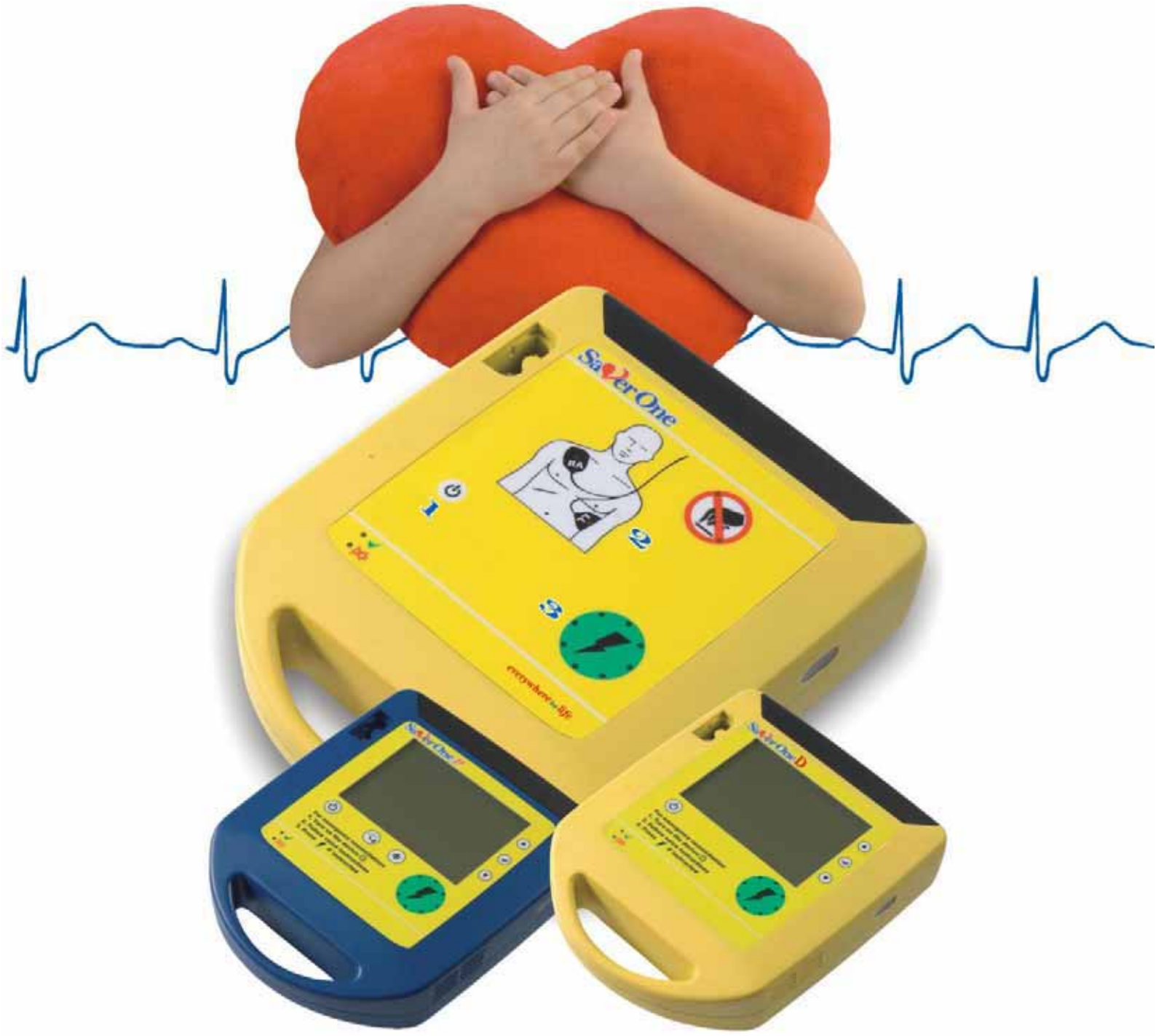
SaVer One®

Defibrillators Series



User's Manual

Made in Italy

A.M.I. ITALIA

A.M.I. ITALIA s.r.l.

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1 Range of Products

AMI ITALIA. S.r.l. is the designer and the manufacturer of the *SAVER ONE Defibrillators Series*.
Device series intended to administer lifesaving easy and safety treatments against sudden cardiac arrests (SCA), including the following models:

SaverOne®

User-friendly **Public Access Defibrillator (PAD)** designed to support rescuers in performing fast and safe lifesaving treatment with only two steps to shock. Reliable for anyone even without minimal training, Highly practical, intuitive with CPR guidance and clear instructions for supporting rescuers through the protocol for effective lifesaving actions. Small and lightweight, works with long-life batteries for a maximum portability. The right solution to save lives anywhere: home, offices, schools, hotels, airports, trains, beaches, sport facilities, discos, dentists, etc.

Ref: SVO-B0001 for Standard Version Ref: SVO-B0002 for Power Version

SaverOne D®

Easy-to-use **Automated External Defibrillator (AED)** reliable for any lay rescuer. Designed to administer safe treatments against SCA and able to give visual details and information on lifesaving actions throughout a very large display. Intuitive with CPR guidance and clear instructions supporting rescuers through the protocol for effective operations. Handy, fast and practical, is the right solution for more expertise rescuers or paramedics to act anywhere (ambulance, dentist, medical office or department, clinic laboratory and of course at work, school, hotel, airport, railway or bus station, etc.) and to use it as ECG Monitoring too.

Ref: SVD-B0004 for Standard Version Ref: SVD-B0005 for Power Version

SaverOne P®

Tough and practical **Dual-Mode Defibrillator, Manual or Automated (AED)**. Greatly versatile is reliable for any scenery: in manual mode provides an operating capability for EMS responders, hospital and medical professionals or ALS users, allowing access to setup the device, choose energy level and time to shock, select a synchronized cardioversion or an ECG monitoring control; moreover, if necessary, can act as an AED providing a normal operating capability for any rescuer or BLS users with visual and audible instructions and CPR guidance.

Ref: SVP-B0006 for Standard Version Ref: SVP-B0007 for Power Version

Each model can be powered by two different power supplies: Disposable ($LiMnO_2$) or Rechargeable (Li-Ion) batteries and is able to give one or more shocks on victims afflicted by Ventricular Fibrillation (VF) or Ventricular Tachycardia (VT) using a Biphasic Trapezoidal Adaptive (BTA) waveform.

All defibrillators are produced according to IEC60601-2-4 standards and are optimized for a very fast use: the time from initially switching power on to readiness for shock is extremely short.

Each model is available with 2 energy level version:

- ***Standard Version:*** **max energy 200J**
- ***Power Version:*** **max energy 360J**

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1.1 Preface

Dear user, thanks for choosing one of our *SAVER ONE Defibrillators Series*, hereafter named "device".
To use it in a properly manner please read carefully this user's manual familiarizing with the device before using it.
In this user's manual are reported the essential indications/instructions for a correct use of the device.
To obtain correct performances of the device is fundamental to respect the instructions given in this user's manual to warrant the safety of the patient and the operators.
This user's manual is integral part of the device and must be kept nearby it in order to be easily consulted if necessary.

1.2 Conforming Use

The device can be used only following the instructions/indications given in this user's manual.
Any different use is intended not conforming to the indications given and may cause damages to people and/or things.

1.3 Warranty

Our *SAVER ONE Defibrillators Series* is produced following rigid quality standards.
AMI ITALIA general warranty indications are valid. See Limited Warranty (section 20).
AMI ITALIA. Srl hereby warrants the device against all defects in material, workmanship or otherwise for a period of five (5) years under normal use and service as set forth in this User's Manual.
Disposable Battery shelf-life warranty is for a period of five (5) years and four (4) years in stand-by mode whenever installed, if respected all environmental conditions given in this User's Manual (section 13).
Device's memory report will keep prove.
AMI ITALIA obligation under this warranty is limited for repairing or substituting, at the AMI ITALIA option, any part which upon the AMI ITALIA examination proves defective.
Repair, modification, substitution on the device shall be done only by the producer or authorized personnel.

In case of failed device or in case the device must be serviced, please follows this procedure:
a) Contact immediately our Service Department by phone, fax or email (service@amihealthcare.eu).
b) Obtain RMA (Return Materials Authorization) module. Our staff will help you step by step.
c) Return the RMA module completed with model name, serial number, and a brief description of the reason for return to our registered office address.

1.4 Liability Exclusion

The warranty shall not extend to: any product that has been subjected to misuse, negligence or accidents; any product from which the AMI ITALIA original serial number tag or product identification markings have been altered or removed; any product damaged by natural events and acts of Force Majeure like fire, flood, earthquakes, explosions, wars, sabotage, epidemics, etc.; any product of any other manufacturer.

1.5 Indications

The device can be used for giving a shock in emergency SCA (sudden cardiac arrest) situations when:

the victim is unconscious, unresponsive, does not breath, has no signs of circulation

- ***SAVER ONE D*** and ***SAVER ONE P*** can be used in ECG Monitoring mode for monitoring the hearth rhythm directly from the defibrillation pads or throughout a dedicated ECG cable 2 lead.
- ***SAVER ONE P*** can be used for synchronized or unsynchronized cardioversion (manual mode).

1.6 Contraindications

The device cannot be used if the patient is in a state of conscience, with normal signs of circulation (breath, pulse).

1.7 Classifications

The device is classified according to IEC 60601-1 as follows:

Type of protection against electrical shock	II
Degree of protection against electrical shock	BF
Degree of protection against water	IPX4
Degree of protection against dust	IP5X
Degree of safety application in presence of flammable anesthetic mixture with air or with oxygen or with nitrous oxide	Not suitable
Method(s) of sterilization or disinfection recommended by the manufacturer	Go to section 12
Operation Mode	Continuous operation
Internally powered device	YES

2 Safety Indications

The operator should be conscious of all security elements related to the use of the device and is suggested to read them carefully. All security indications are done in this user's manual headed by the following symbols which determine different grades of remark as hereby explained:

	**DANGER**	Report a high risk for people, patient and bystander which may also involve mortality.
	**WARNING**	Report a situation, an hazard or a not safe process which may seriously hurt people, damage the device or destroy data on it.
	**NOTE**	Attract the reader attention for important information or conditions which, however, not necessary damage people or things.

Furthermore:

	**SAVER ONEs COMPARISON**	Report technical differences between the models of *SAVER ONE Defibrillators Series*.

2.1 General Safety Instructions

The device, alone and/or with its related accessories, complies with current safety standard rules and is conforming to Council Directive 93/42/EEC of June 14th, 1993 concerning Medical Devices.

The device and its accessories are extremely safe when used respecting all applications given in this user's manual and will operate accordingly to indications and instructions for use given here.

However, when the device and its accessories are used in a wrong or inappropriate way, it may cause damages for the operator, the patient or standing people.

- Use the device only following the instructions given in this user's manual and pay attention to the indications given for the safety.
- The interference (high frequency electrical signal) sourced by mobile phone, walkie-talkie, radio, etc. may origin wrong functioning of the device.
  The device must be kept away from this kind of electrical fonts for minimum 2m, as indicated in EN 61000-4-3:1996.
- Keep the device away from other energy source, therapeutics or diagnostics, such as high frequency surgery devices, magnetic tomography, diathermia, etc.
- Do not dip any part of the device in water or other liquids. Avoid any penetration of liquid into the device. Avoid to spill liquids on the device and its accessories. On the contrary, it may cause damage or fire or electric shock.
- Do not sterilize the device and/or its related accessories.
- Danger of electric shocks. The device generate high voltage and dangerous levels of electricity. Do not open the device removing external panels and never try to repair it. The device has no components which can be easily repaired by the users.
- The device must be sent to an authorized technical center for service.

- According to IEC standards, is forbidden to use the device face to firing material (fuel or similar) or when the atmosphere is plenty of oxygen or firing gas/steam.
- Do not recharge the Li/MnO_2 disposable battery.
- Keep batteries away from flames. Do not expose them to fire.
- Do not short-circuit terminal batteries contacts.
- In case of liquid overflowing or strange smells from the batteries, keep them away from fire to prevent that battery solution does not catch fire.
- Do not place electrode pads if the patient has nitroglycerin band-aid on his chest. It may cause explosion. First remove the band-aid and then apply the pads.

2.2 Security Instructions for the Protection of Device

- For security reasons some heart rhythm with very low frequency or extension could not be read by the device as VF or VT to be treated.
- Move or transport the patient during rhythm analysis may generate late and/or wrong diagnosis. Do not move the patient during rhythm analysis enabling the device to confirm evaluation of ECG before giving the shock.
- Do not touch the patient during ECG analysis.
- Using the device when damaged and/or using damaged or expired accessory may cause bad running of the device and/or may damage the patient and/or the operator.
- The device could be cleaned only when is turned off. The battery must be disconnected as well as the electrode pads. Please read carefully the cleaning instructions given on section 12.
- Use only accessory and/or instruments indicated by AMI ITALIA.
- Repairs, modifications, enlargements of the device can be done only by authorized and instructed specialists trained or belonging to AMI ITALIA.
- Doing a bad/wrong service on the device may damage it and/or cause malfunction. Refer to all indications given in this manual and/or to what indicated by the medical structure supervisor.
- During the defibrillation keep away from the patient all other medical devices/instruments which may cause resistance to defibrillation.
- The device runs a self-test each time a new battery is inserted as well as periodic auto-tests. Those tests are done to verify that the device is ready-to-use but cannot give warranty for an optimal device performance if/when it has not been used properly and/or has been damaged after last use and/or in case of failure after last self-test.
- If you expect to store the device for a long period make sure that the battery and the defibrillation pads have not expired before connecting them to the device.
- Never detach the battery without first turning off the device.
- Insert/detach the batteries as shown in the sections given into this user's manual.
- Do not insert different batteries as provided by AMI ITALIA.
- Do not open the batteries and/or the charger.
- Do not cut and/or break the cover of the batteries and/or the charger.
- Do not bump or strongly shake the batteries and/or the charger.
- The device has been designed to be tough and solid enough to resist for the use in different and/or critical conditions. However, using it in an excessive violent way may damage it as well as its accessories. Check the whole system regularly.
- Read carefully all the information given on the box of the AMI ITALIA electrode pads. Use them before the expiring date indicated on the box. After use throw them away according to the standard local rules.
- While storing and before use, handle the electrode pads with care. Throw away the electrode pads that seems damaged.
- Throw away the empire batteries according to standard local rules.
- Use only Memory Card approved by AMI ITALIA. The device will not work in a properly way with the use of other accessory not authorized by AMI ITALIA.

2.3 Safety Instructions for the User (Rescuer)

- The device should be used only after attending a BLS (basic life support for using ***SAVER ONE*** and ***SAVER ONE D***) or ALS (advanced life support for using ***SAVER ONE P***) training course.
- Before using the device, be sure that the device is working correctly.
- Do not touch the patient during the defibrillation. Avoid any contact with/between:
  a) parts of the patient's body
  b) conductive liquids like gel, blood or solutions of table-salt
  c) metallic object around the victim like the bed frame or other appliances which can act as involuntary and accidental ways for defibrillation current
- A prolonged intense cardiopulmonary resuscitation with pads placed on the chest of the patient may damage them. In this case replace the electrode pads.
- Before using another defibrillator it is necessary to disconnect the electrode pads.
- The IrDA port may generate invisible optical radiations. The diode is manufactured according to the standards IEC 60825-1 Class 1 "Eye Save".
- Should any liquids came out and get in contact with eyes, wash them carefully with fresh and clean water and call immediately the doctor.

2.4 Safety Instructions for the Patient

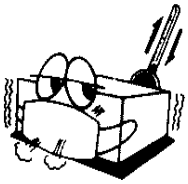
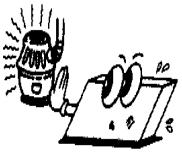
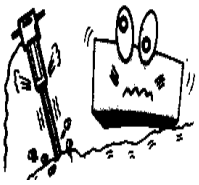
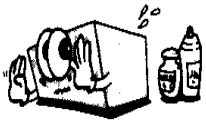
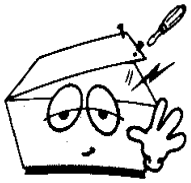
- Do not place electrode pads if the patient has nitroglycerin band-aid on his chest. First remove the band-aid and then apply the electrode pads. On the contrary it may cause explosion.
- Take off any oxygen mask or nasal cannulae and place them at least 1m away from the patient's chest before shock.

- Be sure that electrode pads do not touch or get in contact with any transdermal drug patches or band-aid or tampon or metallic parts and/or with any ECG electrode or derivation of it. On the contrary it may cause electrical arch formation which could burn the patient's skin during the defibrillation or furthermore, in extreme case, even keep away the energy.
- If the patient is less than 8 years old or has a weight less than 25kg, use pediatric electrode pads which will reduce the level of the energy.
- Do not use pediatric electrode pads with reduced energy on adult patients.
- Do not use electrode pads directly on an implanted pace-maker to avoid wrong interpretation of the device and damages due to the electrical defibrillation impulse.
- Air bubbles between skin and pads during the defibrillation could cause burns to the patient. Be careful in placing pads avoiding air bubbles and make pads completely adhere to the skin. Do not use dried electrode pads.
- Be sure of the perfect state of the electrode pads checking that the gel is not dry, otherwise change them and use new ones.
- Check the perfect state of the pads cable and connector, otherwise change them.
- Before using another defibrillator, disconnect the electrode pads from the device.
- Should the device be apparently damaged, do not use it.
- New electrode pads must be used for each patient and before the expiring date to avoid burns on the skin.

2.5 Safety Instructions for Bystanders

- The electricity might damage bystanders.
- Be sure that bystanders do not touch the patient during analysis and defibrillation.

2.6 Environmental Conditions and Precautions

	Do not use or store the device in environmental conditions (temperature and humidity) different from the given range		Keep the device away from direct sunlight
	Do not store the device in places submitted to strong temperature variations		Keep the device away from heat
	Do not use or store the device in places submitted to heavy vibrations		Do not use or store the device in places with dangerous concentration of flame gas or anesthetics
	Do not use or store the device in places submitted to high concentration of powder		The device must only be opened by authorized and instructed specialists trained or belonging to AMI ITALIA. producer. The device does not contain internal parts useful for any other purpose.

3 Device Details

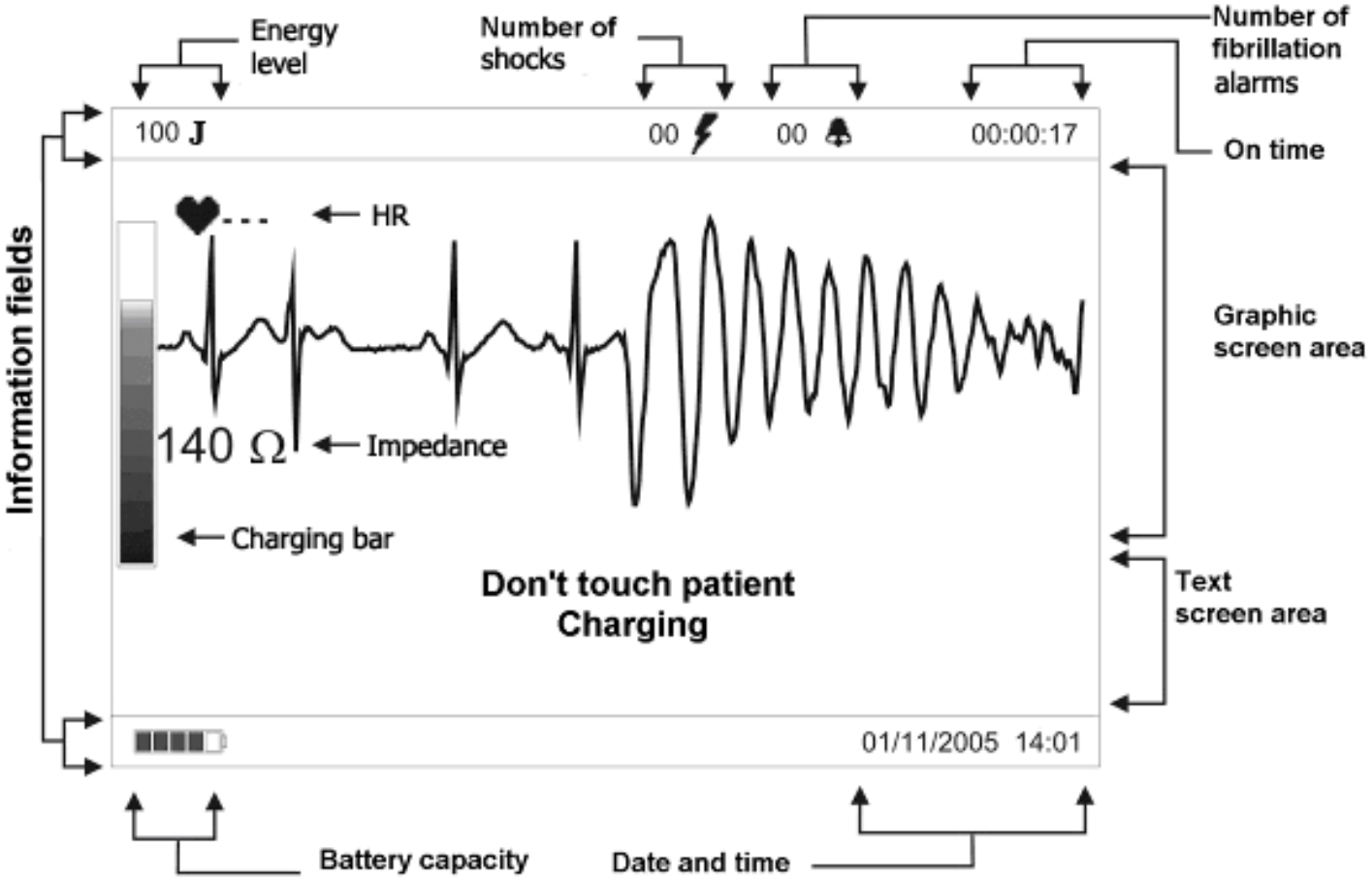
3.1 Front View

Saver One

Saver One D – Saver One P

3.2 Display View Details

- ***SAVER ONE D*** and ***SAVER ONE P*** have a 5.7" LCD display at high resolution (480x320) with LED backlight and special information fields (Display Dimensions 12*8 cm).
- The graphic screen area gives numeric values as heartbeat rate (HR) and impedance and shows the ECG wave and the charging bar to get ready for the shock.
- The text screen area shows all text messages given during the treatment.

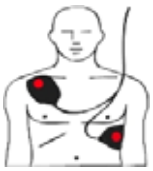


3.3 Rear View Details

Under the battery, on the rear of the device, there are 2 slots allowing the insertion of SM or xD Cards (Memory Card)

3.4 Controls and Indicators Function

➢ The 3 models have different keyboards and control buttons as listed below.

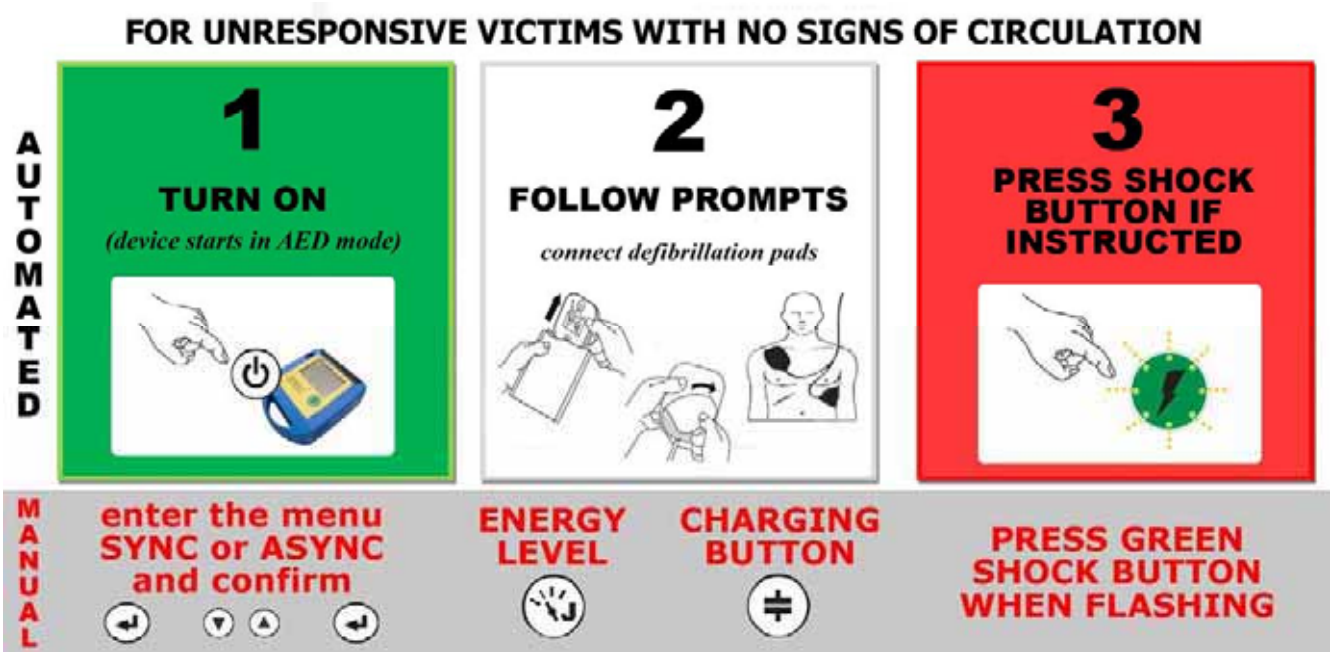
Controls Indicators	Function	Saver One	Saver One D	Saver One P
	**ON / OFF Switch** To turn the device ON or OFF press and hold the button for 2 seconds.	√	√	√
	**SHOCK Switch** **Icon with green flashing LED** Advises that the device is ready for shock. After 15 seconds without pressing this button, the device automatically disarm itself.	√	√	√
	**PADS Connection** **Icon with red flashing LED** Advises to connect the electrode pads to the device and attach them on the victim's chest. Warns for incorrect placement.	√		
	**DO NOT TOUCH THE PATIENT** **Icon with red LED** Warns that no one must touch the patient in particular moment as: during the rhythm analysis, when the shock is advised, during the charging and when is giving the shock.	√		
	**UP Navigation Button** Control button to navigate (up) the menu.		√	√
	**ENTER Button** To enter the menu and confirm selected choices.		√	√
	**DOWN Navigation Button** Control button to navigate (down) the menu.		√	√
	**ENERGY Button** Control button to select energy level (only in Manual Mode).			√
	**CHARGING Button** Button to charge the device for the shock (only in Manual Mode).			√
	**STATUS Indicator with green LED** Advises the good status of the device or warns on its malfunction.	√	√	√
	**BATTERY Indicator with red LED** Advises a low battery or a no battery status.	√	√	√

3.5 Quick Reference

- A quick guide (different for model), inserted into the carry case (optional) pocket, describing the steps for using the device in a lifesaving treatment.

Saver One – Saver One D

Saver One P



4 Measures Before Use

4.1 Inspection

After delivery, first verify the integrity of the external box, than control the device to check any transport damage.

If the device is broken or damaged call immediately AMI ITALIA technical service or its distributor (the seller) indicating the serial number and the damage entity of the device.

Verify the items received with the quantity indicated in the Standard Box Contents (section 15).

Before using the device insert the battery (included into the box).

- Never turn on the device when damages are checked.
- Never detach the battery without first shutting down the device.

- Dispose of packaging material in conformity to your local environment laws.

4.2 Power supplies

The device can work with two different kind of battery:

$LiMnO_2$ Disposable Battery

(black label)

Li-Ion Rechargeable Battery (optional)

(blue label)

- Never detach the battery without shutting down the device.
- After turning off the device wait a few seconds before removing any kind of battery, disposable or rechargeable.
- Disconnecting the battery without turning off the device will result in the battery not entering "sleep mode". This will cause the battery to deteriorate rapidly which will significantly reduce its standby life.

$LiMnO_2$ Disposable Battery

Device standard box contents includes a Disposable Battery (27V; 1,2Ah; $LiMnO_2$) fully charged.

This is the most technological updated type of battery chosen for its long-lasting energy accumulate.

The $LiMnO_2$ disposable battery is supplied separately from the device in a "sleep mode" in order to preserve its capability and is warranted for 5 years (shelf-life from production date) if are respected the environmental conditions stated in the section 13.

- Do not recharge the $LiMnO_2$ disposable battery.
- Look at the warnings given into the back side of the battery.

- Do not insert other kind of battery not supplied by the producer.
- If you would stock the battery for a long period, hold it into its original packaging and keep it at cool temperature.

In case the device needs service, please remove the battery and cover its contacts with adhesive tape.

Li-Ion Rechargeable Battery

The device works even with a Li-Ion Rechargeable Battery (optional).

Rechargeable batteries have no specific expiry date.
A battery's characteristics may vary over load cycle, charge cycle and over life time due to many factors including internal chemistry, current drain and temperature. Therefore we suggest to replace them after 2,5 years or after more than 300 charge cycles.

The following table will show the different features of both batteries:

BATTERY TYPE	***DISPOSABLE***	***RECHARGEABLE***
Technology	Li/MnO_2	Li-Ion
Voltage	3 V	3,6 V
Capacity	1,2 Ah	2,1 Ah
Internal Batteries	9	6
Battery Tension	27 V	21,6 V

Charger

The rechargeable battery can be recharged with a specific charger following these steps:

a. Place the charger steady on a solid surface
b. Remove the rechargeable battery from the device and insert it into the charger
c. For a correct insertion/detach of the battery into the charger please follows the same indication previously stated for insertion/detach of the battery into the device (section 4).
d. Plug the charger to the electricity

The charger has a LED indicating the status of the charger and the level of the battery charging. During the charging phase, the green LED indicator flashes with different frequency depending on the level of charging.

LED indicator	**RED**	**GREEN**
Fixed	- Battery not working	- Battery fully charged
Flashing	- Charger not working	- Battery charging - No battery under charge

- Avoid that batteries and the charger get in contact with flames. Do not expose to fire.
- Do not cause short circuits on electronics terminal of the batteries and the charger.
- If liquid is come out from the batteries or in case of strange smell keep the batteries away from flames to prevent set fire.

- Do not open the batteries and the charger.
- Do not cut or break the batteries and the charger.
- Do not shock the batteries and the charger.
- Do not expose the batteries and the charger to direct sunlight or to high temperatures.
- Dispose of exhaust batteries and the charger respecting the local laws.
- Keep the batteries and the charger away from children.
- If liquids came out from the batteries get in touch with eyes, wash them carefully with clean fresh water and consult immediately a doctor.

- A completely empty battery should be under charging for at least 30 minutes.
- An empty battery will become completely charged after 2,5 hours.
- Charging time may increase with rechargeable batteries suffered from several recharge cycles.

4.3 Battery Insertion

Before using the device please insert the battery (disposable or rechargeable) into its compartment, following these steps:

a. Place the device with its back side steady on a solid surface

b. Push the battery with an oblique direction (1) into the battery compartment of the device till it holds to the opposed angle (2)

c. Push the front of the battery reaching the other angle of the device and fill completely the battery compartment (3)

d. A "click" sound will confirm you that the battery is well connected

e. If not connected in a properly way, the battery risks to come out from the device

- When a new battery is inserted, the device automatically turns on and carry out a complete self-test that will last just few seconds. For more details go to section 4.5
- If the green LED near the symbol ✔ start flashing, it means that the device succeeds the test and is ready-to-use.

4.4 Battery Detach

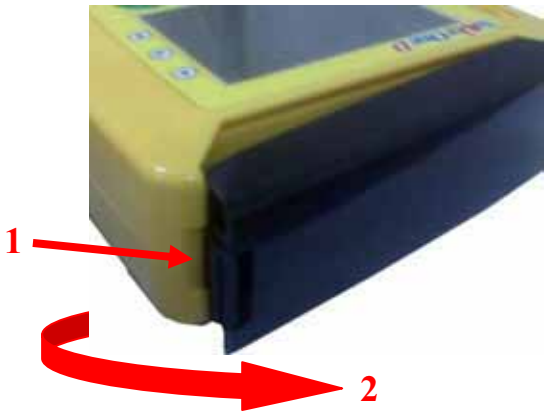
To remove the battery (disposable or rechargeable) from its compartment follows the steps below:

a. Place the device with its back side steady on a solid surface

b. Hold strongly the battery with one hand

c. Pull back the special tab (1) to unhook the battery from its compartment with the other hand

d. Take out the battery (2) from the device



- Never remove the battery without shutting down the device.
- After turning off the device wait a few seconds before removing the battery. Disconnecting prematurely or without shutting down the device will result in the battery not entering "sleep mode". This will cause the battery to deteriorate rapidly which will significantly reduce its standby life.
- Change the battery only when the device is off and with no electrodes connected.

4.5 Self-Tests and Control LED

4.5.1 Automatic Self-Tests

With the battery inserted, the device runs self-tests automatically even when it is turned off in order to verify all its basic operations including hardware and software integrity.

5 types of automatic self-tests are done differentiating for length and entity:

I. Automatic self-test: each time is **Turned On**

II. **Daily** short automatic self-test

III. **Monthly** extended automatic self-test

IV. Every **6 Months** an extended automatic self-test and complete diagnostic

V. At each **Battery Insertion** (new battery or re-attached one) an extended automatic self-test and complete diagnostic and check of the keyboard
(for this test is needed the auxiliary help of the operator – see section 4.5.3)

- Each time is turned on it runs an automatic self-test pointed out by a "TAC-TAC" sound.
- Each time a battery (new or replaced) is inserted it runs an extended auto-diagnostic asking the operator to press down the buttons on the keyboard to check their functionality.

Automatic self-test checks:

- ✓ Power supply
- ✓ High and low voltage circuits
- ✓ High voltage generator
- ✓ ECG analysis system
- ✓ CPU (central processing unit)
- ✓ Speaker and microphone
- ✓ Keyboard buttons and switches
- ✓ All internal components

- Refer to the Service Manual to get knowledge of length and entity of various self-tests.

4.5.2 Control LED

The device has 2 controls LED on its left bottom side:

The green Status LED 

It indicates the status of functional device.
When blinking in stand-by mode indicates that the device is ready for use.
During normal operation (device turned on) it will remain fix lighted.
When blinking joint with the red LED gives some warnings (see table below).

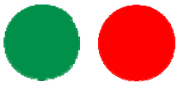
The red Battery LED 

It indicates the presence and the functionality of the battery.
When is OFF indicates a good level of the battery.
When blinking joint with the green LED gives warnings (see table below).

Table: Warnings - Indicators

			
STOCK without the battery	DEVICE NOT OPERATIVE	OFF	 10 days flashing
STAND-BY with the battery on	DEVICE READY FOR USE		OFF
STAND-BY with the battery on	LOW BATTERY	 flashing together	
WORKING	DEVICE OPERATIVE		OFF
WORKING	DEVICE OPERATIVE WITH LOW BATTERY	OFF	
STAND-BY / WORKING	FAULTY DEVICE		
STAND-BY / WORKING	PRE-CONNECTED PADS EXPIRED or NOT WELL CONNECTED		

LEDs blinking 

LEDs fix lighted 

- In case of faulty, see section 12.6 to check a resolution. If is not possible to solve the problem, do not use the device and call the authorized center service.
- With a faulty battery the device could never be turned on.
- A low battery level still grants 10% of its capability.

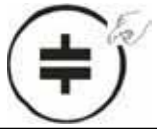
4.5.3 Extended Test at Battery Insertion

Each time a battery, disposable or rechargeable, new or replaced, is attached to device it runs an extended automatic self-test and a complete device diagnostic and keyboard checks to verify its charging capacity (up to more than 700 volts) and the full keyboard buttons functionality.

The test is performed automatically but to verify the functionality of the buttons on the keyboard is required the assistance of the operator.

- The operator must proceed pressing the buttons in sequence following the instructions given by voice and/or only displayed text messages. The sequence depends on the model as listed below.
- For all models, the status ✔ LED will remain lighted fixed green during the test.

Once the battery is attached the device automatically turns on activating the following acoustic and/or just visible signals/messages:

Audible/Visible Messages	Operator's Action	Saver One	Saver One D	Saver One P
"BEEP" (sound signals)	Just wait	√	√	√
"TAC-TAC" (sound signals)	Just wait	√	√	√
voice and text: ***"If you can hear this message. Press green flashing button"***	Press the green shock button 	√	√	√
text on display: ***"Press UP menu button"***	Press the button 			√
text on display: ***"Press DOWN menu button"***	Press the button 			√
text on display: ***"Press ENTER menu button"***	Press the button 			√
text on display: ***"Press ENERGY button"***	Press the button 			√
text on display: ***"Press CHARGING button"***	Press the button 			√

If the full test is not completed within 8-15 seconds (depends on the model), the device will automatically turn off.

It will turn off even when the device and/or one or more buttons of the keyboard are not correctly working.

On the contrary, if it passed the test, the device is ready for use inviting the rescuer to place the pads with the voice message: ***"place defibrillation pads"***.

4.6 Memory Card

Using a Memory Card (optional) the device automatically records all ECG data and events of the treatment.

Throughout a microphone will catch and record operator's speaking, activities, events and environmental.

- Throughout the menu, for the set-up of the devices with the display the operator should decide to exclude the microphone. In this case, environmental sounds and events (voices and sounds) during the treatment will not be recorded into the Memory Card.

Memory Card accepted by the device: ***SMC (smart media card) or xD Card***

Maximum Card Storage Capacity: ***2GB***

To insert the Memory Card into the device please follows these steps:

a. Detach the battery from the rear of the device

b. Put the Memory Card in the related slot following indications for SMC or xD Card

c. Then place back the battery

xD Card

Smart Media Card

Slot for Memory Cards (under the battery)

4.6.1 Storing Ability

Memory	64MB	150 min (2,5 h) ECG, events and environmental recordings or 1.438 min (24 h) ECG only
Smart Media Card	128MB	300 min (5 h) ECG, events and environmental recordings or 2.876 min (48 h) ECG only
xD Card	512MB	1.200 min (20 h) ECG, events and environmental recordings or 11.500 min (191 h) ECG only
xD Card	1 GB	2.400 min (40 h) ECG, events and environmental recordings or 23.000 min (382 h) ECG only
xD Card	2 GB	4.800 min (80 h) ECG, events and environmental recordings or 46.000 min (764 h) ECG only

Recorded data could be showed and managed by means of a dedicated software "Saver View Express" throughout PC/Laptop or PDA.

Data evaluation will be useful for administrative or legal purpose but cannot be used for diagnosis or therapy on patient.

For more information on the software please refer to its related manual.

- It is suggested to save recorded data from Memory Card to files after each treatment.
- When the Memory Card is full no more data could be recorded on it.
- The device will work even with full Memory Card or without it.

- Use only Memory Cards approved by AMI ITALIA.
- The device will not work properly with Memory Card not approved by AMI ITALIA.
- It is suggested to format the Memory Card before using it.

5 Device Configuration

- The configuration of device is possible only with ***SAVER ONE D*** and ***SAVER ONE P***.
- All devices starts always in Automated mode (AED) whenever turned on.

<u>All devices have a factory standard configuration.</u>

You can modify several parameters of the device navigating into the menu.

Each new configuration is memorized and kept even without battery till you choose a new one.

At the first start we recommend to control and modify the date and time and set-up the device at your pleasure.

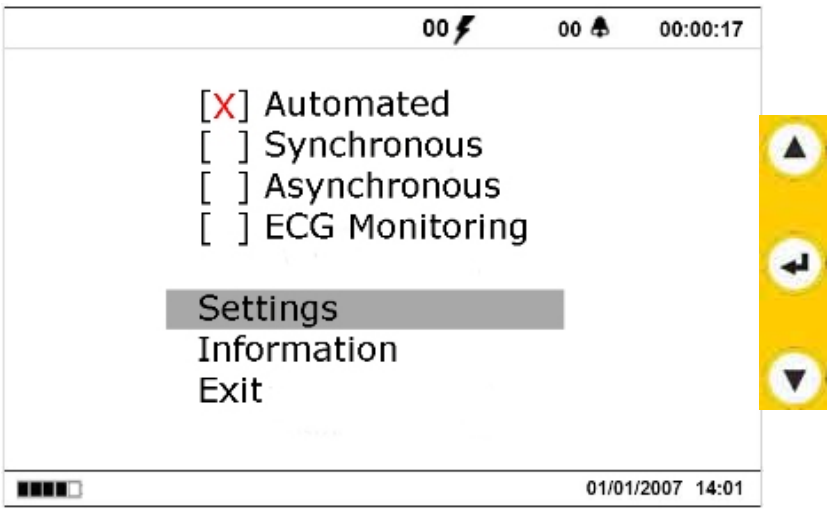
5.1 Device Set-Up

To vary the standard configuration follows these steps:

a) **Push the button ON/OFF to turn on the device**

b) **Push the "Enter" button** 

c) **Navigate "Down" pressing**  **till to select "Settings" and push the "Enter" button**  **to confirm**



- Synchronous and Asynchronous modality is available only for ***SAVER ONE P***.
- ECG Monitoring mode is available for both ***SAVER ONE D*** and ***SAVER ONE P***.

d) Into the "Settings" menu, navigate Up/Down till to select the voice you want to modify

> Press the "Enter" button to get into the selected voice.
> Navigate Up/Down to choose your preferences.
> Then confirm with the "Enter" button.
> Repeat for each voice you need to vary.

Settings		
Volume	80%	➢ vary from 10 to 100%
Microphone	ON	➢ choose ON/OFF
Contrast	40%	➢ vary from 0 to 100%
Local Time	01/01/2007 14:01	➢ add day/month/year & local time
Language	English	➢ choose your language
CPR Ratio	2 minutes (30:2)	➢ vary to ratio 15:2 for pediatric ALS rescuers
CPR Messages	ON	➢ choose ON/OFF
Exit		

- Always change "Local Time" and "Language" at the first start-up of the device according to your location and language.
- Vary "Volume" and display "Contrast" according to each environmental circumstance.
- Select "Microphone" OFF if you don't want to record voice and environmental during the treatment.

- "CPR Ratio" is an option, available on both ***SAVER ONE D*** and ***SAVER ONE P***, that appears automatically on display whenever pediatric pads are applied to the device. In case of pediatric ALS treatment attended by two or more healthcare professionals with a duty to respond, with this option they can pass to a CPR ratio of 15:2 (compression : rescue breaths).
- "CPR Messages" option is available only for ***SAVER ONE P***. Select OFF if you don't want to be guided for Cardiopulmonary Resuscitation, with voice messages and metronome during the treatment. CPR guidance is given only in AED mode and when the device is using in manual mode that's automatically OFF.

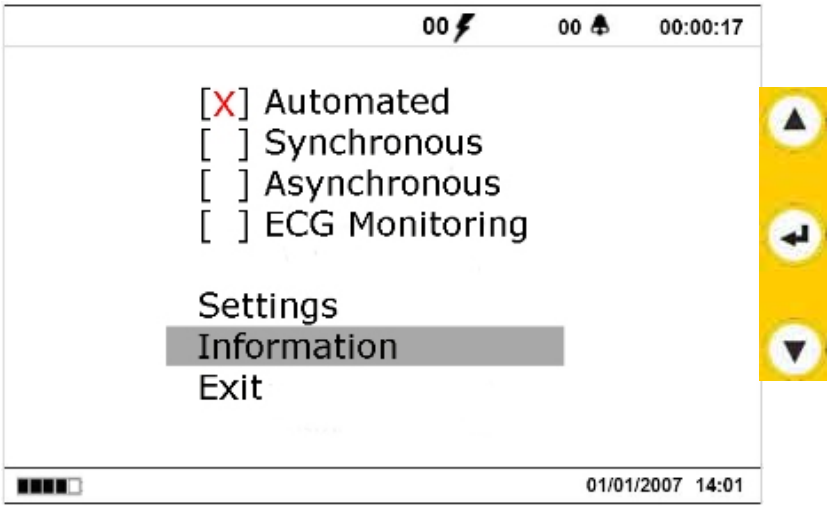
e) Select "Exit" to terminate and confirm the new chosen configuration

5.2 Device Information

To get information on the battery, the software and the model number of the device:

a) Push the "Enter" button

b) Navigate "Down" pressing till to select "Information" and push the "Enter" button to confirm



There you will have the model and the serial number of the device and the version of the software.

Information	
Model Number	0
Product Number	00000000000
Software Version	00.00.00000.00
Power Supply	
Exit	

- Production information
- Production information
- Software version number
- Choose to get information on Power Supply

5.3 Power Supply Information

Furthermore you can have information on the type of power supply applied to the device.
Navigate till to select "Power Supply" and push the "Enter" button to entry and get the following information:

Power Supply	
Type	Rechargeable
Capacity	70%
Charging Count	4
Voltage	22.6 V
Exit	

- Disposable or Rechargeable
- Remaining battery capacity (percentage)
- Charging count (only rechargeable)
- Voltage

- If, instead of the remaining capacity (70%), will appear question marks (??) it means that the battery is failed and needs service.

6 Lifesaving Treatment with AED (Automated Mode)

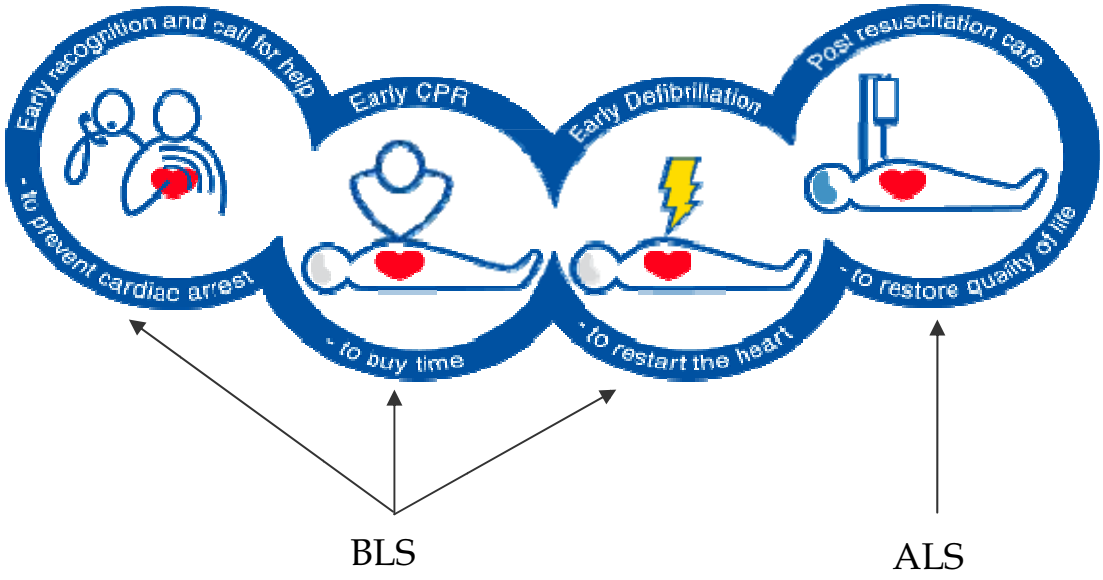
When the patient is a person afflicted by SCA (sudden cardiac arrest) you must follow acting sequences recommended by American Heart Association (AHA) and European Resuscitation Council (ERC).

- A CPR (cardiopulmonary resuscitation) and the use of an AED should be done only by trained rescuers that previously attended to basic or advanced life support courses (BLS or ALS) and been trained to use a defibrillator.

6.1 Chain of Survival

In case of SCA emergency, the following steps called chain of survival are vital for successful resuscitation.

CHAIN OF SURVIVAL



I. **Early Recognition**: Emergency recognition and call for help (call the local emergency phone number)

II. **Early CPR**: Start bystander CPR (cardiopulmonary resuscitation)

III. **Early Defibrillation**: Give an electric defibrillation shock

IV. **Advanced Support**: Transfer the patient to the nearest hospital for a post resuscitation care

6.2 Using the Device

- AHA and ERC guidelines recommend CPR before defibrillation. Rescuers begin CPR if the victim is unconscious or unresponsive, not moving and not breathing.
- They give CPR with a ratio of 30 chest compressions (almost 2 compressions/second) followed by 2 breaths (1 second each ventilation) and will continue for 5 cycles (approximately 2 minutes).
- That's a BLS (basic life support) technique used by lay rescuers or lone rescuers to resuscitate infant, child or adult victim (excluding newborns).
- For pediatric ALS (advanced life support), two or more rescuers with a duty to respond should use a ratio of 15 compressions to 2 rescue breaths.

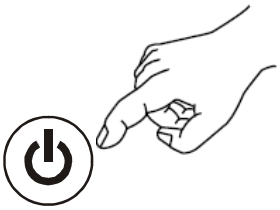
- During the defibrillation the operator or other assigned personal and/or standing people must keep away from the patient avoiding the contact with:
  a) patient's body and exposed parts of it as skin or limbs
  b) conductive liquids as gel, blood or infusion solutions
  c) metallic objects linked to the patient that could act as conductors for the electrical defibrillation, as stretcher or bed structure
- Remove from the patient any other electrical medical device which could be not resistant to the electrical defibrillation done using the device
- Make sure that during the defibrillation the patient is not placed down on a wet surface

<u>Here are listed the operative steps for a lifesaving treatment with the device</u>

6.3 Turn On the Device

Press the button ON/OFF to turn on the device

All models starts in Automated Mode (AED) whenever turned on.



The device activates automatically in sequence the following advice indicators and acoustic signals/messages:

- Prolonged BEEP sound
- "TAC-TAC" sound for automatic self-tests
- Prompt ***"place defibrillation pads"***
- Status LED lights fixed green

- The prompt ***"place defibrillation pads"*** is repeated until the pads will be connected to the device and to the patients' chest in a properly manner.

6.4 Get the Patient Ready

Release clothes from the chest of the patient to facilitate the positioning of the electrodes.

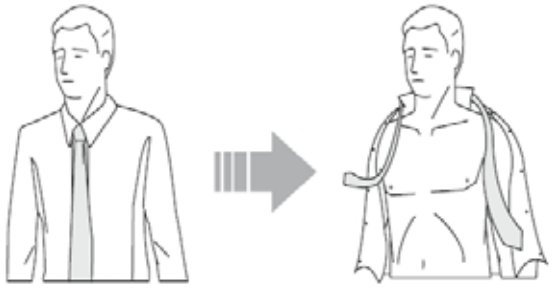
Patients with a hairy chest have air trapping beneath the electrode and poor electrode-to-skin electrical contact. This causes high impedance, reduced defibrillation efficacy, risk of arcing from electrode to skin and electrode to electrode and is more likely to cause burns to the patient's chest.

Undress the patient

- Do not waste time to undress the patient. If necessary cut or rip the clothes.

Cut hair on the chest

- Rapid shaving of the area of intended electrode placement may be necessary, but do not delay defibrillation if a shaver is not immediately available.

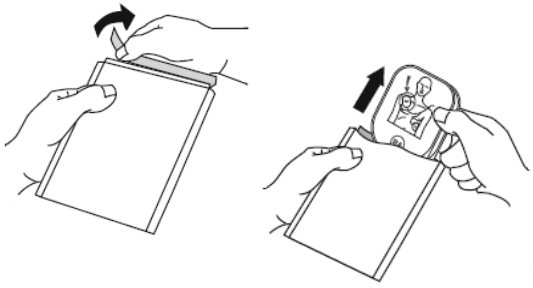


6.5 Connect Electrode Pads

Electrode pads are single-patient devices. Use new and not damaged electrode pads for each patient.

Open pads packaging

- Use electrode pads before its expiring date.
- Before using the electrode pads verify the integrity of the cable and connector.



Connect pads to the device

- Plug the connector of the pads directly into the device.

Connecting pediatric pads

- When pediatric pads are connected to the device you will be informed by the prompt: ***"pediatric mode"***.
- By using the pediatric pads, the device will automatically reduce the energy to 50J.

6.6 Place Electrode Pads

Adult and Pediatric electrode pads are multifunction, single-use, self-adhesive and pre-gelled. They are supplied completed with cable and connector.

Remove protective covers

- Before using the pads, verify the integrity of their surface and its cable. If damaged, don't use them and take a new box.
- Peel off the protective cover from the pads only when you are ready to apply them.

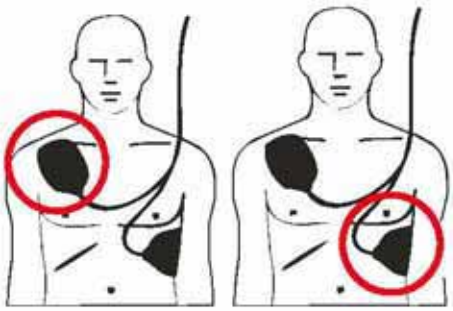
To place electrode pads in a correct way is essential to determine a decisive rhythm analysis and to decide if shock is advised or not.
The device highlights with the following prompt: "***Place Defibrillation Pads***"

Place electrodes in the conventional anterolateral (sternal-apical) position:

1. The sternal electrode is placed to the right of the sternum, below the right clavicle;
2. The apical electrode is placed in the left midaxillary line (approximately level with the V6 ECG electrode or female breast). It is important to place it sufficiently laterally.

Apply the pads

- Apply the pads following instructions given on its back side label.
- Place the pads firmly to the patient's bare chest in the anterolateral position.
- Rub both pads on the chest for a perfect adhesion removing air bubbles.



Other acceptable pad positions include:
a. Each electrode on the lateral chest wall, one on the right and the other on the left side (biaxillary);
b. One electrode in the standard apical position and the other on the right or left upper back;
c. One electrode anteriorly, over the left precordium, and the other electrode posterior to the heart just inferior to the left scapula (anteroposterior position).

- If the patient's chest is too tight (especially for children), and there is a danger of charge arcing across the pads, apply them in the anteroposterior position.
- Do not place electrode pads if the patient has nitroglycerin band-aid on his chest. First remove them from his chest and then place the electrode pads. On the contrary it may cause explosions.

- Do not use pediatric electrode pads on adult patients. Their reduced energy will be not enough.
- Do not apply electrode pads directly on implanted pacemaker to avoid damages.
- Air bubbles between skin and pads during the defibrillation could cause burns to the patient. Be careful in placing pads avoiding air bubbles and make pads adhere completely to the skin.
- Do not use electrode pads if the gel is dry.
- Be sure that electrode pads do not touch or get in contact with any trans-dermal band-aid or tampon and with any ECG electrode or derivation of.

- The device checks the conductivity of adhesive electrodes (pads) regarding the gel contact. In any case please visually inspect the electrodes for scratches or piecemeal dryness.
- If the electrodes are not placed within 3 minutes of activating, the device will disarm itself automatically. Throughout this period the device will provide voice guidance for placement of the electrodes.

6.7 Adult or Pediatric Electrode Pads

If you are going to treat an adult patient you should use Adult Pads (F7958/AMBI).

Adult Patient is a victim**:** ***>8 years old or weight >25kg (55 pounds)***

If you are going to treat an infant or a child patient you should use only Pediatric Electrode Pads (F7958P/AMBI).

Pediatric Patient is a victim**:** ***1÷8 years old and weight <25Kg***

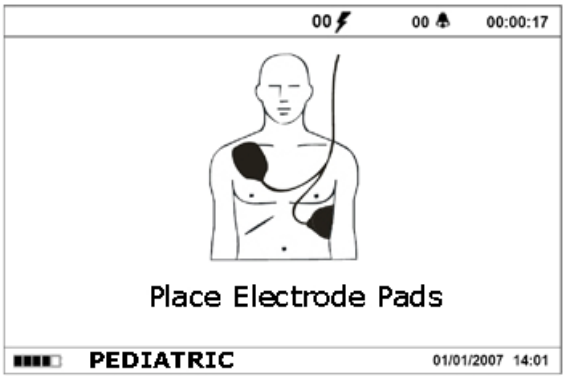
- By using pediatric electrode pads the device will automatically reduce the energy to 50J.
- Do not use pediatric electrode pads on adult patients. Their reduced energy will be not enough for an adult save-life treatment.

Once Pediatric Pads are correctly connected, the operator will be informed that the Pediatric Mode is ON and the device is acting with reduced energy level.

This information is given by the prompt: ***"pediatric mode"***

Devices with the display will:
- show the text message "PEDIATRIC" displayed during all the pediatric treatment
- have the option to vary the "CPR Ratio" to 15:2 for pediatric ALS rescuers

Pediatric Mode is ON



- A patient with an age among 1÷8 years old and a weight less than 25Kg must be treated only with pediatric electrode pads.
- Do not use pediatric electrode pads with adult patients.

6.8 Rhythm Analysis

When electrode pads are properly applied the device starts automatically to perform the rhythm analysis.

From this moment is forbidden to touch the patient.

This moment is highlighted by the device throughout the following prompt:

"Do not touch patient. Analysing Heart Rhythm"

The software algorithm analyzes several features of ECG in an extremely accurate way checking VF (ventricular fibrillation) or VT (ventricular tachycardia). This will last from 5 to 15 seconds.

When VF or VT is detected, the device suggests the rescuer to give a shock.
On the contrary drives the rescuer to the CPR.

When VF or VT has not been detected, the device points up this case throughout the prompt:

"No shock advised"

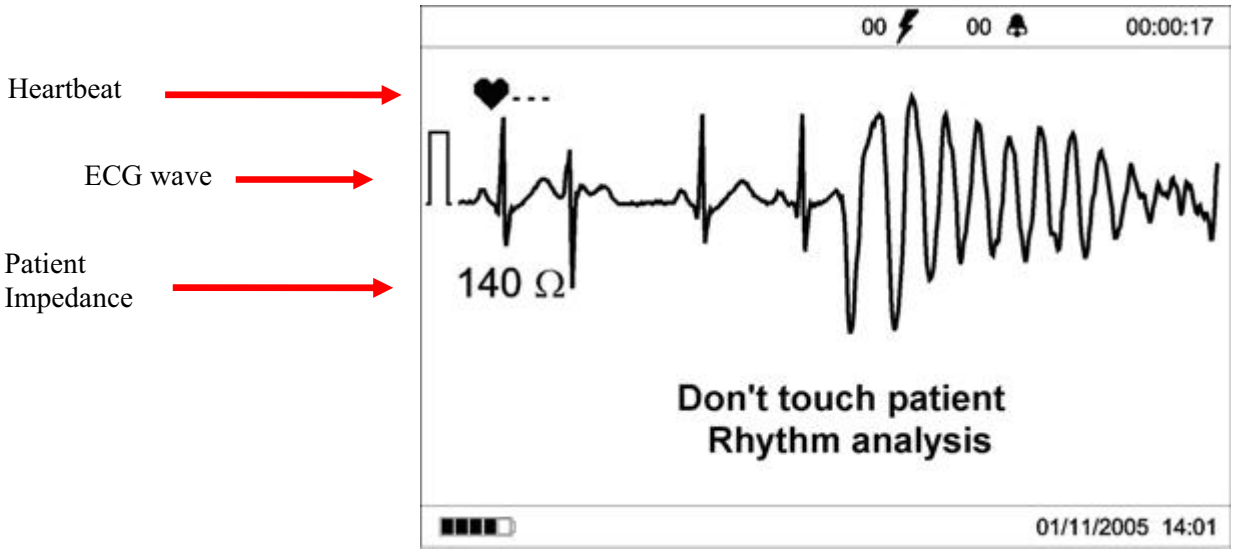
And drives the rescuer directly to the CPR with the prompt:

"Begin cardiopulmonary resuscitation, now"

- During ECG analysis the operator or other assigned personal and/or standing people should keep away from the patient avoiding the contact with:
  a) patient's body and exposed parts of it as skin or limbs
  b) conductive liquids as gel, blood or salt solutions
  c) metallic objects linked to the patient that could act as conductors for the electrical defibrillation, as stretcher or bed structure
- Move or transport the patient during rhythm analysis may generate late and/or wrong diagnosis. Do not move the patient during rhythm analysis enabling the device to confirm evaluation of ECG feature before giving the shock.
- For security reasons some heart rhythm with very low frequency or extension could not be read by the device as VF or VT to be treated

- Keep surveying the patient during the whole save-life treatment.
- The patient could reawaken from unconsciousness status at any moment and not be treated anymore. In this case stop with defibrillation procedures.
- The device never stop to analyze ECG even when is charging to give the shock. If the patient will reawaken during this short time, the device immediately recognizes this new event disarming itself and guiding the rescuer to CPR instead of the shock.

- Devices with the display will give more information as: heartbeat rate (BPM), patient impedance value and will show the ECG wave. The display will appear as shown below.



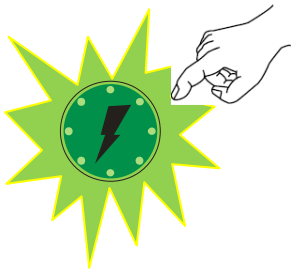
6.9 Defibrillation

When the device clearly checked VF or VT, a shock is immediately recommended.
This point is highlighted by the device throughout the prompts:

"Shockable rhythm detected, shock advised"

"Stay clear of patient. Charging"

By this moment the device starts charging.
This is introduced throughout a continuous raising BEEP and will last few seco nds. (max 9 sec in full charge)



Now the device is ready to give the shock.

The green shock button starts flashing and a prompt says:

"Press shock button"

When the shock flashing button will be pressed, the device gives an electric shock to the patient and highlights this moment with the prompt:

"Shock delivered"

After the shock, the green button stop flashing and the device drives the rescuer to the CPR (Cardiopulmonary Resuscitation) with the prompt:

"Begin cardiopulmonary resuscitation, now"

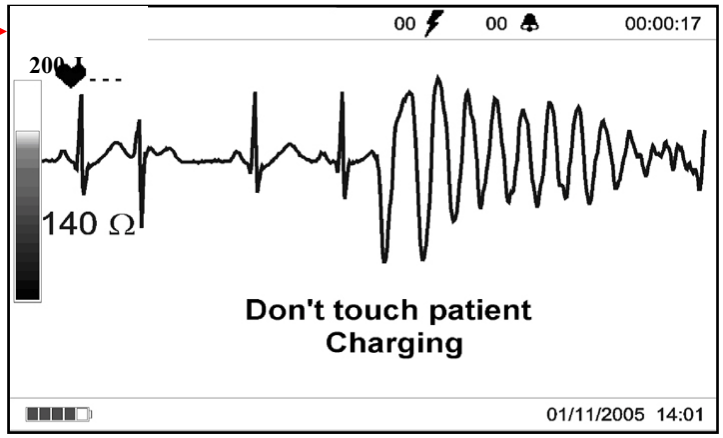
- If the green flashing shock button is not pressed during the 15 seconds after the prompt, the device will automatically disarm itself and is progressing to guide the rescuer to CPR giving the following messages: ***"Shock button not pressed" - "Cardiopulmonary resuscitation"***

- No one must touch the patient during the shock.
- The shock could damage the operator or other assigned personal and/or standing people.

- Devices with the display will show a charging bar and the energy level.

Energy to Delivery

Charging Bar



6.10 CPR Procedure

After given the shock, the device invites the rescuer to perform CPR (Cardio Pulmonary Resuscitation).

- CPR is suggested even when a not shockable rhythm has been detected or even if the shock button has not been pressed in time.

Cardiopulmonary resuscitation is highlighted by the prompts:

"Begin cardiopulmonary resuscitation, now"

"Two minutes"

"Press patient's chest down fast"

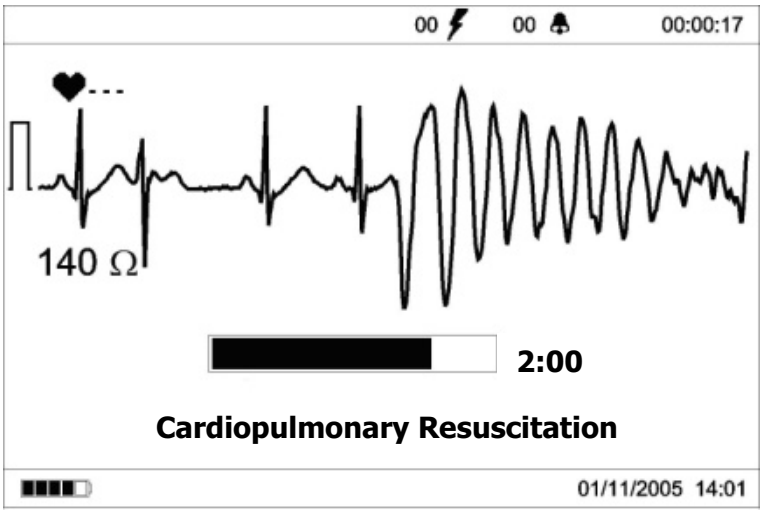
A metronome will guide the rescuer giving a "BEEP" sound for correct time to compressions.

After each compressions cycle the device invites the rescuer to inflate with the prompt:

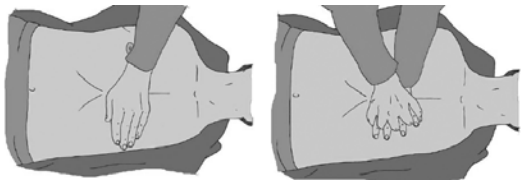
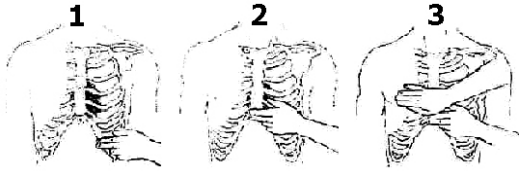
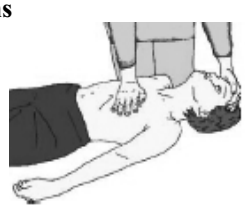
"Give two breaths"

- AHA and ERC 2010 Guidelines suggest the following ratio for compressions cycles:
  a. Ratio 30:2 (30 compressions to 2 inflates) for lay rescuers or lone rescuers on infant, child and adult victim (excluding newborns) for 2 minutes
  b. Ratio 15:2 (15 compressions to 2 inflates) for pediatric life support attended by two or more rescuers with a duty to respond
- A prolonged intense CPR with pads placed on the chest of the patient may damage them. In this case replace the pads

- During the CPR, the devices with the display will show a timing bar starting the 2 minutes countdown (see picture below).
- Factory default CPR ratio is 5 cycles at 30:2 conformed for lay rescuers or lone rescuers attended to resuscitate infant, child or adult victims (excluding newborns). Into the menu of devices with the display is possible to select the ratio 15:2 suitable for rescuers with a duty to respond in pediatric life support.



Consult the below "CPR procedure" suggested by AHA and ERC 2010 Guidelines:

	Description	Acting with ADULT patient	Acting with PEDIATRIC patient
1	Voice/Text prompts: "**Cardiopulmonary resuscitation**" (CPR) "**Two minutes**" "**Press patient's chest down fast**"	Kneel by the side of adult victim and start chest compressions as follows: 1. Think to an imaginary line between two nipples and place the heel of one hand in its centre, that supposed to be the centre of victim's chest 2. Place the heel of the other hand on top of the first hand and interlock the fingers of your hands Ensure that pressure is not applied on the victim's ribs **1** **2** 	For pediatric patient the compression point is the lower third of the sternum. Follows this step to find it: 1. Locate the xiphoid (sternum bottom part) letting index and middle finger run along the right arch of the rib cage towards the centre of the chest 2. Leave two fingers on the xiphoid transverse to the sternum 3. Place the heel of your hand close to index finger (higher than xiphoid) over the lower third of the sternum 
2	Heartbeat: A BEEP metronome gives time for each single compression Ratio 30:2 attended by lay rescuers or lone rescuers on infant, child and adult victim (excluding newborns) Ratio 15:2 for pediatric life support attended by two or more rescuers with a duty to respond	Position yourself vertically above the victim's chest with your arms straight. Compression must be perpendicular to sternum having fulcrum your hips. **Give chest compressions**  Press down on the sternum 4-5 cm. Then release the pressure without losing contact between your hands and the sternum. Repeat at a rate of about 100 compression per minute. Compression and release should take the same time.	Position yourself vertically above the victim's chest with your arm straight. Compressions could be done with only one hand perpendicular to sternum. **Give chest compressions** 1 or 2 hand technique is up to the rescuer preference and to the patient's size.  Compress the lower third of the sternum. Press sufficiently to depress the sternum by approximately one third of the depth of the chest. Repeat at a rate of about 100 compression per minute. Compression and release should take the same time.
3	Voice/Text prompts: "**Give two breathes**"	After compressions open the airway using head tilt and chin lift 	
		Give two rescue breaths: close the nose pinching its soft part using the index finger and thumb of your hand on the forehead. Maintaining chin lift allow 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). Move your mouth away and watch for the victim's chest to fall as air passes out. Take other normal breath and blow into the mouth once more, to achieve a total of two effective rescue breaths. 	
4	Repeat Sequences:	Give 5 cycles of chest compressions and rescue breaths (CPR for 2 minutes)	

7 Manual Mode (SAVER ONE P)

- Manual Mode is available only for ***SAVER ONE P***.
- Using the device in manual mode is more complicated and need more experience from the emergency rescuer.

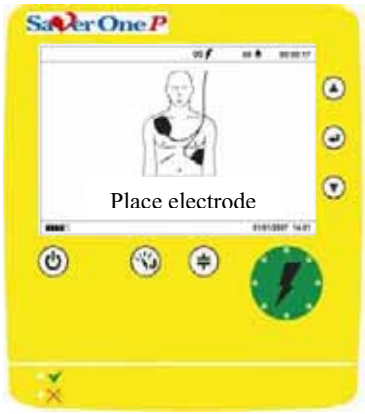
- You must be sure that the patient needs the shock by monitoring carefully the hearth rhythm of the patient given on the display.
- If the hearth rhythm suggests a shock, you can go for choosing the energy level required and decide when deliver it by pressing the charging button.

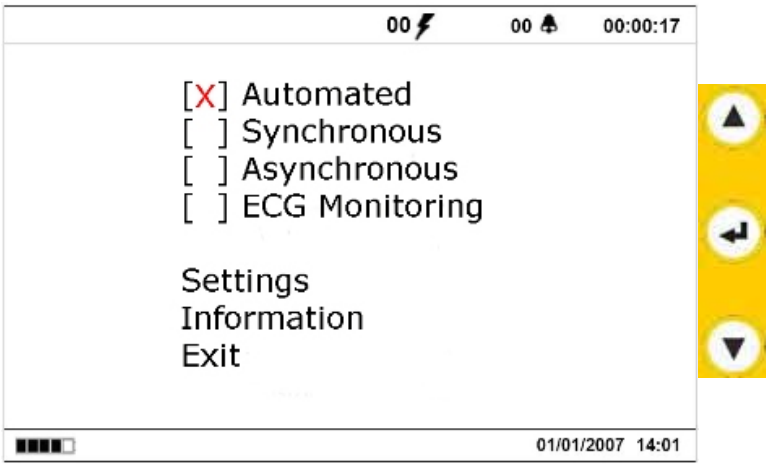
- Manual mode can be used only by professional rescuers.
- If you are not sure on what to do is preferable to leave the device in AED mode and work with the standard lifesaving treatment.

- During the lifesaving treatment the defibrillator algorithm and shock sequences will be the same in Manual or Automated mode.
- In Manual mode CPR guidance is automatically OFF.

<u>Any time you turn on the device, it's always starting in AED mode.</u>

To change for manual mode, the professional rescuer must push the "Enter" button 





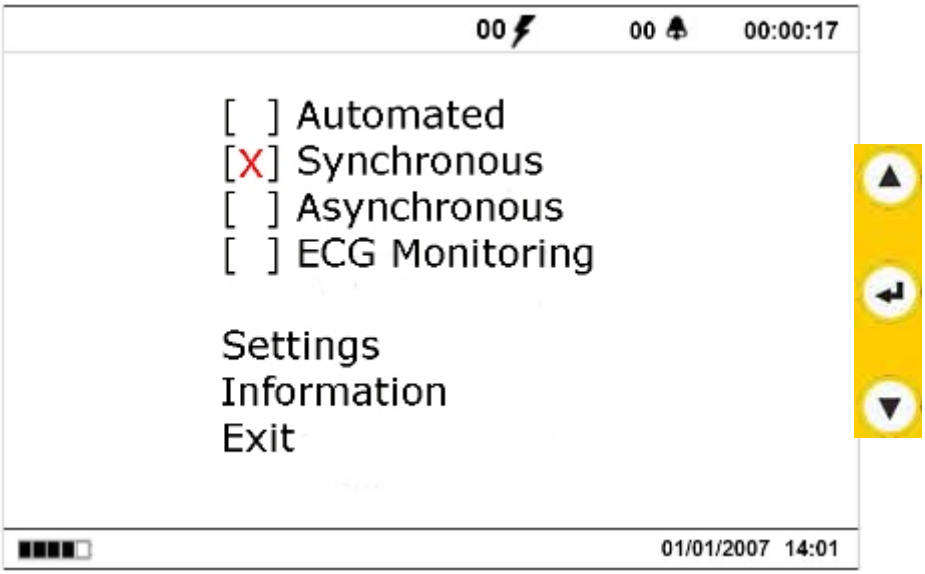
And select the modality desired between:

I. **AUTOMATED (per default)**
II. **SYNCHRONOUS**
III. **ASYNCHRONOUS**
IV. **ECG Monitoring**

- Automated mode is given per default whenever the device is turned on.
- For other modalities you need a password.

7.1 Synchronous Cardioversion

To choose this modality go down pressing ▼ till to select "Synchronous" and push "Enter" button ↵ to confirm. Then enter the password (section 9).

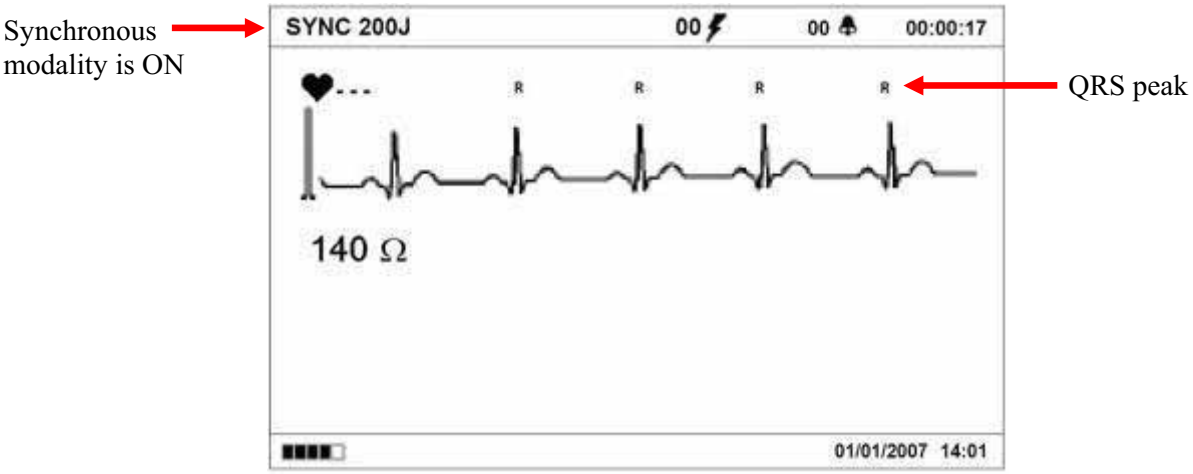


With this modality the device will perform automatically a synchronized electrical cardioversion.

It will allow the device to deliver the shock at R wave of the QRS complex on the ECG.

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

The display will appear as shown below:

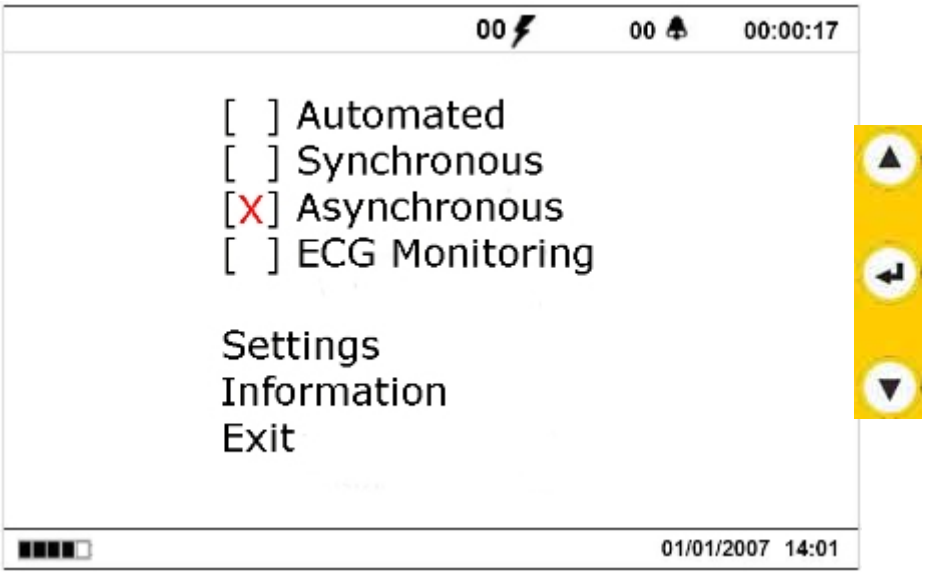


- If you are using the synchronous cardioversion as the sole procedure, the shocks can be delivered in conjunction with drug therapy till attaining a normal heartbeat.
- Keep monitoring the victim after the procedure to ensure stability of his sinus rhythm.
- Synchronization can be difficult with pulseless VT or VF. In this case give unsynchronized shocks avoiding prolonged delay in restoring sinus rhythm.

7.2 Asynchronous Cardioversion

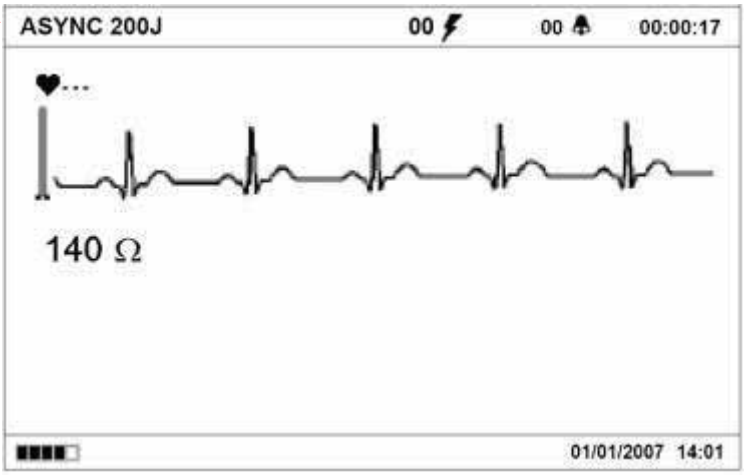
To choose this modality go down pressing till to select "Asynchronous" and push "Enter" button to confirm.

Then enter the password (section 9).



The display will appear as shown below:

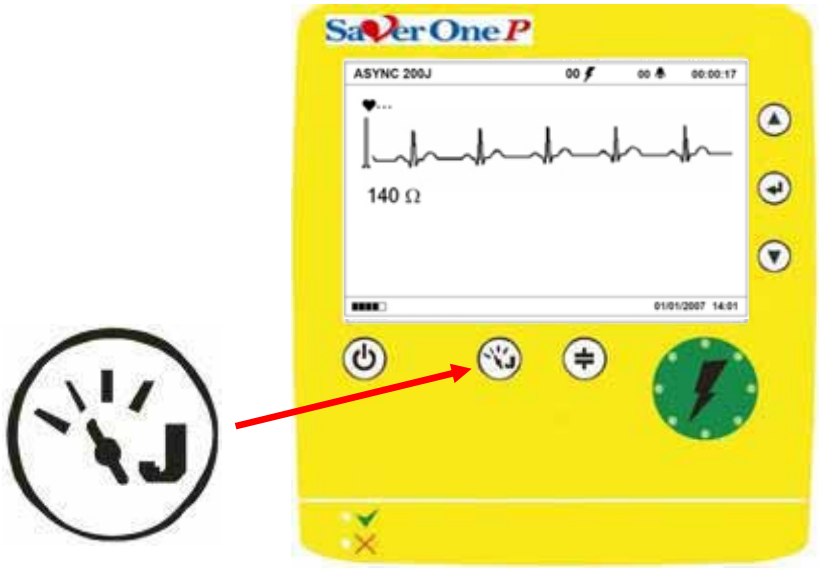
Asynchronous modality is ON



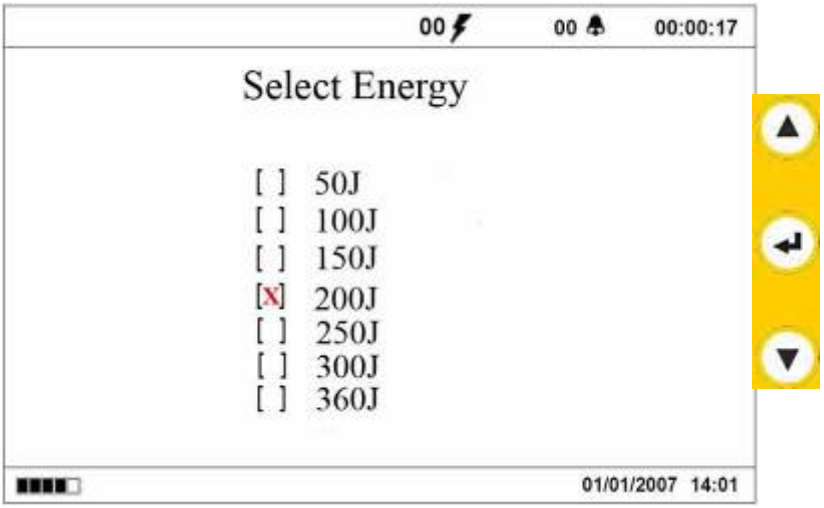
7.3 Manual Defibrillation

Once selected Synchronous or Asynchronous modality you can choose the energy level to deliver.

Push the "Energy" button to enter the menu and select the energy level required

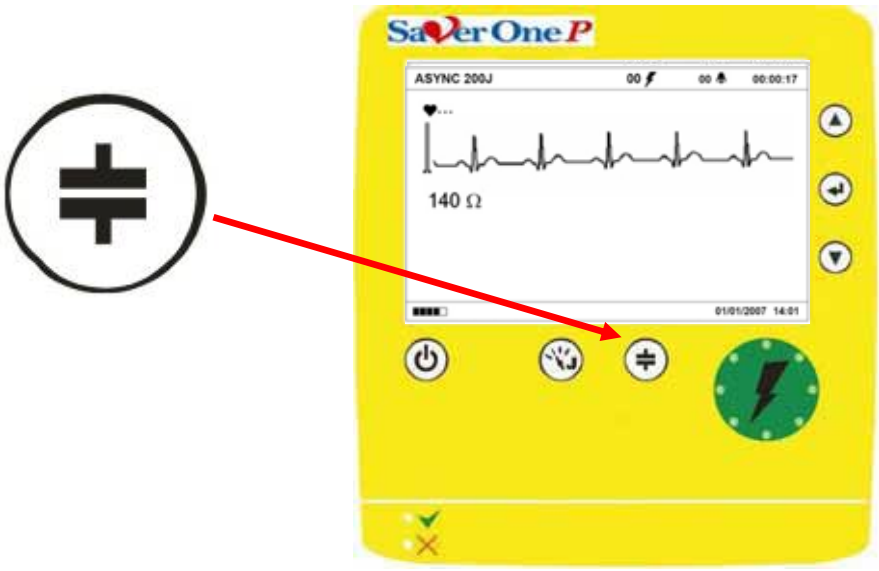


Navigate Up/Down till to select the energy level you wish and press the "Enter" button to confirm.

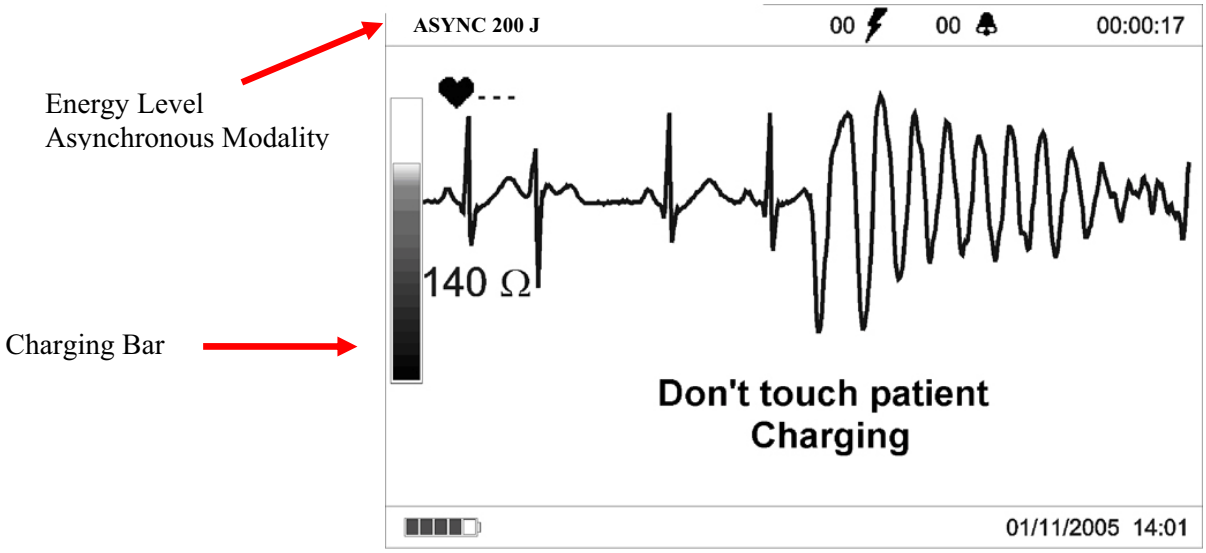


- Power Version will have energy selection till 360J. Standard version till 200J
- From this moment the rescuer can decide to deliver the shock at any time simply pushing the "Charging" button

Push the "Charging" button to get ready for the shock

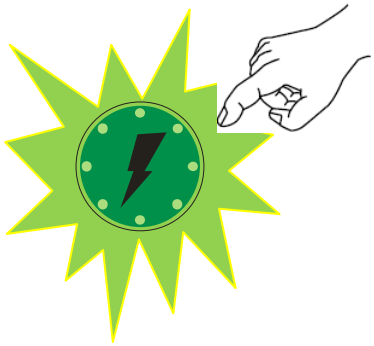


By this moment the device starts charging. This is introduced throughout a continuous raising BEEP and the display will show a charging bar with the chosen energy level:



The charging will last few seconds.

After that, the device is ready to give the shock !

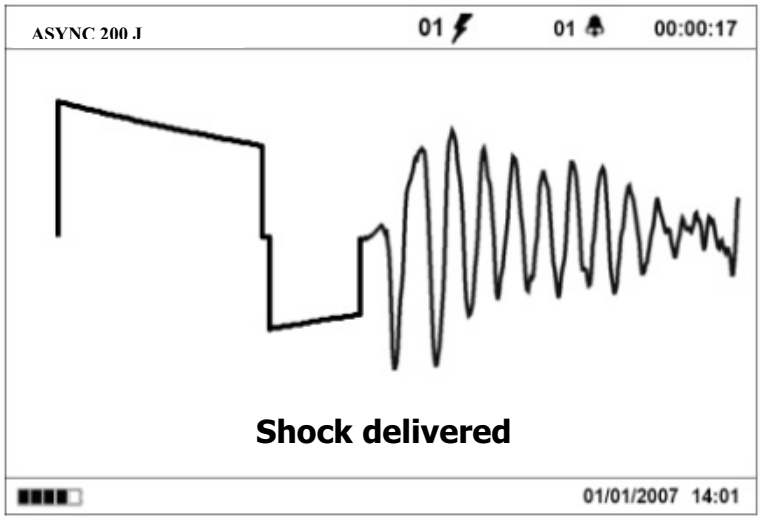


The following prompt will suggest you to give the shock:

"Press shock button"

When the shock flashing button is pressed, the device gives an electric shock to the patient and highlights this moment with the following text and voice message:

"Shock delivered"



- No one must touch the patient during the shock.
- The shock could damage the operator or other assigned personal and/or standing people

If the green shock button will not be pressed within 15 seconds, the device disarm automatically itself advising with the following voice and text message:

"Shock cancelled. Shock button not pressed"

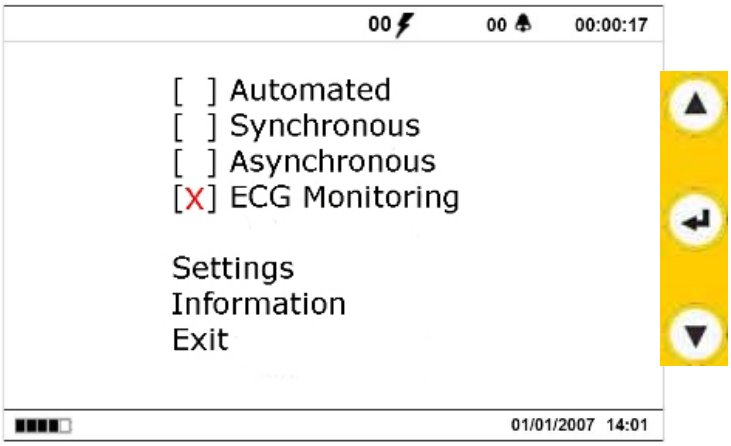
8 ECG Monitoring

- The modality "ECG Monitoring" is available for ***SAVER ONE D*** and ***SAVER ONE P***.
- To enter this modality you need to put the password (section 9).
- In this modality the device cannot give any defibrillation. It will keep on analyzing only the patient ECG rhythm.

To choose this modality go down pressing ▼ till to select "ECG Monitoring"

Then push the "Enter" button ↵ to confirm.

Then enter the password (section 9).



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

a. Multifunction Electrode Pads
b. ECG patient cable (Lead II, standard IEC)

- In this modality the device does not allow the selection of energy, cannot be charged and does not give any shock
- This modality is only intended for specialized medical personnel and is password protected

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

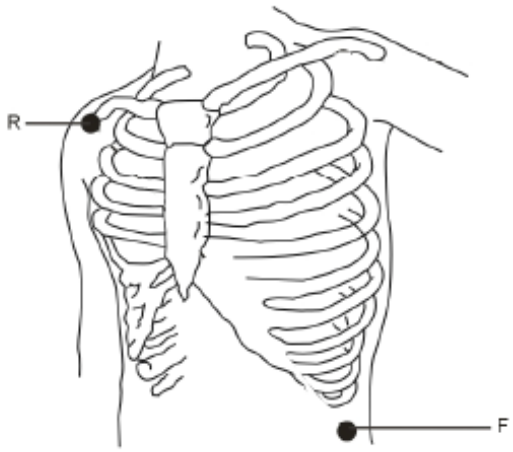
For the application of the Multifunction Electrode Pads please refer to the previous 6.5 section.

For the application of the ECG Cable Electrodes identify anatomical traits plans and devoid of muscles and follow these steps:

a. Eliminate the presence of hair or scalp or dry skin at the due point. Clean completely the point of application through solution mild soap and water (not used ether or pure alcohol, because the impedance increase occurring) and dry completely before application.
b. Connect the ECG cable to the device and fix the cables to ECG electrodes
c. Put the conductive gel to the electrodes
d. Place the electrodes "R" and "F" to the patient as follows:

"R" (red) electrode:
to be placed near the right shoulder directly under the Clavicle

"F" (green) electrode:
to be placed near the left side of Hypogastric into the left lower abdomen quadrant (LLQ)

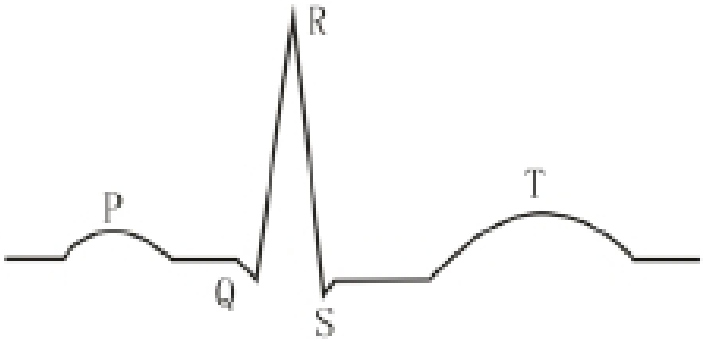


The table below shows the identification card of each electric cable. There is also the code on the chromatic regulations respectively American (AHA) and European Union (IEC):

AHA		IEC	
CARD	**COLOUR**	**CARD**	**COLOUR**
RA	White	R	Red
LL	Red	F	Green

The regular QRS complex has the following characteristics:

- ✓ Depth in vertical direction, brevity in horizontal direction and no peaks down
- ✓ "R" wave developed completely above or below the base line
- ✓ "P" peak not greater than "R"
- ✓ "T" wave less than one third the height top of "R"
- ✓ "P" wave size much smaller than "T"



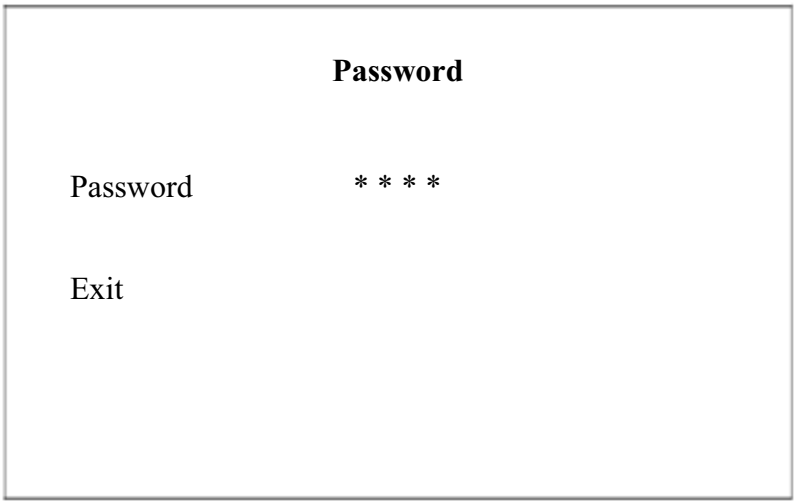
Using the ECG Monitoring modality, the device can be connecting to a thermal printer via IrDA Port for printing directly the ECG in real time.

Alternatively, with the memory card into the device, you can print saved ECGs (registered with different date) recalling them from the menu and print down in any moment you need.

9 Password

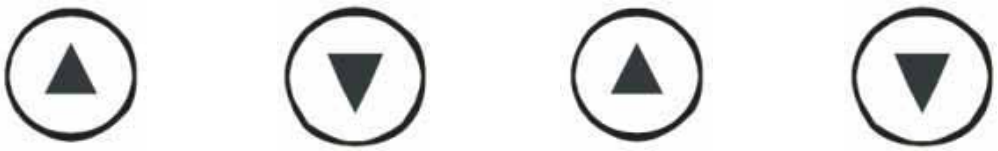
- Password is requested by the devices with the display to enter the following modalities:
  I. Synchronous modality (***SAVER ONE P***)
  II. Asynchronous modality (***SAVER ONE P***)
  III. ECG Monitoring mode (***SAVER ONE D*** and ***SAVER ONE P***)

This is what is showing on the display when the device requires the password:



To put the password you must push in progression the following 4 buttons:

PASSWORD:



1) UP **2) DOWN** **3) UP** **4) DOWN**

10 Voice and Text Prompts List

Here the list of all voice and displayed text prompts with related descriptions.

- All voice prompts are given also as text messages into display of the models ***SAVER ONE D*** and ***SAVER ONE P***.
- For the same models, in some cases you will have just text prompts. Below *(in round bracket)*.

Voice and/or *(only Text)*	**Description**	**Saver One**	**Saver One D**	**Saver One P**
If you can hear this message	Keyboard buttons and software diagnostic. This test is done each time a new or replaced battery is applied to the device.	√	√	√
Press SHOCK button	The shock button on the keyboard is blinking and the operator is invited to press it to check its functionality.	√	√	√
(Press UP button)	The operator should press the buttons in sequence to finalize keyboard diagnostic.			√
(Press DOWN button)				√
(Press ENTER button)				√
(Press ENERGY button)				√
(Press CHARGING button)				√
Place defibrillation pads	Advise to connect the cable to the device and to place pads on the victim's chest. The prompt is repeating till a good connection is done.	√	√	√
Pediatric mode	Advise that the pediatric mode is ON and the device is acting with reduced energy. Text prompt on devices with display will remain displayed during all the treatment time.	√	√	√
Do not touch patient	Warn that the operator or other assigned personal and/or standing people should not touch the patient.	√	√	√
Analysing Heart Rhythm	The device is performing rhythm analysis. It will last from 5 to 15 seconds and the operator will have task that no one would touch the victim.	√	√	√
No shockable rhythm detected	In case of no fibrillation: the device informs that no VF or VT has been detected. The shock is not needed and the operator is invited to perform CPR.	√	√	√
Fibrillation detected Shock advised	Advise that VF or VT has been detected and the device will get ready for the shock.	√	√	√
Do not touch patient Charging	The device starts charging for the shock. The operator has the task that no one should touch the victim.	√	√	√

Voice and/or *(only Text)*	Description	Saver One	Saver One D	Saver One P
Press shock button	The green shock button starts blinking and the operator must press it to give the shock to the victim. The operator has always the task that no one should touch the victim.	√	√	√
Shock delivered	Inform that the shock has been delivered to the patient.	√	√	√
Shock button not pressed	Inform that the shock button has not been pressed during last 15 seconds after blinking and the device has automatically disarmed itself.	√	√	√
Cardiopulmonary resuscitation	Inform that the operator must start CPR (cardiopulmonary resuscitation).	√	√	√
Two minutes	A full cycle of CPR should last 2 minutes	√	√	√
Press patient's chest down fast	Inform that the operator should make compressions on victim's chest.	√	√	√
Give two breaths	Warn the rescuer to give 2 rescue breaths (one second each) to the victim.	√	√	√
Press patient's chest down fast	The cycle of compression:breaths is carried on for 5 cycles (2 minutes).	√	√	√
(AUTO)	Inform that the automated mode (AED) is on.		√	√
(SYNC)	Inform that the synchronous mode has been selected.			√
(ASYNC)	Inform that the asynchronous mode has been selected.			√
(ECG)	Inform that the ECG monitoring mode has been selected.		√	√
(Password)	Inform that the operator need to insert the password to get into specific modalities of the device.		√	√
(Energy selection)	Inform on the energy level selected.			√
Low battery	Warn that the battery level is not enough to go on with the treatment. Inform to replace the battery.	√	√	√
Replace battery				
Device failed	Warn that there is an error. Try to restart the device. Turn the device off and turn it on again. If you hear this prompt again, turn off the device, take out the battery and install it again. Only after that turn the device on. If you still hear the prompt apply to the service centre.	√	√	√
Internal error				

11 After Use

11.1 After each employ

Check if the device has any damage marks or contaminations.

Verify that status green LED near this symbol ✔ keep flashing. That's indicating the device is in good condition and ready for next rescuing operations.

Replace used electrode pads with a box of new pairs.

Place the device in its carrying bag or into the wall cabinet or in a safe place.

11.2 Data recordings

To record data and events of the treatment you need to insert a Memory Card into the device following this procedure:

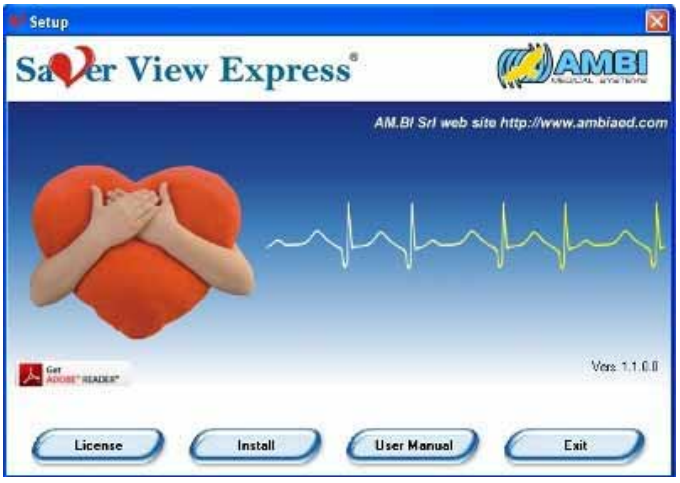
a. Turn off the device and remove the battery
b. Insert the Memory Card with its contacts up
c. Apply the battery back to the device
d. Turn on the device for recording data

- Use only Memory Card approved by AMI ITALIA.
- Memory Card should be formatted before use.
- Turn off the device before removing the battery and the Memory Card. There is the risk of unreadable and/or loss of data in the case the Memory Card is removing before turning off the device (for example just detaching the battery).

Recorded ECG data and events of the treatment can be transfer to a PC/Laptop and be showed and managed by means of a dedicated software "Saver View Express".

Recorded data referring to each treatment/patient can be saved and reviewed every time you may need. Data evaluation will be useful for administrative or legal purpose.

For data transmission to PC/Laptop and their management throughout the dedicated software "Saver View Express" please refer to the manual given with the software.



12 Maintenance & Troubleshooting

12.1 Controls

The device performs automatic self-tests and whenever finds error, the green Status LED stop flashing.

Control periodically the Status LED  and the Battery LED  of device to be sure that is always ready for use.

12.2 Ordinary maintenance

The device has been designed to require limited maintenance, nevertheless in order to ensure the reliability of the equipment the user must regularly perform some simple maintenance operations.

Daily	Monthly	After each use	Suggested actions
√	√	√	Check if the Status LED blinks green
√	√	√	Check if the Battery LED is off
	√	√	Check the integrity of the device and its accessories
		√	Electrodes substitution
	√		Check the electrodes expiring date
		√	Check the XD memory card (when installed)

12.2.1 Check Status LED

The green Status LED  indicates if the unit is ready or not to be used.

A device ready for use must have the above status LED blinking green.

Please see the section 12.6 of this user manual or get in touch with an Authorized Service Centre in the case that the Status LED does not blink at all.

12.2.2 Check Battery LED

The red Battery LED  indicates the battery status.

A device ready for use must have the above battery LED off (not lighted at all).

If the Battery LED is lighted fixed red means that the battery must be replaced or there is a problem. Please see the section 12.6 of this user manual for possible actions to do.

In case the battery must be removed please follow the instruction described in the section 4.

- It is recommended to have one battery more (disposable or rechargeable) in order to be always able to do a lifesaving emergency treatment.

12.2.3 Check integrity of device

Carefully inspect the device and make sure that the unit is not dirty or contaminated, especially the external and internal side of the pads connector.

Please refer to the section 12.3 to follow the cleaning instructions of your device.

Please make sure that the device has not visible damage.

Carefully ensure there are no cracks or other signs of damage on the device.
In case the device has visible cracks or other signs of damage, please interrupt the use of defibrillator and contact the authorized service centre.

12.2.4 Check defibrillation pads

The defibrillation pads are disposable and must be replaced after each use.

Do not use the defibrillation pads after the expiring date given on the external side of the sealed package.

- Do not remove defibrillation pads from its sealed package before use.
- The box must be open immediately before the use, otherwise electrodes may dry up and become useless.
- Do not use defibrillation pads when its packaging is damaged.

12.2.5 Check memory card

When the memory card is inserted, the device creates an archive event file at every use.

If the unit has been used to treat the patient, the Memory Card must be removed and delivered to who will be charged to give advanced support to the patient.

Install another Memory Card before reuse the device.

Please refer to the section 4.2 of this manual to install or remove the Memory Card.

- The Memory Card is not essential for the device operating.

12.3 Cleaning the Device

The whole device, including the electrode pads connection, may be cleaned with a soft moistened cloth soaked with one of the medical detergents solutions listed below.
The following guidelines include some important factors to bear in mind.

- Do not immerse the device in any liquid
- Do not use any kind of abrasive detergents, fibers or strong solvents as well as acetone or detergents acetone based and enzymatic detergents.
- Clean the device and its connection socket with a soft moistened cloth soaked with one of the medical detergents solutions listed below:
    a) Isopropyl alcohol (a solution of approximately 70%)
    b) Soapy Water
    c) Bleach (30 ml per 1 per liter of water)
    d) Cleaners containing ammonia
    e) Cleaners containing glutaraldehyde
    f) Hydrogen peroxide
- Do not immerse any part or component of the device in the water or any other kind of liquid.
- Do not sterilize the device and its accessories.

12.4 Storing the Device

The device must be positioned in a location easily accessible and oriented in a way that the indicators (Status LED and Battery LED) are well visible.

Mainly, the device must be stored in a clean, dry and appropriate environmental temperatures condition.
Please refer to the section 2.6 of this manual.

- The $LiMnO_2$ disposable battery is given in "sleep mode" and not connected to the device.
- If you expect to stock the device (not in use) for a long period, you don't need to connect the battery.

12.5 Test Module

The following test module may be used as a foundation to draw up an operating control list.

The module must be filled up as suggested in the section 12.2 of this manual.

Flag the fields once checked.

SAVER ONE Test Module						
Grading of the product	Automated External Defibrillator					
Model Name			Version	Standard (200J)	Power (360J)	
Serial Number			Purchase Date			
Product End User						
Test Date:						
Please check if the unit and its accessories are damaged, dirty or has any kind of contamination. Clean if necessary.						
Please check that the battery pack and the electrodes are supplied.						
Please check the Status indicator						
Please check the Battery LED indicator						
Remarks:						
Checked by :						

12.6 Troubleshooting Guidelines

The following charts provides the solutions to the different kind of problems occurred during operation, recommending how to solve them up.

Descriptions	Possible Causes	Effects	Recommended Actions
Standby Mode Battery LED  Fixed Red	Low battery level	The device may turn off without any notice	Replace the battery with a new one. Where not provided with a new battery or not provided with another defibrillator, immediately start the CPR if necessary till up the rescue team occurred.
	The power unit is not well connected	The device not turns on	
Operating Mode Voice/Text prompt: Place defibrillation pads	The pads are not properly connected to the device	The device does not start analysing the hearth rhythm till a good pads connection is done	Plug again the pads connector into the device in a properly manner.
	The pads are not properly positioned on the patient		Clean or dry the chest of the patient where the pads must be placed.
	The pads are seared and not useful		Replace pads with a new pairs.
Operating Mode Voice/Text prompt: Low Battery Battery LED  Fixed Red	Low battery level	The device will turn off after 10 minutes or after delivered 3 shocks	Replace the battery with a new one. Where not provided with a new battery or not provided with another defibrillator, immediately start the CPR if necessary till up the rescue team occurred.
Device not turns on the Status LED  Blinking Green	ON/OFF switch is broken	The device cannot be used for rescue operation	Perform the CPR on the victim. Please use another defibrillator. Where not provided with another defibrillator, keep perform the CPR till up the rescue team occurred. Please contact the Service Centre.
Device not turns on Status LED  off Battery LED  off	Both the power module that the back up battery inside the device are empty	The device cannot be used for rescue operation	Perform the CPR on the victim. Please use another defibrillator. Where not provided with another defibrillator, keep perform the CPR till up the rescue team occurred. Please contact the Service Centre.
	Device Internal Error		

13 Technical Specification

13.1 Physical Features

Category	Nominal Specification	
Weight	***SAVER ONE***	***SAVER ONE D - SAVER ONE P***
with disposable battery	1,85 kg	1,95 kg
with rechargeable battery	2,00 kg	2,10 kg
Dimension	26,5 x 21,5 x 7,5 cm	
External Case	Medical Grade ABS	

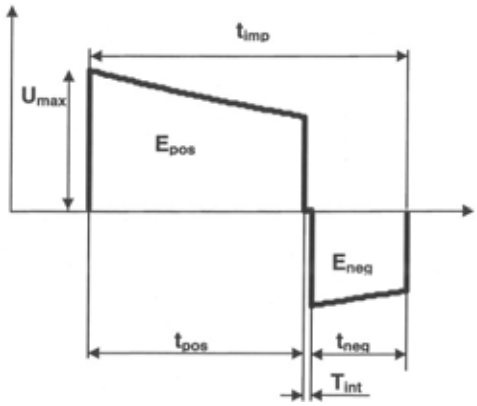
13.2 Environmental Requirements

Category	Nominal Specification
Operating Temperatures and Humidity (without battery and defibrillation pads)	Temperature: 0 ~ +50° C Humidity: 0 ~ 95% (relative humidity not-condensing)
Temperature and Humidity during inactivity period (without battery and defibrillation pads)	Temperature: -35 ~ +60° C (test for transport condition: 2 hours in a climatic chamber, then 4 hours at normal temperature) Humidity: 0 ~ 95% (relative humidity not-condensing)
Altitude	Currently unspecified
Shock and drop resistance	Conform to the EN60601-1
Vibration	MIL-STD-810F,Method_514.5
Protection	Conform to the IEC 60529 class IP54; Waterproof and dustproof with installed battery
Electrostatic Shocks	Conform to the EN 61000-4-2:2002 (3), Security Level 4
Electromagnetic Interference (Radiation)	Conform to the standard limit of EN 60601-1-2 (2002 (3)), method EN 55011:1998, group 1 level B
Electromagnetic Interference (Protection)	Conform to the standard limit of EN 60601-1-2 (2002 (3)), method EN 61000-4-3:1998 level 2

13.3 ECG Analysis System

Category	Nominal Specification
Function	Evaluate ECG rhythm, analyze patient's chest impedance through multifunction defibrillation electrodes and determine if the shock is advised.
ECG Analysis time	From 5 to 15 seconds
Impedance Range	From 20 Ω to 200 Ω
Sensitivity	97% Comply with the guidelines 60602-2-4 2002 (3) AHADB, MITDB source
Specificity	99% Comply with the guidelines 60602-2-4 2002 (3) AHADB, MITDB source
Shockable Rhythms	Ventricular Fibrillation (Coarse or Fine) Ventricular Tachycardia (Monomorphic or Polymorphic) with QRS greater than 120ms (ventricular or unknown origin) and with a rate greater than 150bpm
Non Shockable Rhythms	All ECG Rhythm except above Ventricular Fibrillation or Ventricular Tachycardia

13.4 Defibrillator

<table>
<tr><th>Category</th><th>Nominal Specification</th></tr>
<tr><td>Waveform
 
</td><td>Biphasic Trapezoidal Adaptive

The waveform parameters are automatically adjusted according to the patient impedance.

In the graphic shown on the left t_{pos} represents the duration of phase 1 (ms), t_{neg} the duration of phase 2 (ms), t_{int} the delay between phases, U_{max} the peak voltage , t_{imp} the final voltage.
In order to compensate the variation of the patient impedance, the duration of each phase of the waveform is dynamically adjusted according to the power delivered, as well shown in following instances:

AED mode (semi-automatic), pre-programmed at lowest energy (Standard Version)

<table>
<tr><th>Load Resistance (Ω)</th><th>Phase 1 duration (ms) t_{pos}</th><th>Phase 2 duration (ms) t_{neg}</th><th>Power delivered (J)</th></tr>
<tr><td>25</td><td>4</td><td>6</td><td>150,6</td></tr>
<tr><td>50</td><td>6</td><td>4</td><td>150,4</td></tr>
<tr><td>75</td><td>7</td><td>3</td><td>150,2</td></tr>
<tr><td>100</td><td>7</td><td>3</td><td>150,1</td></tr>
<tr><td>125</td><td>7</td><td>3</td><td>150,1</td></tr>
<tr><td>150</td><td>7</td><td>3</td><td>150,0</td></tr>
<tr><td>175</td><td>7</td><td>3</td><td>150,0</td></tr>
</table>

Manual mode with the maximum of energy (Power Version)

<table>
<tr><th>Load Resistance (Ω)</th><th>Phase 1 duration (ms) t_{pos}</th><th>Phase 2 duration (ms) t_{neg}</th><th>Power delivered (J)</th></tr>
<tr><td>25</td><td>4</td><td>8</td><td>350,4</td></tr>
<tr><td>50</td><td>6</td><td>4</td><td>350,4</td></tr>
<tr><td>75</td><td>8</td><td>5</td><td>350,4</td></tr>
<tr><td>100</td><td>11</td><td>7</td><td>350,4</td></tr>
<tr><td>125</td><td>13</td><td>8</td><td>350,4</td></tr>
<tr><td>150</td><td>15</td><td>9</td><td>350,4</td></tr>
<tr><td>175</td><td>16</td><td>9</td><td>350,4</td></tr>
</table>
</td></tr>
<tr><td rowspan="2">Operating Mode</td><td>SAVER ONE – SAVER ONE D</td><td colspan="2">SAVER ONE P</td></tr>
<tr><td>semi-automatic</td><td>semi-automatic</td><td>manual SYNC / ASYNC</td></tr>
<tr><td>Shock Protocol</td><td colspan="2">AED mode: automatic pre-programmed selection. The shock protocol is factory pre-programmed by the producer and is conforming to local directives referring to emergency systems or health protocols. Only the producer can modify it.</td><td>Manual mode: selected by the operator</td></tr>
<tr><td rowspan="2">Max Energy Adult Mode</td><td colspan="3">Standard Version : 200 J nominal at 50 Ω load</td></tr>
<tr><td colspan="3">Power Version : 360 J nominal at 50 Ω load</td></tr>
<tr><td>Max Energy Pediatric Mode</td><td colspan="3">Standard and Power Version: 50 J nominal at 50 Ω load
(using pediatric defibrillation pads)</td></tr>
</table>

Category	Nominal Specification
Accuracy	± 15%
Energy Level Selection ***(only for SAVER ONE P in Manual Mode)***	*Standard Version (200J):* 50 – 100 – 150 – 200 *Power Version (360J):* 50 – 100 – 150 – 200 – 250 – 300 - 360
Charging Control	Automatic through Software (Arrhythmia Detection System)
Vector of shock detective	Through the defibrillation pads (Lead II)
Maximum time from initiation of ECG (prompt "Rhythm Analysis") to readiness for discharge	≤ 9 sec (IEC 60601-2-4 §6.8.2 (8a)) ≤ 11 sec (IEC 60601-2-4 §6.8.2 (8b))
Maximum time from initially device switching power on to charge ready at maximum energy	≤ 22 sec (IEC 60601-2-4 §6.8.2 (8c))
Disarm	Once armed, the device disarm itself when/if: - The patient heart rhythm changes into a not traumatic trends rhythm, or - If the shock button is not pressed within 15 seconds after the device is armed, or - The ON/OFF button is pressed to turn off the device, or - The defibrillation pads are not well connected or not connected to the patient , or - The defibrillation pads are disconnected from the device, or - If the battery is removed from its housing
Patient Isolation	BF Type
Automatic Self-Test	Each time the device is turned on Daily / Monthly / 6 Months Each time a battery (new or replaced) is attached to device

13.5 Display

Only for models: SAVER ONE D and SAVER ONE P

Category	Nominal Specification
Screen Type	High resolution (480x320) LCD with LED backlight
Screen Size	5.7" (13 * 8 cm)
ECG Waveform	Lead: II
Number of ECG Waveform	1
ECG Waveform Speed	25 mm/sec
Energy Level Information Field	Numerical value expressing the joule
Shock Information Field	Numerical value counting the quantity of shock delivered
Fibrillation Information Field	Numerical value counting the quantity of fibrillation detected
Treatment Length Information Field	On time treatment expressed in hh/mm/ss
Heart Rate Information Field	Numerical value expressing heartbeat from 30 to 300 bpm
Patient Impedance Information Field	Numerical value expressing the Ohm
Charging Information Field	Graphic charging bar
Text Information Field	Text screen area for visual prompts
Battery Information Field	Graphic battery icon showing its remaining capacity
Date & Time Information Field	Text area showing the local date and time

13.6 Controls and Indicators

Category	Nominal Specification
Controls	On/Off Button Shock Button Up/Down/Enter Menu Buttons ***(only for SAVER ONE D and SAVER ONE P)*** Energy/Charging Buttons ***(only for SAVER ONE P)***
LED Indicators	"Shock" LED button, blinks green when the defibrillator is armed.
Audio Speaker	Provides voice prompts
Status Indicator	"Status" LED, blinks green to advice that the defibrillator succeed automatic self-tests and is ready to be used.
Battery Indicator	"Battery" LED, blinks red to advice that the battery is low or not working.

13.7 Disposable Battery

Category	Nominal Specification
Part Number	BATT
Battery Technology	Not rechargeable battery $LiMnO_2$
Highest number of shocks	250-300 shocks at 200J with a new battery (Temperature +20° C)
Standby Life	4 years from the installation date (Temperature +20° C)
Shelf-Life (storing)	5 years from production date (Temperature +20° C)
Voltage	27 V DC; 1,2 Ah
Operating Temperature and Humidity	Temperature: 0° ~ +50° C Humidity: 0 ~ 95% (relative humidity not-condensing)
Temperature and Humidity during inactivity period	Temperature: -35 ~ +60° C (test for transport condition: 2 hours in a climatic chamber, then 4 hours at normal temperature) Humidity: 0 ~ 95% (relative humidity not-condensing)

13.8 Rechargeable Battery

Category	Nominal Specification
Part Number	ACC
Battery Technology	Rechargeable Accumulators Li-Ion
Highest number of shocks	400 shocks at 200J with new or fully charged battery (Temperature +20° C)
Charging Time	2,5 hours (Temperature 0 ~ +40° C)
Shelf-Life	2,5 years or 300 charge cycles (Temperature +20° C)
Voltage	21,6 V DC; 2,1 Ah
Operating Temperature and Humidity	Temperature: 0° ~ +50° C Humidity: 0 ~ 95% (relative humidity not-condensing)
Temperature and Humidity during inactivity period	Temperature: -35 ~ +60° C (test for transport condition: 2 hours in a climatic chamber, then 4 hours at normal temperature) Humidity: 0 ~ 95% (relative humidity not-condensing)

13.9 Battery Charger

Category	Nominal Specification
Part Number	CBACCS1
Input	12 V DC, 5A
Output	26 V DC, 1,5A
Absorption	40W
Li-Ion Battery charging time	2,5 hours (Temperatura 0 ~ +40° C)

13.10 Memory and Transmission

Category	Nominal Specification
Internal Memory	64 Mb used for working protocol - state protocol - data and events recording
Flash Memory capability	SMC or xD Card up to 2GB for events storing and environmental recording
IrDA Port	Wireless communication data to thermal printer

13.11 Adult Defibrillation Pads

Category	Nominal Specification
Part Number	F7958/AMBI
Type	Self-Adhesive, Disposable non- polarized with cable and connector
Size	Electrodes for patient >8 years old or with a weight >25Kg
Conductive Area	81 cm ² (both pads)
Conductive Material	Tin Lamina
Cable length	120 cm
Temperature and Humidity during inactivity period	Temperature: +5° ~ +30° C Humidity: 30 ~ 95% not-condensing

13.12 Pediatric Defibrillation Pads

Category	Nominal Specification
Part Number	F7958P/AMBI
Type	Self-Adhesive, Disposable non- polarized with cable and connector
Size	Electrodes for patient with 1÷8 years old and weight less than 25Kg
Conductive Area	31 cm ² (both pads)
Conductive Material	Tin Lamina
Cable length	120 cm
Temperature and Humidity during inactivity period	Temperature: +5° ~ +30° C Humidity: 30 ~ 95% not-condensing

14 Electromagnetic Compatibility

Guidance and manufacturer's declarations.

14.1 Electromagnetic Emissions

The device is intended to be used under the following mentioned environmental conditions. The customer or the end user have to ensure that the device will be operating observing the following environmental specification:

Emission Test	Conformity	Electromagnetic Environment (guide)
RF Emission CISPR 11	Group 1	The device use the RF power only for the internal function. Therefore, its RF emission are very low and are not such as to cause interference in the electronic equipment
RF Emission CISPR 11	Class B	The device may be used in all domestic environments and in those environments where the device is directly linked to public housing low voltage supplies for home use.
Harmonics Emission IEC 61000-3-2	Not applicable	
Vibration Voltage/ Vibration of the emission IEC 61000-3-3	Not applicable	

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

14.2 Electromagnetic Immunity

The device is intended to be used under the following mentioned environmental conditions. The customer or the end user have to ensure that the device will be operating observing the following environmental specification:

Immunity Test	IEC 60601-1 Test Level	Compliance Level	Electromagnetic Environment (guide)
Static electricity discharge (ESD) IEC 61000-4-2	±6 kV contact	±6 kV contact	Floors should be in wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%.
	±8 kV Air	±8 kV Air	
Electrical fast transient / Burst according to IEC 61000-4-4	±2 kV for power supply lines	Not Applicable	Mains power quality should match to a typical commercial building or hospital environment..
	±1 kV for input/output lines	±1 kV for input/output lines	
Surges according to IEC 61000-4-5	±1 kV differential mode tension against phase	Not Applicable	Mains power quality should match to a typical commercial building or hospital environment..
	±2 kV common mode tension isophase	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5% U_T (> 95% Dip in U_T) for ½ cycles 40% U_T (60% Dip in U_T) for 5 cycles 70% U_T (30% Dip in U_T) for 25 cycles < 5% U_T (>95% Dip in U_T) for 5s	Not Applicable	Mains power quality should match to a typical commercial building or hospital environment.. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field according to IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic field should match to a typical characteristic levels that belong to a commercial building or hospital environment.

Immunity Test	IEC 60601-1 Test Level	Compliance Level	Electromagnetic Environment (guide)
Conducted RF according to IEC 61000-4-6	3 Vrms 150kHz to 80MHz outside ISM (a) bands	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance
	10 Vrms 150kHz to 80MHz in ISM (a) bands	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF according to IEC 61000-4-6	10 V/m from 80 MHz to 2,5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHZ to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (b) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey (c), should be less than the compliance level in each frequency range (d). Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40,66 MHz to 40.70 MHz.
b	The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
c	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as or relocating the device.
d	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

14.3 RF Communication Equipments

There is a recommended separation distance between portable and mobile RF communication equipments and the device.

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

Maximum rated output power of the transmitter W	Separation distance according to frequency of transmitter M			
	150kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0,12 m	0,12 m	0,12 m	0,23 m
0.1	0,37 m	0,38 m	0,38 m	0,73 m
1	1,12 m	1,2 m	1,2 m	2,3 m
10	3,7 m	3,8 m	3,8 m	7,3 m
100	12 m	12 m	12 m	23 m

For transmitters rated at a maximum power output not listed above, the recommended separation distance "*d*" in meters (m) may be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watt (W) according to transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz and 40,66 MHz to 40,70 MHz

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communication equipment could cause interference if it is inadvertently brought into patient area.

NOTE 4 These Guidelines may not apply in all situation. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.

15 Related Accessories

15.1 Standard Box Contents

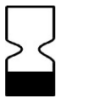
Code	*Description*	*Quantity*
SVO-B0001 **SVD-B0004** **SVP-B0006**	**Saver One Standard Version at 200J** **Saver One D Standard Version at 200J** **Saver One P Standard Version at 200J**	1 Unit (your model choice)
SVO-B0002 **SVD-B0005** **SVP-B0007**	**Saver One Power Version at 360J** **Saver One D Power Version at 360J** **Saver One P Power Version at 360J**	
SAV-C0015	Adult Disposable Defibrillation Pads (F7958/AMBI)	1 Pair
SAV-C0010	$LiMnO_2$ Disposable Battery (BATT)	1 Unit
	User's Manual	1 Unit
	Quick Reference	1 Unit

15.2 Optional Accessories

Code	*Description*
SAV-C0011	Li-Ion Rechargeable Battery (ACC)
SAV-C0014	Li-Ion Battery Charger (CBACCS1 - complete charge station)
SAV-C0016	Pediatric Disposable Defibrillation Pads (F7958P/AMBI)
SAV-C0023	xD Memory Card
SAV-C0027	Smart Media Card Reader
SAV-C0019	"SAVER VIEW EXPRESS" PC Software
SAV-C0020	Carry Case
SAV-C0028	Wall Cabinet
SAV-C0018	Thermal Printer
SAV-C0017	ECG Cable
SVT-B0008	"SAVER ONE T" AED Trainer
SSS-B0009	"SMART SIMULATOR S1" Simulator for defibrillators

16 Symbology

	Universal ILCOR sign for AED
	Dangerous electric high voltage
	General Warning: refer to accompanying documents before use!
	BF Type, defibrillation-proof equipment
	Do not expose to high temperature or to open flames
	Do not recharge
	Do not open
	Do not damage or crash
	Do not use inside paddles of water
	Read user's manual
	Battery recycle
	Please follow local regulations to waste
	Fragile, breakable
	Keep Dry
	Do not directly expose to sunlight

	IMQ Mark
	CE Mark with identification number
IP54	Device protection against dust and water (battery included)
SN	Serial Number
	Manufacturing Date
LOT	Batch (LOT) Number
	Expiry Date
REF	Reference order Number
	Manufacturer Name
	Latex Free
	Single use only, do not reuse
	Non Sterile
	Outer box indications
	This side up
	Temperature Limits
	Stack up to 6 cartons high only

17 Contact AMI ITALIA

AMI ITALIA. Srl

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80010 Quarto
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18 Glossary

A

Automatic Self-test	Automatic self-test is performed every time the device is turned on and verifies the main processor, defibrillator battery and internal circuitry status.
AED	Automated External Defibrillator. A device that evaluates the victim's heart rhythm and delivers an electrical shock to the heart when a shockable rhythm is detected.
AHA	American Heart Association
ALS	Advanced Life Support
Arrhythmia	Heart rhythm alteration (or abnormal heart rhythm)

B

Back-up battery	Internal Battery to be replaced by AMI ITALIA srl Technical product specialist only
Beat sound	Beat Sound emitted by the device to beat time during the cardiac massage
BLS	Basic Life Support
Bradycardia	Heart rate decrease below the standard
BTA	Biphasic Trapezoidal Adaptive. Defibrillation shock waveform used by the device. It's a Biphasic waveform at max 360J delivered at 50 ohm load. Waveform is automatically adjusted according to the patient impedance.

C

Chain of Survival	AHA/ERC 2005 procedures to perform during the rescue of a patient affected by SCA.
CPR	Cardiopulmonary resuscitation. This involves delivering rescue breathing and chest compressions to a victim in cardiac arrest emergency

D

Defibrillation	High energy electrical pulse (shock) delivered to the cardiac muscle to reverse VF and restore the standard cardiac activity.
Defibrillation Protocol	Operation sequences performed by the device for patients treatment in AED mode.
Disarm	Automatic procedure performed by the defibrillator in order to discharge inside of the device the stored energy when shock is not delivered.

E

ECG	Electrocardiogram. A composite picture of what is occurring electrically in the heart.
Electrocardiogram	Records the electrical activity of the heart over time
Electrode Pads	Terminology used as a synonym for defibrillation Pads
ERC	European Resuscitation Council

F

Fibrillation	See VF or VT.

G

Glutaraldehyde	Sterilizing for Defibrillators is a colourless liquid with a pungent smell used to disinfect medical equipment.

H

Heart	Is a muscular organ responsible for pumping blood through the blood vessels by repeated, rhythmic contractions. The term *cardiac* (as in cardiology) means "related to the heart" and comes from the Greek καρδία, *kardia*, for "heart."
Heart Failure	This clinical situation is characterized by a cardiac activity inefficacy. It may originate from different kind of electric impulse alteration, or any sort of mechanical obstacles. Either the genesis is primarily electrical or mechanical, it results in the ineffectiveness of both factors.

I

Impedance	It is a measure of opposition of the body to waveform flow of the electrical shock delivered by the device. The device checks automatically the electrical impedance between the pads applied on patient's chest skin and adjust the waveform of the shock accordingly.
Inflate	Operation performed during CPR process which consist in delivering a certain air volume data through "mouth to mouth " resuscitation methods.
IrDA Port	Infra-red Data Association. Communication Port which allows the interface between the device and a thermal printer
Isopropyl Alcohol	Sterilizing for the device. Also called isopropanol or 2-propanol is a colourless alcohol with a strong peculiar smell.

J

Joule	(symbol: J) Is the SI unit (International System of Units) of energy measuring heat, electricity and mechanical work. In the device is used to indicate the energy released by the device during the defibrillation, which is related to the intensity discharge output.

L

LED	Light Emitting Diodes.

M

Monitoring	Analysis used to determine the patient's heart rhythm in real time

N

Non-Shockable Rhythm	A heart rhythm detected by the defibrillator that does not need a shock, but may need CPR.

P

Pacemaker	A pacemaker is a medical device that act as support of cardiac functions of patients with not hemodynamically adequate normal rate.
Pads	see Electrode Pads
Pulse	Terminology used as a synonym for the patient's heartbeat

R

RAM	Random Access Memory. Is the internal device memory support where is possible to read and write information with a "random access"
RCP	Cardiopulmonary resuscitation. Sequences of compressions and inflates.
Rescuer	The person giving aid to a victim in cardiac arrest. Can be the user or another person helping him.
RF	Radiofrequency

S

SCA	Sudden Cardiac Arrest. The unexpected termination of the heart's pumping action resulting in the lack of a heartbeat or pulse and breathing.
Shock	Defibrillation electrical impulse
Shockable Rhythm	A heart rhythm that is detected by the defibrillator as requiring a shock, for example, VF.
Standby	Device standby mode function during which performs normal auto-test
Status Indicator	Device special LED indicators highlighting device status
Synchronous	Modality where the device synchronizes the delivery of shocks to the QRS wave peak (R). (antonym: Asynchronous).

V

Victim	The person suffering from cardiac arrest.
VF	Ventricular Fibrillation. Abnormal heart rhythm from which arise an irregular and chaotic heart activity that prevent heart from effectively pumping blood. The VF (i.e. in the Cardiac lower cavity) is associated to sudden heart failure.
VT	Ventricular Tachycardia. Technically, three or more beats in a row on an ECG that originate from the ventricle at a rate of more than 100 beats per minute constitute a ventricular tachycardia.

19 Certificates

EC CERTIFICATE

Certificate No 1104/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, section 3 of Legislative Decree of 1997-02-24, No 46, national transposition of the Directive 93/42/EEC, we hereby certify that:

A.M.I. ITALIA SRL

manages in the factories of:

QUARTO (NA) - VIA CUPA REGINELLA 17/A (ITA) - Italy

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

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

with the relevant essential requirements of the aforementioned national legislation transposing the Directive 93/42/EEC, from design to final inspection and testing.

Reference to IMQ files Nos: 10AI00006; 10AJ00117.

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

Date: 2008-02-18
Updated: 2009-07-27
Substitution Date: 2008-02-18

IMQ

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".
In any case, it does not remain valid after 2013-02-17 (article 11, clause 11 of the Directive).

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

IMQ CSQ
IMQ S.p.A. I-20158 Milano - Via Quintiliano 45 - tel. 0250731(r.a.) - fax 0250991500 - info@imq.it - www.imq.it
Rea MI 1595884 - Registro Imprese MI 12898410159 - C.F./P.I.: 12898410159 - Capitale sociale 4.000.000 euro

A.M.I. ITALIA s.r.l.

CE 0051 IMQ CSQ MED

EC Declaration of Conformity
Dichiarazione di conformità CE

A.M.I. ITALIA Srl con sede legale in Via Cupa Reginella 17A, 80010 Quarto (NA), Italia, fabbricante di dispositivi medici con marcatura CE, qui di seguito dichiara che:
A.M.I. ITALIA Srl with registered office in Via Cupa Reginella 17A, 80010 QUARTO (NA), Italy, manufacturer of CE registered medical products, hereby declares that:

Prodotti: Serie Defibrillatori Esterni Manuali/Semi-Automatici SAVER ONE e relativi Accessori
Products: SAVER ONE Manual/Semiautomatic Defibrillators Series with related Accessories

Modelli / *Models:* **SAVER ONE, SAVER ONE D, SAVER ONE P**

Soddisfano i requisiti essenziali della Direttiva 93/42/CEE (Certificato No. 1104/MDD)
Conforms to the relevant essential requirements of Directive 93/42/EEC (Approval No. 1104/MDD)

Classe di Rischio: Classe IIb secondo la regola 9 dell'Allegato IX
Risk Classification: Class IIb assessed per Annex IX, Rule 9

Grado di Protezione: Tipo BF Classe I
Protection Degree: Type BF Class I

Norme Applicate / *Standards Applied:* **ISO 9001:2008 (Certificato No. 9120.AMIT); ISO 13485:2003 (Certificato No. 9124.AMI2); ISO 10993-1:2003; ISO 14971:2000 + AI:2003; EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996; EN 60601-1-4:1996 + A1:1999; EN 60601-2-4:2003**

Organismo Notificato / *Notify Body:* **IMQ SpA (0051) Via Quintiliano 43, 20138 Milano, Italia**

Inclusi i seguenti accessori: Cavo ECG (F6702/AMI); Batteria Monouso LiMnO2 (BATT); Batteria Ricaricabile Li-Ion (ACC); Caricabatteria (CBACCS1)
Included these accessories: ECG Cable (F6702/AMI); LiMnO2 Disposable Battery (BATT); Li-Ion Rechargeable Battery (ACC); Battery Charger (CBACCS1)

Quarto li, 4 Settembre 2009

Quality Assurance Manager
Ing. Sergio Arbitrio

Questa dichiarazione si applica ai dispositivi marcati CE prodotti dopo la data di emissione della presente dichiarazione e prima che la stessa sia stata sostituita da altre dichiarazioni. Tutti i documenti sono a disposizione nella sede della AMI.
This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn. All technical documentations are available at AMI facility.

SAVER-TCF-DOC rev.1

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20 Limited Warranty

A.M.I. ITALIA s.r.l.

LIMITED WARRANTY

SAVER ONE Defibrillators Series

Limited Warranty

AMI ITALIA Srl, warrants that its *SAVER ONE Defibrillators Series* and stated battery operating life 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 Defibrillators Series and $LiMnO_2$ Disposable Battery (code "BATT") have a warranty of Five (5) years starting from 30 days after the date of the original shipment from AMI ITALIA facility to the original purchaser. Disposable Electrode Pads shall be warranted until their expiry date. When installed, the $LiMnO_2$ Disposable Battery (code "BATT") have an operational stand-by warranty of Four (4) years from the date of its insertion into the defibrillator. Accessories shall be warranted for Six (6) months starting from 30 days after the date of the original shipment.

Validation of Warranty

The original purchaser should validate this warranty within 30 days from the original shipment completing and submitting the "Warranty Registration" form at the following web page:
http://www.amihealthcare.eu/support/warranty_registration.php
or, if not possible, calling our Customer Service at +39 081 8063475 and obtain warranty service of the product. AMI ITALIA reserves at its sole discretion the exclusive right to repair or replace the product that prove defective 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 user's manual, unauthorized disassembly, repair or modification or replacements of parts.
This warranty is void if the product 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: (i) the serial number of the product is amended, deleted, become unreadable or otherwise tampered with; (ii) the seal of guarantee has been removed from the product (opening the case); (iii) the name of the product or the manufacturer has been covered, altered or deleted.
This warranty does not cover the purchasing of used product(s). In this case AMI ITALIA is not responsible for any product defects and the warranty shall be offered by the seller of the used product(s).

Disclaimers

The foregoing is the complete warranty for AMI ITALIA products and specifically excludes and replaces all other warranties and representations, whether oral or written. No other warranties are made with respect to AMI ITALIA products and AMI ITALIA 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 product purchasing. No person, including any Agent, Dealer or AMI ITALIA Representative, is authorized to make any representation or warranty concerning AMI ITALIA products, except to refer purchasers to this Limited Warranty.

In no event will AMI ITALIA be liable to the purchaser of AMI ITALIA product 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 AMI ITALIA product, even if AMI ITALIA 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 Defibrillators Series* exclusively following instructions contained into the user's manual.

Legal Rights

This warranty gives you specific legal rights. You may also have other rights which vary from state to state.

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 AMI ITALIA *SAVER ONE Defibrillators Series* will 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.

SaverOne Everywhere for Life

Thank you for purchasing AMI ITALIA products

Everywhere* for *Life

A.M.I. ITALIA s.r.l.

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