printer battery is charged and working
- Insert the paper roll
- Position the printer so that its IrDA port is in line with that of the ***Saver One D S1 Series***

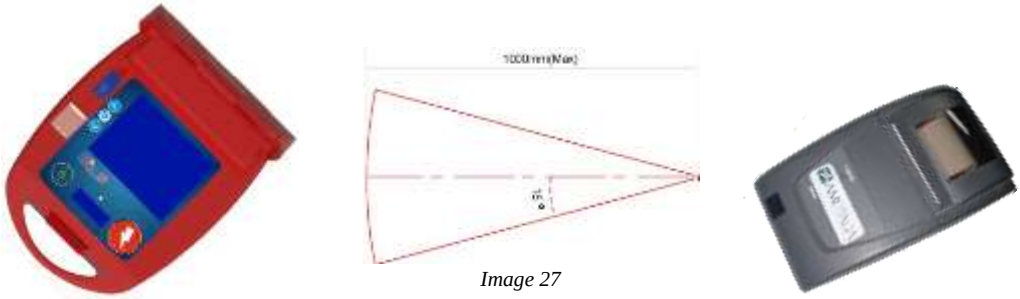
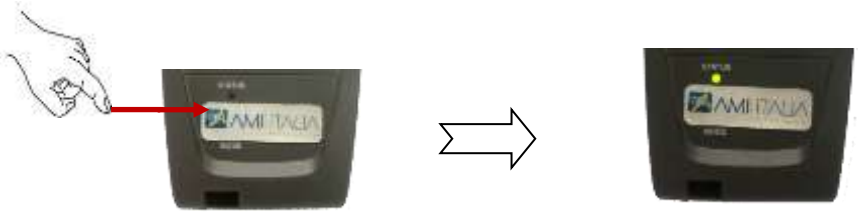


*Image 27*

**2 Turn on the printer Martel MCP7830**



Push for one second and verify that the printer has been turned on when the LED with fixed green light.

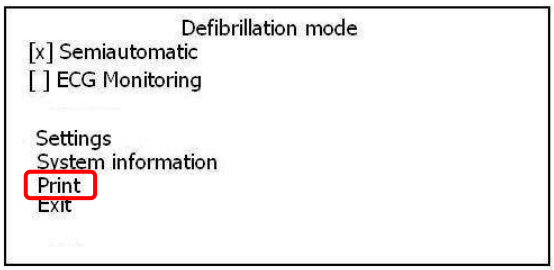
**3 Turn on the Saver One D S1 Series**

When turned on, the ***Saver One D S1 Series*** will automatically detect the printer and be ready to print the stored data.
The correct connection of the printer will be displayed in the settings menu in the print section.

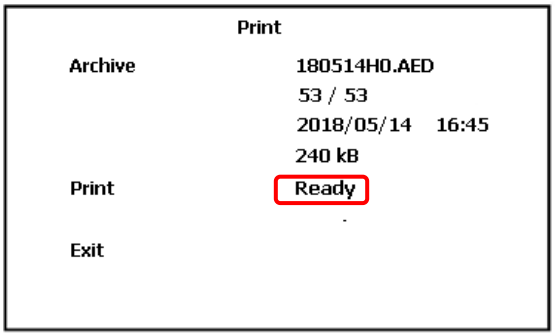
### 10.2.2 Selection of the data to be printed

After interfacing the printer with the ***Saver One D S1 Series*** defibrillator, the operator will have to select the data and start printing. The printing of the data will only be possible if the device is not in operating mode (PADs not placed on patient). To be able to select the various rescues to be printed, the operator must follow the procedure below:

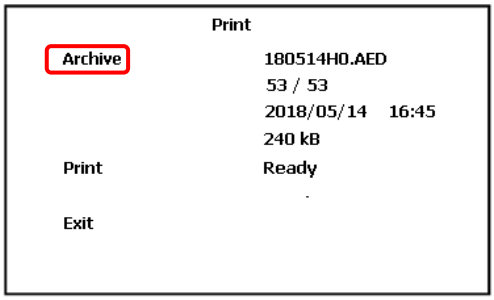
1 Enter the ***Saver One D S1 Series*** menu and select the PRINT item

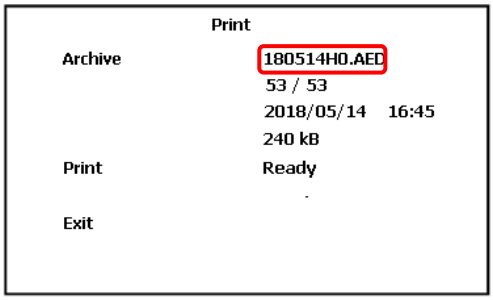



2 Make sure the ***Saver One D S1 Series*** defibrillator has correctly detected the printer




If the ***Saver One D S1 Series*** does not detect the printer, the message "No connection" will be displayed.
In the print menu select the ARCHIVE item and select the rescue data to print.

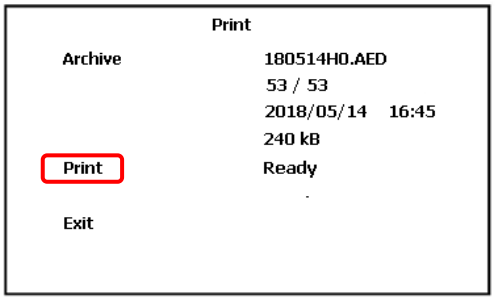


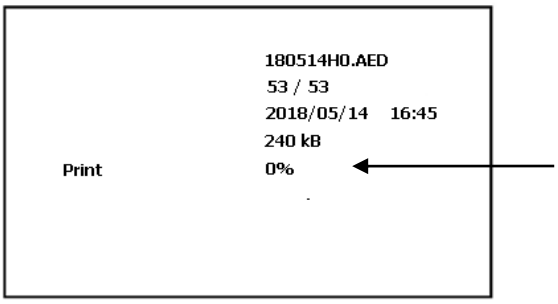

Each single file with the .AED extension corresponds to the recording of the data of one single rescue. It is possible to select the file by consulting the information directly below its name (date and time of beginning of rescue).
For more information on the print menu see the relevant paragraph.

### 10.2.3 Print execution

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




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




If the operator wishes to interrupt the printing procedure, they must select the PRINT item again and confirm; printing will be interrupted and we automatically return to the previous menu.
All the rescue events, the data relating to the device and the ECG tracing of the patient will be displayed on the print slip. It will also be possible to note down some personal data relating to the patient and the name of the resuscitator.

## 10.3 Data storage on PC

The rescue data recorded by the ***Saver One D S1 Series*** defibrillator can be stored, analysed and printed from a Personal Computer using the management software Saver View Express.


Saver View Express®

*Image 28*

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

# 11 Maintenance

The ***Saver One D S1 Series*** 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
**Tel.:** +39 081 806 05 74
**Website:** **www.amiitalia.com**

## 11.1 After each use

After using the ***Saver One D S1 Series*** 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 4.4 and 6.5)
**2** Check that the control LED is on with flashing lighting (flashing green)
**4** If they have been used, replace the PADs with a new package
**5** If not used, check the expiry date of the PADs, if expired replace them with a new package

## 11.2 Ordinary maintenance

Thanks to the control tests carried out in total autonomy by ***Saver One D S1 Series***, 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. |

## 11.3 Cleaning

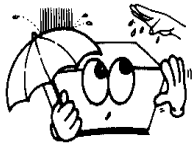
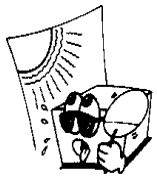
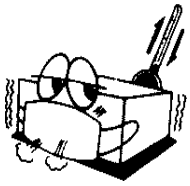
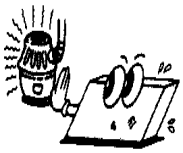
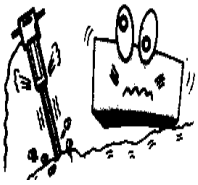
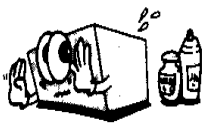
The structure of the ***Saver One D S1 Series*** defibrillator, including the connection port of the defibrillation electrodes, can be sanitized using a soft cloth dampened with one of the cleaning solutions listed below:

**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 D S1 Series*** 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 D S1 Series*** or its accessories.

## 11.4 Preservation

The ***Saver One D S1 Series*** 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 13.2. 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 D S1 Series*** in conditions of temperature or humidity that exceed the ranges indicated in this user manual. |  | Do not install or store the ***Saver One D S1 Series*** in areas directly exposed to sunlight. |
|  | Do not install or store the ***Saver One D S1 Series*** in areas subjected to sudden changes in temperature or humidity. |  | Do not install or store the ***Saver One D S1 Series*** near heat sources. |
|  | Do not use, install or store the ***Saver One D S1 Series*** in places subjected to strong vibrations. |  | Do not use, install or store the ***Saver One D S1 Series*** in environments with high concentrations of flammable gases or anaesthetics. |
|  | Do not install or store the ***Saver One D S1 Series*** in areas with a high concentration of dust. |  | The ***Saver One D S1 Series*** must be opened for maintenance only by A.M.I. Italia S.r.l or by personnel authorized by the same. |

## 11.5 Troubleshooting Guide

The following table lists the symptoms, the possible causes and the possible corrective actions of the problems that may arise. For more information on the implementation of corrective actions, refer to the other sections of the 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 dead 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 center |
| 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 center |
| 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 center 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<br>Level <1%<br>The device may turn off during use.<br>*(see the relevant paragraph)* | Replace the battery |
| In the **operating mode** the voice command "Low battery" is issued. |  <br>**OFF** |  | Low battery.<br>5% battery level.<br>It is possible to use the device but the battery level is low<br>*(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.<br>Level <1%<br>The device may turn off during use.<br>*(see the relevant paragraph)* | Avoid using the device if possible.<br>Replace the battery |
| With the device turned on and after placing the PADs on the patient, the device continues to communicate:<br>"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 |
| Installing the battery the **Activation test** requires you to press the shock button to start the test. The button is pressed but the test is not started. For about 60 seconds the AED requires to press the button and then it turns off automatically, signalling “Error xx” on the mini LCD. | **OFF** |   | The shock button does not work properly | Try turning off the device and retesting. If the problem persists, call for assistance |
| The device turns on, the mini Display and the TFT are on but no voice command is issued | **OFF** |   | The device's speaker does not work | Ask for assistance |

# 12 Technical specifications

The technical specifications of the ***Saver One D S1 Series*** defibrillator, its parts and accessories are shown below.

## 12.1 Physical characteristics

| Category | Nominal specifications |
|---|---|
| **Dimensions** | 29,5 x 23,0 x 11,5 cm |
| **Weight** | with battery **Li-SOCl$_2$** *(SAV-C1032)*: 2,74 Kg + Pad Adult (2,83 Kg)<br>with battery **Li-ion** *( SAV-C1033)*: 2,77 Kg + Pad Adult (2,86 Kg) |

## 12.2 Environmental requirements

| Category | Nominal specifications | |
|---|---|---|
| **Temperature** | Operational and standby:<br>Storage and transport: | 0 a 55°C (32 to 131°F)<br>-40 a 70°C (-40 to 158°F) |
| **Relative humidity** | Operational and standby: | 10% to 95% (without condensation) |
| | Storage and transport: | without humidity control (from -40°C to +5°C)<br>up to 90% (from +5°C to +35°C)<br>with water vapour up to 50 hPa (from >35°C to +70°C) |
| **Atmospheric pressure** | Operating conditions: | 620 hPa to 1060 hPa<br>(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. |
| **IrDA Port** | Free of biological risks. Compliant with IEC 62471 (2006) “photo biological safety of lamps and lamp systems" exempt. | |
| **Tolerance to impacts and falls** | Complies with IEC/EN 60601-1 clause 21 (mechanical forces) | |
| **Sealing system** | Complies with IEC/EN 60529 class IP56 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 14 | |

## 12.3 Reference regulations

| | |
|---|---|
| **Regulations and Directives** | DIRECTIVE 2007/47/CE<br>IEC/EN 60601-1<br>IEC/EN 60601-1-2<br>IEC/EN 60601-1-4<br>IEC/EN 60601-1-6<br>IEC/EN 60601-1-8<br>IEC/EN 60601-1-11<br>IEC/EN 60601-1-12<br>IEC/EN 60601-2-4<br>IEC/EN 60086-4<br>IEC/EN 60529<br>IEC/EN 60601-2-27 except points 202.6.2.101, 201.12.1.101.12.13, 208.6.6.2.101, not executed because of the intended use of the device not intended for environments such as operating theatres or intensive care units (see section warnings for use of monitoring mode) |

## 12.4 Technical alarms table

| Priority | Cause | Visual signal | Operating Mode |
|---|---|---|---|
| **HIGH** | Device ready to deliver the shock | Shock button LED flashing | Defibrillator |
| **HIGH** | Low battery (<1% capacity) | Control LED flashing | Defibrillator / Monitoring |

## 12.5 Physiological Alarms Table (only in Monitoring Mode)

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

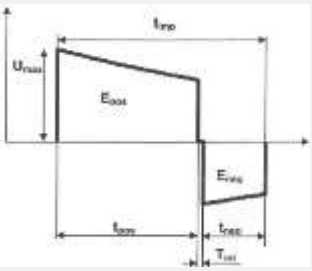
## 12.6 Controls and indicators

| Category | Nominal specifications |
|---|---|
| **Buttons** | ON / OFF button (device switching on and off)<br>3 Navigation Buttons UP, ENTER, DOWN<br>Shock button (to deliver the defibrillation shock) |
| **Visual Indicators** | • Mini Display LCD control of device status<br>• Device status control LED (RED / GREEN bicolour)<br>• ON / OFF button LED (2 green LEDs)<br>• Shock button LED (8 Red LEDs) |
| **Sound Indicators** | Multilingual voices for instructions during use of the device<br>Acoustic signals of warnings and dangers |
| **Speaker** | Adjustable volume 20-100% (Emissions in compliance with IEC/EN 60601-2-4 point 6.1)<br>Min. Variation 20% max 100% (60 dBA to 80 dBA ± 3 dBA) |
| **Microphone** | ON / OFF setting from menu for recording voices and environmental noise |
| **Streaming** | ON / OFF setting from menu for sending ECG data to remote |

## 12.7 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,<br>Device information |
| | **AEDFILE.aed** | Rescue events, voices and environmental noises, ECG tracing of rescue,<br>Vital parameters of the patient analysed and detected by the ***Saver One D S1 Series*** |
| **Data display** | Via PC Saver View Express software (Microsoft Windows compatible) | |

## 12.8 Defibrillator

| Category | Nominal specifications | |
|---|---|---|
| **Waveform**  | **Biphasic Truncated Exponential (BTE)**<br>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), $\mathbf{t_{neg}}$ represents the duration of phase 2 (ms), $\mathbf{t_{int}}$ is the delay between phases, $\mathbf{U_{max}}$indicates the peak voltage, $\mathbf{t_{imp}}$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:***<br>***Version 360J:*** | 200J nominal with a charge of 50 Ω<br>350J nominal with a charge of 50 Ω |
| **Shock protocol (Adults)** | ***Version 200J:***<br>***Version 360J:*** | Incremental: ***First***: 150J – ***Subsequent***: 200J<br>Incremental: ***First***: 200J – ***Second***: 250J – ***Subsequent***:350J |
| **Energy delivered (max) (Children)** | ***Version 200J:***<br>***Version 360J:*** | 50 J nominal with a charge of 50 Ω<br>(when using defibrillation PADs SAV-C0016) |
| **Shock protocol (Children)** | ***Version 200J:***<br>***Version 360J:*** | Fixed: ***First and subsequent***: 50J |
| **Charge control** | Automatic through patient analysis system | |
| **Charge time (from the shock notice)** | ***Version 200J:***<br>***Version 360J:*** | ≤ 9 sec (according to IEC/EN 60601-2-4 §6.8.2 (7a)) (150J with new fully charged SAV-C1032 battery)<br>≤ 15 sec (according to IEC/EN 60601-2-4 §6.8.2 (7a)) (360J with new fully charged SAV-C1032 battery) |
| **Charge time (from the beginning of the analysis)** | ***Version 200J:***<br>***Version 360J:*** | ≤ 15 sec (according to IEC/EN 60601-2-4 §6.8.2 (8a)) (150J with new fully charged SAV-C1032 battery)<br>≤ 21 sec (according to IEC/EN 60601-2-4 §6.8.2 (8a)) (360J with new fully charged SAV-C1032 battery) |
| **Indication charge completed** | • The SHOCK button flashes<br>• Voice command "Press red flashing button" | |
| **Shock delivery** | The shock is delivered by a single SHOCK button | |
| **Disarmament** | ***Automatic:***<br>***Manual:*** | • If the patient's analysis system considers the rhythm no longer shockable, or<br>• If the operator has not pressed the Shock button within 15 seconds of completing charge, or<br>• If defibrillation PADs have been removed from the patient or disconnected from the unit.<br>• 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 | |

## 12.9 Efficiency of delivered energy

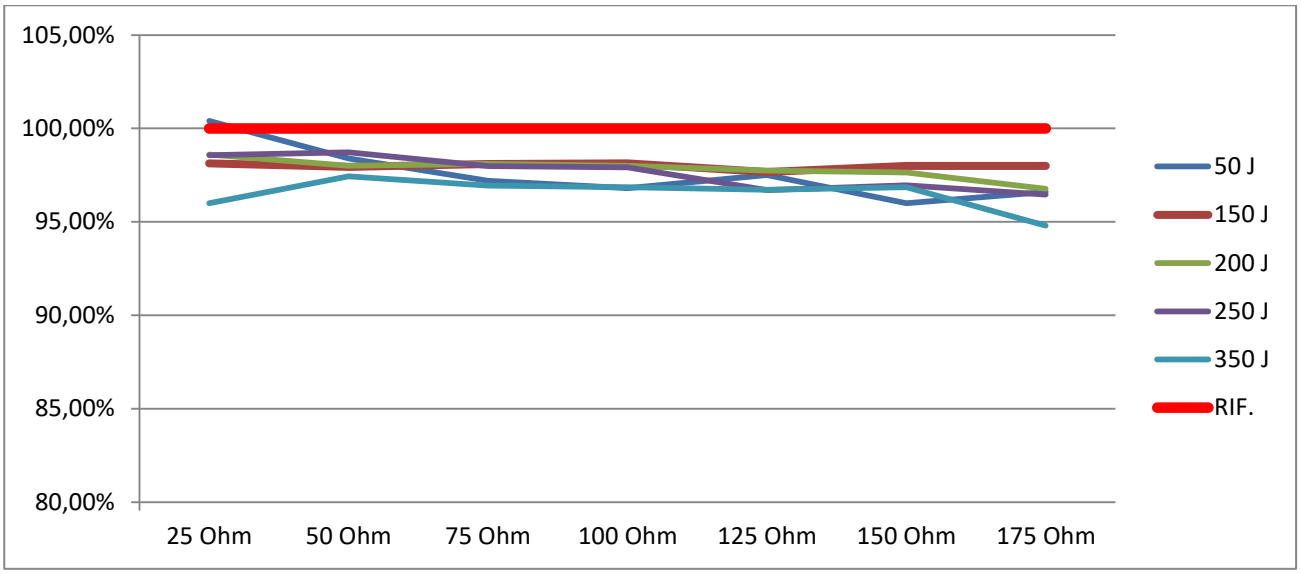
| Impedance | Shock of 50 J (Paediatric) | | | | Energy delivered (Joules) |
|---|---|---|---|---|---|
| | $T_{pos}$ (ms) | $T_{neg}$ (ms) | delivered (Joules) | Set energy(J) | |
| 25 Ohm | 6,8 | 3,3 | 18,6 | 50 | **50,2** |
| 50 Ohm | 7,2 | 3 | 12,3 | 50 | **49,2** |
| 75 Ohm | 7,4 | 2,8 | 9,6 | 50 | **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 150J | | | | 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 200J | | | | 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** |




*Graph showing the efficiency of delivered energy*

## 12.10 Patient analysis system

| Category | Nominal specifications |
|---|---|
| **Function** | Determines the patient's impedance and evaluates the ECG rhythm and signal quality to determine whether or not the shock delivery is appropriate. |
| **Impedance range** | 20- 200 Ω |
| **ECG analysis time** | ≥4 seconds (with new fully charged battery) in compliance to IEC/EN 60601-2-4 |
| **Sensibility** | 97% Respects the guidelines IEC/EN 60601-2-4 2002 (3) sources AHADB, MITDB and EDB |
| **Specificity** | 99% Respects the guidelines IEC/EN 60601-2-4 2002 (3) sources AHADB, MITDB and EDB |
| **Shockable rhythms** | If used on a patient who has the characteristics listed in the usage criteria, the ***Geo Saver P*** defibrillator is designed to recommend a defibrillating shock when it detects the right impedance and when the following situations occur:<br><br>**Ventricular Fibrillation** peak-to-peak amplitude at least 200µVolts<br>**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 D S1 Series*** 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. |

## 12.11 ECG Analysis Function

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

## 12.12 ECG Monitoring

| Category | Nominal specifications |
|---|---|
| **Type of protection** | **BF** with defibrillation PADs<br>**CF** only with SAV-C0017 cable |
| **Intended use** | The ECG Monitoring function is intended to be used in situations where the patient is always followed by an operator and is never left alone |
| **Bandwidth** | 0,5 a 40Hz (default) with defibrillation PADs or ECG cable SAV-C0017 |
| **Lead ECG** | Lead II |
| **ECG Amplitude Range** | 10 mm/mV |
| **Heart Rate Range** | 30 – 200 bpm |
| **Heart Rate Resolution** | 1 bpm |
| **Heart Rate Alarm (*)** | Threshold MIN = 30 bpm; Threshold MAX 120 bpm |

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

## 12.13 Display

| Category | Nominal specifications |
|---|---|
| **Type** | **Colour TFT** with LED backlight |
| **Visible area** | 5,7" (diagonal) - 112 x 80 mm |
| **Resolution** | 640 x 480 pixel |
| **ECG tracing displayed** | 1 (Derivation II) |
| **ECG tracing speed** | 25 mm/sec (default) |
| **Information shown on Display** | • Patient's heart rate (bpm)<br>• Patient thoracic impedance (Ω)<br>• FV or TV detected (numeric value)<br>• Shocks delivered (numeric value)<br>• Textual commands on operations to be performed (text)<br>• Graphic images on operations to be performed (graphic icons)<br>• Active technical and physiological alarms (graphic icons)<br>• Operational mode<br>• Set energy level (J)<br>• Charge duration (graphic incremental bar)<br>• Treatment duration (hh / mm / sec)<br>• Battery level (graphic incremental bar)<br>• Local date and time (dd / month / year - hh / mm / sec) |

## 12.14 Non-rechargeable battery

| Category | Nominal specifications | |
|---|---|---|
| **REF (Model)** | SAV-C1032 | |
| **Type** | Li-SOCl2 (lithium-thionyl chloride) disposable, non-rechargeable | |
| **Voltage** | 28,8 VDC – 3500 mAh | |
| **Capacity** | ***Version 200J*** | 250 continuous shocks with new fully charged battery * |
| | ***Version 360J*** | 160 continuous shocks with new fully charged battery * |
| | ***Monitoring*** | ECG monitoring duration 24 hours continuously * |
| **Duration in Standby (*battery installed*)** | 4 years if installed in the AED, assuming an activation test, daily self-tests without turning on the AED * | |

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

## 12.15 Rechargeable battery

| Category | Nominal specifications | |
|---|---|---|
| **REF (Model)** | SAV-C1033 | |
| **Type** | Li ion (lithium ions) Rechargeable | |
| **Voltage** | 21,6 VDC - 2100 mAh | |
| **Capacity** | ***Version 200J*** | 200 continuous shocks with new fully charged battery * |
| | ***Version 360J*** | 110 continuous shocks with new fully charged battery * |
| | ***Monitoring*** | ECG monitoring duration 14 hours continuously * |
| **Charging time** | ≤ 2,5 hours with charging station SAV-C1035* | |
| **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%**

## 12.16 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)<br>Maintains data for 6 years (with external battery inserted within 12 months) |

## 12.17 Rechargeable battery charger

| Category | Nominal specifications | |
|---|---|---|
| **REF (Model)** | SAV-C1035 | |
| **Charge control** | LED multicolour red green (see par 5.1.6) | |
| **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-C1037 |
| | ***Input*** | 100-240VAC – 50/60Hz – 1.5A |
| | ***Output*** | 15V – 2.67A |
| | ***Absorption*** | 40W |

## 12.18 Thermal printer

| Category | Nominal specifications |
|---|---|
| **Model** | Martel MCP7830 |
| **Identification Code** | SAV-C0018 |
| **Type** | Thermal, Dot matrix |
| **Dimensions** | 85,5 x150x55mm |
| **Weight** | 226g |
| **Power Supply** | Rechargeable battery 4,8 V DC/1600 mAh (4 x cell AA Ni-MH ) |
| **Autonomy** | 1 hour of continuous printing |
| **Recharge duration** | 4 hours |
| **Print speed** | 80 mm/sec |
| **Resolution** | 203dpi, 8dots/mm |
| **Paper type** | Thermal paper (57mm, 30Ø) |

## 12.19 Defibrillation PADs

| Category | ADULTS | CHILDREN |
|---|---|---|
| **REF (Model)** | SAV-C0846 | SAV-C0016 |
| **Series** | Pre-connected<br>(Cable and connector external to the envelope) | |
| **Patient range** | Adult age **>8 years** or weight **> 25Kg** | Childrenage **1 - 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)** | 148 cm ² | 75 cm ² |
| **Active area (for pad)** | 81 cm ² | 31 cm ² |
| **Conductive material** | Metal foil | |
| **Connection** | Anti-shock safety connector | |
| **Cable length** | 120 cm (normally) | |

## 12.20 ECG Cables

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

## 12.21 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 ignition to completion of charging at maximum energy | < 40 seconds | OK |

# 13 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

## 13.1 Guidelines and manufacturer's declaration - Electromagnetic emissions

The ***Saver One D S1 Series*** was designed to be used in electromagnetic environments with features listed below. The customer or the user of the ***Saver One D S1 Series*** must ensure that it is used in such an environment

| Emissions test | Compliance | Electromagnetic environment - Guidelines |
|---|---|---|
| RF Emissions<br>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<br>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<br>**IEC/EN 61000-3-2** | Not applicable | |
| Voltage fluctuations / flicker<br>**IEC/EN 61000-3-3** | Not applicable | |

## 13.2 Guidelines and manufacturer's declaration - Electromagnetic immunity

The ***Saver One D S1 Series*** was designed to be used in electromagnetic environments with features listed below. The customer or the user of the ***Saver One D S1 Series*** must ensure that it is used in such an environment.

| Immunity test | Test level<br>IEC 60601-1 | Compliance level | Electromagnetic environment - Guidelines |
|---|---|---|---|
| Electrostatic shock (ESD)<br>**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<br>**IEC /EN 61000-4-4** | ±2 kV by electricity networks | Not applicable | |
| | ±1 kV by input / output networks | ±1 kV for input and output lines | |
| **IEC/EN 61000-4-11** | < 5% $U_T$ (> 95% dip in $U_T$) for 0,5 cycles<br>40% $U_T$ (60% dip in $U_T$) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$) for 25 cycles<br>< 5% $U_T$ (>95% dip in $U_T$) for 5 seconds | Not applicable | |

| Immunity test | Test level IEC 60601-1 | Compliance level | Electromagnetic environment - Guidelines |
|---|---|---|---|
| Supply frequency (magnetic field) 50/60 Hz<br><br>**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 conduct | 3 Vrms | Not applicable | |
| **IEC/EN 61000-4-6** | 3 Vrms<br>from 150 kHz to 80 MHz outside the ISM[a] bands<br><br>10 Vrms<br>from 150 kHz to 80 MHz inside the ISM[a] bands | Not applicable | |
| RF radiated<br><br>**IEC/EN 61000-4-3** | 10 V/m<br><br>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.<br>**Recommended separation distance**<br>$d = 1.2\sqrt{P}$ from 80 MHz to 800 MHz<br><br>$d = 2.3\sqrt{P}$ from 800 MHZ to 2,5 GHz<br><br>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].<br><br>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]<br><br>Interference may occur near the devices marked with this symbol.<br>  |

| | |
|---|---|
| **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. |

## 13.3 Recommended separation distance between portable and mobile RF communication equipment and Saver One D S1 Series device

The **Saver One D S1 Series** must be used in an electromagnetic environment in which radiated RF interference is controlled. The customer or the operator of the **Saver One D S1 Series** can help prevent electromagnetic interference by maintaining the minimum distances recommended below, between the portable and mobile RF communications equipment (transmitters) and the **Saver One D S1 Series**, 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 outside the ISM bands** $d = 1.2\sqrt{P}$ | **From 80 MHz to 800 MHz** $d = 1.2\sqrt{P}$ | **From 80 MHz to 800 MHz** $d = 2.3\sqrt{P}$ |
| 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 to 27,283 MHz and 40,66 MHz up to 40,70 MHz | | | |
| **NOTE 3:** | An additional factor of 10/3 is used in the calculation of the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency 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. | | | |

# 14 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 |
| IP56 | 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 |
| | |

# 15 Certifications

## 15.1 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

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

## 15.2 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
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** *for the following products*

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

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

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

IMQ S.p.A.

# 16 Saver One S1 Series Defibrillator Warranty

**1 Warranty Restriction**
A.M.I. Italia S.r.l guarantees the original purchasers that its Saver One S1 series defibrillators and related accessories and batteries are free from any material or manufacturing defect according to the terms and conditions of this restrictive warranty. The original purchaser is considered to be the final user of the product purchased. This limited warranty is granted only to the original purchaser of the Saver One S1 series defibrillator of A.M.I. Italia S.r.l and is not transferable or assignable to third parties.
The Saver One S1 Series defibrillators are as follows:
**Saver One S1 Series Semi-Automatic** (code S1S-B0978 o S1S-B0979)
**Saver One S1 Series Automatic** (code S1A-B0982 or S1A-B0983)
**Saver One D S1 Series** (code S1D-B0984 or S1D-B0985)
**Saver One P S1 Series** (code S1P-B0986 or S1P-B0987)

**2 Duration**
A.M.I. Italia S.r.l guarantees the original purchaser of Saver One S1 series 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 S1 Series** have a six (6) year warranty
- **Non-rechargeable batteries Li-SOCl2** (SAV-C1032) 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-C1033) 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 S1 series 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 S.r.l , 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 S1 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 D S1 Series AED 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 One S1 series AEDs 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 ONE S1 SERIES DEFIBRILLATOR 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 S1 series defibrillators by A.M.I. Italia S.r.l 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 S1 series defibrillators by A.M.I. Italia S.r.l will be governed by Italian law, at the Court of Naples, Italy

# 17 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.



SaVer One® S1 series
Complete AEDs range to save lives

**Warranty** Card
**Scheda** di Garanzia
**Carte** de Garantie
**Tarjeta** de Garantía

/ /

Device Model
Modello del Dispositivo
Modèle du Dispositif
Modelo de Dispositivo

Serial Number (see label on the back)
Numero di Serie (vedere l'etichetta sul retro)
Numéro de Série (voir l'étiquette sur le dos)
Número de Serie (ver la etiqueta en la parte posterior)

Date of Purchase
Data d'Acquisto
Date d'Achat
Fecha de la Compra

End User's Name
Nome dell'Utente Finale
Nom de l'Utilisateur Final
Nombre del Usuario Final

Address
Indirizzo
Adresse
Dirección

City
Città
Ville
Ciudad

State/Province/Region
Stato/Provincia/Regione
Etat/Province/Région
Estado/Provincia/Región

Postal Code
Codice Postale
Code Postal
Código Postal

Country
Paese
Pays
País

Telephone Number
Numero di Telefono
Numéro de Téléphone
Número Telefónico

Fax Number
Numero di Fax
Numéro de Fax
Número de Fax

Email Address
Indirizzo Email
Adresse Email
Correo Electrónico

Seller's Company Name
Ragione Sociale del Venditore
Nom du Vendeur
Nombre del Vendedor

Seller's Country
Paese del Venditore
Pays du Vendeur
País del Vendedor

Seller's Phone Number
Telefono del Venditore
Téléphone du Vendeur
Teléfono del Vendedor

# SaVer One® D
## S1 series

AEDs

AMI ITALIA
MEDICAL PRODUCT

IMQ