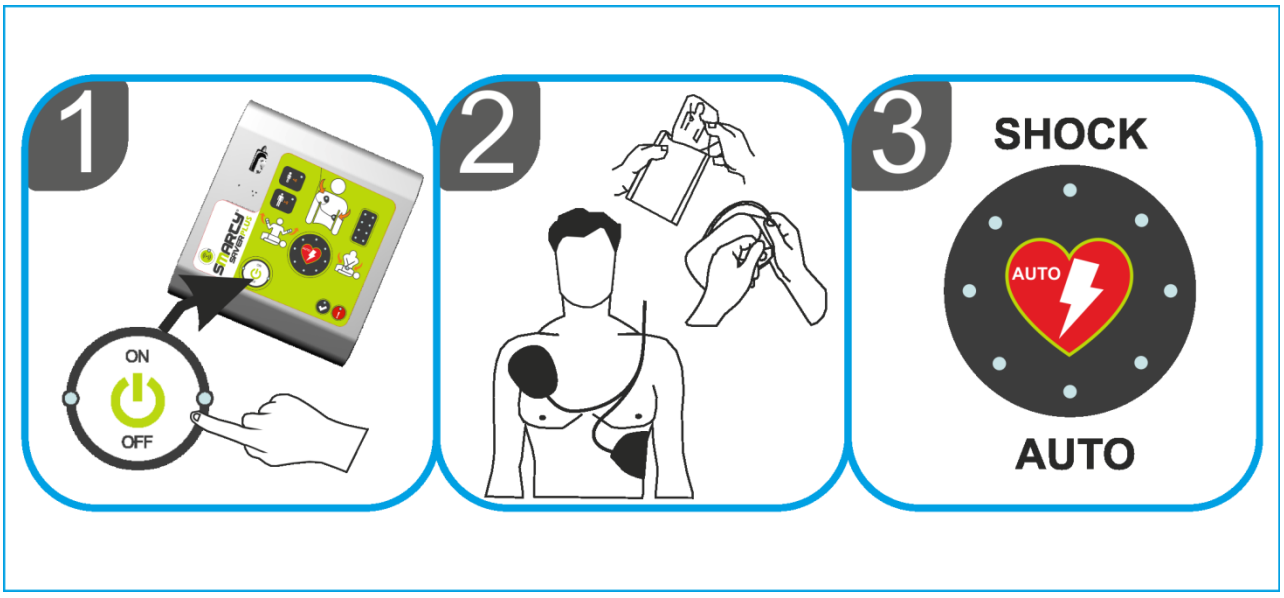
SMARTY Saver
User Manual
Automatic External Defibrillator

SMARTY® SAVER

Rev.1.8

QUICK START GUIDE



These instructions for use are subject to amendment.

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1 Introduction

1.1 Preamble

Thank you for choosing the defibrillator manufactured by A.M.I. Italia S.r.l., ***SMARTY Saver*** model.
In order to use the device correctly, you must read this user manual carefully before use. This user manual contains the instructions for the use of ***SMARTY Saver*** in compliance with its functionality and purpose. For an error-free operation, it is fundamental that you comply with the requirements of this manual, in order to guarantee the safety of the patient, of the rescuer and that of third parties.
This manual forms an integral part of the defibrillator and must always be kept in close proximity to the defibrillator, so that it may be easily consulted whenever needed.
Note: In order to guarantee the correct and fast traceability of the product and to receive information regarding all implemented updates, the user is requested to register the device at the appropriate section of the AMI ITALIA website, www.amiitalia.com.

1.2 Use in conformity with the provisions

The ***SMARTY Saver Series*** devices can be used only if the conditions indicated in this user manual are complied with.
All uses that differ from the intended use shall be understood not to comply with the provisions and may cause harm/damage to persons and/or property; in such case, A.M.I. Italia S.r.l. hereby declines all liability.

1.3 Warranty

The ***SMARTY Saver Series*** devices are under warranty for a period of 5 (five)* years.
The non-rechargeable battery SMT-C14031 is under warranty for 3 (three)* years in Stand-by mode (with battery activation tests, daily self-tests and without the AED being switched on).
This information refers to new batteries, that are fully charged and kept at a temperature of 20°C and 45% humidity.
**For more information, please see paragraph 14, "Warranty contract for SMARTY Saver series defibrillators"*

1.4 Exclusion of liability

Liability rights in case of harm/damage to persons or to property shall be excluded, if attributable to one of the causes below:

- Using the device for uses other than its intended use.
- Using and maintaining the device inappropriately.
- Using the device and/or its accessories when they are visibly or partially damaged.
- Failing to comply with the instructions of the user manual concerning the precautions, use, maintenance and repair of the device.
- Using non-original accessories and spare parts and/or of accessories and spare parts that are not approved by the manufacturer.
- Performing arbitrary operations, repairs or modifications of the device.
- Arbitrarily exceeding the performance limits.
- Failing to supervise the parts that are subject to wear and tear.

1.5 Instructions

SMARTY Saver device may be used only if the patient:

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

1.6 Counterindications

SMARTY Saver device may not be used if the patient:

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

1.7 Information on the version

This user manual has a version number; this varies each time the manual is updated due to changes in the device's operation or to the device itself. The contents of this user manual shall be subject to amendment without advance notice.

Version number: 1.7
Issue date: 06/04/2021

1.8 Symbols used in the manual

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

SYMBOL	INDICATION	DESCRIPTION
	HAZARD	It signals an immediate risk to the safety of persons, which **might result in death** and damage to the device or its parts
	WARNING	It signals an unsafe situation or practice which **might lead to serious injury** to persons and damage to the device or its parts.

1.9 Contact details of the manufacturer

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

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Via G. Porzio Centro Direzionale Isola G/2 - 80143 Napoli (NA) Italy
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Request for assistance

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2 Safety instructions

For the correct use of a ***SMARTY Saver Series*** defibrillator, the users must be aware of the safety factors listed below.
We recommend that you read them carefully.
The ***SMARTY Saver Series*** defibrillators and their accessories comply with the rules and regulations on safety that are currently in force and with the provisions of the directives on medical products.
The device and its accessories must be deemed to be safe in the case of application in compliance with the provisions and if the descriptions and instructions listed in this user manual are complied with.
Below please find the main precautions for the correct and safe use of the defibrillator, divided - for easier consultation - in hazard statements, warnings and instructions for disposal.

2.1 HAZARD statements

- Use ***SMARTY Saver*** in compliance with what is laid down in this user manual.
  Read these instructions and, in particular, the safety instructions carefully.
- In compliance with IEC standards (section 0), use of the ***SMARTY Saver*** device or of its accessories is not allowed in the presence of inflammable substances (gasoline or similar) or in an oxygen-rich atmosphere or an atmosphere rich in inflammable gases/vapours.
- Do not recharge the single-use batteries SMT-C14031: risk of explosion!
- Avoid contact of the batteries with open flames. Do not expose to fire.
- Do not cause a short-circuit of the battery terminals.
- In case of leakage of fluids or strange odours from the batteries, keep them away from fire to prevent the possible combustion of leaking electrolytes.
- Shock hazard. The device generates high voltage and hazardous current levels. Do not open ***SMARTY Saver*** do not remove the panels and do not attempt to repair it. ***SMARTY Saver*** does not contain components that can be repaired by the users. In order to perform repairs, ***SMARTY Saver*** must be sent to an authorised technical support centre.
- Do not apply the defibrillation pads on the patient's chest if nitroglycerine plasters are present. Only place the electrodes once you have removed the plasters. Otherwise, there is a risk of explosion.
- Do not touch the patient and prevent third parties from coming into contact with the patient during the defibrillation shock. Avoid all contact between:
  - parts of the patient's body
  - conducting liquids (such as gel, blood, or saline solution)
  - metal objects near the patient (such as the bed frame or a stretching device) that may potentially act as conductors for the defibrillation current.
- Before using the device, make sure that the patient is safe; if necessary, move them carefully to a protected location, as set forth by the AHA/ERC directives.
- Do not immerse any part of ***SMARTY Saver*** or its accessories in water or other liquids.
- Do not allow liquids to enter ***SMARTY Saver*** or its accessories. Avoid pouring liquids on the device and its accessories. Otherwise, damage may be caused or there may a risk of fire or shock. Do not sterilise ***SMARTY Saver*** and/or its accessories.

2.2 WARNINGS

- Avoid the formation of air bubbles between the skin and the defibrillation pads. The formation of air bubbles during defibrillation may cause severe burns to the patient's epidermis. To avoid the formation of air bubbles, make sure that the electrodes are in full contact with the skin. Do not use electrodes whose gel has dried out and check its expiry date before use.
- Do not delay treatment in case of patients with an implanted pacemaker and perform an attempt at defibrillation if the patient has lost consciousness and is not breathing or is not breathing normally.
- Do not apply the defibrillation electrodes directly on an implanted pacemaker, to avoid possible device interpretation errors and to avoid damaging the pacemaker with the defibrillation pulse.
  During the application of the electrodes:
  • Do not apply the electrodes directly on an implanted device.
  • Apply the electrodes at least 2.54 cm (1 inch) from any implanted device.

  If a pacemaker is present, the defibrillators of the Smarty Saver series will, in any case, make it possible to release the shock, unless, although they envisage a treatment of the ECG signal such as to guarantee an accurate rejection of the artefacts, the interference of the pacemaker is such (e.g., due to the electrodes being placed in a way that does not comply with the warning indicated) as to alter the ECG signal and not allow the shock.

- RF (radiofrequency) interference from devices such as mobile phones and radio two-way transmitters, can cause ***SMARTY Saver*** to malfunction. ***SMARTY Saver*** must be kept at least 2 metres away from such RF devices, as indicated in the IEC/EN 61000-4-3 standards. Keep at sufficient distance from other therapeutic and diagnostic sources of energy (e.g., diathermy, high-frequency surgery, magnetic tomography).
- Use ***SMARTY Saver*** only if you have followed a BLS-AED or ALS-AED training course.
- Before using the device, make sure that it is not obviously damaged.
- Do not use universal defibrillation pads SMT-C2001 in paediatric mode on adult patients (older than 8 and weighing more than 25 kg). In fact, in paediatric mode, ***SMARTY Saver*** automatically reduces the maximum energy that can be delivered to 50J.
- Place the patient cables in such a way as to reduce the possibility of them getting entangled in or strangling the patient.
- In a domestic environment, keep the defibrillator away from the reach of children and pets.
- Disconnect the patient from equipment that is sensitive to high voltage pulses, or equipment that is not defibrillator-proof, before delivering the shock.

WARNING

- Do not allow the defibrillation electrodes to touch or to come into contact with ECG electrodes, pads, transdermal plasters, etc. Otherwise, the formation of electric arcs and burns to the patient could be caused during defibrillation; the current may even be dispersed.
- Place the defibrillation pads as indicated in this user manual and on the packaging.
- Do not use the defibrillation pads if the gel has come away from the support or if it appears torn, divided or dry.
- If damage has been found, in no case should you switch ***SMARTY Saver*** on.
- Before using the device, remove metal objects from the patient's body (including necklaces or bracelets, etc.).
- Do not use defibrillation pads other than those supplied by the manufacturer. Otherwise, the defibrillator may perform false interpretations.
- Do not use the defibrillation pads if they are damaged, even partly.
- Do not touch the patient or the defibrillation pads during the automatic analysis of the heartbeat.
- Moving or transporting the patient during the analysis of the heartbeat by the device may lead to a wrong or untimely diagnosis. Reduce movements to a minimum while the heartbeat is being analysed. If the device is used in a moving ambulance, stop the vehicle and only start driving after the shock has been delivered.
- In order to use ***SMARTY Saver***, you must have followed a basic or advanced training course for cardio-pulmonary resuscitation with use of defibrillator (BLS-AED or ALS-AED course).
- Avoid using the universal defibrillation pads SMT-C2001 in adult mode on children (aged 1-8 or weighing 8-25 kg). In fact, in adult mode, SMARTY Saver does not automatically reduce the maximum energy that can be delivered to 50J and may, therefore, become hazardous for the paediatric patient.
- Avoid using the universal defibrillation pads SMT-C2001 in adult mode on children (aged 1-8 or weighing 8-25 kg). When paediatric mode is set, the maximum energy that can be delivered is 50J.
- If needed, before applying the defibrillation pads dry the patient's chest and remove excess hair.
- Do not subject ***SMARTY Saver***, its accessories and/or its parts to falls and/or strong impacts.
- Do not use damaged accessories and/or parts; otherwise, the device may be caused to malfunction.
- Use solely original accessories and/or spare parts.
- Avoid handling the device, its accessories or its parts too aggressively to avoid possible damage. Inspect the entire system regularly.
- Sanitise the device in compliance with the rules of paragraph 10.3, and, in any case, always make sure that the device is switched off, without battery and with the pads disconnected.
- The defibrillation pads are single-use, to be used on just one patient. Do not reuse the defibrillation pads; throw them away after use and replace them with a new pair.
- The defibrillation pads are not sterile or sterilisable.
- The intense or prolonged administration of cardiopulmonary resuscitation with the defibrillation electrodes applied to the patient can damage the electrodes. Replace them if they are damaged due to use or handling.
- Inappropriate maintenance may damage ***SMARTY Saver*** or cause it to malfunction. Comply with what is described in this User Manual.
- Use the non-rechargeable batteries SMT-C14031 within the duration indicated in this user manual.
- Remove the batteries from the device only if it has been off for at least 5 seconds. Otherwise, the device and the batteries may be damaged.
- ***SMARTY Saver***, its parts and accessories are manufactured non-sterile and non-sterilisable.
- Do not expose ***SMARTY Saver***, its parts or accessories to direct light or high temperatures.
- All products, product data and specifications are subject to modification to improve their reliability, functionality, design or other aspects.

2.3 Instructions for DISPOSAL 

- ***SMARTY Saver***, its parts and accessories must not be disposed of with other household waste within the European Union. To prevent possible harm to the environment or to persons' health caused by incorrect disposal of waste, recycle this product responsibly, also to promote a sustainable use of resources. In order to discard the used product, go to the appropriate waste collection centre or take it to the area distributor. It will then be possible to recycle the product with safety for the environment.

2.4 Classifications

UMDNS code	11132
GMDN code	11132
CND code	Z12030503
RDM [(It.) Medical Device Register] number	2085996
CIVAB [Biomedical Equipment Information and Assessment Centre] code	[T.B.D.]
Class in accordance with Directive **2007/47/EC**	IIb
Type of protection from electric shock	Powered Internally
Type of patient insulation	BF
Degree of protection against penetration by liquids	IPx6
Degree of protection against penetration by dust	IP5x
Degree of safety in the presence of inflammable anaesthetic mixtures with air, oxygen or nitrous oxide	Not protected
Sterilisation or disinfection method suggested by the supplier	See Paragraph
Operation mode	Continuous operation

3 Device description

3.1 Information on the defibrillator

SMARTY Saver is known as an **AED**, i.e. **A**utomatic **E**xternal **D**efibrillator.
Its purpose is to cope with the emergency of a patient suffering from sudden cardiac arrest and to assist in Cardio Pulmonary Resuscitation (CPR).
The device was designed for use by non-experts and by healthcare providers who have duly followed and successfully completed a BLS-AED course, in accordance with international guidelines.
Designed to automatically detect and analyse the victim's heartbeat, it is able to deliver one or more defibrillation shocks if it detects a ventricular defibrillation or a ventricular tachycardia (monomorphic or polymorphic with >180 beats). The energy is delivered through a biphasic truncated exponential (BTE) electrical shock that can self-adapt to the patient's thoracic impedance.

SMARTY Saver is available in two versions:

- **SM1-B1001: *SMARTY Saver*** Semi-automatic. Maximum energy delivered 200J
- **SM2-B1002: *SMARTY Saver*** Automatic. Maximum energy delivered 200J

It is powered by the following battery:

- **SMT-C14031**: Non-rechargeable battery made up of a pack of 8 Li-MnO_2 cells

The device makes it possible to register rescue data on an external µSD Memory Card (optional) so that they can be displayed on a PC using a special software owned by A.M.I. Italy S.r.l. In stand-by mode (not in use but with the battery installed), the device performs daily self-tests to check its operating status, in order to guarantee ready use in case of emergency.
The keyboard of the device is equipped with two LEDs (red and green) that make it possible to ascertain the outcome of the operational tests and know the status of the device even if it is switched off (stand-by mode).

3.2 Procedure for the activation of the defibrillator

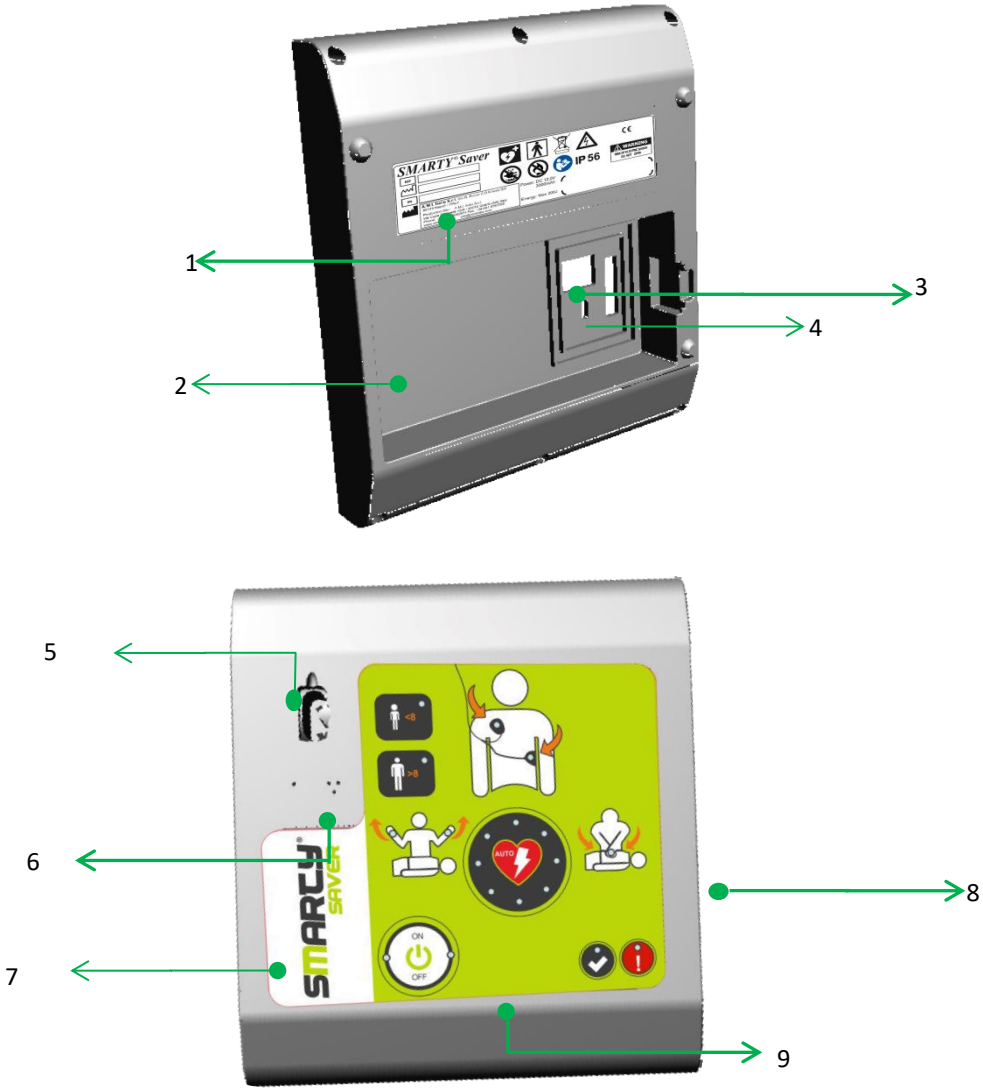
Open the packaging and make sure that all materials supplied are intact, checking their expiry date (defibrillation plates) and storage conditions.

Connect the plates' connector and the battery to the defibrillator and wait for the initial test to start.

If the activation test is successful, the device invites you to connect the plates to the patient. At this point, switch off the device, leave the plates and the battery connected and check that the green LED blinks every six seconds. Lastly, place the defibrillator back in a safe and accessible place, so that it is ready for use.

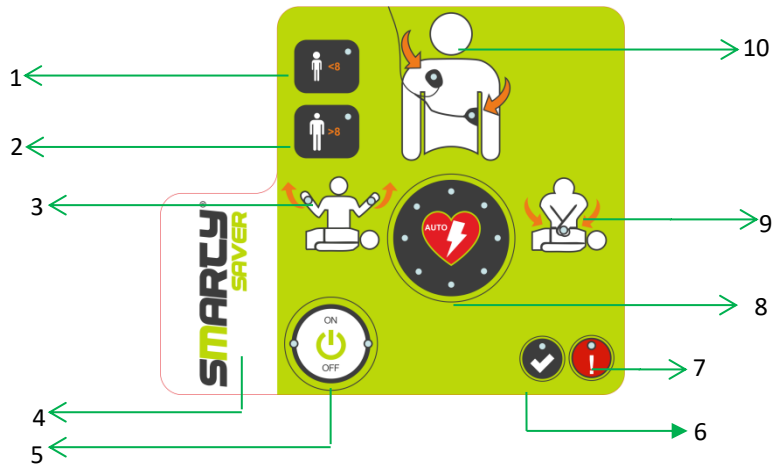
4 Device description

4.1 General structure



No.	Description
1	SMARTY Saver label
2	Battery compartment
3	µSD Memory Card compartment
4	USB-C port (for the exclusive use of A.M.I. Italia)
5	Plate connector
6	SMARTY Saver device microphone
7	SMARTY Saver logo
8	SMARTY Saver speaker
9	Keyboard with buttons and illuminated icons

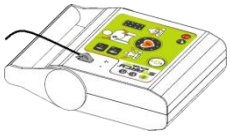
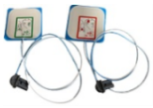
4.2 Keys, icons and indicators



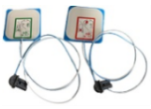
No.	Function	No.	Function
1	**Paediatric Selection Button** Selection of the paediatric patient type using universal plates	6	**Green control LED** In stand-by mode: correct operation status of the device
2	**Adult Selection Button** Selection of the adult patient type using universal plates	7	**Red control LED** In stand-by mode: device error status
3	**“Do Not Touch” indicator** Icon with lit illuminated LEDs: do not touch the patient	8	**Shock icon** Equipped with 8 illuminated LEDs if blinking it indicates the imminent defibrillation shock
4	**Product logo** Device model	9	**“CPR” indicator** Start Cardio-Pulmonary Resuscitation
5	**“ON/OFF” button** Switch the device on/off	10	**“Place plates” indicator** Place the defibrillation pads.

4.3 Standard and optional accessories of the device

The ***SMARTY Saver*** defibrillator is supplied with the following accessories:

Code	Image	Quantity	Description
SM2-B1002		**1 Unit**	***SMARTY Saver*** Automatic 200J
SMT-C2001		**1 Pair**	Pre-connected universal pads for adult and paediatric use (Class I device)
SMT-C14031		**1 Unit**	Non-rechargeable battery
SMT-C1077		**1 Unit**	User Guide
SMT-C1916		**1 Unit**	AED carry bag

Below please find a list of optional accessories, that may be purchased separately:

Code	Image	Quantity	Description
SMT-C2002		**1 Pair**	Pre-connected universal pads for paediatric and adult use Face-to-face (Class I device)
SAV-C0950		**1 Unit**	CD-ROM Saver View Express
SMT-C1907		**1 Unit**	µSD Card
SAV-C0027		**1 Unit**	Memory Card reader for PC

5 SMARTY Saver power supply and accessories

5.1 Non-rechargeable battery SMT-C14031

The non-rechargeable battery SMT-C14031 is made up of 1 pack with 8 Li-MnO_2 cells

It is supplied with the AED, fully charged and ready to use; it was designed for long-lasting autonomy and to perform approximately 200 full rescue cycles (shocks at 200J and CPR).

The estimated duration is approximately 3 (three) years from the installation of the AED and from the first activation test, with the device in stand-by mode, i.e. with daily self-tests, daily self-tests with no subsequent AED switch-on.

If the level of residual charge in the battery is low, the user will be informed with audio and visual messages.
SMARTY Saver will issue a warning of a low battery with a level ≤5% and an empty battery alarm with level ≤ 1%:

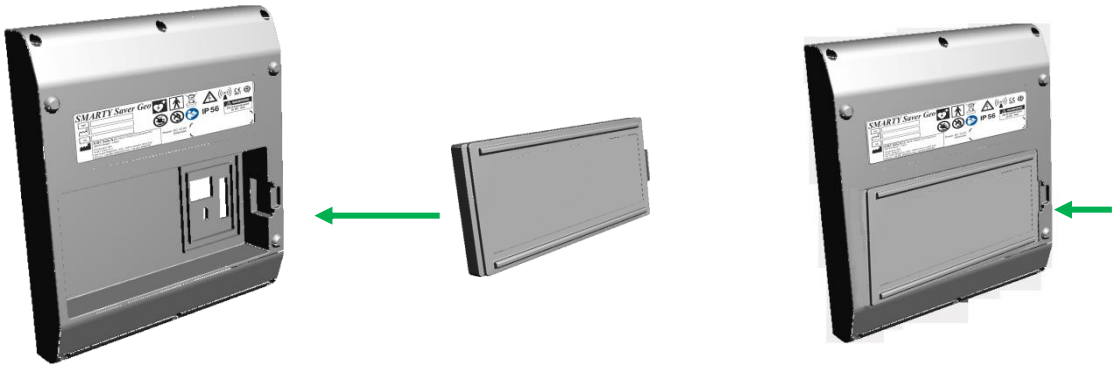
- **WARNING:** Residual battery level equal to or lower than **5%**.
  This warning will only be issued in Operation mode.
  Battery level at 5% makes it possible to perform approximately 14 shocks and allows the device to operate in stand-by mode for about 40 days

- **ALARM:** Battery residual capacity level **≤ 1%**
  This warning will be issued in both stand-by and operation mode.
  With the battery at ≤ 1%, *SMARTY Saver* makes it possible to perform approximately 7 shocks and allows the device to operate in stand-by mode for about 20 days
  We do not recommend using the device in this condition.

!!ATTENTION!!
In order to safeguard the duration of the battery SMT-C14031 and guarantee the automatic tests of the device, it is recommended, after installing the battery, not to remove it until you replace it.
The removal and subsequent reintroduction of the battery, in fact, results in a full test of the AED which significantly affects its longevity. In addition, if the battery is not connected correctly, it may be damaged.

5.1.1 Insertion and removal of the batteries

Below please find detailed instructions for the correct installation of the battery in the device ***SMARTY Saver***.



- Place the device as shown in figure (first on the left)
- Place the battery as shown in figure (central)
- Inserting it in the dedicated compartment, push the battery as shown in figure (last on the right)

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

- Make sure the device is switched off.
- Pull on the tab on the side of the battery and take the battery out of the dedicated compartment as shown in figure (last on the right).

5.2 Defibrillation pads

SMARTY Saver is made to use two different types of universal defibrillation pads, to be used on adult and paediatric patients;

- **SMT-C2001:** Pre-connected universal defibrillation pads
- **SMT-C2002:** Pre-connected "face-to-face" universal defibrillation pads

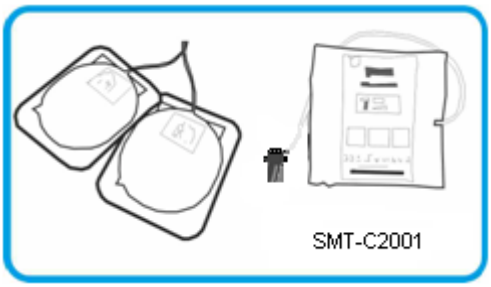
Depending on the patient to be treated, you must select on the keyboard of the SMARTY Saver device the type of patient (adult age >8 or weight >25 kg / paediatric age from 1 to 8 or weight <25 kg). The use of this type of pads is, in general, contraindicated in patients younger than 12 months and weighing less than 10 kg.

The pre-connected universal defibrillation pads are class I medical devices; the term "pre-connected" means that the cable and the connector are external to the sealed packaging, so that they can be pre-connected to the device, thus avoiding having to insert the connector during aid.

For more detailed information, please always refer to the related user manual and to the indications on the electrodes' bag.

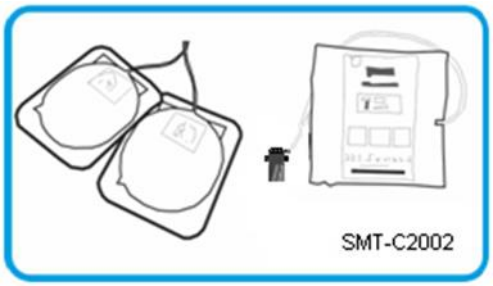
5.2.1 Pre-connected universal defibrillation pads SMT-C2001

The defibrillation pads SMT-C2001 are universal, single-use and pre-gelled.
They are supplied in individual sealed packaging which mentions the expiry date (typically 30 months); on the indicated expiry date, the pads must be replaced, even if they have never been used.



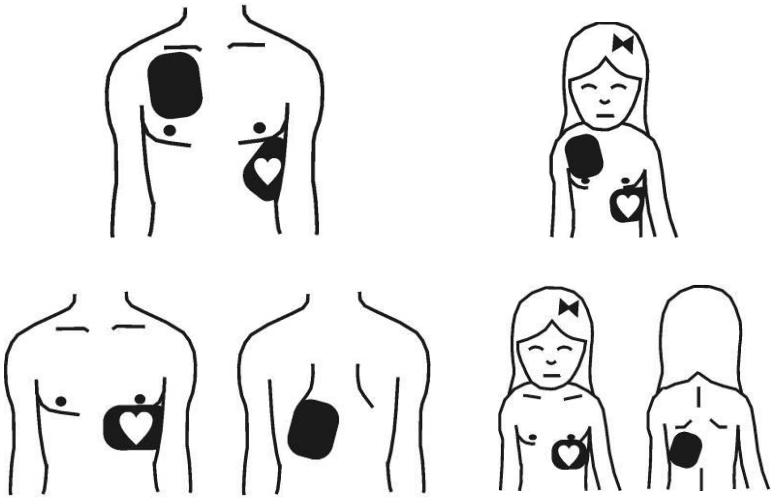
5.2.2 Pre-connected Face-to-Face universal defibrillation pads SMT-C2002

Face-to-Face universal defibrillation pads SMT-C2002 are universal, single-use and pre-gelled.
The term "face-to-face" indicates that the plates are electrically paired so that the ***SMARTY Saver*** device can measure their effectiveness - based on the quality of the gel's conductibility - and warn - using control LEDs - when it has declined. This signal must result in the replacement of the pads.
After the expiry date mentioned on the packaging, it is recommended to replace the pads, regardless of the signal issued by the defibrillator



5.2.3 Placement of the defibrillation pads

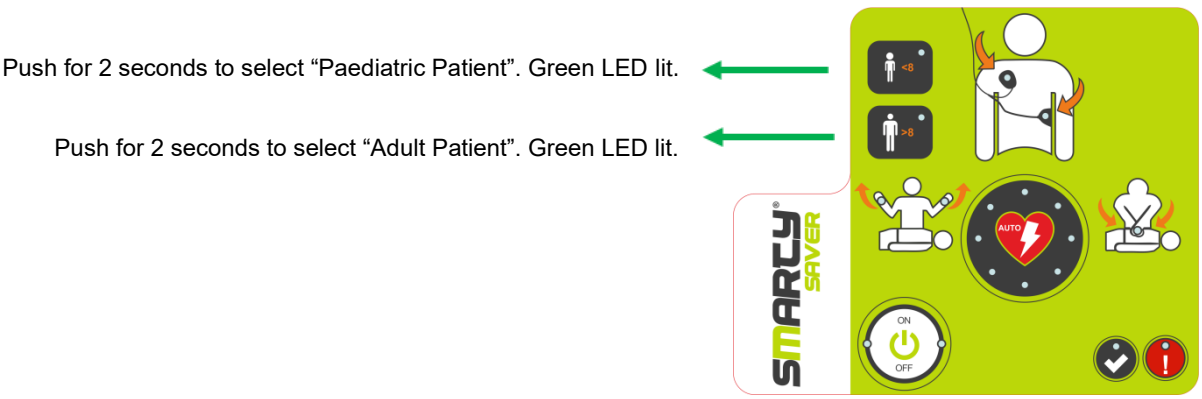
The correct placement of the pads on the patient is essential for an effective analysis of the heartbeat and for the consequent delivery of the shock (if needed).
Please always refer to the instructions on the packaging and to the specific user manual.



5.2.4 Adult and Paediatric mode

SMARTY Saver makes it possible to use universal defibrillation plates, i.e. that can be used on adult (age >8 or weight >25 kg) and paediatric (age from 1 to 8 or weight <25 kg) patients.
The type of patient must be selected before placing the plates on the chest, with the dedicated button on the device's keyboard (see figure below).
By pushing the dedicated button for 2 seconds, you will activate the pre-selected mode, and the corresponding control LED will light up.

Note: On being switched on, the device - by default - is supplied with the universal plates in Adult Patient mode.



6 Self-test

SMARTY Saver was designed to be a totally safe device, always ready to use and able to automatically and constantly check the proper operation of its parts, reducing maintenance operations by the user to a minimum.
In fact, ***SMARTY Saver*** performs three types of self-test:

- **Activation:** On insertion of the battery
- **Automatic:** In stand-by mode, daily/monthly/bi-annually
- **On:** On the device being switched on

The outcome of the control test can be viewed through the control LEDs (green and/or red) that make it possible to see, at any time, when the device is switched off (stand-by mode), the operating status of the device and its main accessories.
SMARTY Saver performs the operation tests only when the battery is installed; we, therefore, recommend not to remove the battery from the device, except only for the time needed to replace it.

6.1 ACTIVATION test

On each insertion of the battery, the device will perform the ACTIVATION diagnostic test; this self-test results in a small consumption of energy, as it involves all components of the device and also requires a manual intervention by the operator, who must:

❖ **Insert the battery in the device**

If the battery has been inserted properly, ***SMARTY Saver*** will automatically switch on emitting an acoustic signal, and the on button  will turn green, while the control LED will switch off.
The device will launch the activation test.
If the test ends with an error, the device switches off automatically and the red control LED will blink approximately every 6 seconds.
If, instead, the device activation test concludes without errors, the device will emit the voice message "place the PADs"; the two red LEDs of the "place the PADs" indicator on the keypad will blink.

❖ **Switch off the device**

If immediate use is not required, switch off ***SMARTY Saver*** and leave the battery inserted to guarantee the performance of periodic diagnostic self-tests (see Paragraph 6.2)

6.2 AUTOMATIC test:

In stand-by mode (device off and battery installed), the AED performs automatic diagnostic tests:

- Daily (basic tests with minimum battery consumption)
- Monthly (in-depth test with moderate battery consumption)
- Bi-annually (full test with substantial battery consumption)

The automatic self-tests do not require any manual operation by the operator; the outcome can be checked with the control LEDs on the device's keyboard (Please see paragraph 6.4).

6.3 ON test

SMARTY Saver performs a diagnostic self-test every time it is switched on.
This test is performed in order to check the proper operation of the device before use, is automatic and takes a few seconds.
When the on button is pushed, ***SMARTY Saver*** will emit an acoustic signal, confirming it is on, and the control LED will go off.
If no errors are found following the test, the device will be ready to be used and will provide the operator with the first instructions to initiate the intervention.

6.4 Control LEDs

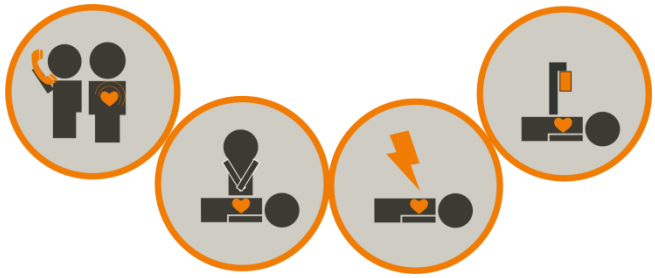
The control LEDs are placed on the keyboard of the ***SMARTY Saver***.
Based on the various colours of the control LED, the operator can independently deduce the operation status of the defibrillator and of its main accessories.
The table below shows the control LED blinking codes:

Device mode	Blinking LED	
STAND-BY (turned off with battery connected)		Device ready for use
		Warning for a low battery level, replace the battery
		Faulty device, service required
		Face to Face PADs on to expiration or degraded
IN USE	OFF	Device working
	OFF + 	Warning: battery is getting low (5% left), replace it ASAP
		Caution! low battery replace it immediately

7 Defibrillation

7.1 "Chain of survival"

If it is necessary to aid a person suffering from Sudden Cardiac Arrest, please remember to follow the sequence of actions recommended by the AHA/ERC guidelines.
The ERC has endorsed an aid protocol to be complied with during the resuscitation of a person suffering from Sudden Cardiac Arrest; this protocol has been given the name "chain of survival".

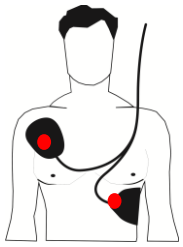


1. Make sure that the person is unconscious, is not breathing and has no heartbeat and call the emergency number immediately.
2. While waiting for a defibrillator to become available, start Cardio-Pulmonary Resuscitation manoeuvres immediately.
3. Switch on the defibrillator and follow the audio instructions to restore normal heartbeat.
4. Continue until the arrival of medical personnel.

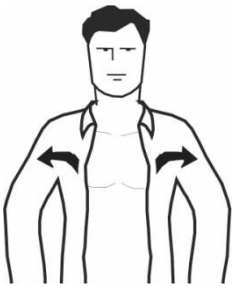
7.2 Switching *SMARTY Saver* on

Push the device's on button 

SMARTY Saver will emit an acoustic signal confirming it is on, the ON/OFF button will turn green.
If the on self-test has a positive outcome, the device will suggest to the operator the first operations to be performed by emitting voice (audio) and visual (illuminated icons) commands:

Voice messages	Keyboard Illuminated Icons
Place the emergency call	 Command Place the pads Defibrillation
Keep calm and follow the voice instructions. If the patient is unconscious and is not breathing, remove their clothes in order to apply the electrodes to the patient's naked chest	
Open the packaging and look carefully at the images on the electrodes Remove the plastic wrapping from the electrode and place it squarely on the patient's chest, as shown in the images	

7.3 Preparing the patient

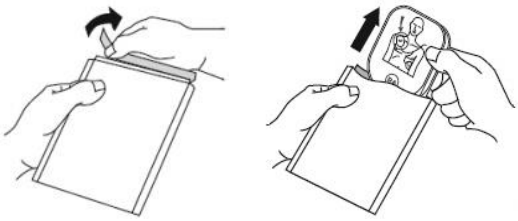


In order to be able to place the defibrillation pads on the chest, you must perform the preliminary operations below:

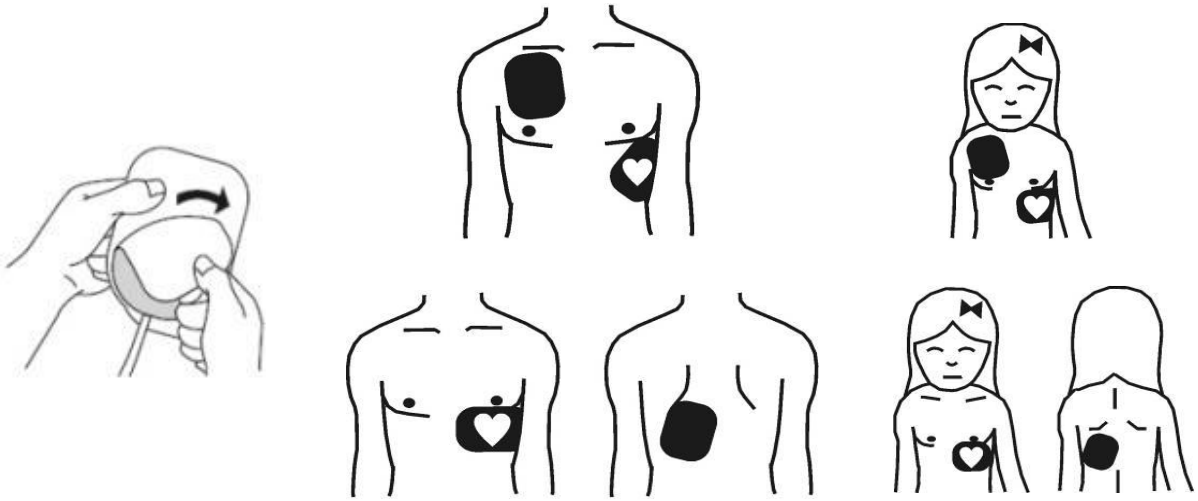
- Remove clothing from the patient's chest
- If the patient's chest is very hairy, you must shave the places where the pads will be placed.

7.4 Place the pads

A Take the defibrillation pads out of their original packaging.



B Remove the individual pad's protective film and place it on the patient's chest

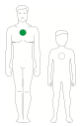


The correct placement of the pads is essential for an effective analysis of the patient's heartbeat and for the consequent delivery of the shock, if needed.
If the patient is a child (age 1 to 8 or weight <25 kg), before placing the defibrillation pads on the patient's chest, select the paediatric mode with the dedicated selector on the AED's keyboard
(please see paragraph 5.2.4 for more information).

Note: Please always refer to the instructions on the packaging and to the specific user manual of the pads.

7.5 Heartbeat analysis

If the defibrillation pads have been applied correctly on the patient and the connector has been inserted in the dedicated compartment, ***SMARTY Saver*** will automatically analyse the patient's heartbeat.
During the heartbeat analysis, the patient's body must not be touched and it must not be subject to vibrations or movements.
This stage of the analysis is characterised by the following voice messages:

Voice commands	Keyboard Illuminated Icons
Do not touch the patient	 Icon "do not touch the patient" lit without blinking
Heartbeat analysis in progress	 Icon "pad type used" Adult or child lit without blinking

The analysis software of ***SMARTY Saver*** has been designed to recommend the treatment with defibrillation shock only if the patient is suffering from the following arrhythmias:

VF *Ventricular Fibrillation*

Peak-to-peak amplitude of min. 200 µVolts
Certain rhythms with a very low amplitude or low-frequency VF can be interpreted as non-defibrillable.

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

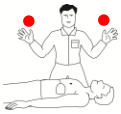
Rhythm frequency min. 180 bpm
and peak-to-peak amplitude of min. 200 µVolts
Certain rhythms with a very low amplitude or low-frequency VT can be interpreted as non-defibrillable.

The presence of noise artefacts (caused, for example, from the patient's movement or from the regulation of the defibrillation electrodes) or electronic disturbance emitted by external sources may delay or interrupt the ECG analysis.

Note: The ***SMARTY Saver*** analysis software can filter pulses originating from an implanted pacemaker.

7.6 Defibrillable rhythm

If a Ventricular Fibrillation or Tachycardia is detected, ***SMARTY Saver*** will inform the operator with the following commands:

Voice messages	Illuminated Icons/Buttons
Shock recommended	 Icon "do not touch the patient" Lit without blinking
Keep your distance, charging	
Keep your distance the shock will be delivered automatically within about 5 seconds	 Shock icon Blinking AUTO
A 5-second countdown starts *(five BEEPS)*	

At the end of the countdown, SMARTY Saver Auto will perform the defibrillation shock.
At this stage, the shock icon will no longer blink and the device will inform the operator with the following voice messages:

Voice messages
Shock delivered

SMARTY Saver delivers the shock using the BTE waveform with automatic compensation of the patient's thoracic impedance. The value of the impedance detected must range between 20 and 200 Ohm; if the value detected is outside of this range, the device will ask for the pads to be placed once more.

The shock protocol of ***SMARTY Saver*** is incremental, i.e. the energy delivered to the patient varies incrementally based on the number of shocks performed:

- first shock, energy 150J
- subsequent shocks at 200J.

This protocol is preset and cannot be modified by the user; it can be modified and customised solely and exclusively by A.M.I. Italia S.r.l. at the express request of the client (endorsed by a competent body).

7.7 Change of rhythm

SMARTY Saver performs a continuous analysis of the patient's heartbeat, throughout resuscitation.
If, after having recommended the shock, the device detects a change in the patient's heartbeat which no longer requires defibrillation, the AED will disarm automatically.
In this case, you will hear the following commands:

Voice messages
Shock cancelled
Rhythm changed

7.8 Non-defibrillable rhythm

If, during the analysis of the heartbeat, ***SMARTY Saver*** does not detect a VF o a VT, it will inform the operator with the following commands:

Voice messages
Shock not recommended

All rhythms other than VT and VF will be assessed as non-defibrillable.
For more information, please see paragraph 10.9.

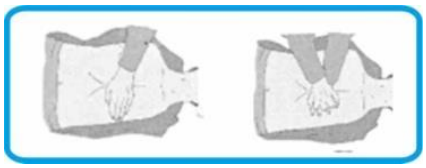
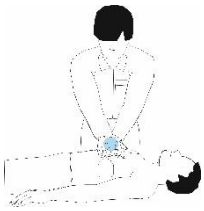
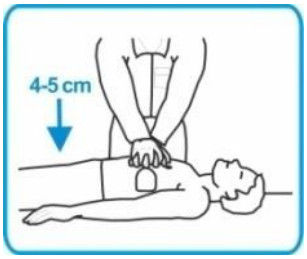
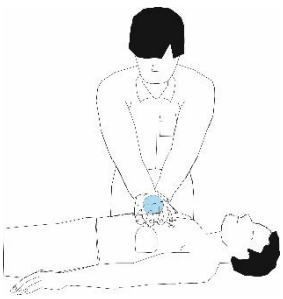
7.9 Cardio-Pulmonary Resuscitation

A ***SMARTY Saver*** defibrillator will guide the operator towards CPR in one of the following cases:

- A defibrillable rhythm has been detected and a defibrillation shock has been delivered
- A non-defibrillable rhythm has been detected
- A defibrillable rhythm has been detected by the patient's rhythm has changed

SMARTY Saver will provide voice instructions to perform CPR, guiding the operator on how to perform the chest compressions and insufflations.
SMARTY Saver will mark the rhythm of chest compressions with a metronome; once the compressions are finished, it will ask for the insufflations to be performed.
In accordance with the requirements of the AHA/ERC guidelines, the duration of the cardio-pulmonary resuscitation is approximately 2 minutes, with a compression/insufflation ratio of 30/2 for a total of 5 full cycles.
The voice instructions of ***SMARTY Saver*** are repeated for all cycles, i.e. for approximately 2 minutes.

The table below shows the main operations to be performed during CPR and the related visual/voice/text commands provided by ***SMARTY Saver.***

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

8 Recording, displaying and storing the data

The ***SMARTY Saver*** defibrillator records and stores, on the external memory (if present), the files generated each time the device is switched on and after each self-test (AEDLOG) and the data of the rescues performed (AEDFILE).
The number and duration of the recordings depend on the storage capacity of the µSD Card; an 8 GB µSD card makes it possible to store approximately 400 hours of recordings/data.

8.1 Files that can be stored.

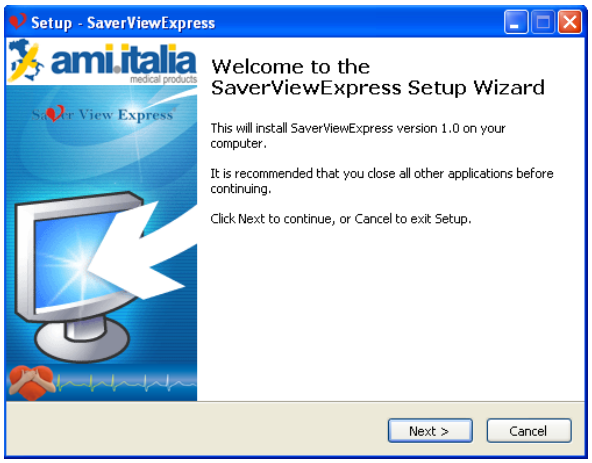
The data that can be stored on the µSD Card external memory can be divided into two types of files:

- **AED1LOG.txt:** files generated each time the device is manually switched on and after each automatic self-test performed by the device, with its outcome. The files can be displayed on a PC using a simple software that reads them.

- **AEDFILE.aed:** data of the rescue, such as environmental recordings (audio), ECG trace, patient data (patient Heart Rhythm and thoracic impedance) and all events of the rescue. The files can be displayed on a PC with the Saver View Express software owned by Ami Italia.

8.2 Storage of data on a PC

The data recorded by the ***SMARTY Saver*** defibrillator and saved on the µSD external memory can be stored in, analysed by and printed from a PC with the management software Saver View Express (SAV-C0950).



Saver View Express®

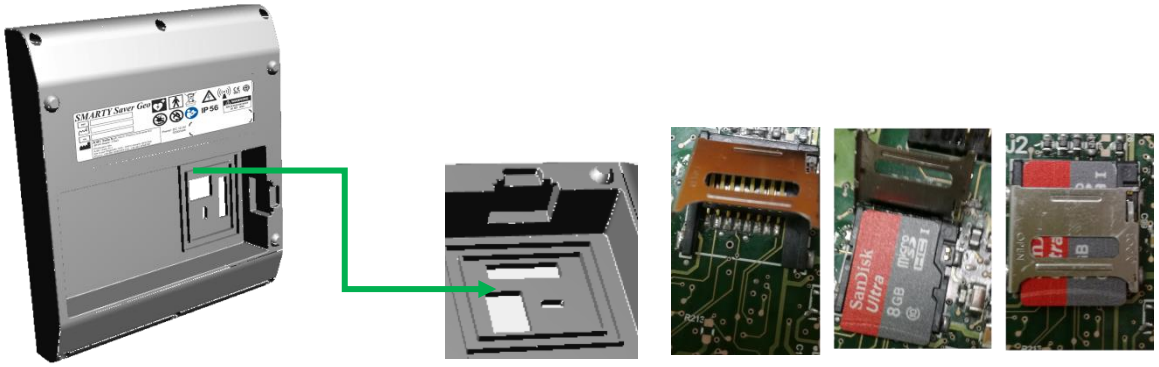
For more details on the PC Saver View Express software, please consult the related user manual.

8.3 µSD memory Card

Memory cards supported are µSD/SDHC cards with a capacity of up to 32 GB.

To install the memory card in ***SMARTY Saver***, please follow the procedure below:

- **A.** Make sure the device is switched off and place it on a hard and stable surface and remove the battery (see par. 5.1.1)
- **B.** Identify the housing of the µSD card as indicated (see figure below).
- **C.** Lift the lid, insert the memory card with the contacts turned inwards and close the lid as indicated in figure
- **D.** Re-attach the battery (see par. 5.1.1)



The data recorded directly on the µSD memory can be downloaded and displayed on a PC using the PC Saver View Express software owned by Ami Italia.

9 Maintenance

The ***SMARTY Saver*** defibrillator was designed to make maintenance operations simple and automatic. In fact, thanks to the control tests performed by the device itself, no extraordinary maintenance is required, just scheduled maintenance which consists in visually checking the control LED, at the same time as visually checking the related accessories.
If assistance is required during the device's installation or to report any malfunctions, please use the following contact details:

email:*info@amiitalia.com;* Tel.:+390818060574; website:www.amiitalia.com

9.1 Maintenance after use

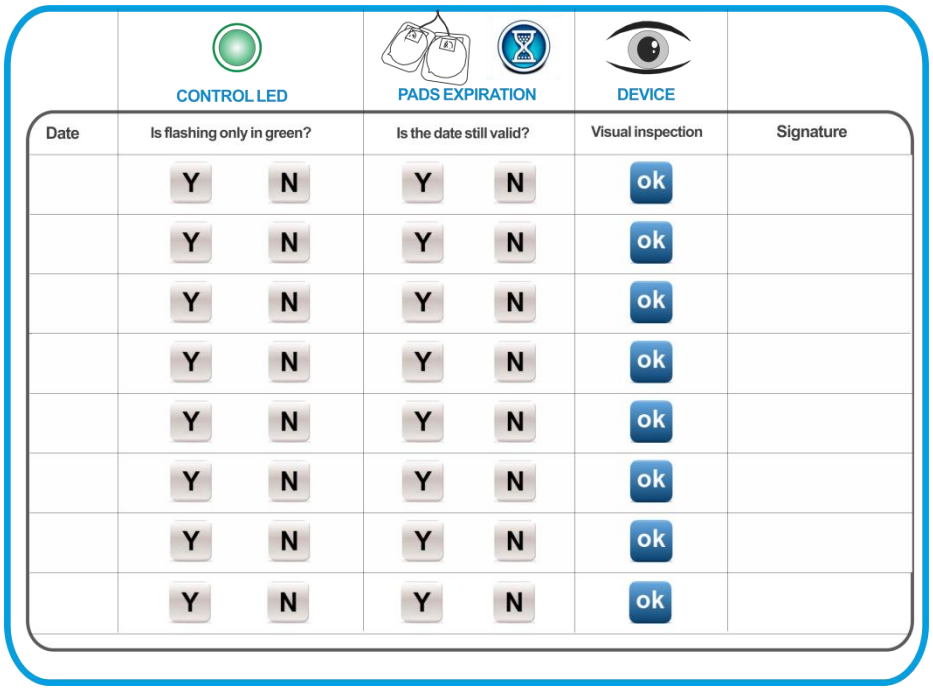
After having used the ***SMARTY Saver*** defibrillator, it is necessary to perform the following operations to ready the device for subsequent uses:

1. Check the presence of the memory card (if present) and its residual capacity
2. Check that the control LED is on and blinking green
3. Replace the pads with a new pack

9.2 Scheduled maintenance

Thanks to the tests performed by the device itself, scheduled maintenance will require a simple and quick visual inspection following the operations described in the table:

Daily Check	Monthly Check	Check before use	Check after use	Action indicated
*		*	*	Check the control LED (see par. 6.4)
*		*	*	Check the integrity of the device, of its parts and of the accessories supplied
	*	*		Check the expiry date of the defibrillation pads
			*	Check the residual capacity of the memory card (if present)



9.3 Cleaning

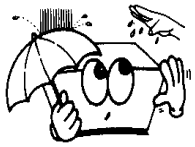
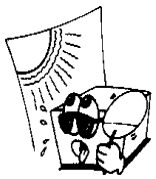
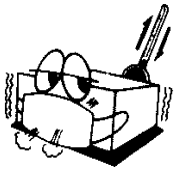
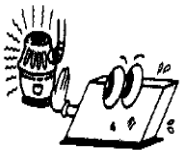
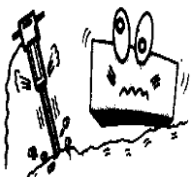
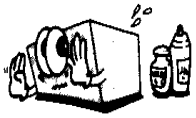
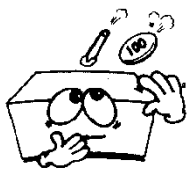
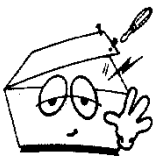
The structure of the ***SMARTY Saver*** defibrillator, including the port for the connection of the defibrillation electrodes, can be sanitised with the help of a soft cloth dampened with one of the detergent solutions listed below:

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

Do not immerse ***SMARTY Saver*** in any liquids.
Do not use abrasive materials or detergents, strong solvents, such as acetone or acetone-based detergents, and enzymatic detergents.
Do not sterilise ***SMARTY Saver*** or its accessories

9.4 Storage

SMARTY Saver must be placed in a place that complies with the environmental and safety conditions of the table below and at the temperature and humidity indicated in paragraph 10.2
The device must be stored with the battery always inserted, to allow periodic self-testing.
So that the device is easy to find in case it is needed, place it where it will be easily accessible and turned around so that the control LEDs are visible.

	Do not use, install or store ***SMARTY Saver*** in temperature or humidity conditions outside of the ranges mentioned in this user manual.		Do not install or store ***SMARTY Saver*** in areas directly exposed to sunlight
	Do not install or store ***SMARTY Saver*** in areas subject to significant fluctuations of temperature or humidity		Do not install or store ***SMARTY Saver*** near sources of heat
	Do not use, install or store ***SMARTY Saver*** in places subject to strong vibrations		Do not use, install or store ***SMARTY Saver*** in spaces with a high concentration of anaesthetic or inflammable gases
	Do not install or store ***SMARTY Saver*** in areas with high concentrations of dust		Tampering with ***SMARTY Saver*** can only and exclusively be done by A.M.I. Italia or personnel authorised thereby.

9.5 Guide to identifying faults

The table below lists the device's statuses, the possible causes and the possible corrective actions that will resolve issues that have emerged.
For more details regarding the implementation of corrective actions, please refer to the specific sections of this user manual. If the fault persists, please contact technical support.

STATUS	LED	POSSIBLE CAUSE	CORRECTIVE ACTION
The device, with the battery installed, does not switch on Both control LEDs are off	**OFF**	The battery is completely empty or faulty	Replace the battery. If the problem persists, please call technical support
		The device is not working	Please contact technical support
In stand-by mode, the control LED is off.	**OFF**	The control LED is broken	Please contact technical support
		The battery is completely empty or faulty	Replace the battery. If the problem persists, please call technical support
In stand-by mode, the control LED blinks RED.		A critical error of the device was found during the daily self-test.	Please contact technical support and give them the error code.
In stand-by mode, the control LED blinks alternatively GREEN/RED.		Battery empty Level <1% The device could switch off during use. *(please see paragraph 5.1)*	Please replace the battery immediately
In stand-by, the control LEDs blink alternatively once GREEN and twice RED.		The Face-to-Face pads are about to expire or are worn	Check the expiration date on the Pads package
In operation mode, the device emits the voice message "Batteries low"	 **OFF**	Battery low. Battery level 5%. It is possible to use the device *(please see paragraph 5.1)*	Please prepare to replace the battery
In operation mode, the device emits the voice message "Batteries empty, please replace them"		The battery is empty. Level <1% The device could switch off during use. *(please see paragraph 5.1)*	Please replace the battery immediately
In operation mode, after the pads have been placed on the patient's chest, the device continues to communicate: "Place the Pads"	**OFF**	The Pads' connector has not been inserted correctly or has been removed	Please insert the Pads' connector correctly in the dedicated compartment
		The Pads have been placed incorrectly	Please place the Pads correctly on the patient's naked chest. If needed, remove chest hair with a razor
		The Pads are faulty	Please control that the Pads are intact and their expiry date; replace them, if needed
The device switches on, but no voice messages are emitted	**OFF**	The device's speaker is not working	Please contact technical support

10 Technical specifications

Below please find the technical specifications of the ***SMARTY Saver*** defibrillator, its parts and accessories.

10.1 Physical characteristics

Category	Rated specifications
Dimensions	200 x 213 x 71 mm (handle folded) 257 x 213 x 71 mm (handle extended)
Weight	1.56 Kg (including Pads and battery)

10.2 Environmental requirements

Category	Rated specifications	
Temperature	Operational and stand-by: Storage and transport:	0°C to 45°C (32°F to 113°F) -40°C to 70°C (-40°F to 158°F)
Relative humidity	Operational and stand-by:	10% to 95% (without condensation)
	Storage and transport:	- without humidity control: from -40°C to +5°C - up to 90% humidity: from +5°C to +35°C - with water vapour up to 50hPa: from >35°C to +70°C
Atmospheric pressure	Operating conditions:	620hPa to 1060 hPa (calculated altitude min -382 and max 3,955 mt)
Operating conditions	Normal use:	Keep the AED device within the operating and stand-by range (10% to 95% without condensation), so that the device is ready for use. Instead, after storage and transport conditions, let the device stabilise for at least 2 hours at operating conditions, before normal use.
Tolerance to shocks and falls	In compliance with standards IEC/EN 60601-1 clause 21 (mechanical forces)	
Sealing system	In compliance with standards IEN/EN 60529 class IP56; splash-proof, dust-proof (with the battery installed)	
ESD (electrostatic discharge)	In compliance with the standards IEC/EN 61000-4 2	
EMC emissions/immunity	Please see paragraph 11	

10.3 Reference regulatory frameworks

Regulatory frameworks and Directives	DIRECTIVE 2007/47/EC EN 60601-1 EN 60601-1-2 EN60601-1-4 EN60601-1-6 EN60601-1-8 IEC 60601-1-11 IEC 60601-1-12 EN 60601-2-4 IEC 60086-4 EN 60529

10.4 Table of Alarms

Priority	Cause	Visual signal
HIGH	Device ready to administer shock	Blinking shock icon
HIGH	Battery empty (capacity < 1%)	Blinking control LED

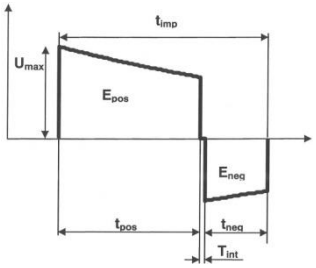
10.5 Controls and indicators

Category	Rated specifications
Buttons	• ON/OFF: switches the device on and off • "Adult" selection • "Paediatric" selection
Visual Indicators	• Shock Icon (8 red LEDs) • Device status control LED (2 LEDs: red and green) • Defibrillation pad placement LED (2 red LEDs) • Do not touch the patient LED (2 red LEDs) • You can touch the patient LED (1 green LED) • Adult patient LED (1 green LED) • Paediatric patient LED (1 green LED) • ON/OFF button LED (2 green LEDs)
Audio Indicators	Audio messages for instructions during use Warning and hazard acoustic signals
Speaker	Preset volume (Emissions compliant with IEC/EN 60601-2-4 point 6.1) Variation min. 20% max 100% (60 dBA to 80dBA ±3 dBA)
Microphone	Automatically activated recording on device switching on

10.6 Data memory

Category	Rated specifications	
External memory (optional)	µSD/SDHC-type Memory Card up to 32 GB (max)	
Stored data	AED1LOG.txt	Daily self-tests, Errors detected, Device use data, Device information
	AEDFILE.aed	Rescue data, Environmental voices and sounds, Rescue ECG trace, Analysed and detected patient vital parameters
Data display	Through PC Saver View Express Software (Microsoft Windows compatible)	

10.7 Defibrillator

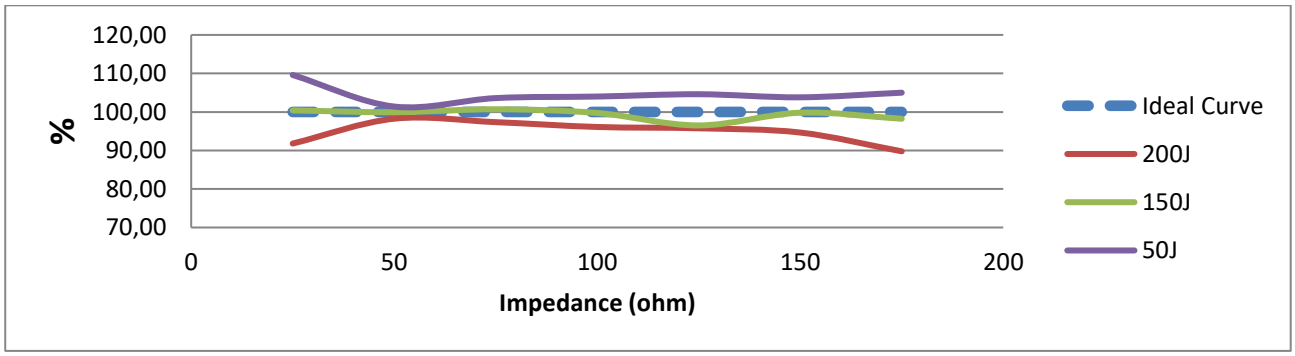
Category	Rated specifications
Waveform 	Biphasic Truncated Exponential (BTE) The waveform parameters are regulated automatically depending on the patient's autonomy In the graph on the left, t_{pos} represents the duration of phase 1 (ms), t_{neg} represents the duration of phase 2 (ms), t_{int} is the delay between the phases, U_{max} indicates the peak voltage, t_{imp} is the end voltage. In order to compensate for variations in patient impedance, the duration of each phase of the waveform is regulated dynamically based on the shock delivered, as indicated in the following paragraph.
Max Energy delivered (Adults)	nominal 200J
Adult shock protocol	Incremental: *First*: 150J – *Subsequent*: 200J
Max Energy delivered (Children)	nominal 50 J
Children shock protocol	Fixed: *First and subsequent*: 50J
Charge control:	Automatic through a patient analysis system
Charge time (from shock warning)	≤ 9 sec (in accordance with IEC60601-2-4 150J with new, fully charged battery SMT-C14031 ≤ 12 sec (in accordance with IEC60601-2-4 200J with new, fully charged battery SMT-C14031
Charge time (from the start of the analysis)	≤ 13 sec (in accordance with IEC60601-2-4 150J with new, fully charged battery SMT-C14031 ≤ 16 sec (in accordance with IEC60601-2-4 200J with new, fully charged battery SMT-C14031
Indication of full charge	• The SHOCK icon is blinking
Delivery of the shock	The shock is automatically delivered after 5 seconds
Disarming	*Automatic:* • If the patient analysis system considers the rhythm to be no longer defibrillable, or • If the defibrillation pads have been removed from the patient or disconnected from the unit. *Manual:* • If the operator pushes the OFF/DEACTIVATION button, at any time, to deactivate or switch off the device.
Shock detection vector	Through the defibrillation pads (Lead II)
Patient insulation	Through the Type BF defibrillation pads

10.8 Efficiency of the energy delivered

Impedance	Shocks at 50 J (Paediatric)				Energy delivered (Joules)
	Tpos (ms)	Tneg (ms)	U_{max} (V)	Energy set (J)	
25 Ohm	7.2	4.3	513	50	54.8
50 Ohm	7.2	3.7	653	50	50.7
75 Ohm	8	3.7	503	50	51.8
100 Ohm	8	3.7	421	50	52.0
125 Ohm	8	3.7	368	50	52.3
150 Ohm	8	3.7	327	50	51.9
175 Ohm	8	3.7	299	50	52.5

Impedance	Shocks at 150 J				Energy delivered (Joules)
	Tpos (ms)	Tneg (ms)	U_{max} (V)	Energy set (J)	
25 Ohm	3.7	7.3	1370.0	150	150.6
50 Ohm	5.5	5.4	1536.0	150	149.9
75 Ohm	7.4	3.7	1065.0	150	151.05
100 Ohm	6.8	4.0	815.0	150	149.6
125 Ohm	7.6	3.5	663.0	150	144.75
150 Ohm	10.0	3.9	557.0	150	149.7
175 Ohm	11.3	4.5	480.0	150	147.35

Impedance	Shocks at 200 J				Energy delivered (Joules)
	Tpos (ms)	Tneg (ms)	U_{max} (V)	Energy set (J)	
25 Ohm	3.9	8.0	1370.0	200	183.6
50 Ohm	7.2	7.7	1536.0	200	196.5
75 Ohm	9.1	7.7	1065.0	200	194.7
100 Ohm	11.2	8.3	815.0	200	192.2
125 Ohm	13.0	9.7	663.0	200	191.5
150 Ohm	15.0	10.6	557.0	200	189.3
175 Ohm	15.2	9.8	480.0	200	179.55



Delivered energy efficiency graph

10.9 Patient analysis system

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

10.10 ECG Analysis operation

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

10.11 Defibrillator battery

Category	Rated specifications
Code	SMT-C14031
Type	Li-MnO_2 (Lithium - manganese dioxide) single-use, non rechargeable
Voltage/ Capacity	12 VDC – 3000 mAh
Performance*	*Standard 200J* 200 full rescue cycles (shocks + CPR) at 200J. and Temp. 20°C Humidity 45%
	ECG analysis 36 continuous hours
Duration in Stand-by mode	Estimated 3 (three) years supposing a battery activation test and daily self-tests, without the AED being switched on (at environmental conditions of temperature 20°C and humidity 45% without condensation)

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

10.12 Internal back-up energy source

Category	Rated specifications
Type	Electric Double Layer Capacitor (Super-Cap)
Purpose	Preserving configuration data (date/time, etc.)
Voltage	3 VDC
Duration	30 minutes (with AED battery inserted at least 15 minutes earlier)

10.13 Defibrillation pads

Category	ADULT/CHILD
Code	SMT-C2001 Pre-connected universal plates
	SMT-C2002 Face-to-face pre-connected universal plates
Packaging	Cable and connector external to the bag
Patient range	Adult age >8 years or weight > 25Kg Child age 1 - 8 years or weight < 25Kg
Intended use	Single-use
Number of shocks tolerated	50 shocks at 360J (please refer to the specific user manual)
Support material	Medical FOAM, thickness 1 mm
Conducting gel	Adhesive low-impedance conducting gel
Total surface *(per pad)*	136cm²
Active area *(per pad)*	94 cm²
Conducting material	Metal foil
Connection	Safety shock-proof connector
Cable length	120 cm (standard)

10.14 Timing of Shock cycles

Charge time performance in compliance with 60601-2-4 (201.101)	Maximum time	Compliance
The maximum time between the start of the ECG Analysis and the completion of maximum energy charge	< 30 seconds	√
The maximum time from when the AED is switched on until the completion of maximum energy charge	< 40 seconds	√

11 Compliance with electromagnetic emission standards

The following paragraphs specify compliance with the electromagnetic emission standards:

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

11.1 Guidelines and manufacturer declaration - Electromagnetic emissions

SMARTY Saver was designed to be used in electromagnetic environments with the following characteristics.

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

11.2 Guidelines and manufacturer declaration - Electromagnetic immunity

SMARTY Saver was designed to be used in electromagnetic environments with the following characteristics.

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

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

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

11.3 Recommended separation distances between portable and mobile RF communication devices and the SMARTY Saver device

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

Maximum Rate of transmitter power emission W	**Separation distance in accordance with the transmitter's frequency m**			
	From 150kHz to 80 MHz outside the ISM bands $d = 1.2\sqrt{P}$	**From 150kHz to 80 MHz inside the ISM bands** $d = 1.2\sqrt{P}$	**From 80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**From 800 MHz to 2.5 Hz** $d = 2.3\sqrt{P}$
0.01	0.12 m	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.38 m	0.38 m	0.73 m
1	1.12 m	1.2 m	1.2 m	2.3 m
10	3.7 m	3.8 m	3.8 m	7.3 m
100	12 m	12 m	12 m	23 m
For transmitters whose estimated maximum power is not listed above, the separation distance *"d"* in metres (m) can be determined using the equation that applies to the transmitter's frequency, where P represents the maximum power produced by the transmitter in watt (W) in accordance with the transmitter's manufacturer.				
NOTE 1:	At 80 MHz and 800 MHz, the separation distance applied is the one used for high frequency intervals.			
NOTE 2:	The ISM frequency bands (for industrial, scientific and medical application) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz and 40.66 MHz to 40.70 MHz			
NOTE 3:	An additional factor of 10/3 is used in the calculation of the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency interval from 80 MHz to 2.5 GHz to reduce the possibility that portable/mobile equipment can interfere, if accidentally brought into the patient's area.			
NOTE 4:	These guidelines may not be applicable to all situations. Electromagnetic diffusion is affected by absorption and reflected from structures, objects and people.			

12 Symbols

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

ECM	Certification body marking
CE 1282	CE marking with identification number
IP56	Level of Protection of the device against dust and water (including the battery)
SN	Serial Number
	Manufacture Date
LOT	Lot Number (LOT)
	Expiry Date
REF	Model identification number
	Manufacturer Name
	Latex-Free
	Single-use, do not reuse
	Non-Sterile
	External instructions of the box
	This Side Up
	Temperature Limits
	Do not stack in piles of more than 6 boxes

13 Certifications

13.1 CE certificate

CERTIFICATO CE
EC CERTIFICATE

n. **ECM20MDD022 rev. 0**

Data di prima emissione *Date of first issue*	21/12/2020
Data di emissione *Date of issue*	21/12/2020
Data di ultimo rinnovo *Date of last renewal*	///
Data di revisione *Date of revision*	///
Data di scadenza *Expiry date*	27/05/2024

CERTIFICATO CE
EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Richiedente
Applicant

Ragione Sociale *Company Name*	A.M.I. Italia S.r.l
Sede Legale *Legal address*	Via G. Porzio Centro Direzionale IS.G2 – CAP 80143 – Napoli (NA)
Località *Place*	ITALY
Sito produttivo *Place of production*	Via Cupa Reginella 15A, 80010 Quarto (NA) - ITALY
Dispositivo Medico *Medical device*	Defibrillatori *Defibrillators*
Identificato come *Identified as*	Vedi allegato al presente certificato *See the annex of this certificate*

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità in accordo all'allegato II (escluso punto 4) della direttiva 93/42/CEE) e ha rilevato che ne soddisfa i requisiti.
Si fa riferimento al rapporto di audit di emissione del presente certificato del *15 ottobre 2020*; rif. piano di certificazione: *AMI ITALIA-19.09*

ECM, Notified Body n° 1282 has verified the Quality System in accordance with annex II (excluding clause 4) of the 93/42/EEC directive and found that it meets aforesaid requirements.
Reference to the audit report related to issue of the present certificate dated *15th October 2020*; ref. certification plan: *AMI ITALIA-19.09*

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

MDD13_M00 rev. 00 10.12.2020

Questo certificato, compreso l'allegato (se presente), può essere riprodotto solo integralmente e senza alcuna variazione
This certificate, annex included (where applicable), may only be reproduced in its entirety and without any change

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Pag. 1/2

CERTIFICATO CE
EC CERTIFICATE

n. **ECM20MDD022 rev. 0**

Data di prima emissione *Date of first issue*	21/12/2020
Data di emissione *Date of issue*	21/12/2020
Data di ultimo rinnovo *Date of last renewal*	///
Data di revisione *Date of revision*	///
Data di scadenza *Expiry date*	27/05/2024

Allegato al Certificato CE
Annex to EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Elenco dei Dispositivi Medici inclusi in questo certificato
List of Medical Devices included in this certificate

Descrizione ***Description***	**Classe di rischio** ***Risk class***	**Codice NBOG** ***NBOG code***	**Modello** ***Model***	**Taglie** ***Sizes***
Defibrillatore semiautomatico	IIb	MD1103+MDS7010	SMARTY Saver Base SMB-B0001	
Defibrillatore automatico	IIb	MD1103+MDS7010	SMARTY Saver Base SMA-B0002	
Defibrillatore semiautomatico	IIb	MD1103+MDS7010	SMARTY Saver SM1-B1001	
Defibrillatore automatico	IIb	MD1103+MDS7010	SMARTY Saver SM2-B1002	
Defibrillatore semiautomatico	IIb	MD1103+MDS7010	SMARTY SaverPlus SM3-B1003	
Defibrillatore automatico	IIb	MD1103+MDS7010	SMARTY SaverPlus SM4-B1004	
Defibrillatore semiautomatico	IIb	MD1103+MDS7010	SMARTYSaverGeo SM5-B1005	
Defibrillatore automatico	IIb	MD1103+MDS7010	SMARTYSaverGeo SM6-B1006	

Firma autorizzata
Authorized signature

(Federica Secchi - Technical Director)

MDD13_M00 rev. 00 10.12.2020

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14 SMARTY Saver Series defibrillator warranty

1 Restriction of the Warranty

A.M.I. Italia S.r.l. guarantees original buyers that its SMARTY Saver series defibrillators and the related accessories and batteries are free of all material and manufacture defects, in accordance with the terms and conditions of this limited warranty. The original buyer shall be considered to be the end user of the product purchased. This limited warranty is granted solely to the original buyer of the SMARTY Saver defibrillator and may not be leased or assigned to third parties.

The SMARTY Saver Series defibrillators are as follows:

- **SMARTY Saver** basic **s**emi-automatic or automatic (code **SMB-B0001 or SMA-B0002**)
- **SMARTY Saver s**emi-automatic or automatic (code **SM1-B1001** or **SM2-B1002**)
- **SMARTY Saver Plus s**emi-automatic or automatic (code **SM3-B1003** or **SM4-B1004**)
- **SMARTY Saver Geo s**emi-automatic or automatic (code **SM5-B1005** or **SM6-B1006**)

2 Term

The warranty offered by A.M.I. Italia S.r.l. has the following term (starting from the date of purchase):

- **SMARTY Saver Series AED**: Five (5) years
- **Non-rechargeable batteries:** Three (3) years (in Stand-by mode, supposing a battery activation test, daily self-tests, without the AED being switched on and under the environmental conditions of temperature at 20°C and humidity 45% without condensation)
- **Single-use pads:** until the expiry date indicated on the packaging.
- All **other accessories** shall be under warranty for one (1) year.

3 Procedure for the activation of the warranty

The user is required to register the device in the dedicated section of the website of AMI ITALIA www.amiitalia.com.

If a defect covered by this warranty is found, the original buyer must activate the Return Material Authorisation (RMA) procedure through the dedicated section on the website www.amiitalia.com. The repaired or replaced product will be guaranteed - for the specific defect - for one (1) year, while the terms and conditions of this Warranty shall apply to all other parts that were not subjected to the repair service.

4 Exclusions

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

This warranty shall not cover - as it does not constitute a case of original non-conformity - the normal wear and tear of components subject to degradation during use, such as Buttons, LEDs and battery contacts. Furthermore, this warranty will be automatically declared invalid in one of the following cases:

- the serial number of the SMARTY Saver AED is modified, erased, rendered illegible or, in any case, tampered with
- the warranty seal placed on the SMARTY Saver AED is removed (the device is opened)
- the commercial name of the product or of the manufacturer is covered, modified or erased

Lastly, this warranty shall not be valid for the SMARTY Saver AEDs that were sold used; in such case, the warranty must be offered by the reseller of the used product with exclusion of all liability, also indirect, of A.M.I. Italia S.r.l.

5 Damage

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

6 Waiver

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

7 Territorial limits

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

8 Warning

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

9 Other rights

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

10 Jurisdiction

Any dispute relating to this agreement or arising from the use of the SMARTY Saver series defibrillators of A.M.I. Italia S.r.l. will be governed by Italian law, before the Courts of Naples, Italy

SMARTY® SAVER

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MEDICAL PRODUCT

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