User Manual

Amisavercloud Platform

Rev.1.0

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

Via Cupa Reginella, 15/A - 80010 Quarto (NA) Italy
Tel. +39 081 806 34 75 +39 081 806 05 74
Fax +39 081 876 47 69

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

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1 Introduction

This guide is intended for users of AMI ITALIA defibrillators equipped with the "Geo" system and therefore compatible with use of the AMISAVERCLOUD platform.
Compatible AEDs are Geo Saver series models and SMARTY Saver Geo model as they are equipped with GPS/GSM/GPRS radio module and SIM card.
The presence of the SIM and of the GPRS system make it possible for the compatible AED to transmit and receive data over the mobile telephony network, while the GPS system makes it possible to track its movements.
These features make these AEDs particularly suitable for installation in public areas and in moving vehicles, such as trains, buses and ambulances.
The battery power supply of the system's components dedicated to geolocation and communication over the mobile telephony network is autonomous and supplementary to that of the components dedicated to the defibrillator's basic functions.
The provision of two independent batteries, therefore, guarantees the primary function of the defibrillator and the functions that can be used remotely.

Note: For detailed instructions on the use of the defibrillators, refer to the relevant user manuals.

1.1 Version information

Version number: 1.0
Date of issue: 15/03/2021

1.2 Contact details of the manufacturer

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

REGISTERED OFFICE
Via G. Porzio Centro Direzionale Isola G/2 - 80143 Napoli (NA) Italy
MANUFACTURE, LABORATORIES, OFFICES
Via Cupa Reginella, 15/A - 80010 Quarto (NA) Italy
Tel: +39 081 806 34 75 - Fax: +39 081 876 47 69

A.M.I. International KFT

REGISTERED OFFICE
Dòzsa Gyorgyùt 86/b 3/1 1068 - Budapest Hungary
MANUFACTURE, LABORATORIES, OFFICES
Kőzúzóu. 5/A - 2000 Szentendre Hungary
Tel: +36 26 302.210

Request for assistance

email: info@amiitalia.com
website: www.amiitalia.com
Tel: +39 081 806 05 74

2 General information on the "Geo" system

The information that the compatible AEDs send remotely through the GPS/GPRS system can be consulted via the AMISAVERCLOUD web platform (www.amisavercloud.com) accessible from any device equipped with an Internet connection and a browser; the use of other devices or any dedicated software it's not required.
AMISAVERCLOUD is the web platform through which it is possible to control and monitor the compatible devices. Each user can access this platform securely, using personal credentials provided by the system.
Using a simple map, it will be possible to locate the position of the devices that form part of the machine fleet and view their status; each device will, in fact, be represented on the map by an icon that shows the actual operating status.

2.1 Additional functions of "Geo" system

Compared to other defibrillators manufactured by AMI ITALIA, the ones equipped with the "Geo" system have the following additional functions, all of which can be managed remotely through the AMISAVERCLOUD platform:

- Remote control
- Telemetry
- Geolocation
- Remote assistance
- VIVO calls

Remote control
By accessing the section that is dedicated to the individual device, it is possible to know the current configuration and to modify certain aspects of it by executing simple commands.

Telemetry
Compatible AED models connect to the portal automatically -at least once a day- sending a log containing detailed information on their status, which can be consulted via the platform; if the device presents an anomaly (low battery, malfunction or continuous absence of coverage) AMISAVERCLOUD will notify the event to the authorised user by SMS or e-mail.
The device's status will be shown on the map with a coloured icon:

- green: device ready to use
- yellow: warning of an anomaly that does not compromise the defibrillator functions
- red: faulty device, assistance required

Geolocation
For each compatible device it will be possible:

- to know its location; the exact position will, in fact, be identifiable on the map.
- to track its movements (self-tracking) and see its journey on the map.
- to set the "anti-theft" function: each time the AED is moved, the user will be notified by SMS or e-mail.

This function can be deactivated using a specific procedure: refer to the user manual of the specific defibrillator model for detailed information on how to deactivate the function.

Remote assistance - Streaming ECG
The device equipped with the "Geo" system is able to remotelly transmit the electrocardiogram in real time; it will then be consultable in streaming via the AMISAVERCLOUD portal.
In addition, all ECGs sent will be saved in the portal and made available for subsequent consultations.

Note: As, at this time, the Amisavercloud Platform is not a medical device validated in accordance with Directive 93/42, the ECG trace viewed on the platform must not, therefore, be deemed to be a means of diagnosis.

VIVO calls
With the dedicated button on the device's keyboard, the operator can - during the rescue - made a voice call directly from the AED.
Using the portal, it is possible to set up to three phone numbers that will receive the call (taking into account the regulatory framework in force in the country where the device is installed); these numbers will be contacted one after the other, until one of them replies.
Refer to the user manual of the specific defibrillator model for how to initiate the call.

2.2 Procedure for the activation of the additional services of the "Geo" system

In order to use the services of the Geo system, the following activation procedure must be followed::

1. Check that the SIM supplied is correctly inserted
2. Make sure that you are in an area covered by a GSM/GPRS signal
3. Insert the battery of the AED in the dedicated compartment
4. Check that the AED performs the activation test when the battery is inserted
5. Switch off the AED
6. Wait for a few minutes and check, on the AMISAVERCLOUD platform - in the page that relates to the device being used - that the session log has arrived.

Note: The SIM cards supplied by the manufacturer may be used only and exclusively for the compatible AED; it is recommended to use the SIM supplied only with the AED with which it has been associated.
Refer to the user manual of the specific defibrillator model for proper battery insertion of the AED.

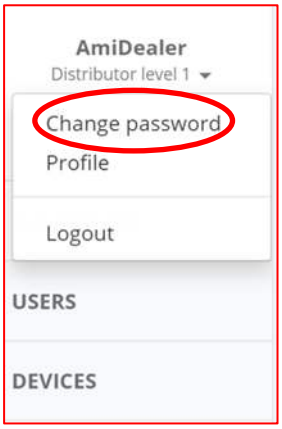
3 AMISAVERCLOUD PLATFORM

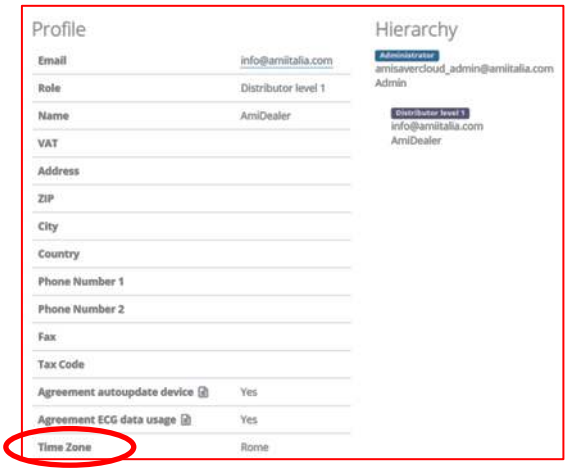
The information sent remotely by the compatible AEDs through the GPS/GPRS system can be consulted via the AMISAVERCLOUD - www.amisavercloud.com - web platform, accessible from any device equipped with an Internet connection and a browser; the use of other devices or any dedicated software is not required.

3.1 First access to the platform

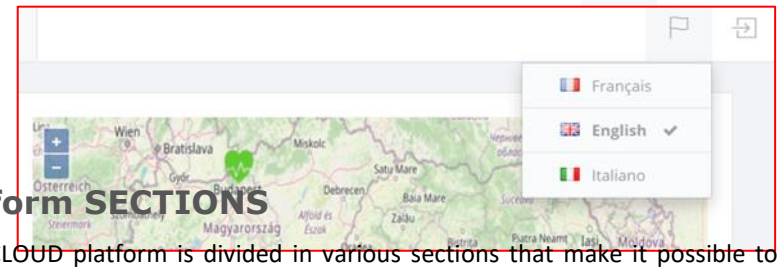
Each user may access the platform securely, as an authentication mechanism with password is envisaged.
On purchase of the compatible device, AMI ITALIA will generate a new user on the AMISAVERCLOUD platform, taking the e-mail address provided by the customer as reference. On creation of this new user, the system will automatically send the access credentials with an invitation to change the password on first access.
To access your profile:

- Type into the browser: ***www.amisavercloud.com***
- Click the key Login and enter the credentials you have received
- Change the password
- Set the local time





Once you have accessed the platform, it will also be possible to select one of the available languages from the drop-down menu that can be displayed by clicking the dedicated icon on the upper right-hand side.



3.2 Platform SECTIONS

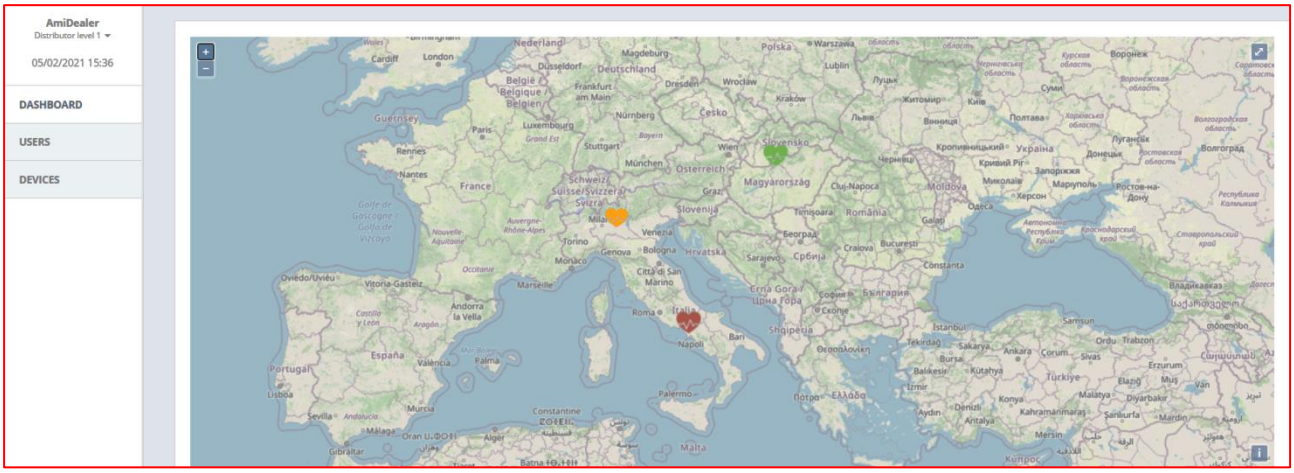
The AMISAVERCLOUD platform is divided in various sections that make it possible to manage and monitor the devices associated with your account:

- DASHBOARD: geolocation and device status
- USERS: management of your account and of related accounts
- DEVICES: global management of the machine fleet and specific management of an individual device

3.2.1 DASHBOARD section

In this section, you can immediately view the geolocation of the devices: in fact, they can be easily identified on the map, as they are represented with a heart icon.
The colour of the heart icon indicates the operating status of the device:

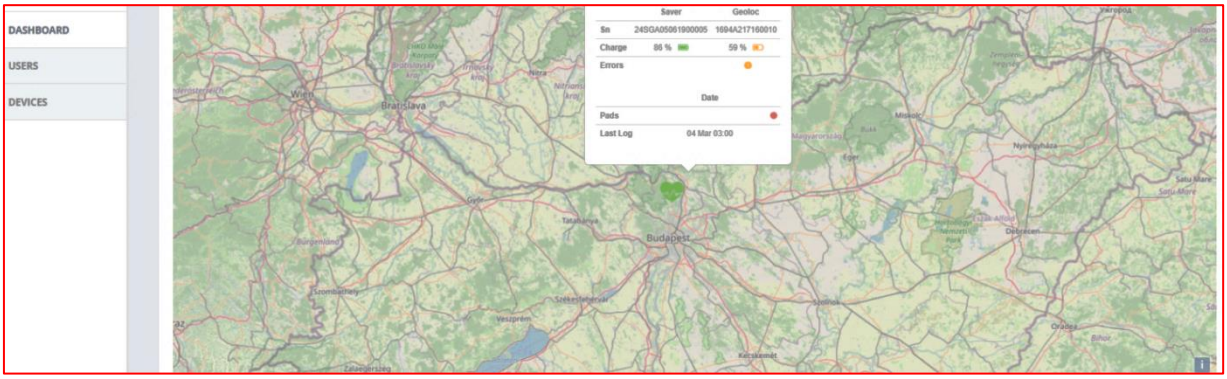
- Green heart icon: device ready to use
- Yellow heart icon: device in alarm status
- Red heart icon: device in error status



Note: The alarm status identified by the yellow icon indicates an anomaly with regard to the additional functions of the Geoloc module and which, therefore, does not compromise the defibrillator functions.

By clicking on one of the heart icons, you will see a pop-up with the following information concerning the specific device:

- Serial number of the AED/Serial number of the Geoloc module
- Battery status of the AED/Battery status of the Geoloc module
- Last error code detected
- Expiry date of the defibrillation pads
- Last LOG file saved



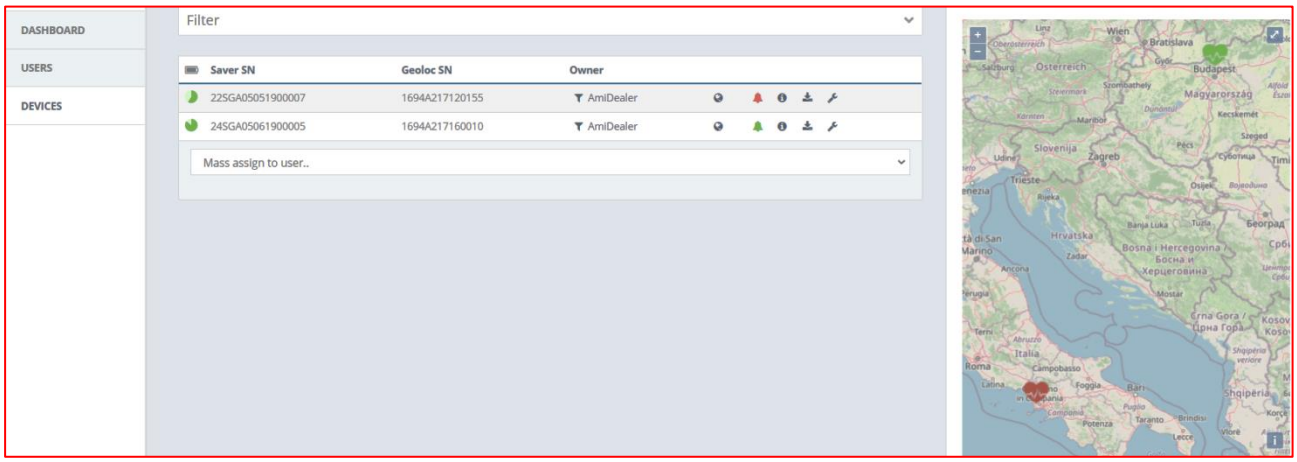
3.2.2 USERS section

This section is mainly intended for the management of your account and of associated accounts.
The typical of this section, in fact, is the allocation of a specific device to a new user, thus generating a new account; this specific system of the AMISAVERCLOUD platform is particularly suited to large distributors who are in charge of managing a large number of AED devices.
The main user can, in fact, generate a network of subordinate users with multi-level accesses; each one of these users (e.g. end user of the AED) will have remote access only and exclusively to their own device.
The remote control and management operations that can be used by the various users will result in saving time and the costs related to the maintenance of the devices distributed on a territory.

3.2.3 DEVICES section - general view

In this section, you will see the list of devices associated with your account; by using the "filter" function, you can filter the list by:

- User
- Range of Defibrillator serial numbers
- Range of Geoloc serial numbers
- Geographical area



For each one of the devices listed you can see various information and commands, such as:

- serial number of the device and of the Geoloc module
- associated owner/user
- icon/key *"show on the map"* : to display the exact location of the device
- icon/key *"last alarm"* : if red, it indicates the alarm code of the last error detected
- icon/key "update available" : if present, it indicates the availability of an update of the AED's software
- icon/key "go to streams" : if present, it leads automatically to the "ECG flow history" section, where all ECGs saved are stored. (Please see dedicated section par. 4.2.3)
- icon/key "more information" : access to the information relating to the specific device (see par. 4.1)

4 DEVICES section: individual view and menu

4.1 Individual view of the device

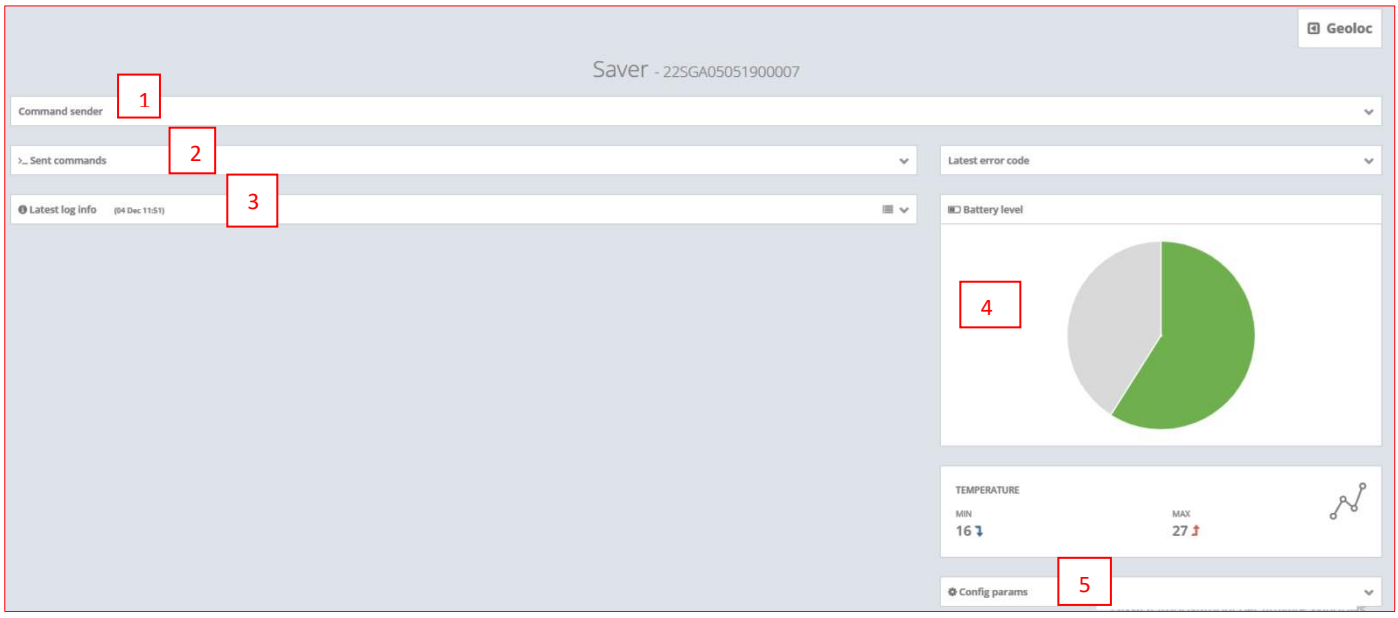
By clicking on the key *"more information"* , the menu will expand showing a submenu and you will access the section dedicated to the device selected.
What is displayed is a page that summarises all detailed information with reference the AED part and the Geoloc part of the specific device.
It is structured so that it can be subdivided into three parts:

Upper part: commands and information

1) Associate: to associate the device to another user (end user or dealer)
2) Alarm reports: to enable alarms to be sent (via e-mail/SMS)
3) "Anti-theft": if the anti-theft function has been enabled by AMI ITALIA on request of the user, the alarm will be sent as soon as the device detects a movement and regularly for its entire duration. A path can be viewed on the map will therefore be generated (see par. 4.2.4)
4) Icon/button *alarm configuration* to directly access the "alarm management" section (see par. 4.2.3)
5) Pads expiry: display of the expiry of the defibrillation pads in use

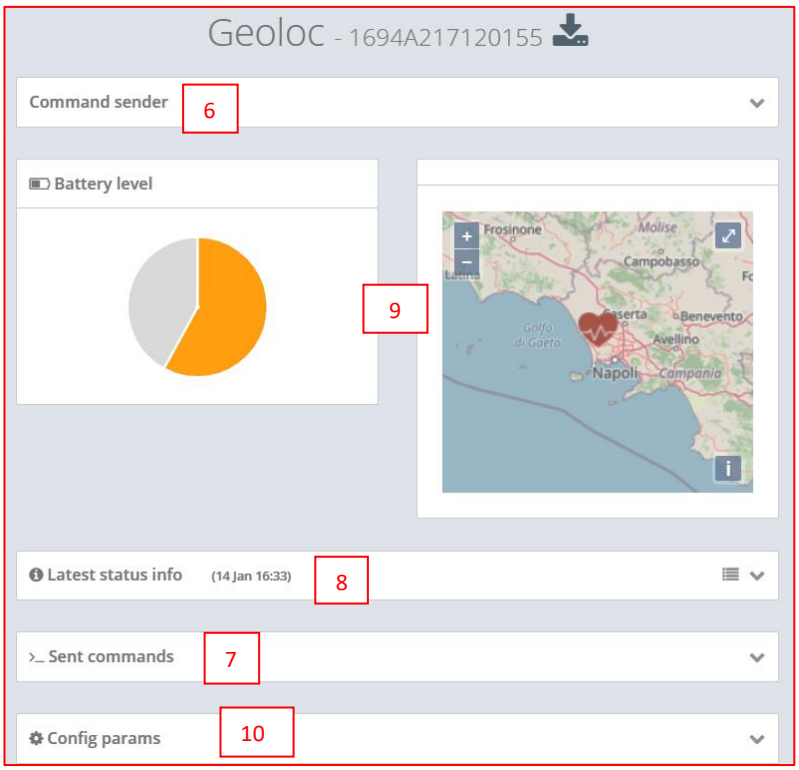
Left-hand side: Saver

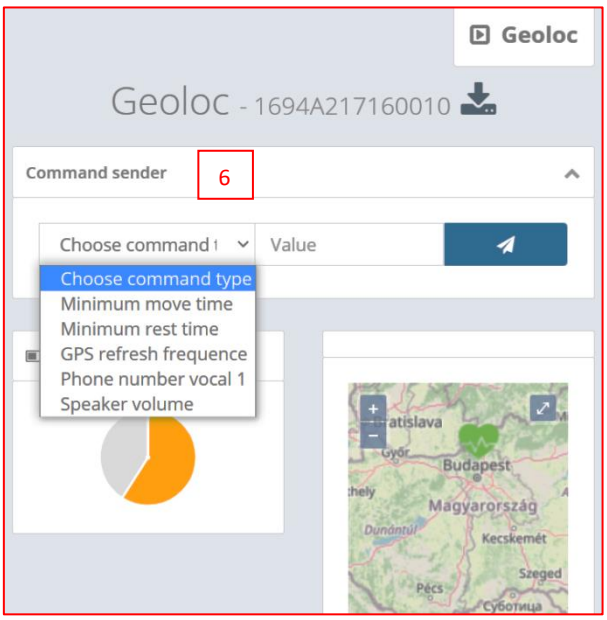
1) Collapsible panel to send the command "modification of the AED speaker volume"
2) Collapsible panel for the last commands sent and the related completion status
3) Collapsible panel with details of the last log received by the AED
4) Pie chart with the battery level
5) Collapsible panel with the last set of configurations

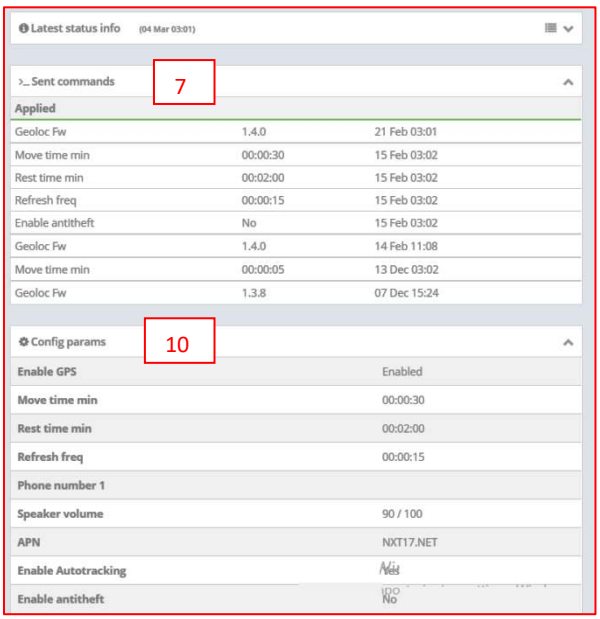


Right-hand side: Geoloc (expandable/collapsible)

6) Collapsible panel to send one of the following commands:
   - Movement/rest time of the tracking function
   - Emergency numbers to be called one after the other with the vivo button
   - Volume of the emergency call speaker
7) Collapsible panel for the last commands sent and the related completion status
8) Collapsible panel with details of the last log received or the code of the last error
9) Map showing the last location received and pie chart with the battery level
10) Collapsible panel with the last set of configurations



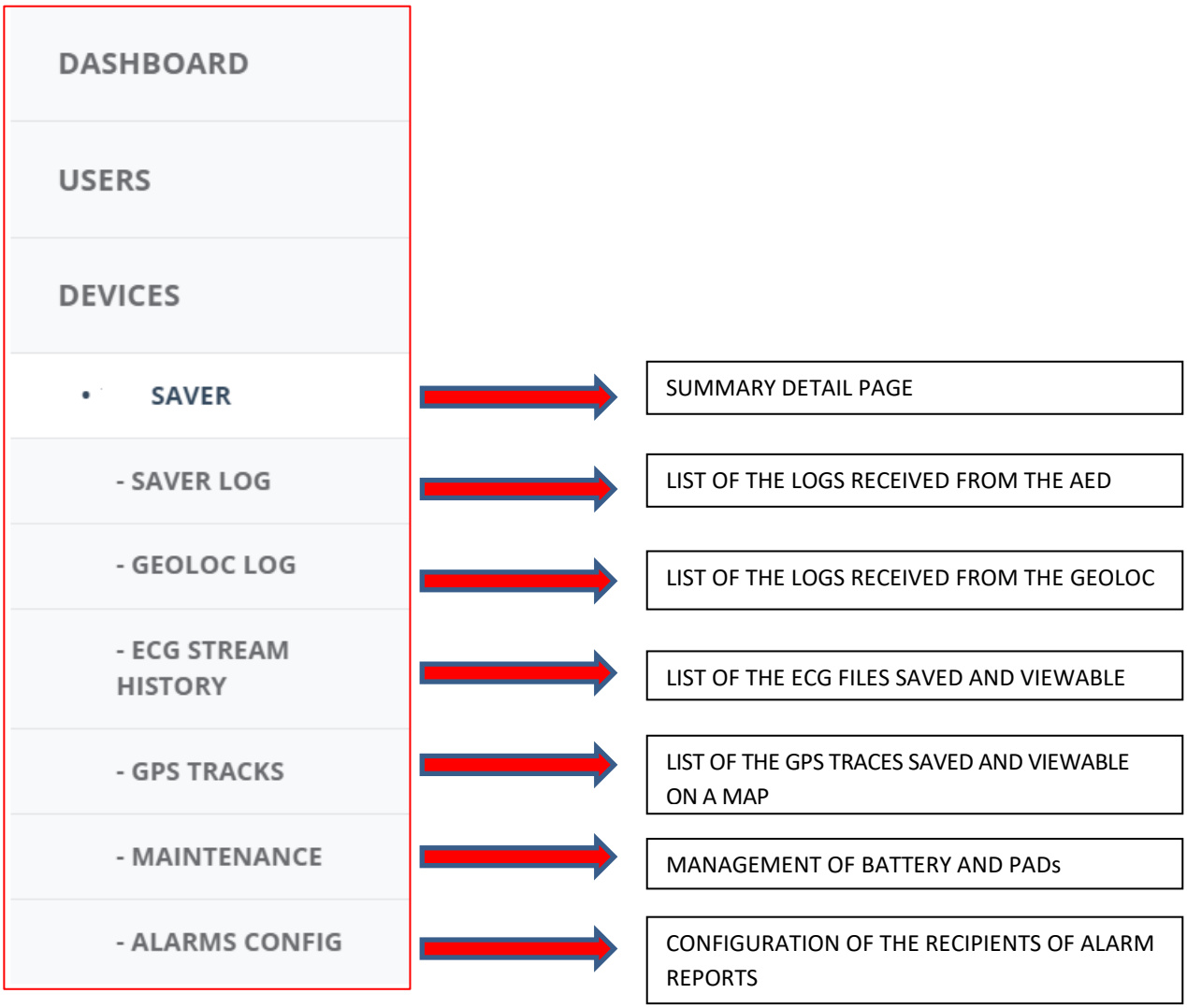




4.2 SUBMENU

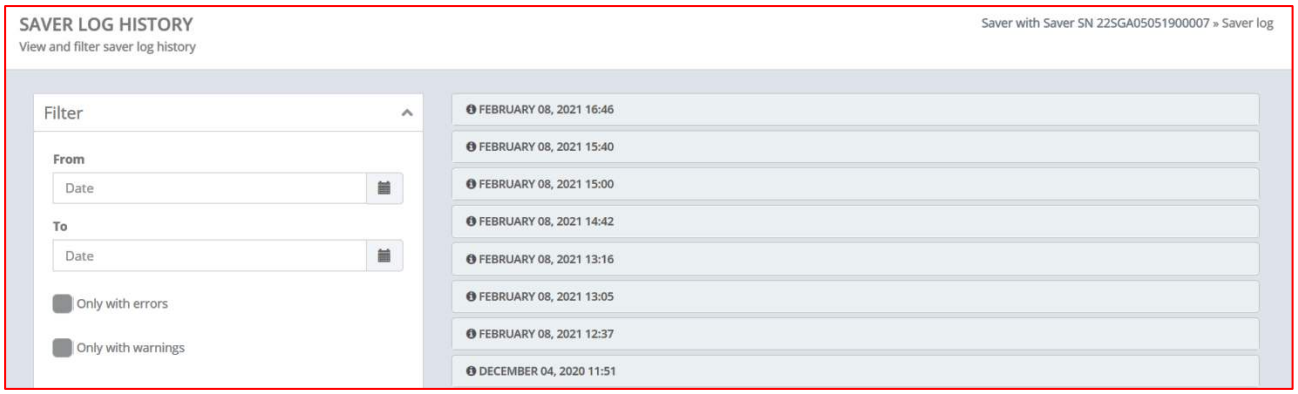
The submenu shown below will be displayed by clicking the *"more information"* icon/key correspondence of the serial numbers - numbers for the identification of each individual device associated to the user - listed in the dedicated "DEVICES" section.
It is made up of the following items:

- Saver: summary detail page
- Saver Log: list of the logs received from the AED.
- Geoloc Log: list of the logs received from the Geoloc Module
- ECG Streaming list (item displayed if ECG files are present): list of the streaming files of saved and viewable ECGs
- GPS trace (item displayed if tracking files are present): list of the GPS traces saved and viewable on a map
- Maintenance: management of accessories (battery, defibrillation pads).
- Alarm management: configuration of the recipients of alarm reports (via SMS or e-mail).



4.2.1 SUBMENU: Saver Log

The compatible device performs the self-tests daily and each time it is switched on/off; the outcome of the test is sent automatically by the device to the platform, via the LOG file.
Each LOG file is saved and given a name with the reference date and time; the full list of all files can be viewed on this page for a prompt check of all parameters contained in the log.
The list can also be filtered by date and time; an additional filter can be added by selecting just the log with presence of errors and/or warnings.



4.2.2 SUBMENU: Geoloc Log

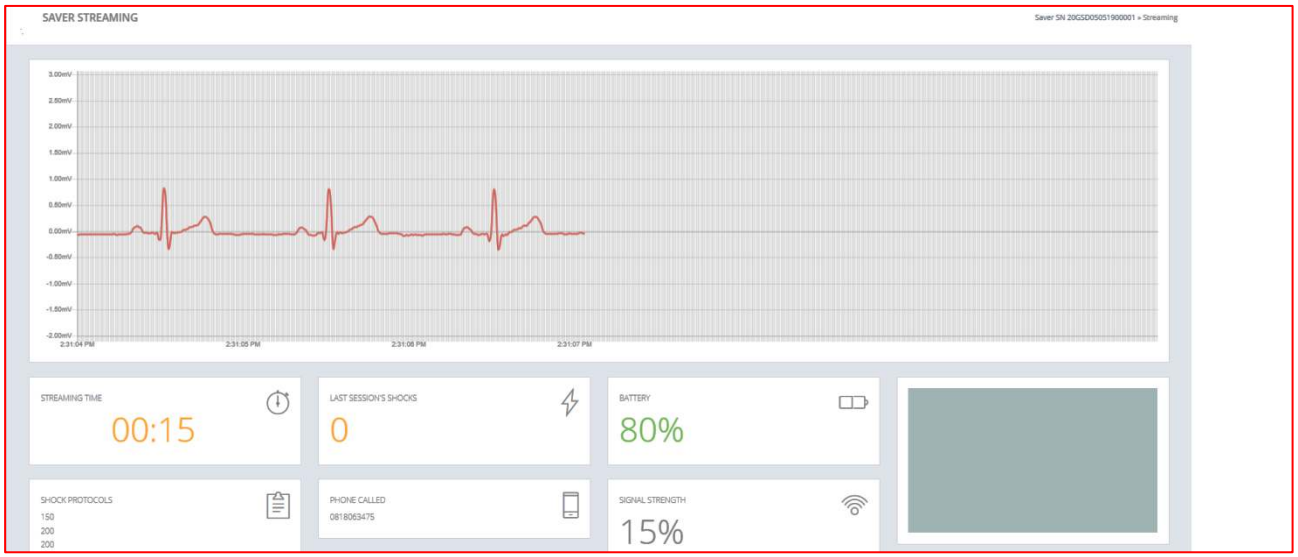
As for the AED part, the logs that relate to the Geoloc part are also saved and viewable in this section.

4.2.3 SUBMENU: STREAM ECG LIST

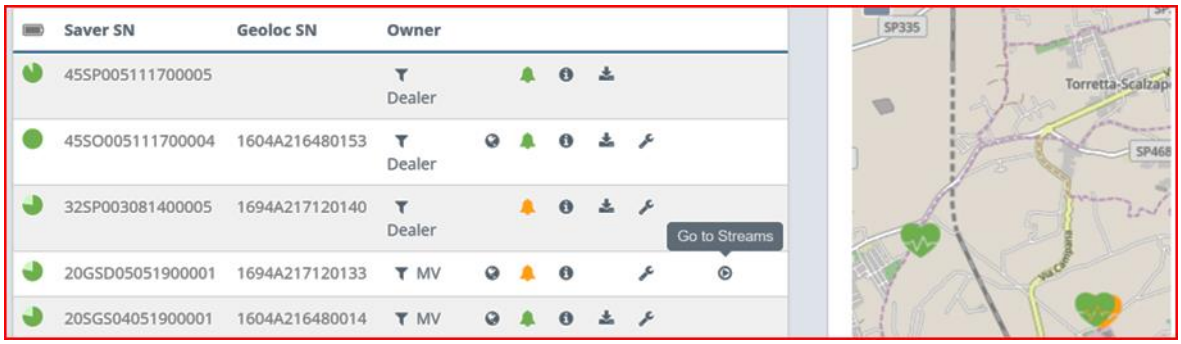
The transmission of the ECG from the defibrillator to the AMISAVERCLOUD platform must be enabled using the appropriate button on the AED keyboard; refer to the specific user manual for further information.
During the ECG streaming, the user will see on the platform:

- A blinking ECG icon that corresponds to the AED involved in sending
- A text notification “one of the devices is streaming ECGs”

By clicking on one of the two areas, the user can view - in real time - the ECG trace that is being performed on the patient.



Once the streaming is completed, the icon *“go to streaming”* will be displayed; by clicking on this icon, you will access the section “ECG FLOW HISTORY” which can also be viewed in the submenu of the specific device.



The section “ECG FLOW HISTORY” collects all ECGs sent, saved and listed as files named with the related sent date, also identifiable by acquisition date and duration.

These files can, therefore, be consulted at any time, after the rescue, for further assessment.

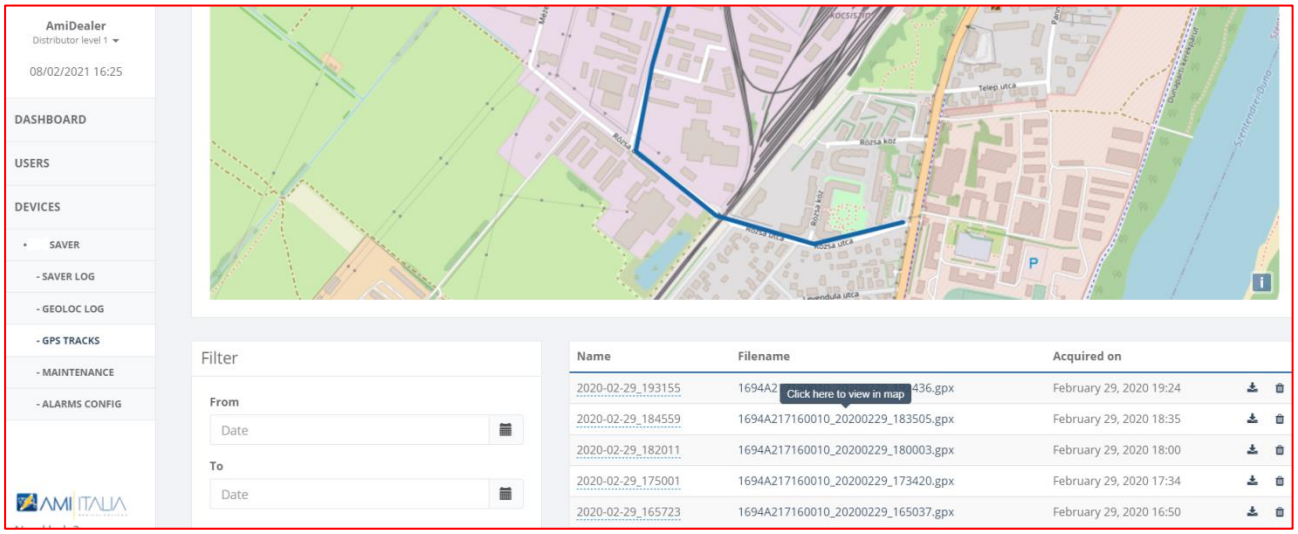
Note: This section will only be visible in the presence of at least one saved ECG and if the function "ECG streaming" has then been activated

4.2.4 SUBMENU: GPS TRACES

If the "self-tracking" or anti-theft function has been activated by AMI ITALIA on specific request of the user, the device will send its location when in movement; it will then be possible to reconstruct the journey made by the AED from detection to the last movement detected.
The file that identifies this journey will be saved in this section with the date and time of the movement.
The following may, therefore, be displayed in this section:

- A map to view the trace
- A filter from which to select the range of dates of interest
- A table with the list of traces saved and perhaps filtered; on selecting one, the journey will be displayed on the map.

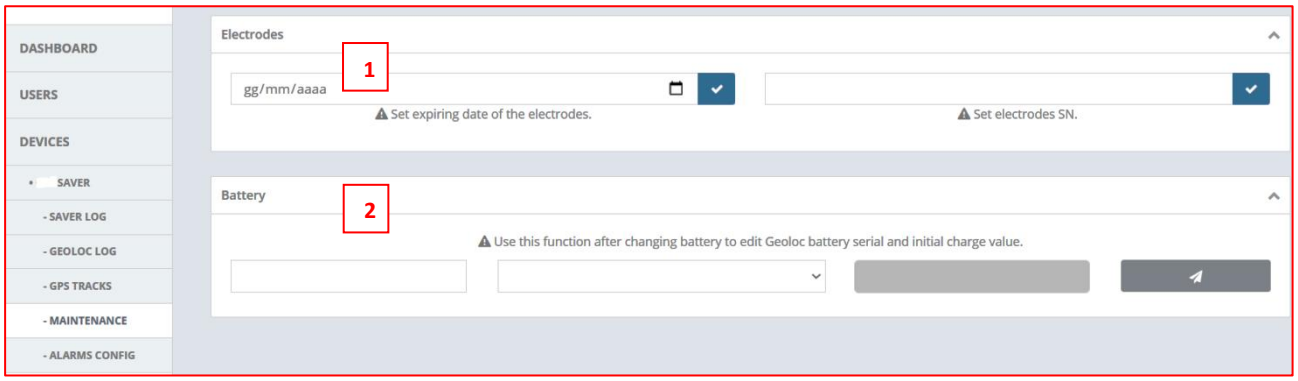
Note: This section will only be visible in the presence of at least one saved tracking file and if the function "self-tracking/anti-theft" has then been activated



4.2.5 SUBMENU: MAINTENANCE

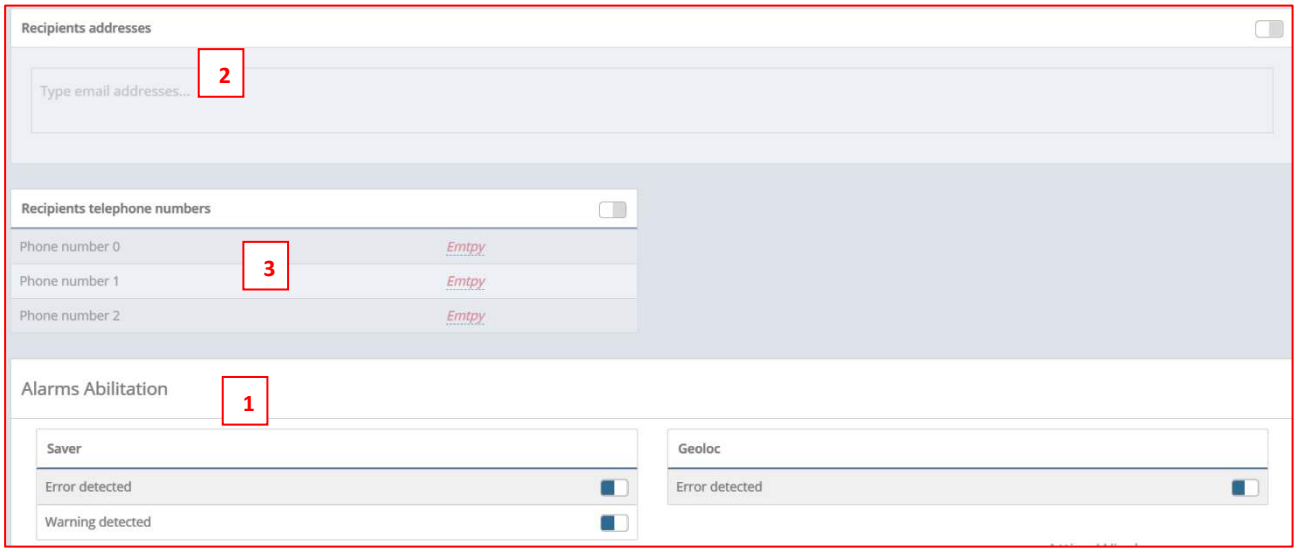
This section is dedicated to the accessories of the compatible device, such as defibrillation pads and battery, which require maintenance as to the check of their expiry and wear and tear.
The platform will, therefore, be an additional aid, other than the visual check by the operator, for monitoring the expiry of the pads and the wear and tear of the battery.

1) Defibrillation pads: enter the expiry date and the lot serial number as mentioned on the sale packaging
2) Battery: enter the battery type (disposable or rechargeable) and the battery serial number



4.2.6 SUBMENU: ALARM CONFIGURATION

In this section it is possible to determine which alarms to enable (1) and configure the recipients of the reports of such alarms, by entering the related e-mail - in which case the recipients will receive the alert via e-mail (2) - or the mobile phone number - in which case the recipients will receive an SMS (3).



AMISAVERCLOUD platform is conceived to be an autonomous device that provides services (consultation of the data that have been sent and/or stored). As, at this time, it is not a medical device validated in accordance with Directive 93/42, the ECG trace viewed on the platform must not, therefore, be deemed to be a means of diagnosis.
AMI Italia intends to launch the procedure for its formal medical validation. Once such validation has been concluded, AMI Italia will inform its users immediately.


AMI ITALIA
MEDICAL PRODUCT


AMI INTERNATIONAL
MEDICAL DEVICE