# SAVER ONE SERIES
# the new generation

## USER MANUAL


**life is a breath,**
**...keep it safe with us**

ami.italia
medical products

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The contents of this user manual are subject to change without notice.

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# CHAPTER 1: Basic Instructions for SAVER ONE AED Series

## 1.1 PREFACE

This Manual is modular. When complete, it provides instructions on the entire SAVER ONE AED Series produced by A.M.I. Italia Srl, which includes the following AED models:

- **SAVER ONE** Semi-Automatic and Fully Automatic Public Access Defibrillator
- **SAVER ONE D** AED with ECG Monitoring (with TFT colour display)
- **SAVER ONE P** AED with ECG Monitoring & Manual Override (with TFT colour display)

SAVER ONE AED Series shares a basic set of instructions and common features which can be combined in just one chapter (CHAPTER 1) of this Manual.
Separated chapters, one for each model of AED, can be integrated to CHAPTER 1 in order to form various Manuals, one for each individual model of AED, as follows:

- Chapters 1 and 2 for SAVER ONE
- Chapters 1 and 3 for SAVER ONE D
- Chapters 1 and 4 for SAVER ONE P
- Chapters 1, 2, 3 and 4 for the complete SAVER ONE AED Series

### 1.1.1 Product Models

Thank you for choosing one of the Saver One AED model manufactured by A.M.I. Italia Srl.

Please read carefully the instructions given in this Manual so that you can use the device properly, according to its function and indication of use. It is important to respect the instructions given in this Manual in order to ensure the safety of the patient, the rescuer and third persons while using the device.

### 1.1.2 Contact Information

You can contact our Company through the website www.amiitalia.com or to the following addresses:

***HEAD REGISTERED OFFICE***
Via G. Porzio Centro Direzionale Is.E2
80143 Napoli (NA)
Italy

***NORTH ITALY OFFICE***
***Marketing & Public Relations***
Viale Gran Sasso, 11
20131 Milano
Tel: +39.02.20509246
Fax: +39.02.29520839

***SOUTH ITALY OFFICE***
***Production & Service***
Via Cupa Reginella, 15A
80010 Quarto (NA)
Tel: +39.081.8063475 / 081.8060574
Fax: +39.081.8764769

To order additional AEDs or accessories worldwide:
Tel: +39.081.8063475
Fax: +39.081.8764769
Email: info@amiitalia.com

To receive customer support (please have the AED model and its Serial Number available when contacting Customer Service. The Serial Number is located on the label, underside the device):
Tel: +39.081.8060574
Fax: +39.081.8764769
Email: support@amiitalia.com

### 1.1.3 Limited Warranty

A.M.I. Italia Srl, warrants that its SAVER ONE AED Series and related Accessory will be free from defects in material and workmanship, under normal use and maintenance, according to the terms and conditions of this warranty. This Limited Warranty is only granted to the original purchaser and is not transferable or assignable to third parties. For purposes of this warranty, the original purchaser is deemed to be the original end-user of the product purchased.

***Duration of Warranty***
SAVER ONE AED Series has a warranty of six (6) years starting from the date of mailing to our facility of the "Warranty Card" or optionally starting from thirty (30) days after the date of the shipment from our facility to the original purchaser (will attest what is chronologically occurring first).
The non-rechargeable Li-$SOCl_2$ battery (SAV-C0903) has a warranty of four (4) years starting from the date of production both for its Standby Life (typical when the battery is installed to the device: will power the AED in standby state within the specified standby temperature range, assuming 1 battery insertion test and no defibrillation uses) or its Shelf-Life (typical when stored within the specified temperature range with its original packaging).
The Li-Ion Rechargeable Battery (SAV-C0011) and has a warranty of two (2) years starting from the date of production within the specified temperature range, if recharged at least one (1) time every four (4) months.
The Disposable Pads shall be warranted until their expiration date.
Any other Accessory is warranted for six (6) months starting from 30 days after the date of the original shipment.

***Validation of Warranty***
The original purchaser should validate the warranty of the device by completing the “Warranty Card” (included inside each original box packing) and by sending it with registered mailing back to our facility or optionally should register it in our web site: www.amiitalia.com
In case of defects covered by this warranty, the original purchaser must get in contact with the direct seller or with an Authorized Service Centre for obtaining RMA (return materials authorization). A.M.I. Italia Srl reserves at its sole discretion the exclusive right to repair or replace the device that proves defects by reason of improper workmanship or materials.

***Exclusion of Warranty***
This warranty does not cover defects or damages of any sort resulting from, but not limited to, accident, abuse, misuse, neglect, natural or personal disaster, alterations, improper installation or use, failure to follow instructions or warnings recommended by the manufacturer into the manual, unauthorized disassembly, repair or modification or replacements of parts.
This warranty is void if the device is used in conjunction with incompatible parts and Accessories not authorized by the manufacturer.
This warranty does not cover items and components subject to normal wear and burnout during use, including but not limited to buttons, lamps, fuses, battery contacts, patient cables and accessories.
This warranty will be automatically invalidated if:
- ✓ the serial number of the device is amended, deleted, become unreadable or otherwise tampered with
- ✓ the seal of guarantee has been removed from the device (opening the case)
- ✓ the products' trade name or the manufacturer's name has been covered, altered or deleted

This warranty does not cover the purchasing of used device(s). In this case A.M.I. Italia Srl is not responsible for any product defects and the warranty shall be offered by the seller of the used device(s).

***Disclaimers***
The foregoing is the complete warranty for A.M.I. Italia Srl device(s) and specifically excludes and replaces all other warranties and representations, whether oral or written.
No other warranties are made with respect to A.M.I. Italia Srl device(s) and A.M.I. Italia Srl expressly disclaims all warranties not stated herein, including, to the extent permitted by applicable law, any implied warranty of merchantability or fitness for a particular purpose.
This Limited Warranty will be the sole and exclusive remedy in relation to your device purchasing.
No person, including any Agent, Dealer or A.M.I. Italia Srl Representative, is authorized to make any representation or warranty concerning A.M.I. Italia Srl device(s), except to refer purchasers to this Limited

Warranty. In no event will A.M.I. Italia Srl be liable to the purchaser of A.M.I. Italia Srl device(s) for any damages, expenses, lost revenue, lost savings, lost profits or any other incidental or consequential damages arising from the purchase, use or inability to use the A.M.I. Italia Srl device(s), even if A.M.I. Italia Srl has been advised of the possibility of such damages.
Some states do not allow limitations on duration and exclusions or limitations of incidents or consequential damages, therefore the above limitation or exclusion may not apply to you.

***Warnings***
Install, use and perform maintenance on SAVER ONE AED Series exclusively following instructions given into the user's manual.

***Legal Rights***
This warranty gives to the original purchaser specific legal rights whenever AEDs are installed, used, maintained and stored exclusively following instructions given into the user's manual.

***Place of Jurisdiction***
This Limited Warranty is subject to Italian material and procedural law. Any dispute concerning this warranty or that might arise from the use of SAVER ONE AED Series shall be handled definitely by the court in Naples (Italy), which will be the place of jurisdiction for any legal action arising out of this warranty.

## 1.2 PRODUCT INFORMATION & SAFETY

### 1.2.1 Product References

For purposes of retaining simple and clear instructions in this manual, note the product references given. Features, specifications, operating instructions and maintenance common to all models will be referred to as: "AED" or "device" refers to **SAVER ONE** Semi-Automatic or Fully Automatic and to **SAVER ONE D** and **SAVER ONE P** unless otherwise specified.

### 1.2.2 AED Tracking

Defibrillator manufacturers and distributors are required to track the location of defibrillators they sell. Please notify A.M.I. Italia Srl Customer Service in the event that your AED is sold, donated, lost, stolen, destroyed or if it was not purchased directly from A.M.I. Italia or an authorized dealer.

### 1.2.3 Safety Terms

This manual contains symbols indicating potential hazard categories which definition is as follows:

**HAZARD** reports an immediate risk to the safety of persons, which also involves death or damage to the device or parts thereof

**WARNING** reports a situation or unsafe practice which involves serious injury to persons and damage to the device or its parts

### 1.2.4 Safety Descriptions

The following is a list of AED safety alerts that appear throughout this manual. Read and understand these safety alerts before operating the AED.

***HAZARD***

- According to the IEC standards, it is not allowed to use the device or its accessories in the presence of flammable substances (petrol or similar) or in an atmosphere enriched with oxygen or combustible gas/vapours.
- Do not recharge the non-rechargeable battery Li-$MnO_2$ (SAV-C0010) or Li-$SOCl_2$ (SAV-C0903), there may be the risk of explosions.
- Do not allow the battery to come into contact with open flames. Do not expose to fire.
- Do not short-circuit the battery terminals.
- In the event of leakage or strange odour from the batteries, keep them away from fire in order to prevent the ignition of any leaked chemical fluids.
- Danger of electric shock. The device generates high voltages and dangerous levels of current. Do not open the device, do not remove the panels and do not try to repair it. The AED does not have components that users can repair. For the purposes of repair, the device must be sent to an authorized service centre.
- Do not apply the defibrillation PADs on the chest of the patient if there are nitro-glycerine patches. Remove the patches and place the electrodes afterwards. 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 defibrillation shock. Avoid any contact between:
  - parts of the patient's body
  - conductive liquids (such as gels, blood or salt solution)
  - metallic objects in the vicinity of the patient (such as a bed frame or stretching device) that represents pathways for unintentional defibrillation current.

- Do not immerse the AED, its parts or accessories, in water or other liquids.

- Do not allow the penetration of liquids into the AED, its parts or accessories. Avoid spilling liquids on the AED and its accessories: it may cause damage or risk of fire or electric shock. Do not sterilize the device or its accessories.

***WARNING***

- Avoid the formation of air bubbles between the skin and the defibrillation pads (electrodes). The formation of air bubbles during defibrillation can cause severe burns to the skin of the patient. To avoid the formation of air bubbles, make sure the pads completely adhere to the skin. Do not use electrodes whose gel is dried. Check the expiry date before use.

- The RF (radio frequency) interferences from devices, such as cell phones and two-way radios, can cause the malfunction of the AED. The device must be kept at least 2 meters away from RF devices, as specified in EN 61000-4-3. Keep a sufficient distance from other sources of therapeutic and diagnostic energy (e.g. diathermy, high-frequency surgery, magnetic tomography).

- Use the AED only if you received a BLS-D or ALS-D training course.

- Before using the device be sure there is no visible damage.

- The interface issues optically invisible infrared radiation. The diode emission complies with IEC 60825-1 Class “Eye Save”.

- Do not use the SAV-C0016 defibrillation Paediatric pads on adult patients (older than 8 years old and weighing more than 25 kg). By using the paediatric pads, the AED automatically switches to the paediatric mode, reducing the maximum energy that can be delivered to 50J.

- Do not apply the defibrillation electrodes directly on a pacemaker to avoid any misinterpretation of the ECG and to avoid damage to the pacemaker through the shock.

- Do not allow the defibrillation pads to touch or come into contact with tampons, trans dermal patches, etc.. Failure to do so may result in the formation of electric arcs and patient skin burns during defibrillation, and even the loss of the current.

- Place the defibrillation pads as indicated in this manual and marked on the packaging.

- Do not use the defibrillation PADs if the gel is detached from the support or if it is torn, split or dry.

- If you have identified any damage on device and/or accessories, do not use the AED in any case.

- Before using AED remove metal objects from the patient's body (including necklaces or bracelets, etc.).

- Do not use other defibrillation pads than those provided by the manufacturer.

- Do not touch the patient or the defibrillation pads during the ECG analysis.
- Handling or transporting the patient during the ECG analysis performed by the device can lead to incorrect or delayed diagnosis. Minimize movement during the analysis phase. If the device is used while the ambulance is in motion, stop the car and start again only after delivering a shock.
- Avoid using the Adult defibrillation pads on children (aged 1-8 or weighing between 8-25kg).
- Before applying the defibrillation pads you have to dry the patient's chest and remove unwanted hair.
- Do not subject AED, its accessories and parts to falls and/or impacts.
- Do not use damaged accessories, otherwise they may cause the malfunction of the device.
- Using batteries, pads, cables or optional equipment other than those approved by A.M.I. Italia Srl may cause the AED to function improperly during a rescue.
- Avoid excessive rough handling of the device or its accessories or parts in order to avoid possible damage. Inspect the entire system periodically.
- Perform the sanitization of the device in accordance with the rules set out in this manual and in any case always verify that the device is switched off, with the battery disconnected and pads unconnected.
- The defibrillation pads are disposable, to be used only on one patient. Do not reuse it; throw them after use and replace them with a new pair.
- Intense or prolonged administration of cardiopulmonary resuscitation with the defibrillation pads applied to patient may damage the electrodes. Replace them if they are damaged during use or handling.
- Improper maintenance may damage the AED or cause it to malfunction. Follow the instructions in this manual.
- Use the non-rechargeable batteries Li-MnO2 (SAV-C0010) or Li-SOCI2 (SAV-C0903) manufactured by A.M.I. Italia Srl before their expiration date.
- The rechargeable Li-Ion (SAV-C0011) battery must be charged using only the CBACCS1 (SAV-C0012) charger model manufactured by A.M.I. Italia Srl Otherwise the batteries may be damaged.
- The CBACCS1 (SAV-C0012) Charger must be used only with the Meanwell power supply P66A-3P2JA (SAV-C0013) model provided by A.M.I. Italia Srl The use of different power supplies may result in incorrect operation of the charger and may damage the ACC (SAV-C0011) rechargeable batteries.
- Remove the batteries from the device only if the device is turned off for at least 5 seconds. Failure to do so could severely damage the device and the battery.
- The AED, its accessories and parts are not sterile and cannot be sterilized.
- Do not expose the device, its parts or accessories to direct light or high temperature.

### 1.2.5 Disposal

The device, its accessories and parts shall not be disposed of with other household waste within the European community. To prevent possible harm to the environment or human health caused by improper waste disposal, recycle this item responsibly in order to promote a sustainable use of resources. When disposing a used device use an appropriate waste collection service or return it to the dealer in the area. In this way it will be possible to carry out an environmentally safe recycling.

### 1.2.6 Symbols Description

The following symbols may appear in this manual, on the AED or on its accessories.
Some of the symbols represent standards and compliances associated with the AED and its use.

| | |
|---|---|
|  | ILCOR Universal Symbols for AED |
|  | Danger High Voltage |
|  | General notices: Consult the accompanying documents before using the device |
|  | Type BF, Defibrillation equipment |
|  | Do not expose to high temperatures or flames |
|  | Do not recharge |
|  | Do not open |
|  | Do not destroy, or damage |
|  | Do not use it in pools of water |
|  | Read the User Manual |
|  | Battery recycling |
|  | Please follow local regulations for waste disposal |
|  | Fragile |
|  | Store in a dry place |
|  | Do not expose to direct sunlight |
|   | Danger of electric shock, do not open |

| | |
|---|---|
|  | IMQ Mark |
|  | CE mark with identification number |
| IP54 | The equipment's degree of protection against dust and water (battery included) |
|   | Serial number |
|  | Manufacturing date |
|   | Lot Number (LOT) |
|  | Expiry date |
|   | Order Reference Number |
|  | The Manufacturer's name |
|   | No Latex |
|   | Single use, do not reuse |
|   | Not Sterile |
|  | External indications on the box |
|  | This side upwards |
|  | Temperature limits |
|   | Stack in height only up to 6 cartons |

### 1.2.7 Electromagnetic compatibility

The AED is intended for use in the electromagnetic environment specified in the following paragraphs. The user of the device must ensure that it is used in such an environment as specified below.

***Electromagnetic Emission***

| Emission test | Conformity | Electromagnetic environment (guide) |
|---|---|---|
| RF emissions<br>CISPR 11 | Group 1 | The AED uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference with electronic devices. |
| RF emissions<br>CISPR 11 | Class B | The AED is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2 | Not applicable | |
| Fluctuation voltage / Fluctuation emissions<br>IEC 61000-3-3 | Not applicable | |

***Electromagnetic Immunity***

| Immunity Test | IEC 60601-1 test level | Compliance Level | Electromagnetic Environment (guide) |
|---|---|---|---|
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ± 6 kV contact<br><br>± 8 kV air | ± 6 kV contact<br><br>± 8 kV air | Floors should be wood or concrete or be fitted with ceramic tiles.<br>If the floor is provided with synthetic material, the relative air humidity should be at least 30% |
| Electrical fast transient/burst<br><br>IEC 61000-4-4 | ± 2 kV for power supply lines<br><br>± 1 kV for input / output lines | Not applicable | The quality of the supply voltage should correspond to that of a typical environment of a business building or hospital. |
| Surge<br><br>IEC 61000-4-5 | ± 1 kV voltage in antiphase<br><br>±2 kV isophase voltage | Not applicable | The quality of the supply voltage should correspond to that of a typical environment of a business building or hospital. |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4-11 | <5% $U_T$<br>(>95% dip in $U_T$)<br>for ½ cycle<br><br>40% $U_T$<br>(60% dip in $U_T$ )<br>for 5 cycles<br><br>70% $U_T$<br>(30% dip in $U_T$)<br>for 25 cycles<br><br><5% $U_T$<br>(>95% dip in $U_T$)<br>for 5seconds | Not applicable | The quality of the supply voltage should correspond to that of a typical environment of a business building or hospital. |
| Power frequency (50/60 Hz) Magnetic field<br><br>IEC 61000-4-8 | 3 A/m | 3 A/m | The magnetic fields in the network frequency should correspond to typical values found in the environment of office buildings or hospital. |

***Electromagnetic Immunity (continued)***

| Immunity Test | IEC 60601-1 test level | Compliance Level | Electromagnetic Environment (guide) |
|---|---|---|---|
| | | | Portable or mobile RF communications equipment should not be used near to any part of the AED, including cables. Then you have to calculate the separation distance recommended by the applicable equation to the frequency of the transmitter.<br><br>***Recommended separation distance*** |
| Conducted RF<br><br>IEC 61000-4-6 | 3 Vrms<br>150kHz up to 80MHz<br>outside ISM bands [a] | 3 Vrms | $d = 1.2\sqrt{P}$ |
| | 10 Vrms<br>150kHz up to 80MHz<br>within ISM bands [a] | 10 Vrms | $d = 1.2\sqrt{P}$ |
| Radiated RF<br><br>IEC 61000-4-6 | 10 V/m<br>80 MHz up to 2.5 GHz | 10 V/m | $d = 1.2\sqrt{P}$ 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 maximum power produced by the watt transmitter (W) according to the manufacturer of the transmitter and *d* is the separation distance in meters (m) [b]<br><br>The force fields of the fixed RF transmitters as determined by an electromagnetic survey in situ [c], should be less than the frequency interval [d].<br><br>Interference may occur in the vicinity of equipment marked with this symbol:<br><br>  |

| | |
|---|---|
| NOTE 1: At 80 MHz and 800 MHz, the applied separation distance is the one used for very frequent intervals.<br>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection from structures, objects and people. | |
| A | 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 |
| B | The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz to 2.5 GHz are intended to reduce the likelihood of mobile/portable communication equipment to cause problems if they are inadvertently brought into the area of the patient. For this reason the additional factor of 10/3 is applied in the calculation of the protection distances recommended in these frequency areas |
| C | Force fields arising from fixed transmitters, such as radio stations (mobile/cordless) for telephones and mobile radios, amateur radio, AM and FM radio stations and TV channels can be theoretically estimated with accuracy; A survey should be considered for assessing the impact of electromagnetic waves on the environment due to fixed RF wave transmitters. If the measured field in which the AED is located is higher than the applicable compliance level, you should observe the device to prove the operation complies with the provisions. In case of any malfunctions, additional measures are needed, such as reorienting or providing a new location for the AED. |
| D | Over the frequency range between 150kHz and 80MHz, the force fields should be less than 3 V/m |

***Recommended separation distance between mobile RF communications equipment and the AED***

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

| Maximum emission rate of the transmitter W | Separation distance according to the transmitter's frequency m | | | |
|---|---|---|---|---|
| | 150kHz to 80 MHz Outside ISM bands $d = 1.2\sqrt{P}$ | 150kHz to 80 MHz Within ISM bands $d = 1.2\sqrt{P}$ | 80 MHz to800 MHz $d = 1.2\sqrt{P}$ | 800 MHz to2.5 GHz $d = 2.3\sqrt{P}$ |
| 0.01 | 0.12 m | 0.12 m | 0.12 m | 0.23 m |
| 0.1 | 0.37 m | 0.38 m | 0.38 m | 0.73 m |
| 1 | 1.12 m | 1.2 m | 1.2 m | 2.3 m |
| 10 | 3.7 m | 3.8 m | 3.8 m | 7.3 m |
| 100 | 12 m | 12 m | 12 m | 23 m |
| For transmitters estimated at a maximum power that is not listed above, the recommended separation distance "*d*" in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum power produced by the transmitter watts (W) according to the transmitter's manufacturer. | | | | |
| NOTE 1: | At 80 MHz and 800 MHz, the applied separation distance is the one used for very frequent intervals. | | | |
| 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 calculating 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 chance that a mobile/portable communications equipment could cause interference if it is inadvertently brought into the patient's areas. | | | |
| NOTE 4: | These guidelines may not apply in all situations. Electromagnetic propagation is influenced by the absorption and reflection from structures, objects and people. | | | |

## 1.3 INTRODUCTION

This section presents information about the AED, its use, and the training requirements for operation.

### 1.3.1 AED Description

The AED is a self-testing, battery-operated Automated External Defibrillator.
Once applied the defibrillation pads (electrodes) to the patient's bare chest, the AED automatically performs an analyses of the patient's electrocardiogram (ECG) and advises the operator to deliver a shock, if needed.
The AED guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators.

### 1.3.2 Indications for use

The AED is a medical device intended to be used by personnel who have been trained in its operation.
User should be qualified by training in basic life support or other physician authorized emergency medical response.

The device should only be used when a suspected cardiac arrest victim has an apparent lack of circulation as indicated by:
1. Unconsciousness, and
2. Absence of normal breathing, and
3. Absence of a pulse or signs of circulation.

When a patient is a child (age <8 years or weighing <25Kg) the device should be used with the Paediatric defibrillation pads, in order to attenuate the delivered energy. Therefore, the therapy should not be delayed to determine the patient's exact age or weight.

### 1.3.3 Rescue Protocol

The AED rescue protocol is consistent with the guidelines in force and recommended by the ERC (European Resuscitation Council) and the AHA (American Heart Association).
Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button (Semi-Automatic models only) to deliver a defibrillation shock followed by performing 2 minutes of CPR.
For the SAVER ONE Fully Automatic model, upon detecting a shockable rhythm, the AED will automatically deliver defibrillation shocks followed by performing 2 minutes of CPR.

### 1.3.4 Energy Protocols

The Adaptive BTE (biphasic truncated exponential) will deliver variable escalating energy conforming to patient chest's impedance.

Each AED model of the SAVER ONE series can be produced with 2 energy versions:

- **STANDARD** with energy level **maximum at 200J**
- **POWER** with energy level **maximum at 360J**

Therefore, in accordance to what purchased, the AED could be equipped with the following factory default adult shock sequence:

- **150J – 200J – 200J** for the STANDARD version
- **200J – 250J – 360J** for the POWER version

The paediatric energy protocol will be fixed at 50J if Paediatric defibrillation pads are installed.

The AED senses when Paediatric electrodes are connected to the device and will automatically adjust to use a more appropriate lower energy level (50J).

## 1.4 GETTING STARTED

This section presents information on unpacking and the AED activation, on essential parts and accessories and provides a complete overview on self-tests.

### 1.4.1 Unpacking and Inspecting

The AED can be equipped with different configurations, therefore the box contents may differ according to the configuration ordered.
To be sure that your order is correct verify the contents of the box against your packing slip.
If you have any questions about your order contact our Customer Service or the local Distributor.

### 1.4.2 AED Modes

Operating Mode: Defined as having the battery installed and device is switched on.
This is the mode the AED would be in during an actual rescue situation.

Standby Mode: When the battery is installed but the device is switched off.
In this mode the AED is not being used in a rescue.
The device will conduct its routine self-tests to ensure proper operation.

Storage Mode: When the battery is removed such as during shipping or transport.
With the battery removed, the AED is unable to perform self-tests or rescues.

BEING A LIFE-SAVING DEVICE, THE AED SHOULD ALWAYS BE AVAILABLE FOR USE. ONCE PURCHASED, IT'S GOOD PRACTICE TO ACTIVATE IT, INSTALLING THE BATTERY, AND KEEP IT IN STANDBY MODE.

### 1.4.3 Battery Options

The AED can work with both these two types of batteries:

- (SAV-C0903) Non-rechargeable Battery Li-$SOCl_2$
- (SAV-C0011) Rechargeable Battery Li-Ion

The battery operating life and performance depends on the type of battery, actual usage and environmental factors.

DATA ON BATTERY GIVEN IN THIS MANUAL ARE INTENDED FOR A NEW AND FULLY CHARGED BATTERY WITH CONSTANT TEMPERATURE AT 20°C AND 45% OF RELATIVE HUMIDITY WITHOUT CONDENSATION.

***Non-rechargeable battery (SAV-C0903)***
The non-rechargeable battery is supplied fully charged and ready for use.
It's designed to have a long life and does not require any maintenance.

Estimated Shelf Life (from date of manufacture): 8 years when stored in its original packaging

Estimated Standby Life (from date of installation): 5 years once connected to AED, assuming one battery insertion test (AED activation) and daily self-tests but without using the AED in a rescue

SHELF LIFE IS DEFINED AS THE LENGTH OF TIME A BATTERY CAN BE STORED, PRIOR TO INSTALLATION INTO AED, WITHOUT DEGRADING ITS PERFORMANCE. STORING THE BATTERY OUTSIDE THE TEMPERATURE RANGE GIVEN IN THIS MANUAL WILL DECREASE BATTERY LIFE.

STANDBY LIFE IS DEFINED AS THE LENGTH OF TIME A BATTERY, ONCE INSTALLED TO AED, WILL POWER THE AED ONLY FOR CONDUCTING ITS ROUTINE DAILY SELF-TESTS BUT NOT FOR USING THE AED IN A RESCUE.
KEEPING AED WITH ITS BATTERY OUTSIDE THE TEMPERATURE RANGE GIVEN IN THIS MANUAL WILL DECREASE BATTERY LIFE.

This battery is able to perform a high number of shocks that vary according to the model and versions:

SAVER ONE
- Standard 200J: 300 complete cycles (shocks at 200J and CPR) or 35 hours ECG Monitoring
- Power 360J: 200 complete cycles (shocks at 360J and CPR) or 35 hours ECG Monitoring

SAVER ONE D and SAVER ONE P
- Standard 200J: 250 complete cycles (shocks at 200J and CPR) or 24 hours ECG Monitoring
- Power 360J: 160 complete cycles (shocks at 360J and CPR) or 24 hours ECG Monitoring

***Rechargeable battery (SAV-C0011)***
The rechargeable battery is supplied fully charged and ready for use.
It's designed to have a long life but needs to be recharged with the dedicated charger (SAV-C0012) and related accessories supplied by A.M.I. Italia Srl.
This battery is able to perform a high number of shocks that vary according to the model and versions:

SAVER ONE
- Standard 200J: 250 shocks at 200J or 21 hours ECG Monitoring
- Power 360J: 150 shocks at 360J or 21 hours ECG Monitoring

SAVER ONE D and SAVER ONE P
- Standard 200J: 200 shocks at 200J or 14 hours ECG Monitoring
- Power 360J: 110 shocks at 360J or 14 hours ECG Monitoring

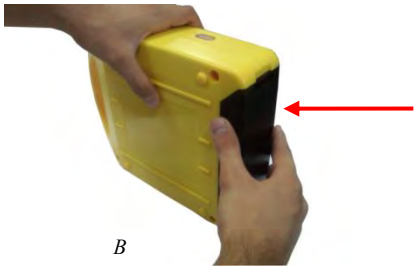
It is advisable to replace these batteries every 2.5 years or after more than 300 charge cycles (whichever occurs first).

RECHARGE THE BATTERY AT LEAST ONCE EVERY 4 MONTHS TO ALLOW PERFECT OPERATION AND EXTEND ITS LIFE.

### 1.4.4 Battery Installation

The following are detailed instructions for properly installing both the type of batteries, non-rechargeable or rechargeable) in the AED.

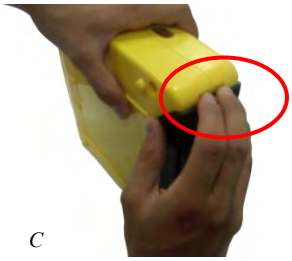
*A*



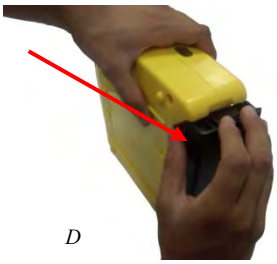
*B*

A. Place the device on the side as shown and hold it securely with the left hand. Then insert the battery in the direction of the arrow making it fit perfectly with the point indicated by the circle.
B. Push the battery as shown in the direction of the arrow until you hear a click that confirms the correct insertion.

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



*C*



*D*

C. Place the device on the side as shown and hold it securely with the left hand. Then, using two fingers of the right hand press on the hook of the battery highlighted by the circle.
D. Simultaneously pull the battery in the direction indicated by the arrow.

REMOVE THE BATTERY FROM THE DEVICE ONLY IF THE DEVICE IS TURNED OFF FOR AT LEAST 5 SECONDS. FAILURE TO DO SO, COULD SEVERELY DAMAGE THE DEVICE AND THE BATTERY.

### 1.4.5 Charging Station for Rechargeable Battery

The complete charging station (SAV-C0014) allows recharging the rechargeable battery (SAV-C0011).

The complete charging station is formed of the following parts:

- (SAV-C0012) Battery charger model CBACCS1
- (SAV-C0013) Power supplier AC/DC Adapter P66A-3P2JA Meanwell model
- (SAV-C0366) Power cord

The CBACCS1 charger is structured as follows:


| No. | Description | Function |
|---|---|---|
| 1 | Recharge LED | Indicates the battery power, or the functional status of the battery charger |
| 2 | Supply | Inlet for connecting the power supplier 12V, 5A |
| 3 | Battery contacts | Contacts for exchange of energy between the charger and battery |

The CBACCS1 charger shall be used only with the power supplier AC/DC Adapter P66A-3P2JA Meanwell model (SAV-C0013) provided by A.M.I. Italia Srl.

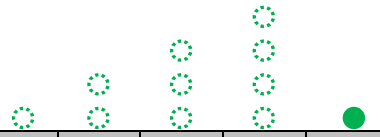
The charger station has to be assembled for getting started: connect the AC/DC Adapter to the CBACCS1 charger, then connect the power cord to the AC/DC Adapter and plug it into the main power supply.

To connect/disconnect the rechargeable battery (SAV-C0011) in the charger CBACCS1 follows the instructions as it was installed to AED (see Battery Installation section).

The charging time of about 2.5 hours could increase in case of a battery that has been charging for more cycles than indicated. The CBACCS1 charger is equipped with a status LED that indicates both its functional status, as well as the battery's charge level, if inserted.
Below is a table that allows identifying the encoding of the status LED:

<table>
<tr><td>INDICATOR</td><td colspan="2">RED</td><td colspan="2">GREEN</td></tr>
<tr><td>FIXED</td><td colspan="2">Non-operational battery</td><td colspan="2">Full battery charge</td></tr>
<tr><td rowspan="2">FLASHING</td><td>Inserted battery</td><td rowspan="2">Charger failure</td><td>Inserted battery</td><td>Battery charging</td></tr>
<tr><td>Non-inserted battery</td><td>Non-inserted battery</td><td>Charger waiting for battery insertion</td></tr>
</table>

When charging, the status LED of the charger will flash green with different frequencies depending on the charging level until full charge indicated by the status LED with FIXED green light.



| Charging level | 0% | 25% | 50% | 75% | 100% |
|---|---|---|---|---|---|
| Number of consecutive flashes | 1 | 2 | 3 | 4 | Fixed |

### 1.4.6 Defibrillation Pads Options

The AED allows using two different defibrillation pads according to the patient's needs:

- (SAV-C0846) Adult defibrillation pads
- (SAV-C0016) Paediatric defibrillation pads

The defibrillation pads come in a sealed package containing one pair of pre-gelled self-adhesive pads with an attached cable and a special anti-shock safety connector to be plugged to AED.

The pads are disposable and should be discarded after each rescue.

The pads have a limited shelf life and should not be used beyond the expiration date (typically 30 months).

Keep a fresh, unopened pair of pads into the AED at all times.

Refer to the pad package label for operation temperatures.

They are polarized, meaning, the positioning of the electrodes **must not be reversed**. Improper placement of the electrodes may distort the reading of the patient's heart rate.

USING PADS THAT ARE DAMAGED OR EXPIRED MAY RESULT IN IMPROPER AED PERFORMANCE.
PADS ARE FOR SHORT TERM USE ONLY. DO NOT OPEN UNTIL READY TO USE.

***Defibrillation Pads for Adults (SAV-C0846)***
They shall be used on adult patients **(age >8 years or weighing >25Kg).**

***Defibrillation Pads for Children (SAV-C0016)***
They shall be used only on children **(age <8 years or weighing <25Kg).**
This defibrillation pads allow giving shocks to paediatric patients with reduced energy level equal to 50J.
Device senses when these type of pads are installed and adjusts to use a more appropriate lower energy level.

### 1.4.7 Automatic Self-Tests

The AED is designed to be completely safe, always ready for use and requires little maintenance. In fact, thanks to a sophisticated software system it is able to automatically and continuously verify if the device is able to function properly. The AED is able to automatically perform tests in different ways:

- **Activation:** Whenever you insert a battery in the device
- **Start-Up:** When switching on the device
- **Daily Routine:** During the standby mode on a daily/monthly/semi-annual basis

***Activation Test***
Each time a battery, new or replaced, is installed the device will perform a diagnostic activation test.
Once the battery is connected the device automatically turns on activating the following voice instruction:

Voice message: *Device test*
*Press shock button*

The test is performed automatically but to verify the functionality of the buttons on the keyboard is required the assistance of the operator. The shock button will light up with flashing lights and then the operator will have maximum 1 minute to press the shock button.

IF THE SHOCK BUTTON IS NOT PRESSED WITHIN 1 MINUTE (TIME LIMIT), THE DEVICE SHALL DISPLAY AN ERROR.
SWITCH ON THE DEVICE AGAIN AND PRESS THE SHOCK BUTTON WITHIN THE TIME LIMIT INDICATED.
HOWEVER, IF THE SHOCK BUTTON IS PRESSED BUT CONTINUES TO FLASH, THEN IT MEANS THAT THE SHOCK BUTTON IS NOT WORKING PROPERLY. TURN OFF THE DEVICE AND PERFORM THE OPERATION AGAIN, IF THE PROBLEM PERSISTS, CONTACT YOUR AUTHORIZED SERVICE CENTRE.

If the shock button is pressed properly it will stop flashing and the device will start the activation test.
During this test, the device makes a complete check (firmware/hardware) that considerably drains the battery therefore we recommend to never disconnect it from the device.
Turn off the device if not to be used immediately and leave the battery in place to ensure the execution of periodic self-testing.

***Start-Up Test***
This test is performed automatically and takes a few seconds in order to verify the correct operation of the device before the use.

After pressing the ON/OFF button, the device will beep as it powers up, the status LED will switch off and the AED will prompt:

Voice message: *Device test*
Text displayed: START-UP TEST IN PROGRESS
TEST SUCCEDED

From this moment the device is ready for use and shall provide the operator with the first instructions to start the rescue.

***Daily Routine Test***
This test is performed automatically in standby mode (device turned off with battery installed) everyday at the same time set at the factory (typically during the night).

When performing the daily self-tests the AED automatically turns ON and the ON/OFF button lights up; performs the self-test for a few seconds and if successful, the Status LED Indicator reverts to GREEN FLASHING and the device turns itself OFF.

### 1.4.8 AED Indicators

The results of the self-test can be viewed via a bi-colour (green/red) STATUS LED INDICATOR and prompts on the LCD MINI-DISPLAY. Both are located on the front of the device and, based on the information given the operator can establish the functional status of the device and its battery.

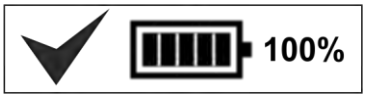
The STATUS LED INDICATOR may show various lighting combination with green and/or red colour.

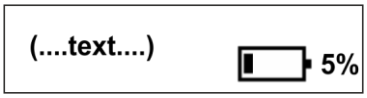
Flashing GREEN or RED 

Alternately flashing 1 time GREEN and 1 time RED 

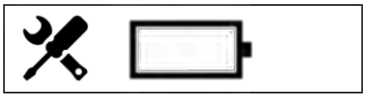
Fix RED light 

The LCD MINI-DISPLAY may show TEXT WITH ERROR CODE for service and/or a BATTERY GAUGE INDICATOR.

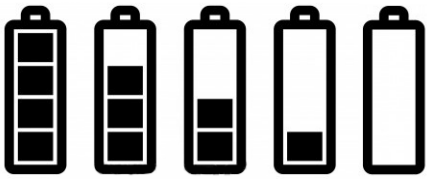




First Low Battery warning



Second Low Battery Alarm

The battery gauge indicator has 5 levels of degradation. With the use of the AED, the Battery Gauge Indicator will gradually go down from right to left as the battery capacity decreases.



There are two alarm thresholds informing the user when the power of the battery is low.

In Operating Mode, a voice message and displayed prompt:

- 1st warning with a ≤5% battery level only when the device is operating.
  In this case the AED is able to carry out about 14 shocks or 40 days in standby mode.

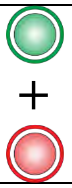
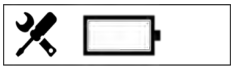
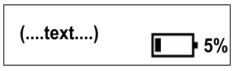
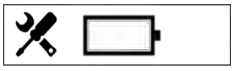
  Voice message: *The battery is getting low*
  Prompt displayed: The battery gauge indicator at 5% next to standard operating text

In Standby and Operating Mode a voice message and displayed prompt:

- 2nd alarm with a ≤1% battery level when the device is in standby or operating.
  In this case the AED is able to carry out about 7 shocks or 20 days in standby mode (with this condition it is not advisable to use the device).

  Voice message: *Low battery. Replace the battery*
  Prompt displayed: An empty battery gauge indicator next to a wrench for service icon

The following table shows the coding of the flashing STATUS LED INDICATOR and prompts displayed on the LCD Mini-Display:

| AED Mode | | Status LED | Mini Display |
|---|---|---|---|
| **STANDBY** | AED is ready for use |  |  |
| | Second alarm for low battery level <1%<br>(battery should be replaced) |  |  |
| | AED has an error<br>(service required) |  |  |
| **OPERATING** | AED functioning | **OFF** | ……Standard Operations…..… |
| | First warning for low battery level <5%<br>AED will prompt "Battery is getting low"<br>(battery should be replaced as soon as possible) | **OFF** |  |
| | Second alarm for low battery level <1%<br>AED will prompt "Low battery. Replace battery"<br>(battery should be replaced immediately) |  |  |

### 1.4.9 Voice Prompts

The voice prompts activate when the AED is turned on and help guide the operator through the rescue. The following table lists the voice messages and a description of when the prompts are issued.

| Voice Prompt | Situation |
|---|---|
| *Device Test* | Plays after turning on the AED as self-test |
| *Stay calm and follow these voice instructions*<br>*Call the Emergency Services now!* | Initial instructions |
| *If the patient is unresponsive and is not breathing*<br>*Loosen or remove clothing to expose the bare chest and apply the electrodes* | Prompts the rescuer to remove patient clothing in order to expose the bare chest and apply the pads. |
| *Open the package and look carefully at the picture on the electrodes*<br>*Peel electrodes from plastic liner* | Prompts the rescuer to open pads package before applying to patient chest. |
| *Place the two electrodes firmly to bare chest as shown in the picture* | Repeats every 2 seconds until the defibrillation pads are well connected to patient and device. |
| *Do not touch patient! Analysing heart rhythm* | Prompts during the analysis of the patient's cardiac rhythm and repeats until is completed. |
| *Shockable rhythm detected* | Prompts the rescuer AED detected a cardiac rhythm where a shock is needed |
| *Stay clear of patient! Charging for the shock* | AED is preparing for the shock and repeats until is ready to shock |

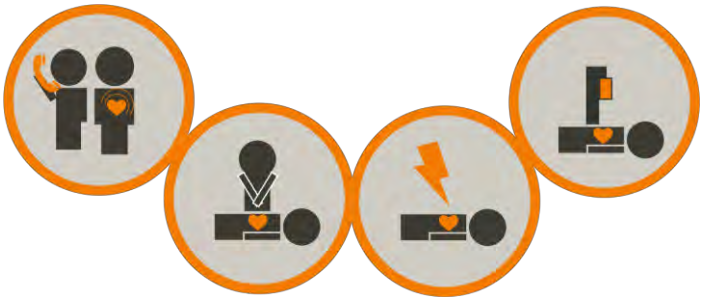
| | |
|---|---|
| *Press shock button* | Prompts after the AED Semi-Automatic is fully charged and ready to deliver the shock.<br>The SHOCK button flashes and the prompt repeats for 18 seconds or until the SHOCK button is pushed. |
| *Caution. The shock will be delivered automatically in 5 seconds* | Prompts after the AED Fully Automatic is fully charged and ready to deliver an automatic shock.<br>The SHOCK light flashes and the SHOCK will automatically be administered approximately five seconds after the end of the voice prompt. Time is marked by 5 beep sound. |
| *Shock delivered* | Prompts when the shock is delivered |
| *It is safe to touch the patient.*<br>*Begin Cardio Pulmonary Resuscitation, now*<br>*Make 5 cycles of 30 chest compressions followed by 2 rescue breaths* | Advises the rescuer that it is safe to touch the patient and have to perform CPR:<br>• After the AED delivers a shock.<br>• After the AED detects a non-shockable rhythm. |
| *Press patient's chest down fast* | Prompts the rescuer to press down one third depth of patient's chest (from5 to 6 centimetres).<br>A built-in metronome assist rescuer providing audio cues for the appropriate number and rate of chest compressions (30 times at100/minute). |
| *Give 2 rescue breaths* | Prompts to give two breaths to patient. |
| *Blow* | Prompts to give the first breath |
| *Blow* | Prompts to give the second breath |
| *No shock advised* | Prompts the rescuer that no shock is needed. |
| *The battery is getting low* | Warns for the first time a low battery level ≤5% |
| *Low battery*<br>*Replace the battery* | Alarms for a discharged battery level ≤1% when the rescuer should replace the battery. |
| *Shock Cancelled. Shock button not pressed* | When the device is ready to shock but the user has not pressed the shock button (Semi-Automatic AED) therefore the device cancels the shock and disarms itself. |
| *Shock Cancelled. Rhythm changed* | When the device is prepared to shock then detects a change in rhythm and therefore cancels the shock and disarms itself. |
| *Device failed. Service required* | Occurs after the self-test determine that the AED is not functioning properly.<br>The prompt will be heard when the device is turned ON and will repeat until is turned OFF. |
| *Paediatric Mode* | Occurs when paediatric pads are installed to AED. |

## 1.5 INSTRUCTIONS FOR USE

This section provides information about how to use the AED to perform a rescue.

### 1.5.1 Chain of Survival

ERC (European Resuscitation Council) and the AHA (American Heart Association) have established a protocol with sequence of rescue actions to be observed during the resuscitation of a person suffering from sudden cardiac arrest. This protocol is called the "chain of survival".



1. Make sure that the victim needs aid (no signs of circulation) and call EMS immediately
2. While waiting for a defibrillator to become available, immediately start CPR
3. Use the AED to restore the normal heart rhythm
4. Post resuscitation care by ALS personnel

### 1.5.2 Patient Preparation

Determine that the patient is over 8 years of age or weighs more than 25 kg and is both:

- Unresponsive
- Not breathing

As soon as the AED is available for the rescue turn it on and follow the instructions.

The AED will prompt:

- *Stay calm and follow these voice instructions*
- *Call Emergency Services now*
- *If the patient is unresponsive and is not breathing*
- *Loosen or remove clothing to expose the bare chest and apply the electrodes*

Remove or cut clothing (if needed) from the patient's chest. If the patient's chest has a thick hair it is necessary to shave it in the places where the Pads shall be placed.

WHEN THE PATIENT IS A CHILD UNDER 8 YEARS OF AGE OR WEIGHS LESS THAN 25KG. THE AED SHOULD BE USED WITH THE SAV-C0016 PAEDIATRIC DEFIBRILLATION PADS. THERAPY SHOULD NOT BE DELAYED TO DETERMINE THE PATIENT'S EXACT AGE OR WEIGHT.

### 1.5.3 Place Defibrillation Pads

The AED will prompt "*Open the package and look carefully at the picture on the electrodes*"

Remove the defibrillation PADs from the package.

If you are using not pre-connected defibrillation pads or paediatric pads, plug the pads connector to AED.

The AED will prompt "*Peel electrodes from plastic liner. Place the two electrodes firmly to bare chest as shown in the picture*"

Remove the protective film from each pad and place both defibrillation pads on the patient's chest as shown on the picture.


The defibrillation PADs are polarized, and require to be positioned at the points indicated by the picture given on each pad. When the patient is a child use the SAV-C0016 paediatric defibrillation pads.

The correct placement of the pads is essential for the efficient analysis of the patient's heart rate and the subsequent shock delivery (if needed).

### 1.5.4 Heart Rate Analysis

When the pads are placed the AED will prompt "*Do Not Touch Patient. Analysing Heart Rhythm*"

The AED will automatically begin to analyse the cardiac rhythm of the patient.

If, during the analysis, the pads become disconnected from the AED, the prompt "*Place the two electrodes firmly to bare chest as shown in the picture*" will be heard.

If this occurs, check to be sure the connector is properly plugged into the AED and that pads are firmly placed on clean, dry skin.

During the analysis, the body of the patient should not be touched and should not be subjected to vibration or movement.

### 1.5.5 Shock Delivery

If a shock is advised the AED will prompt "*Shockable rhythm detected. Stay clear of patient. Charging for the shock*" and rescuer should ensure that no one is touching the patient.

When the AED is fully charged ready to deliver a defibrillation shock:

A. The SEMI-AUTOMATIC AED will flash the shock button and the prompt "*Press shock button*" will be heard. Make sure no one is touching the patient and press the shock button to deliver a defibrillation shock. If the shock button is not pressed within 18 seconds of hearing the prompt, the AED will disarm with the voice prompt "*Shock cancelled. Shock button not pressed*". Then will prompt to start CPR.

B. The FULLY AUTOMATIC AED will light up a shock icon and the prompt "*Caution! The shock will be delivered automatically in 5 seconds*" will be heard. Make sure no one is touching the patient because the device will deliver the defibrillation shock after 5 beep sounds.

For both models, after the AED delivers the defibrillation shock, the voice prompt will say "*Shock Delivered*" and prompt to start CPR.

When the AED is charged, it continues to analyse the patient's heart rhythm and in case the rhythm changes and a shock is no longer needed, the AED will prompt the message "*Shock cancelled. Rhythm changed*" and prompt to start CPR.

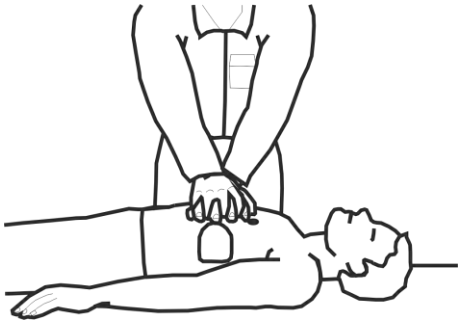
If during the analysis the AED does not detect shockable rhythm (VF or VT) the defibrillation shock is not needed and the AED will prompt "*No shock advised*". Then will prompt to start CPR.

### 1.5.6 CPR

The AED will guide rescuer through all steps of CPR (**C**ardio **P**ulmonary **R**esuscitation) and will prompt *"It is safe to touch the patient. Begin Cardio Pulmonary Resuscitation, now. Make 5 cycles of 30 chest compressions followed by 2 rescue breaths"*

Kneel by the side of patient and prepare to make compressions as follows:

1. Place the heel of one hand on the centre of the chest, between nipples
2. Place the heel of the other hand directly on top of first hand
3. Lean over patient with elbows straight
4. Press the patient's chest down rapidly one third depth of chest ensuring that pressure is not applied on the victim's ribs



The AED will prompt *"Press patient's chest down fast"*

Press down on the sternum 5-6 cm. Then, release the pressure without losing contact between your hands and the sternum. Repeat at a rate of 100 compressions per minute.
Compression and release should take the same time.

The metronome will provide audio cues for the appropriate number and rate of chest compressions.

After 30 compressions the AED will prompt *"Give 2 rescue breaths"*

| | |
|---|---|
| Close the nose pinching its soft part using the index finger and thumb of your hand on the forehead.<br>Maintaining chin lift allows the mouth to open, take a normal breath and place your lips around his mouth. |  |
| Blow steadily into the mouth while watching for the chest to rise (take about 1 second as in normal breathing).<br>Move your mouth away, take other normal breath and blow into the mouth once more, to achieve a total of two effective rescue breaths.<br>The AED will prompt *"blow"* twice. |  |

This cycle will continue until the CPR time expires (about 2 minutes).
At the end of CPR the AED will return analysing the heart rhythm.

If the patient is conscious and breathing normally, leave the pads on the patient's chest connected to the AED. Make the patient as comfortable as possible and wait for Advanced Life Support (ALS) personnel to arrive.

Continue to follow the voice prompts until the ALS personnel arrive.

### 1.5.7 Post Rescue

After transferring the patient to ALS personnel, prepare the AED for the next rescue:

1. Check the remaining capacity of the memory card or, if required, retrieve the rescue data stored in the AED (see Data Management section).
2. Connect a new pair of pads to the AED
3. Verify the remaining capacity of the battery
4. Verify that the Status LED Indicator is flashing green.

## 1.6 DATA MANAGEMENT

The AED is designed for ease of data management and review.

The AED is able to record and store both the **SERVICE data** as well as the **RESCUE data** (full details of the rescue operations performed).

The recording and storing of data occurs automatically (cannot be disabled by the user) on the **internal memory** of the device as well as on a **removable memory Card** when installed.

The data stored can be displayed on the PC screen using the dedicated data management software SAVER VIEW EXPRESS.

### 1.6.1 Rescue Data

The AED can store up to 6 hours of rescue data (audio, ECG and events) in the device's internal memory.
Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC.
Each rescue session generate a file saved as "**nnnnnnXX.aed**" where the first six "n" represents the current date (day-month-year) and the following two "X" are a daily progressive counts expressed with uppercase letters. Those files, called "AEDFILE" have extension ".aed" and can be reviewed only with the dedicated PC Software SAVER VIEW EXPRESS.
Should the internal memory become full, the AED will purge rescues as needed, beginning with the oldest AEDFILE.

**SD Removable Cards** can be used to extend AED's memory. The card must be inserted before connecting the battery into the dedicated port on the rear of the AED.

The length of storage depends on the card capacity:

- 512 MB up to 25 hours of rescue data
- 1 GB up to 50 hours of rescue data
- 2 GB up to 100 hours of rescue data
- 4 GB up to 200 hours of rescue data

Further to the rescue data (AEDFILE.aed) the AED is able to record a file named "**AED1LOG.txt**" able to store all automatic daily self-tests performed by the device with their result and any information needed for service. That's a simple text file that can be displayed on PC with common text software.

### 1.6.2 Reviewing Rescue Data

The data stored can be displayed on the PC screen, analysed and printed out, using the dedicated data management software SAVER VIEW EXPRESS (SAV-C0017).


For more details please refer to its User Manual.

## 1.7 MAINTENANCE AND TROUBLESHOOTING

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

### 1.7.1 Routine Maintenance

The AED has a comprehensive self-tests systems which automatically test the electronics; battery and high voltage circuitry. There are three types of automatic self-test:

1. The Daily Self-test checks the battery, pads, and the electronic components
2. The Monthly Self-test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-test
3. The Half-Yearly Self-test, the high voltage electronics are charged to full energy

Thanks to the routine self-tests there is no need to perform any special maintenance but just visual inspection of the Status LED Indicator and of the prompts given in the LCD Mini-Display along with a visual inspection of the related accessories.

| Daily Check | Monthly Check | After Use Check | Inspection |
|---|---|---|---|
| ✻ | | ✻ | Verify that the STATUS LED INDICATOR is flashing green and the LCD MINI-DISPLAY doesn't prompt any error. |
| | ✻ | ✻ | Check the BATTERY GAUGE INDICATOR. |
| | ✻ | ✻ | Verify that the EXPIRATION DATE of the ELECTRODES is still valid. |
| | ✻ | ✻ | Check the INTEGRITY of the AED CASE. |
| | | ✻ | Check the capacity of the MEMORY CARD (if installed). |

### 1.7.2 Troubleshooting Guide

The following table lists the symptoms, possible causes and possible corrective actions for problems that may arise. For further clarification about the implementation of corrective actions, refer to the other sections of the operator's manual. If the AED continues to give errors, contact Service Assistance.

---

**STORE** The device DOES NOT SWITCH ON and both the Status Led Indicator and the LCD Mini-Display are OFF.

*Cause/Remedy a)* The battery is totally discharged or damaged. Replace the battery. If the problem persists contact the Service Centre.

*b)* The device does not work. Contact the Service Centre.

**STANDBY** The Status LED Indicator flashes green but the Mini-Display is OFF.

*Cause/Remedy:* The LCD Mini-Display is damaged. Contact the Service Centre.

**STANDBY** The Status LED Indicator is OFF but the LCD Mini-Display is operating and gives prompts.

*Cause/Remedy:* The Status LED Indicator is damaged. Contact the Service Centre.

**STANDBY** The Status LED Indicator flashes RED and a WRENCH for SERVICE ICON with an ERROR CODE appears on the LCD Mini-Display.

*Cause/Remedy:* An error occurred during the daily self-test. Contact the Service Centre and provide the error code displayed.

**STANDBY** The Status LED Indicator flashes alternatively GREEN and RED; a WRENCH for SERVICE ICON is shown on the LCD Mini-Display together with an EMPTY BATTERY GAUCE INDICATOR.

*Cause/Remedy:* Low Battery warning. The level of the battery is <1%.
The device may turn off during the use. Replace the battery.

**OPERATING** The prompt "*The battery is getting low*" is heard and the LCD Mini-Display will show a BATTERY GAUCE INDICATOR 5%.

*Cause/Remedy:* First warning for Low Battery. The level of the battery is <5%.
The battery is running low. It is possible to use the AED but replace the battery as soon as possible.

**OPERATING** The prompt "*Low battery. Replace the battery*" is heard; the Status LED Indicator flashes RED and the LCD Mini-Display will show a WRENCH for SERVICE ICON and an EMPTY BATTERY GAUCE INDICATOR 1%.

*Cause/Remedy:* Second alarm for Low Battery. The level of the battery is <1%.
The device may turn off during the use. Replace the battery.

**OPERATING** Everything seems to be ok but NO VOICE IS HEARD.

*Cause/Remedy:* Device's speaker doesn't work. Contact the Service Centre.

**OPERATING** Once switched on and after positioning the pads on the patient, AED continues to prompt "*Place the two electrodes firmly to bare chest as shown in the picture*".

*Cause/Remedy a):* The Pads connector is not inserted correctly in the AED or has removed.
Plug the connector into the proper port.

*b)* The Pads have been positioned incorrectly. Properly place the pads on the patient's bare chest. If necessary, remove the hair from the chest with a razor.

*c)* The Pads are damaged. Check the integrity and the expiration date of the pads, replace them if necessary.

**ACTIVATION** After installing the battery and pressing the Shock button as requested by the device for the activation test, the START-UP TEST DOES NOT PROGRESS and the LCD Mini-Display will show a WRENCH for SERVICE ICON with an ERROR CODE.

*Cause/Remedy:* The Shock button does not work properly. Try switching off the device and repeat the activation test. If the problem persists contact the Service Centre.

---

### 1.7.3 Authorized Repair Service

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Guide presented in the previous section. If you are unable to resolve the problem, contact A.M.I. Italia Srl Customer Service or contact the local SAVER ONE distributor.

SHOCK HAZARD! DO NOT DISASSEMBLE THE AED. FAILURE TO OBSERVE THIS WARNING CAN RESULT INPERSONAL INJURY OR DEATH. REFER MAINTENANCE ISSUES TO A.M.I. ITALIA AUTHORIZED SERVICE PERSONNEL.

### 1.7.4 Cleaning

The structure of the device, including the connection port of the defibrillation parts, can be sanitized by using a soft cloth moistened with one of the cleaning solutions listed below:

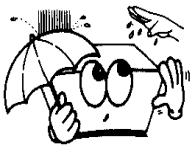
A. Isopropyl alcohol (70% solution)
B. Soapy water
C. Bleach (30 ml per litre of water)
D. Detergents containing ammonia
E. Detergents containing glutaraldehyde

F. Hydrogen peroxide

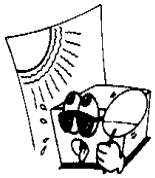
DO NOT IMMERSE THE AED IN ANY LIQUID.
DO NOT USE ABRASIVE MATERIALS, CLEANERS, STRONG SOLVENTS SUCH AS ACETONE OR ACETONE-BASED DETERGENTS, AND ENZYMATIC CLEANERS.
DO NOT STERILIZE THE AED OR ITS ACCESSORIES.

### 1.7.5 Storing

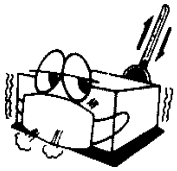
The AED should be installed in a place where the environmental and safety conditions in the table below are observed. When installed it is advisable to store the device with battery inserted to allow the device to perform the routine self-testing operations. For easy retrieval of the device in case of emergency, place it in a location that is easily accessible and oriented so that the Status LED Indicators are sufficiently prominent.



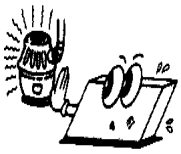
Do not use, install, or maintain AED in conditions of temperature or humidity that exceed the range given in this user manual.



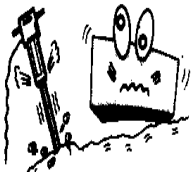
Do not install or store the AED in areas directly exposed to sun light.



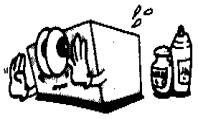
Do not install or store the AED in areas subject to extreme changes in temperature or humidity.



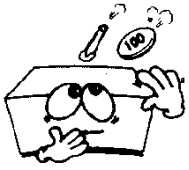
Do not install or store the AED near sources of heat.



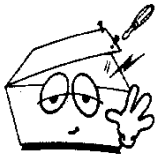
Do not use, install or store the AED in locations subject to strong vibration.



Do not use, install or store the AED in environments with high concentrations of flammable gases or anaesthetics.



Do not install or store the AED in areas with high dust concentration.



The AED shall be opened for maintenance only by A.M.I. Italia Srl or persons authorized by the company.

EXPOSING THE AED TO EXTREME ENVIRONMENTAL CONDITIONS OUTSIDE OF ITS OPERATING PARAMETERS MAY COMPROMISE THE ABILITY OF THE AED TO FUNCTION PROPERLY.

## 1.8 TECHNICAL DATA

This section lists the AED and some Accessories parameters.

| | SAVER ONE | | SAVER ONE D | SAVER ONE P |
|---|---|---|---|---|
| | **SVO-B0001<br>SVO-B0002** | **SVO-B0847<br>SVO-B0848** | **SVD-B0004<br>SVD-B0005** | **SVP-B0006<br>SVP-B0007** |
| **DEVICE** | | | | |
| Size (W x D x H) | 26,5 x 21,5 x 7,5 cm | | | |
| Weight w/disposable battery | 1,95 kg | | 2,30 kg | |
| Weight w/rechargeable battery | 2,10 kg | | 2,45 kg | |
| Battery Option | ➢ Li-SOCI$_2$Non-Rechargeable Battery(SAV-C0903)<br>➢ Li-Ion Rechargeable Battery (SAV-C0011) | | | |
| Device Classification | Class IIb according to Directive 2007/47/EC | | | |
| Defibrillation Pads | Adult (SAV-C0846) and Pediatric (SAV-C0016) | | | |
| Recording | 1Gbit (128 MB) Internal Memory and Removable SD Memory Cards | | | |
| Data Transfer | 2.0 mini USB (USB/Mini USB) and IrDA Port (option) | | | |
| **ENVIRONMENT** | | | | |
| Operating Temperature | 0°to +55° C | | | |
| Storage Temperature | -35°to +65° C | | | |
| Humidity | 0 to 95% relative humidity non-condensing | | | |
| Shock / Drop resistance | Conform to EN 60601-1Clause 21 | | | |
| Dustproof/Waterproof Protection | Class IP54 according to IEC 60529 | | | |
| Electrostatic Shocks | Conform to the EN 61000-4-2, security level 4 | | | |
| Electromagnetic Interference (Radiation) | Conform to EN 60601-1-2, method EN 55011, group 1 level B | | | |
| Electromagnetic Interference (Protection) | Conform to EN 60601-1-2, method EN 61000-4-3, level 2 | | | |
| **DEFIBRILLATOR** | | | | |
| Waveform | Adaptive BTE (Biphasic Truncated Exponential) | | | |
| Patient Safety | All patient connections are electrically completely isolated | | | |
| Operation | Semi-Automatic | Fully-Automatic | Semi-Automatic | ➢ Semi-Automatic<br>➢ Manual |
| Energy Type | Escalating from 50 to 360J | | | |
| Energy Selection | Automated (pre-programmed) | | | ➢ Automated<br>➢ Manual |
| Automated Adult Shock Sequence | Standard Version: 150, 200, 200J (50 Ω load)<br>Power Version: 200, 250, 360J (50 Ω load) | | | |
| Automated Child Shock Sequence | Standard/Power Version: 50J fixed (using pediatric pads SAV-C0016) | | | |
| Manual Shock Sequence | --- | | | From 50J to 360J (50 at time) |
| Accuracy | ± 15% | | | |
| Charging Time (from Shock notice) IEC60601-2-4 §6.8.2 (7a) | ≤ 9 seconds (Standard Version) with new and fully charged battery<br>≤ 15 seconds (Power Version) with new and fully charged battery | | | |
| Charging Time (from Start of Analysis) IEC60601-2-4 §6.8.2 (8a) | ≤ 15 seconds (Standard Version) with new and fully charged battery<br>≤ 21 seconds (Power Version) with new and fully charged battery | | | |

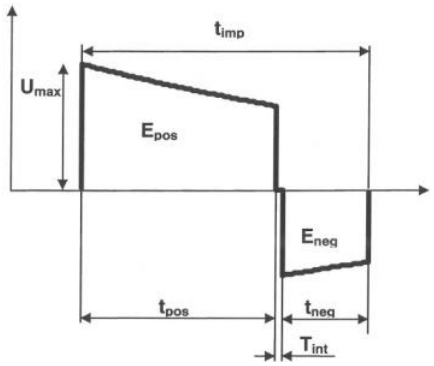
| | SAVER ONE | | SAVER ONE D | SAVER ONE P |
|---|---|---|---|---|
| | SVO-B0001<br>SVO-B0002 | SVO-B0847<br>SVO-B0848 | SVD-B0004<br>SVD-B0005 | SVP-B0006<br>SVP-B0007 |
| **DEFIBRILLATOR (continued)** | | | | |
| Defibrillator Disarm | ➢ Heart rhythm changed in a non-shockable one, or<br>➢ Shock button non pressed within 18 seconds (except Fully Automatic), or<br>➢ ON/OFF button pressed, or<br>➢ Pads disconnected. or<br>➢ Battery removed | | | |
| Patient Isolation | BF Type | | | |
| Automatic Self-Test | ➢ Each time the device is turned on, and<br>➢ Daily / Monthly / 6 Months, and<br>➢ Each time a battery (new or replaced) is attached to device | | | |
| CPR | Instructions and audio cues with a metronome for the appropriate number and rate of chest compressions (100 per minute) | | | |
| Electrode Patient Impedance Measurement Range | 20 to 200 ohms | | | |
| Defibrillator Electrode ECG Circuitry | Protected | | | |
| Algorithm | Arrhythmia detector that evaluates chest's impedance and determines if shock is required | | | |
| Shockable Rhythms | Ventricular Fibrillation (VF) and wide complex Ventricular Tachycardia (VT) | | | |
| Sensitivity | 97% as per EN 60602-2-4 (AHADB, MITDB source) | | | |
| Specificity | 99% as per EN 60602-2-4 (AHADB, MITDB source) | | | |
| **BATTERY** | | | | |
| Non-Rechargeable Battery | Li-$SOCl_2$ (Lithium-thionyl chloride) to lose, non-refillable (SAV-C0903) | | | |
| Voltage | 25,2 VDC – 3500 mAh | | | |
| SAV-C0903 Capacity (typical new battery at 20° C) | Standby life (installed to the device)5 years, or | | | |
| | 300 rescue cycles (shocks at 200J and CPR)<br>or<br>200 rescue cycles (shocks at 360J and CPR)<br>or<br>35 hours ECG Monitoring | | 250 rescue cycles (shocks at 200J and CPR)<br>or<br>160 rescue cycles (shocks at 360J and CPR)<br>or<br>24 hours ECG Monitoring | |
| Rechargeable Battery | Li-Ion (ion battery) Rechargeable (SAV-C0011) | | | |
| Voltage | 21,6 VDC - 2100 mAh | | | |
| Shelf-Life | 2.5 years or 300 charge/shock cycles *(whichever occurs first)* | | | |
| Charging Time | ≤ 2,5 hours (only with SAV-C0014 charging station) | | | |
| SAV-C0011 Capacity (typical new battery at 20° C) | 250 shocks at 200J<br>or<br>150 shocks at 360J<br>or<br>21 hours in ECG Monitoring | | 200 shocks at 200J<br>or<br>110 shocks at 360J<br>or<br>14 hours in ECG Monitoring | |
| | Shelf-Life: 2,5 years or 300 charging cycles | | | |

| | SAVER ONE | | SAVER ONE D | SAVER ONE P |
|---|---|---|---|---|
| | **SVO-B0001**<br>**SVO-B0002** | **SVO-B0847**<br>**SVO-B0848** | **SVD-B0004**<br>**SVD-B0005** | **SVP-B0006**<br>**SVP-B0007** |
| **CHARGER** | | | | |
| Model | CBACCS1 (SAV-C0012) | | | |
| Inlet | 12 VDC – 5A | | | |
| Outlet | 26VDC – 1,5A | | | |
| Absorption | 40W | | | |
| **AC/DC ADAPTER FOR CBACCS1** | | | | |
| Model | Meanwell P66A-3P2J (SAV-C0013) | | | |
| Inlet | 100-240VAC – 50/60Hz – 1.5A | | | |
| Outlet | 12V – 5.5° | | | |
| Absorption | 66W | | | |
| **DEFIBRILLATION PADS** | | | | |
| Type | Disposable, Self-Adhesive and Pre-Gelled | | | |
| Tolerance to Shocks | 50 shocks at 360J | | | |
| Support Material | Medical FOAM. Thickness 1mm | | | |
| Conductive Gel | Low impedance conductive adhesive gel | | | |
| Conductive Material | Metal Sheet | | | |
| Connector Type | Anti-shock safety connector | | | |
| Cable Length | 120cm | | | |
| Adult Pads | Pre-Connected (SAV-C0846) | | | |
| Indication for Use | Adult aged >8 years or weighing >25Kg | | | |
| Total Area (per pad) | 148cm$^2$ | | | |
| Active Area (per pad) | 81cm$^2$ | | | |
| Pediatric Pads | Standard (SAV-C0016) | | | |
| Indication for Use | Children aged 1-8 years or weighing <25Kg | | | |
| Total Area (per pad) | 75cm$^2$ | | | |
| Active Area (per pad) | 31cm$^2$ | | | |

## 1.9 WAVEFORM

BTE (Biphasic truncated exponential)

The parameters of the waveform are regulated automatically based on the patient's impedance. In the graph to the left $t_{pos}$ represents the duration of phase 1 (ms), $t_{neg}$ represents the duration of phase 2 (ms), $t_{int}$ is the delay between the phases, $U_{max}$ denotes the peak voltage, and $t_{imp}$ 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 delivered charge, as indicated in the following examples




Mode at different energy

| Load resistance (Ω) | Energy delivered (J*) | | |
|---|---|---|---|
| 25 | 150 | 200 | 360** |
| 50 | 150 | 200 | 360 |
| 75 | 150 | 200 | 360 |
| 100 | 150 | 200 | 360 |
| 125 | 150 | 200 | 360 |
| 150 | 150 | 200 | 360 |
| 175 | 150 | 200 | 350 |
| 200 | 150 | 200 | 350 |

* energy ±12%

** only for version 360 J

## 1.10 EC CERTIFICATE

# 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 factories of:

A.M.I. INTERNATIONAL KFT - 2000 SZENTENDRE - ROZSA UTCA 16 (HUN) - Hungary

A.M.I. ITALIA SRL - 80010 QUARTO (NA) - VIA CUPA REGINELLA 15A (ITA) - Italy

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

**Semiautomatic and manual semiautomatic external cardiac defibrillator**
Type ref. SAVER ONE P; SAVER ONE D

**Automatic and semiautomatic external cardiac defibrillator**
Type ref. SAVER ONE.

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.

**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:* | 2018-02-16 |
| *Substitution Date:* | 2017-11-20 |
| *Expiry Date:* | 2023-02-15 |

IMQ

cosign

IMQ CSQ
ISTITUTO ITALIANO DEL MARCHIO DI QUALITA'

IMQ S.p.A. - I-20138 Milano
Via Quintiliano 43
tel. + 39 0250731
www.imq.it

This Approval Certificate is subjected to the provisions laid down in the "Rules for managing the EC Certification of Medical Devices on the basis of the Directive 93/42/EEC".

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

# CHAPTER 2: SAVER ONE Semi Automatic & Fully Automatic

Saver One®

*Everywhere for Life*

SEMI-AUTOMATIC AED

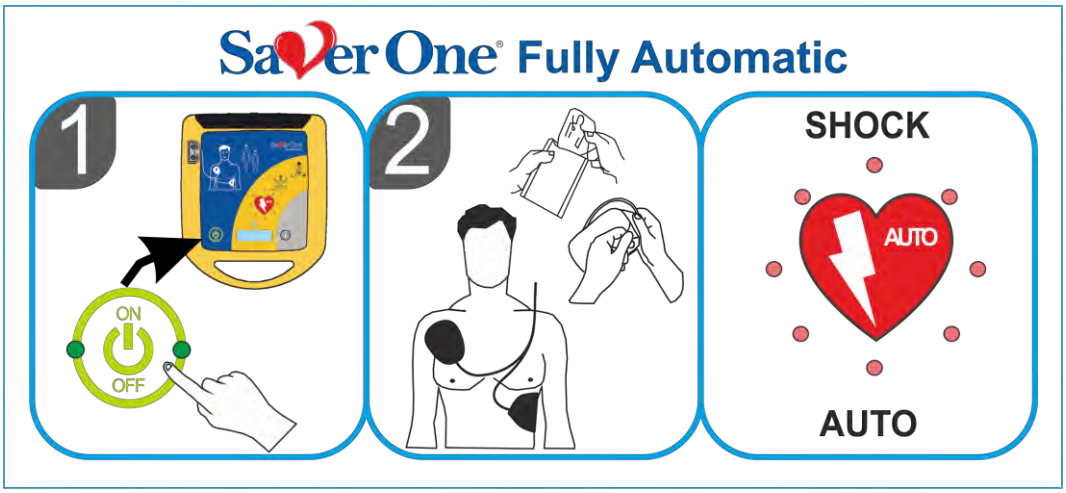
FULLY AUTOMATIC AED

## 2.1 QUICK START GUIDE

This is a quick start guide included into the carry case of AED.

***Semi-Automatic***


***Fully Automatic***




## 2.2 STANDARD BOX CONTENTS

The **Standard Basic Configuration** (Conf-Norm) includes:

- 1 AED unit
- 1 Pair of Adult defibrillation pads
- 1 Non-Rechargeable Battery
- 1 Carrying Case (with a Quick Start Guide)
- 1 Quick Operating Guide and a User Manual

Available optional Configuration for both models:

1. Rechargeable Configuration (Conf-Rech)
   (AED unit, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

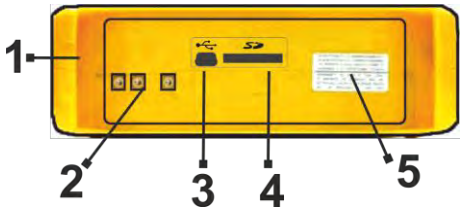
## 2.3 AED PARTS

The following drawings show the AED parts and their locations.

***Semi-Automatic***


| | |
|---|---|
| 1. Battery | 7. Status LED Indicator |
| 2. Icons “Touch/Don’t Touch Patient” | 8. ON/OFF switch |
| 3. Shock button | 9. Microphone |
| 4. Speaker | 10. Pads or ECG cable connection port |
| 5. “i” button | 11. Icon “Place Pads” |
| 6. LCD Mini-Display | 12. Icon “Adult/Child Pads” |

***Rear View***

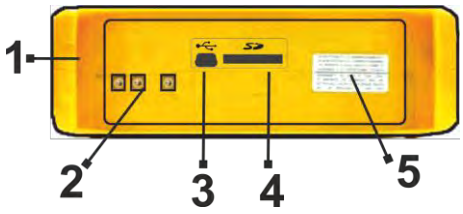



| |
|---|
| 1. Battery compartment |
| 2. Contact PINS |
| 3. USB Port |
| 4. Removable SD Card seat |
| 5. Warranty seal |

***Fully Automatic***


| | |
|---|---|
| 1. Battery | 7. Status LED Indicator |
| 2. Icons “Touch/Don’t Touch Patient” | 8. ON/OFF switch |
| 3. Icon “Automatic Shock” | 9. Microphone |
| 4. Speaker | 10. Pads or ECG cable connection port |
| 5. “i” button | 11. Icon “Place Pads” |
| 6. LCD Mini-Display | 12. Icon “Adult/Child Pads” |

***Rear View***




| |
|---|
| 1. Battery compartment |
| 2. Contact PINS |
| 3. USB Port |
| 4. Removable SD Card seat |
| 5. Warranty seal |

## 2.4 AED DESCRIPTION

***Saver One*** is designed for a public access use and licensed to administer fast and safe rescues.

Practical and intuitive, with CPR guidance and clear instructions able to support users through the whole rescue protocol for effective lifesaving actions.

Highly effective and user-friendly for any lay rescuer is able to detect and automatically analyse the victim's heart rate and capable of delivering one or more defibrillation shocks if a ventricular fibrillation (VF) or ventricular tachycardia (VT monomorphic or polymorphic with heartbeat >180) is detected.

The energy is supplied by an exponential truncated biphasic (B.T.E.) electric shock capable of self-adapting to the patient's thoracic impedance.

***Saver One*** is available in two models:

- ***Semi- Automatic*** with shock button
- ***Fully Automatic*** able to administer a shock (if required) with no shock button for the user to press

Both ***Saver One*** models are available with two energy level versions:

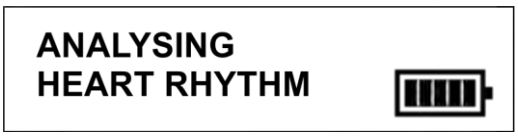
| | | | |
|---|---|---|---|
| ▪ ***Standard*** | ***Maximum output at 200J*** | Saver One Semi-Automatic | (SVO-B0001) |
| ▪ ***Power*** | ***Maximum output at 360J*** | Saver One Semi-Automatic | (SVO-B0002) |
| ▪ ***Standard*** | ***Maximum output at 200J*** | Saver One Fully Automatic | (SVO-B0847) |
| ▪ ***Power*** | ***Maximum output at 360J*** | Saver One Fully Automatic | (SVO-B0848) |

Both ***Saver One*** models can be used with Non-Rechargeable Battery Li-$SOCl_2$ (SAV-C0903) or Rechargeable Battery Li-Ion (SAV-C0011). Furthermore they can be used with Adult Defibrillation Pads (SAV-C0847) or Pediatric Pads (SAV-C0016).

## 2.5 TEXT SCREEN

In Operating Mode, the LCD Mini-Display of both ***Saver One*** models runs text prompts in tandem with audible voice instructions, helpful in noisy and chaotic environments.

The text displayed has 2 lines of multi language uppercase text prompts (text version of the voice prompts) next to the Battery Gauge Indicator.




(This example is given for a device equipped with English software.
Your AED should be equipped with the prompts in your language)

## 2.6 INFO BUTTON

Both ***Saver One*** models are equipped with a synergic ***i*** button.

The “INFO” button provides valuable device or battery technical information (in English) to users and is serviceable for changing the language.

The INFO button can be used only when the AED is functioning (Operating Mode) and will automatically be disabled in case of a rescue operation.

The information on the display is divided in various pages that can be scrolled by pressing the button “n” times (n is for the number of pages).

| | | | |
|---|---|---|---|
| Pressing ***First Time*** |  | MODEL: ONE 200J<br>S/N: 05ISO2213004<br>POWER: BATTERY | AED Model<br>AED Serial Number<br>Battery Type in use |
| Pressing ***Second Time*** |  | PROTOCOL: 150-200-200J<br>SHOCKS: 6<br>DATE: 01/02/2013 | Shock Protocol<br>Number of Shock Delivered<br>Current Date |
| Pressing ***Third Time*** |  | LANGUAGE - -› ITALIAN<br>Italian<br>English | Languages Available into AED |

To change the language, keep pressing the button for about 3 seconds and then release. It will displayed:

LANGUAGE - -› ITALIAN
- -› Italian
English

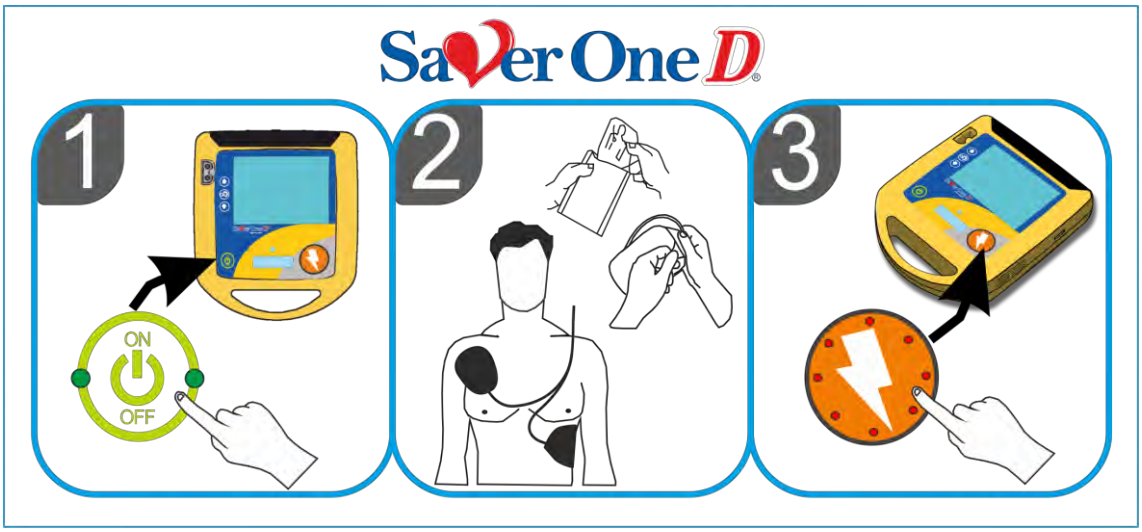
Select the desired language by pressing the button for scrolling between those available. The choice will be black-highlighted.
Therefore keep pressing the button for about 3 seconds to confirm the selection.
The selected language will be kept in memory for the next AED start-up.

# CHAPTER 3: SAVER ONE D

SEMI-AUTOMATIC AED
With ECG MONITORING

## 3.1 QUICK START GUIDE

This is a quick start guide included into the carry case of AED.




## 3.2 STANDARD BOX CONTENTS

The **Standard Basic Configuration** (Conf-Norm) includes:

- 1 AED unit
- 1 Pair of Adult defibrillation pads
- 1 Non-Rechargeable Battery
- 1 Carrying Case (with a Quick Start Guide)
- 1 Quick Operating Guide and a User Manual

Available optional Configurations:

1. **Rechargeable Configuration** (Conf-Rech)
   (AED unit, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

2. **Print Ready Configuration** (Conf-Print)
   (AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Non-Rechargeable Battery, Carrying Case)

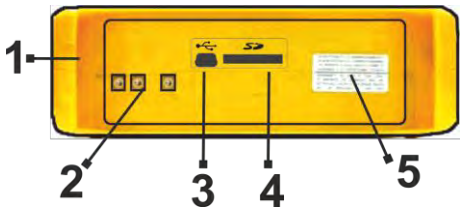
3. **Rechargeable & Print Ready Configuration**(Conf-Rech/Print)
   (AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

## 3.3 AED PARTS

The following drawings show the AED parts and their locations.


| | |
|---|---|
| 1. Battery | 7. ON/OFF switch |
| 2. IrDA Port (option) | 8. Microphone |
| 3. Speaker | 9. Pads or ECG cable connection port |
| 4. Shock button | 10. MENU buttons |
| 5. Service LCD Mini-Display | 11. TFT Colour screen 5.7” |
| 6. Status LED Indicator | |

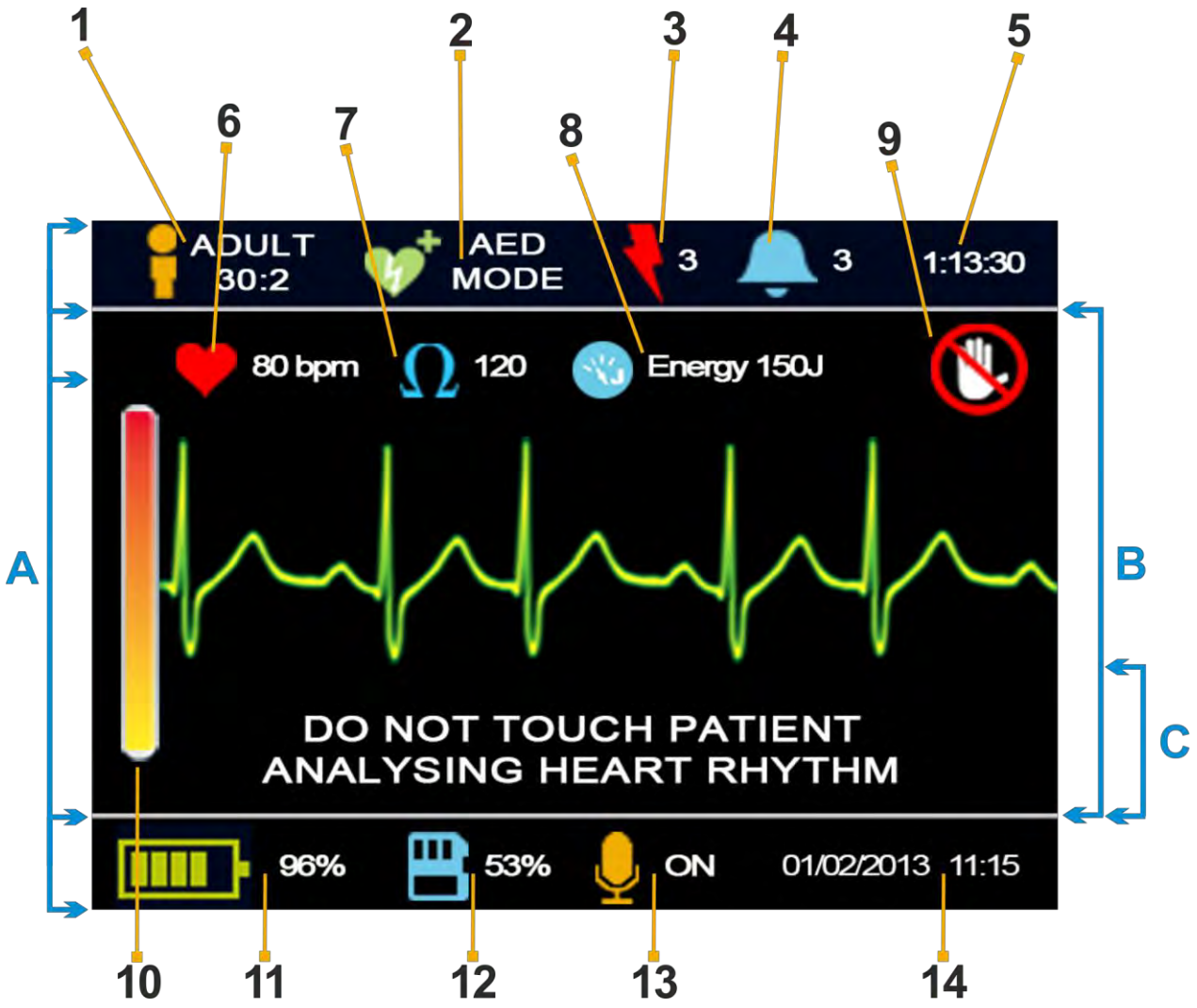
***Rear View***




| |
|---|
| 1. Battery compartment |
| 2. Contact PINS |
| 3. USB Port |
| 4. Removable SD Card seat |
| 5. Warranty seal |

## 3.4 TFT COLOUR DISPLAY 5.7”

The following drawings show the display equipped on ***Saver One D***.




(This example is given for a device equipped with English software.
Your AED should be equipped with the prompts in your language)

| |
|---|
| A. Rescue and AED Set-Up Information Field |
| B. Graphic Area active during rescue. |
| C. Text Area running during rescue |

| | |
|---|---|
| 1. Protocol (AD/PED) and CPR Ratio in use | 8. Energy Level to Deliver |
| 2. Modality (AED/ECG/SYNC/ASYNC) in use | 9. Icon Don’t Touch Patient |
| 3. Shock Counts | 10. Charging Bar (progressing) |
| 4. Fibrillation Alarm Counts | 11. Battery Gauge Indicator |
| 5. On Time Treatment | 12. Removable Card IN with Residual Capacity |
| 6. Heart Rate (BPM) | 13. Microphone ON / OFF |
| 7. Impedance (ohms) | 14. Current Date and Time |

## 3.5 AED DESCRIPTION

***Saver One D*** is an easy-to-use **Automated External Defibrillator (AED)** designed to administer safe treatments against SCA and able to give visual details and rescue information throughout a very large colour display (5.7").

Handy and fast, is the right choice for harsh, outdoor or mobile use for more expertise rescuers or paramedics to act anywhere. Practical and intuitive, with CPR guidance and clear instructions able to support users through rescue protocol for effective actions.

Able to detect and automatically analyse the victim's heart rate and capable of delivering one or more defibrillation shocks if a ventricular fibrillation (VF) or ventricular tachycardia (VT monomorphic or polymorphic with heartbeat >180) is detected. The energy is supplied by exponential truncated biphasic (B.T.E.) electric shock able to self-adapting to the patient's thoracic impedance.

***Saver One D*** has **ECG Monitoring** capability and could print (optional) ECG saved data on an external thermal printer through its Irda Port.

***Saver One D*** is available with two energy level versions:

- ***Standard*** ***Maximum output at 200J*** Saver One D (SVO-B0004)
- ***Power*** ***Maximum output at 360J*** Saver One D (SVO-B0005)

***Saver One D*** can be used with Non-Rechargeable Battery Li-$SOCl_2$ (SAV-C0903) or Rechargeable Battery Li-Ion (SAV-C0011) and with Adult Defibrillation Pads (SAV-C0847) or Paediatric Pads (SAV-C0016).

## 3.6 SERVICE MINI-DISPLAY

The LCD Mini-Display is helpful for receiving information on the status of AED and/or for Service.

In STANDBY Mode will confirm that the AED is ready for use by displaying a "Check Mark" and the Battery Gauge Indicator informing on the residual charge of the battery.

In STANDBY and OPERATING Mode will run text with "Error Code" (warnings for service required) in faulty AED conditions.

## 3.7 MENU & SET-UP

Any AED has a factory standard configuration. Some features can be modified by the user navigating into the MENU and approaching parts of the AED software.

At the first start-up, after the activation test, it's recommended to set-up the AED at user's pleasure and vary the date and time.

AED can be set, in Operating Mode, using the following buttons and procedure:

| ENTRY MENU BUTTON | UP BUTTON | DOWN BUTTON |
|---|---|---|
|  |  |  |
| Entering the MENU<br>Entering the SECTION of the menu<br>Confirming the SELECTION | Scrolling UP | Scrolling DOWN |

The MENU has different sections on pages.

- Press the Entry Menu Button to enter its first page.

Once entered, the first page will display the following Sections:
1. **SEMIAUTOMATIC**
2. **ECG MONITORING**
3. **SETTINGS**
4. **SYSTEM INFORMATION**
5. **PRINT** (will disappear if the AED is operating a rescue)
6. **Exit**

***Settings***
- Enter the MENU
- Scroll down till "**SETTINGS**" and press the Entry Menu Button.

In this section is possible to set-up the following:
a) To vary the **VOLUME** from 10 to 100%
b) To choose **MICROPHONE**OFF if rescue voice and environmental recordings is not required
c) To vary the display **CONTRAST** from 0 to 100%
d) To change current **LOCAL TIME**
e) To change the **LANGUAGE** (if AED equipped with more than one)
f) To choose the **CPR RATIO** 15:2 if Paediatric Pads are installed and users are ALS personnel

Note: "CPR Ratio" option will appear whenever paediatric pads are connected to AED.
In case of PALS (Paediatric ALS) rescue attended by two or more healthcare professionals with a duty to respond, this option should be activated as required by Guidelines in force, and the CPR should have the new ratio of 15:2 (15 compressions and 2 rescue breaths).
The display will show the new Protocol and CPR Ratio: **PEDIATRIC 15:2**
Once the AED is turned off, this option will return in its default operation with the ratio 30:2.

- Scroll down till "**EXIT**" to confirm the new set-up.

The configuration chosen will be kept in memory for the next AED start-up and new changes.

***System Information***
- Enter the MENU
- Scroll down till "**SYSTEM INFORMATION**" and press the Entry Menu Button.

Once entered, this section will display:
1. **MODEL TYPE** (will inform about the AED Model in use)
2. **SERIAL NUMBER** (will inform about the AED Serial Number)
3. **SOFTWARE VERSION** (will inform about the Software Version in use)
4. **POWER SUPPLY**
5. **Exit**

- To have information about the Battery in use, scroll down till "**POWER SUPPLY**" and press the Entry Menu Button.

Once entered, this section will display the following information:
a) The **TYPE OF BATTERY** connected (disposable or rechargeable)
b) The **REMAINING CAPACITY** (percentage) of the battery
c) The **CHARGING COUNTS**(available only with rechargeable battery installed)
d) The **VOLTAGE**

- Scroll down until "**EXIT**" to go out from this section.

## 3.8 ECG MONITORING

***Saver One D*** is able to work in **ECG Monitoring** (protected mode) allowing for watch over the rhythm and heart rate while using Defibrillation Pads or standard ECG Electrodes.

This modality is only intended for specialized medical personnel and is password protected.

- Enter the MENU
- Scroll down until "**ECG MONITORING**" and press the Entry Menu Button
- Then press this sequence **UP**, **DOWN**, **UP**, **DOWN** as password required

| PASSWORD | | | |
|---|---|---|---|
| ▲ | ▼ | ▲ | ▼ |

The device is able to collect 1 ECG waveform Lead II with 2 different accessories:

1. Multifunction Defibrillation Pads
2. Standard ECG Electrodes attached to a separated 2-Lead Patient Monitoring reusable Cable

WHILE OPERATING THIS MODALITY, THE DEVICE CANNOT GIVE ANY SHOCK.
IT WILL KEEP JUST ANALYSING HEARTH RYTHM.
IF A SHOCK IS NEEDED OR WANT TO GO OUT FROM THIS MODALITY, PRESS TWICE THE ENTRY MENU BUTTON IN ORDER TO SWITCH THE AED IN SEMI-AUTOMATIC MODE.

Note: The AED doesn't allow printing ECG in real time (while using this modality).

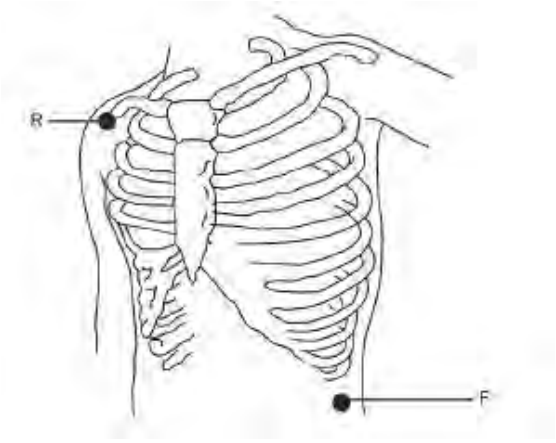
***ECG Electrodes and Reusable Monitoring Cable***
The Patient Monitoring reusable Cable (SAV-C0017), rated Type CF, is equipped with two spring-clip terminals for connecting standard pre-gelled disposable ECG Electrodes (option).

The quality of ECG data displayed on the device is the direct consequence of the electrical signal quality received by the electrodes.

- Connect the Monitoring Cable to AED and clip the two ECG Electrodes.
- Place the two ECG Electrodes to the patient as follows:

Red ("R" code IEC) ECG Electrode
To be placed close to the right shoulder directly below the clavicle.

Green ("F" code IEC) ECG Electrode
To be placed on the left side of the hypogastrium



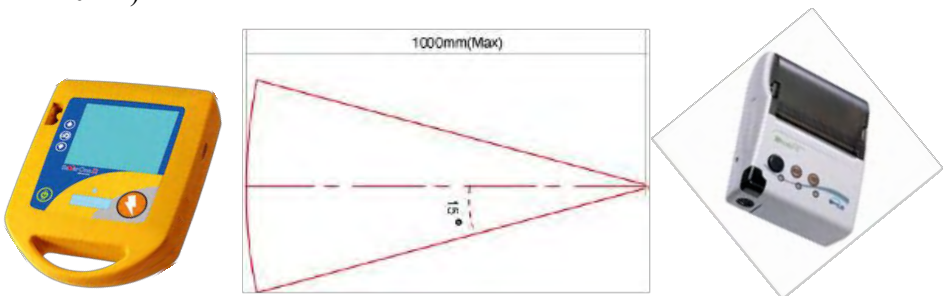

AED will start monitoring the hearth rhythm.

## 3.9 PRINTING (option)

This section is available only for ***Saver One D*** purchased with the ***Print-Ready Configuration*** (Conf-Print).

The Conf-Print provides an AED equipped with IrDA Port (Infrared systems) able to communicate with the external Thermal Printer PORTI-S30 (SAV-C0018) and print ECG saved in the AED.

Once turned on, establish the connection between both devices by approaching the Thermal Printer's infrared (maximum distance 10cm.) to the AED's IrDA Port.




- Enter the MENU

If the connection is established the text prompt "**READY**" will be displayed. Otherwise there will be "**NO CONNECTION**".

- Select the file from the **ARCHIVE** scrolling down between the files saved into AED.

The Archive contains various files (AEDFILE) related to multiple sessions saved and divided by:

1. The name (nnnnnnXX.aed - where the first 6 digits represents the date of rescue)
2. A progressive number of the file on the total of saved files (2/30 – the second file on 30 as total saved)
3. The date and time of the rescue
4. The volume (expressed in Kb) of the file

- Scroll down till "**PRINT**" (is not shown during a rescue) and press the Entry Menu Button for printing.

- Scroll down until "**EXIT**" to go out from this section.

# CHAPTER 4: SAVER ONE P


SEMI-AUTOMATIC AED
With ECG MONITORING
And MANUAL Override

## 4.1 QUICK START GUIDE

This is a quick start guide included into the carry case of AED.


## 4.2 STANDARD BOX CONTENTS

The **Standard Basic Configuration** (Conf-Norm) includes:

- 1 AED unit
- 1 Pair of Adult defibrillation pads
- 1 Non-Rechargeable Battery
- 1 Carrying Case (with a Quick Start Guide)
- 1 Quick Operating Guide and a User Manual

Available optional Configurations:

1. **Rechargeable Configuration** (Conf-Rech)
   (AED unit, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

2. **Print Ready Configuration** (Conf-Print)
   (AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Non-Rechargeable Battery, Carrying Case)

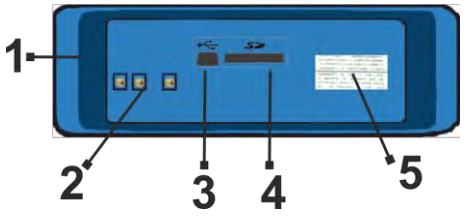
3. **Rechargeable & Print Ready Configuration**(Conf-Rech/Print)
   (AED unit equipped with IrDA Port, Thermal Printer PORTI-S30, Pair of Adult defibrillation pads, Rechargeable Battery, Charger Station, Carrying Case)

## 4.3 AED PARTS

The following drawings show the AED parts and their locations.


| | |
|---|---|
| 1. Battery | 7. Status LED Indicator |
| 2. IrDA Port (option) | 8. ON/OFF switch |
| 3. Disarm / Energy / Charging buttons | 9. Microphone |
| 4. Speaker | 10. Pads or ECG cable connection port |
| 5. Shock button | 11. MENU buttons |
| 6. Service LCD Mini-Display | 12. TFT Colour screen 5.7” |

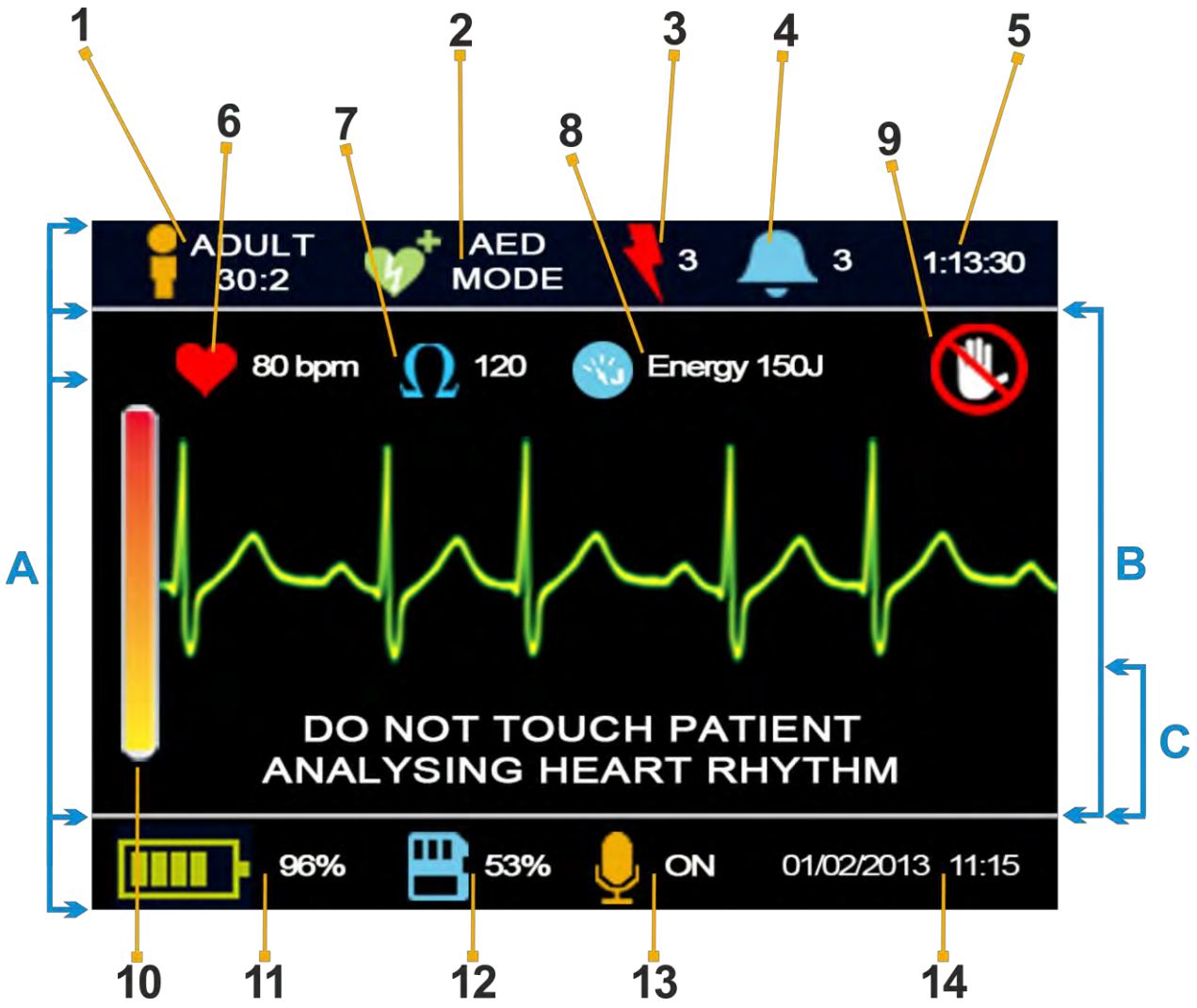
***Rear View***




| |
|---|
| 1. Battery compartment |
| 2. Contact PINS |
| 3. USB Port |
| 4. Removable SD Card seat |
| 5. Warranty seal |

## 4.4 TFT COLOUR DISPLAY 5.7”

The following drawings show the display equipped on ***Saver One P***.




(This example is given for a device equipped with English software.
Your AED should be equipped with the prompts in your language)

| |
|---|
| A. Rescue and AED Set-Up Information Field |
| B. Graphic Area active during rescue. |
| C. Text Area running during rescue |

| | |
|---|---|
| 1. Protocol (AD/PED) and CPR Ratio in use | 8. Energy Level to Deliver |
| 2. Modality (AED/ECG/SYNC/ASYNC) in use | 9. Icon Don’t Touch Patient |
| 3. Shock Counts | 10. Charging Bar (progressing) |
| 4. Fibrillation Alarm Counts | 11. Battery Gauge Indicator |
| 5. On Time Treatment | 12. Removable Card IN with Residual Capacity |
| 6. Heart Rate (BPM) | 13. Microphone ON / OFF |
| 7. Impedance (ohms) | 14. Current Date and Time |

## 4.5 AED DESCRIPTION

***Saver One P*** is a tough, small and lightweight **dual-mode defibrillator** easy to carry and use anywhere. The right choice for harsh, outdoor or mobile use, able to administer safe treatments against SCA and give visual details and rescue information throughout a very large colour display (5.7").

Highly flexible and versatile with advanced capabilities for any scenery: a **Semi-Automatic AED** (per default) reliable for BLS rescuers which can be simply switched to a **MANUAL** defibrillator giving to ALS responders the best decision-making control for a manual shock timing with **Unsynchronized** or **Synchronized Cardioversions**.

***Saver One P*** has **ECG Monitoring** capability and could print (optional) ECG saved data on an external thermal printer throughout its Irda Port.

***Saver One P*** is available with two energy level versions:

- ***Standard*** ***Maximum output at 200J*** Saver One P (SVP-B0006)
- ***Power*** ***Maximum output at 360J*** Saver One P (SVP-B0007)

***Saver One P*** can be used with Non-Rechargeable Battery Li-$SOCl_2$ (SAV-C0903) or Rechargeable Battery Li-Ion (SAV-C0011) and with Adult Defibrillation Pads (SAV-C0847) or Paediatric Pads (SAV-C0016).

## 4.6 SERVICE MINI-DISPLAY

The LCD Mini-Display is helpful for receiving information on the status of AED and/or for Service.

In STANDBY Mode will confirm that the AED is ready for use by displaying a "Check Mark" and the Battery Gauge Indicator informing on the residual charge of the battery.

In STANDBY or OPERATING Mode will run text with "Error Code" (warnings for service required) in faulty AED conditions.

## 4.7 MENU & SET-UP

Any AED has a factory standard configuration. Some features can be modified by the user navigating into the MENU and approaching parts of the AED software.

At the first start-up, after the activation test, it's recommended to set-up the AED at user's pleasure and vary the date and time.

AED can be set, in Operating Mode, using the following buttons and procedure:

| ENTRY MENU BUTTON | UP BUTTON | DOWN BUTTON |
|---|---|---|
|  |  |  |
| Entering the MENU<br>Entering the SECTION of the menu<br>Confirming the SELECTION | Scrolling UP | Scrolling DOWN |

The MENU has different sections.

➢ Press the Entry Menu Button to enter the first page.

Once entered, the first page will display the following Sections:

1. **SEMIAUTOMATIC**
2. **MANUAL SYNCHRONOUS**
3. **MANUAL ASYNCHRONOUS**
4. **ECG MONITORING**
5. **SETTINGS**
6. **SYSTEM INFORMATION**
7. **PRINT** (will disappear if the AED is operating a rescue)
8. **Exit**

***Settings***

- Enter the MENU
- Scroll down till "**SETTINGS**" and press the Entry Menu Button.

In this section is possible to set-up the following:

a) To vary the **VOLUME** from 10 to 100%
b) To choose **MICROPHONE**OFF if don't require voice and environmental recordings
c) To vary the display **CONTRAST** from 0 to 100%
d) To change current **LOCAL TIME**
e) To change the **LANGUAGE** (if AED equipped with more than one)
f) To choose the **CPR RATIO** 15:2 if Paediatric Pads are installed and users are ALS personnel
g) To choose **CPR HELP** OFF if don't require CPR guidance during the rescue session when using the AED in Semi-Automatic mode

Note: "CPR Ratio" option will appear whenever paediatric pads are connected to AED.
In case of PALS (Paediatric ALS) rescue attended by two or more healthcare professionals with a duty to respond, this option should be activated as required by Guidelines in force, and the CPR should have the new ratio of 15:2 (15 compressions and 2 rescue breaths).
The display will show the new Protocol and CPR Ratio: **PEDIATRIC 15:2**
Once the AED is turned off, this option will return in its default operation with the ratio 30:2.

Note: "CPR Help" (ON/OFF option) is used by the rescuer if guidance (voice prompts and metronome) during the CPR sequence is needed or not, when using the AED in Semi-Automatic Mode.
If optioned OFF, the AED will run only text prompt on the colour display but will perform 2 minutes of silence during the CPR (not voice messages neither metronome).
Once the AED is turned off, this option will return in its default operation ON.

- Scroll down till "**EXIT**" to confirm the new set-up.

The configuration chosen will be kept in memory for the next AED start-up and new changes.

***System Information***

- Enter the MENU
- Scroll down till "**SYSTEM INFORMATION**" and press the Entry Menu Button.

Once entered, this section will display:

1. **MODEL TYPE** (will inform about the AED Model in use)
2. **SERIAL NUMBER** (will inform about the AED Serial Number)
3. **SOFTWARE VERSION** (will inform about the Software Version in use)
4. **POWER SUPPLY**
5. **Exit**

- To have information about the Battery in use, scroll down till "**POWER SUPPLY**" and press the Entry Menu Button.

Once entered, this section will display the following information:
a) The **TYPE OF BATTERY** connected (disposable or rechargeable)
b) The **REMAINING CAPACITY** (percentage) of the battery
c) The **CHARGING COUNTS**(available only with rechargeable battery installed)
d) The **VOLTAGE**

➢ Scroll down until "**EXIT**" to go out from this section.

## 4.8 MANUAL MODE & SYNCHRONIZED CARDIOVERSION

***Saver One P*** is capable to operate in MANUAL MODE by simply selecting the modality required:

1. MANUAL SYNCHRONOUS
2. MANUAL ASYNCHRONOUS

BOTH MODALITIES HAS TOBEUSED ONLY BY ALS PERSONNEL.

IF YOU ARE NOT SURE ON WHAT TO DO IS PREFERABLE TO LEAVE AED IN ITS DEFAULT SEMI-AUTOMATIC MODALITYAND USE IT WITH THE STANDARD DEFAULT RESCUE PROTOCOL.

Once turned on, the AED is always running in Semi-Automatic Mode (default modality).

Manual Modalities are protected sections where an entry password is required.

➢ Enter the MENU
➢ Scroll down and choose the "**MANUAL**" modality required, then press the Entry Menu Button
➢ Press this sequence **UP**, **DOWN**, **UP**, **DOWN** as password required

| PASSWORD | | | |
|---|---|---|---|
| ▲ | ▼ | ▲ | ▼ |

The display will show the new Modality in use:

- **SYNC MODE** for the Manual Synchronous
- **ASYNC MODE** for the Manual Asynchronous

For operating with both Manual Modalities, the rescuer should use the following buttons:

| ENERGY | CHARGING | DISARM |
|---|---|---|
|  |  |  |
| Selecting the energy to deliver (shock) | Arming AED (charging for shock) | Disarming AED |

➢ Press the "**ENERGY**" button to enter the section of the energy levels available in the device:

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| STANDARD Version Max 200J | 50J | 100J | 150J | 200J | | | |
| POWER Version Max 360J | | | | | 250J | 300J | 360J |

- Scroll UP / DOWN for selecting the desired energy, then press the Entry Menu Button to confirm
- Press the "**CHARGING**" button to arm the AED and get it ready for shock

The AED will prompt "*Do not touch patient. Charging for the shock*" and a charging bar is progressing on the colour display.

Once armed and ready to deliver a defibrillation shock, the prompt "*Press shock button*" will be heard and the shock button starts flashing.

- Press the "**SHOCK**" button (being sure no one is touching the patient) to deliver a shock

If the shock button is not pressed within 18 seconds of hearing the prompt, the AED will disarm with the voice prompt "*Shock cancelled. Shock button not pressed*".

The AED could be disarmed at any time by pressing the "**DISARM**" button and the prompt "*Shock cancelled"* is heard.

After the AED delivers the defibrillation shock, the voice prompt will say "*Shock Delivered*" and the AED will keep analysing the patient while waiting for the next rescuer's command.

When using both Manual Modalities, the CPR guidance is automatically OFF. There will be no voice messages or metronome during CPR. On the screen will be displayed only text prompts and pictograms.

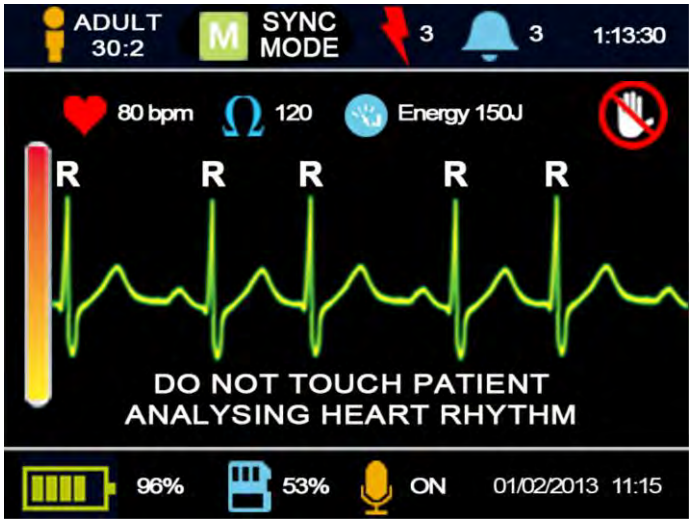
***MANUAL SYNCHRONOUS***
The Manual Synchronous Mode will able the rescuer to provide Synchronized Cardioversions.
The Synchronized Cardioversion is a shock delivery that is timed with the QRS complex.

The most common use of Cardioversion is to treat atrial fibrillation or atrial flutter. But Cardioversion may also be used to treat unstable supraventricular tachycardia, which could lead to ventricular fibrillation.

This synchronization avoids shock delivery during the relative refractory portion of the cardiac cycle (when a shock could produce ventricular fibrillation).

Cardioversion may be a necessary procedure when drugs alone have not been able to convert an arrhythmia to a normal heart rhythm. Cardioversion restores the normal heart rate and rhythm, allowing the heart to pump more effectively.

By pressing the MANUAL SYNCHRONOUS mode, once entered the MENU, the AED will start operating with its SYNC MODE and the AED synchronizing circuit will detect the patient's R-wave.
The SYNC MODE and R-waves are displayed.



Once selected the energy to deliver and charged the AED for the shock, after the voice prompts "*Press shock button*", the rescuer has to press and held the shock button until the AED will discharge with the next detected R-wave.

When the shock button is pressed there will be a delay in the shock.

Delay time between QRS peak and effective shock is maximum 50ms.

During this delay, the AED reads and synchronizes with the patients ECG rhythm. This occurs so that the shock can be delivered with the peak of the R-wave in the patients QRS complex, thus avoiding the vulnerable T wave segment of the cardiac cycle.

***MANUAL ASYNCHRONOUS***
By using the Manual Asynchronous Mode, the rescuer can provide Unsynchronized Cardioversions. A standard defibrillation shock which is delivered as soon as the shock button is pressed.

Unsynchronized Cardioversion is used when there is no coordinated intrinsic electrical activity in the heart (pulseless VT/VF) and the shock may fall randomly anywhere within the cardiac cycle (QRS complex).

By pressing the MANUAL ASYNCHRONOUS mode, once entered the MENU and provided the password, the AED will start operating with its ASYNC MODE.

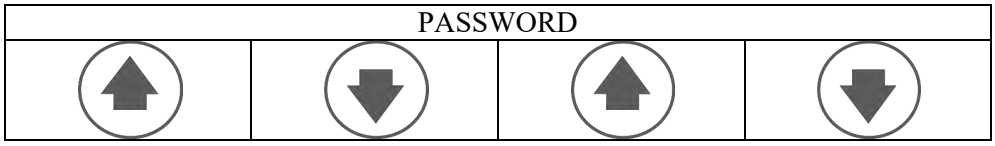
Select the desired energy level to deliver, then charge the AED by pressing the Charging button and, finally press the shock button as soon as the voice prompt "*Press shock button*" is heard.

## 4.9 ECG MONITORING

***Saver One D*** is able to work in **ECG Monitoring** (protected mode) allowing for watch over the rhythm and heart rate while using Defibrillation Pads or standard ECG Electrodes.

This modality is only intended for specialized medical personnel and is password protected.

- Enter the MENU
- Scroll down until "**ECG MONITORING**" and press the Entry Menu Button
- Then press this sequence **UP**, **DOWN**, **UP**, **DOWN** as password required




The device is able to collect 1 ECG waveform Lead II with 2 different accessories:

3. Multifunction Defibrillation Pads
4. Standard ECG Electrodes attached to a separated 2-Lead Patient Monitoring reusable Cable

WHILE OPERATING THIS MODALITY, THE DEVICE CANNOT GIVE ANY SHOCK.
IT WILL KEEP JUST ANALYSING HEARTH RYTHM.
IF A SHOCK IS NEEDED OR WANT TO GO OUT FROM THIS MODALITY, PRESS TWICE THE ENTRY MENU BUTTON IN ORDER TO SWITCH THE AED IN SEMI-AUTOMATIC MODE.

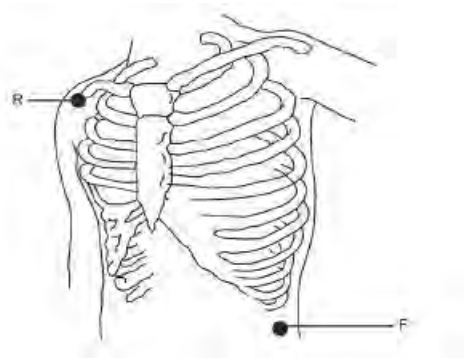
Note: The AED doesn't allow printing ECG in real time (while using this modality).

***ECG Electrodes and Reusable Monitoring Cable***
The Patient Monitoring reusable Cable (SAV-C0017), rated Type CF, is equipped with two spring-clip terminals for connecting standard pre-gelled disposable ECG Electrodes (option).

The quality of ECG data displayed on the device is the direct consequence of the electrical signal quality received by the electrodes.

- Connect the Monitoring Cable to AED and clip the two ECG Electrodes.
- Place the two ECG Electrodes to the patient as follows:

Red ("R" code IEC) ECG Electrode
To be placed close to the right shoulder directly below the clavicle.




Green ("F" code IEC) ECG Electrode
To be placed on the left side of the hypogastrium

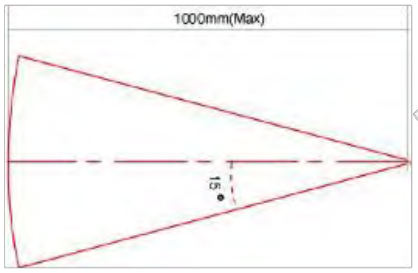
AED will start monitoring the hearth rhythm.

## 4.10 PRINTING (option)

This section is available only for ***Saver One P*** purchased with the ***Print-Ready Configuration*** (Conf-Print).

The Conf-Print provides an AED equipped with IrDA Port (Infrared systems) able to communicate with the external Thermal Printer PORTI-S30 (SAV-C0018) and print ECG saved in the AED.

Once turned on, establish the connection between both devices by approaching the Thermal Printer's infrared (maximum distance 10cm.) to the AED's IrDA Port.




- Enter the MENU of the AED

If the connection is established the text prompt "**READY**" will be displayed. Otherwise there will be "**NO CONNECTION**".

- Select the file from the **ARCHIVE** scrolling down between the files saved into AED.

The Archive contains various files (AEDFILE) related to multiple sessions saved and divided by:

1. The name (nnnnnnXX.aed - where the first 6 digits represents the date of rescue)
2. A progressive number of the file on the total of saved files (2/30 – the second file on 30 as total saved)
3. The date and time of the rescue
4. The volume (expressed in Kb) of the file

- Scroll down till "**PRINT**" (is not shown during a rescue) and press the Entry Menu Button for printing.

- Scroll down until "**EXIT**" to go out from this section.

SaverOne®

AED series

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*everyday*
*everybody*
*everywhere*