

TECHNICAL DATA SHEET

SMARTY SAVERGEO CPR QUALITY AND GEO SYSTEM





Compliant to latest ERC/AHA guidelines

In addition to the Q-CPR module, the SMARTY SaverGeo is equipped also with a SIM card and a GPS/GPRS system; the GPRS system allows the SMARTY SaverGeo to transmit and receive data through the mobile phone network, while the GPS system enables the tracking of the AED movements.

This info is sent by the device to the **Amisavercloud Platform**, which is conceived to **monitor and control multiple AEDs** remotely through any web browser and internet connected device. Among the info and data sent to the platform, such as position and current status of the AED, the device can also **transmit the ECG in real time**.

Hence a professional operator will be able to view and examine the ECG, real time, remotely on the Amisavercloud Platform just while the ECG is being performed on the patient.

Finally, through the dedicated "Vivo" button located on the keyboard the operator will be free to call the local EMS straight away, directly from the AED!

These features make the SMARTY SaverGeo very suitable for the use in moving vehicles such as trains, buses and ambulances.

The device is powered with two independent batteries - one to supply the proper AED functions and another one to supply the additional Geo system functions - in order to preserve the primary use of the device as automatic external defibrillator.

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GEO SYSTEM: REAL TIME AED MANAGEMENT

All the functions can be managed remotely, by any device, through the Amisavercloud Platform:



TELEMETRY

SMARTY SaverGeo connects to the portal daily, sending a log that contains detailed information on its status; this will be shown on the map with a coloured icon.

In case of anomaly, the Amisavercloud will notify the authorized user by SMS or e-mail (customizable alert).



DEVICE READY TO USE



WARNING - anomaly that does not compromise the defibrillator functions



FAULTY DEVICE - assistance required

GEOLOCATION

The platform can show:

- AED location: the exact position will be identifiable on the map.
- AED movements (self-tracking function): the AED journey will be visible on the map; if the "anti-theft" function is on the user will be notified by SMS/e-mail every time the AED is moved.





REMOTE ASSISTANCE - STREAMING ECG

The AED is able to transmit the ECG in real time; this can be consultable in streaming by any web connected device, via the Amisavercloud Portal. In addition, all ECGs sent will be saved in the portal and made available for subsequent consultations.

"VIVO" BUTTON FOR LIVE CALLS

The operator can promptly call the local EMS by pressing the dedicated button on the AED keyboard.

According to the local regulation, three telephone numbers can be set up to automatically attempt multiple calls, until a feedback is finally received.







DEFIBRILLATOR

Maximal Energy: Waveform:

Discharge protocol:

Charging time from shock alert*:

Charging time from analysis time*:

Analysis time:

Impedance range: Sensitivity: Specificity:

Controls:

Semi-automatic model

Fully Automatic model

Light indicators:

Upgradeable:

Code SM5-B1005: Semi-Automatic Code SM6-B1006: Fully Automatic 200J (nominal) Biphasic truncated exponential (BTE) automatically adapts according to patient's impedance . Adult: incremental first shock

IEC/EN 60601-2-4 ≤ 9 sec with shock at 150J ≤ 12 sec with shock at 200J

150J - subsequent 200J Paediatric: fixed 50J

IEC/EN 60601-2-4 ≤ 13 sec with shock at 150J ≤ 16 sec with shock at 200J IEC/EN 60601-2-4 from 4 to 15 seconds 20-200 Ohms 97% (IEC/EN 60601-2-4) 99% (IEC/EN 60601-2-4)

6 buttons: ON/OFF, shock delivery, patient selection (adult/child), live call, ECG streaming

5 buttons: ON/OFF, patient selection (adult/child), live call, ECG streaming - Device status: 2 LEDs red/green

- PADs placement: 2 red LEDs - Do not touch the patient: 2 red LEDs

- Touch the patient: 1 green LED - Adult patient: 1 green LED

Paediatric patient: 1 green LED
ON/OFF button: 2 green LEDs - Shock button: 8 red LEDs

- CPR Quality feedback 8 LED bar: 2 red + 2 orange + 2 yellow + 2 green - Q-CPR module connection:,1 green fixed LED

- ECG streaming: 1 green blinking LED Through USB cable

External memory card, remotely

*on a 50 Ohm patient and with a fully charged new battery

PHYSICAL

Size: 200x213x71mm (folded handle) 257x213x71mm (open handle) 1,70 Kg (with battery and defibrillation Weight: PADs)

EVENT RECORDING

Optional external memory:

Stored data:

Micro uSD/SDHC card up to 32GB "AED1LOG.txt": text file with detailed report of the activities of self-test and power-ups "AEDFILE.aed": ECG trace, rescue events, voices and background audio

"AEDFILE.aed"review: Through data manager software

"SaverViewExpress"

TECHNICAL DATA SHEET

DEFIBRILLATION PADS

Code SMT-C2001: Disposable, universal, Type: pre-gelled, preconnected

4 years, as indicated on the packaging Shelf-life:

Type: Code SMT-C2002: Disposable, universal, pre-gelled, preconnected, Face-to-Face 24 months, as indicated on the packaging Shelf-life: Total surface 136cm²; active surface 94cm²; Dimensions:

120cm cable length (external to the packaging)

BATTERY OPTIONS

Contained in SMT-C14032 Type:

Voltage/capacity: 12VDC-3000mAh

Autonomy: Up to 200 complete rescue cycles

(200J shocks + CPR);

Up to 36 hours of continuous ECG analysis* Stand by life: Up to 3 years with a battery insertion test and daily self-test without any turning on the AED*

ENVIRONMENTAL SPECIFICATION

0°C to 45°C (32°F to 113°F) Operating temperature: -40°C to 70°C (-40°F to 158°F) 10% to 95% Storing/Shipping temperature:

Humidity:

relative humidity without condensation

Sealing (IP Protection): IEC/EN 60529: class IP56 IEC/EN 60601-1 (compliant to 1 m. Drop Test)

Shock/Drop Endurance: IEC/EN 61000-4-2 Electrostatic Discharges: **Electromagnetic Compatibility:** IEC/EN 60601-1-2:2015 Protection from defibrillation: IEC/EN 60601-1;

device internally powered, Type BF MDR (EU) 2017/745 Class III, Annex VIII, Rule 22 Classification:

Q-CPR EXTERNAL MODULE

Description: Code SMT-C14034

External module to support CPR paired with the AED via Bluetooth; Class I Medical Device Weight and Dimension:

95 x 60 x 13mm; 50gr According to AHA/ERC guidelines for both Compression guidance:

adult and paediatric patients

Controls and light icons: Ignition key ON/OFF

Green flashing LED: Bluetooth signal search Green fix LED: Bluetooth connection active Code: SMT- C14035

Battery Coin

 Voltage/capacity 3 VDC / 1Ah Autonomy up to 2 hours in continued use

Radio Equipment compliance: Directive 2014/53/UE- RED

GEOLOC MODULE

Frequency: GSM: 850, 900, 1800, 1900MHz; UMTS: 900, 2100MHz; GPS: 1575, 1600MHZ

Battery: Type

Battery:

 Voltage/capacity Performance

Radio Equipment compliance:

Contained in SMT-C14032

10,8 VDC- 3500 mAh

Geo-location, remote control of the device, live call, ECG streaming

RED- Directive 2014/53/UE



^{*} performance referred to new batteries stored at a temperature of 20°C and relative humidity 45% without condensation