

# **Digistat Smart Central**

## **Quick Reference Guide**

Version 5.0

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#### **Digistat® Smart Central version 8.1**

Digistat® Smart Central is manufactured by Ascom UMS srl (<a href="http://www.ascom.com">http://www.ascom.com</a>).

Digistat® Smart Central is a Class II medical device in accordance with 21 CFR §870.2300 provided by the FDA and therefore it is to be installed, configured, maintained and used in US only.

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This document is a Quick Reference Guide to some of the main Digistat Smart Central product features and functionalities.



This is not the Digistat Smart Central product user manual, and it does not fully describe all the product's features and functionalities. See the Digistat Smart Central user manual for complete instructions on the product's features and functionalities.

## 1. Start-up procedure

## 1.1 Digistat Smart Central installation

The Digistat Smart Central product can only be installed by Ascom UMS technicians or technicians explicitly authorized by Ascom UMS. The end-user will find the system already installed and properly configured on his/her workstation.

## 1.2 How to run Digistat Smart Central

To run Digistat Smart Central

> Double click the icon on the workstation desktop.

A start-up window is displayed while the system is loading.

After a few seconds, the Digistat Smart Central work area is displayed (Fig 1).



Fig 1

## 1.3 Log In procedure

To use Digistat Smart Central user login is required. I.e. the user must insert his/her credentials (user name and password). To log in, at the beginning of every work session,

Click the **User** button indicated in Fig 2 **A**. The following screen is displayed.



Fig 2

Then,

- Insert the username in the "User Name" field (Fig 2 B).
- Insert password in the "Password" field (Fig 2 C).
- Click the **Ok** button (Fig 2 **D**).

The user is this way logged. An acronym indicating the user currently logged is displayed on the **User** button on the control bar (the acronym is "ADM" in Fig 3).



## 1.3.1 How to disable the automatic user log out ("User lock" functionality)

If the system remains idle for a certain time (configurable), the user is automatically logged out. To disable this functionality it is necessary, after username and password specification and before clicking  $\mathbf{Ok}$ ,

Click the **Lock** button on the "Log in" screen command bar (Fig 4 A).



Fig 4

If the user is locked, a padlock is shown at the bottom of the user icon (Fig 5).



#### •

## 1.4 Log out

The user, to close a work session with Digistat Smart Central, must "log out" from the system.

To log out

Click the **User** button on the command bar (Fig 6 and Fig 2 **A**).



The user acronym disappears from the **User** button.

## 2. Digistat Smart Central unavailability

In case the workstation (including mobile devices) where Digistat Smart Central is installed encounters issues when connecting to the server, a specific information message is displayed.

Digistat Smart Central tries to recover automatically. If automatic recovery fails, it is necessary to contact the technical assistance.



It is responsibility of the Healthcare Organization using Digistat Smart Central to define an emergency procedure to put into effect in case of system unavailability. This is necessary to

- 1. Make it possible for the departments to keep on working
- 2. Restore as soon as possible the system to full availability (back-up policy is part of this management).

Ascom UMS/Distributor offers full support for the definition of such procedure. See section 10 for the contacts list.

## 3. Digistat Smart Central main screen

The "Smart Central" screen displays an overview of the situation of each patient in the ward (Fig 7).

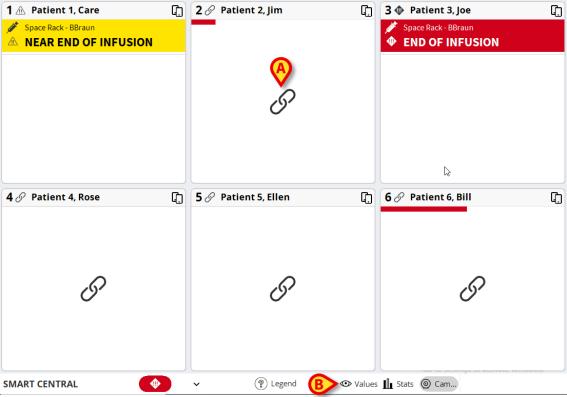


Fig 7

The screen is divided into rectangular areas, named "Bed Cards" (Fig 7 **A**). Every area refers to a bed and displays information on the devices connected to the patient admitted to that bed. By default, only the data referring to alarmed beds is displayed, and only data relating to alarms is displayed. A bed is alarmed if at least one of the devices connected to the bed is alarmed. If multiple alarms occur at the same time on the same bed, the alarm with the highest priority is notified.

It is possible to display all the available data (both referring to the non-alarmed beds and referring to the non-alarmed devices on the alarmed beds) by clicking the "VALUES" button on the command bar (Fig 7 **B**).

#### 3.1 Bed Cards

Each "Bed Card" displays some of the data provided by the devices connected to the patient (Fig 8). The kind of data displayed depends on the design and configuration of the device.

If the "Bed Card" is partly light blue, as in Fig 8, it means that there is at least one low priority alarm, and no medium and/or high priority alarms, coming from the connected devices.

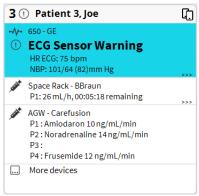


Fig 8

If the "Bed Card" is partly yellow, as in Fig 9, it means that there is at least one medium priority alarm, and no high priority alarms, coming from the connected devices.

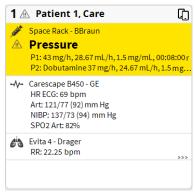


Fig 9

If the "Bed Card" is partly red, as in Fig 10, it means that at least one of the connected devices is in high priority alarm state.

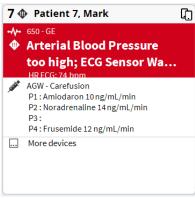


Fig 10

The connected beds from which no alarms are received appear as in Fig 11. No device data is displayed as this might distract the reading of possible alarms occurring on the other beds.



**Fig 11** 

To display device data on these devices, click the **Values** button on the command bar (Fig 7 **B**). The "Bed Card" will appear as in Fig 12.

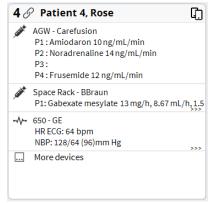


Fig 12

Disconnected beds are displayed as in Fig 13 a, and Fig 13 b (if "Values" button is clicked).

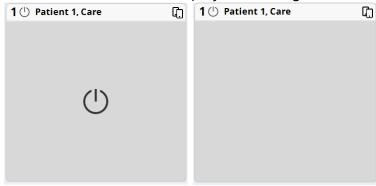


Fig 13 a/b

## 3.2 The Digistat Smart Central command bar

The buttons on the command bar of the Digistat Smart Central make it possible to perform different actions.



The arrow buttons (Fig 14 **A**) make it possible to scroll up and down the screen when it is not possible to display all the configured "Bed Cards" at the same time.

When one (at least) of the non-displayed "Bed Cards" is notifying an alarm, the corresponding button takes the color corresponding to the alarm priority level (blue = low; yellow = medium; red = high).

In case of multiple alarms the arrow color corresponds to the highest priority notified.

An icon can be displayed in the box between the arrow buttons (Fig 15). It indicates that there is an alarm on one of the "Bed Cards" currently displayed.



The **Legend** button displays a reference-window indicating the meaning of all the different icons that can be found while using the software.

The **Values** button displays all the available data (both referring to the non-alarmed beds and referring to the non-alarmed devices on the alarmed beds).

#### 3.3 Events list

It is possible to display a detailed list of all the events occurred in a bed.

To display the events list:

1 – Click a Bed Card to display the patient events.

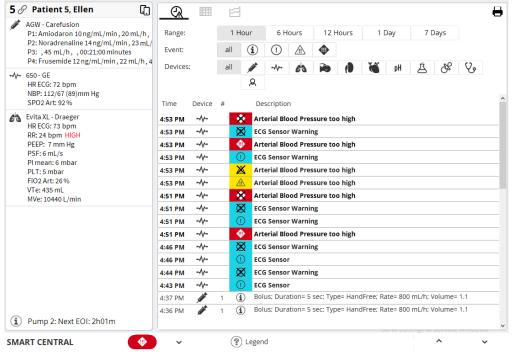


Fig 16

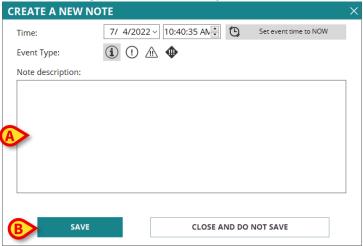
The patient events are displayed on the right.

#### 3.3.1 Add user event

1 – Click the **New** button (A)



The following window is displayed.



- 2 Type the note in the "Note description" field (A).
- 3 Click Save (B).

#### 3.3.2 Edit user events

To edit a user event, on the events grid:

- 1 Click the row corresponding to the user event
- 2 Click **Edit** on the action bar.

The window shown in the above figure is displayed.

- 3 Edit the event (Date/time, priority, description).
- 4 Click Save.

## 3.3.3 Delete user events

To delete a user event, on the events grid:

- 1 Click the row corresponding to the user event.
- 2 Click **Delete** on the action bar. User confirmation is required.
- 3 Click Yes to delete the event.

The corresponding row disappears from the events grid.

## 3.4 Dashboard configuration

If the Digistat Smart Central is configured as a "Dashboard" Smart Central, some additional functionalities are available. These are the "Vital Signs" and "Charts" functionalities. Both functionalities are accessible from the "Events list" (Fig 18 **A**).

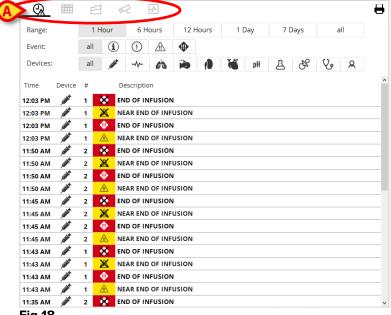


Fig 18

## 3.4.1 Vital Signs

Click the Vital Signs button to activate the "Vital Signs" functionality (Fig 19 A).

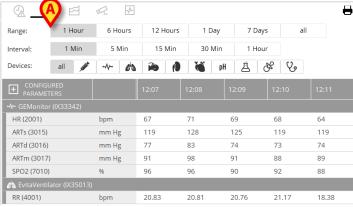


Fig 19

"Vital signs" makes it possible to display in a table some selected patient parameters, as in the figure. The displayed parameters are defined by configuration. In the table they are grouped by acquisition device.

#### **3.4.2 Charts**

Click the Charts button to activate the "Charts" functionality (Fig 20 A).



Fig 20

"Charts" makes it possible to display different charts drawn from the acquired parameters. The charts show the configured parameters as trends. The number of charts, their contents and names are defined by configuration.

## 3.5 Alarms statistics

A printed report of the alarm statistic history can be generated by accessing the System Report menu.

To print an Alarm statistic report:

> Click the **Menu** button on "Control Bar"

The main menu opens:

- > Click on **System Reports** and then
- Click Smart Central Dashboard

Select the data source (either Current Patient, All patients or a Location from a dropdown menu of preconfigured options) and select the Date Range either clicking on the provided ranges or entering the date time manually in the available fields.

Click the Generate button

A print preview of the selected Event statistics will open.

#### 3.6 Notification area

A notification area is displayed on the right of the "Smart Central" screen, reporting various notifications sent by the connected devices (Fig 21 **A**).

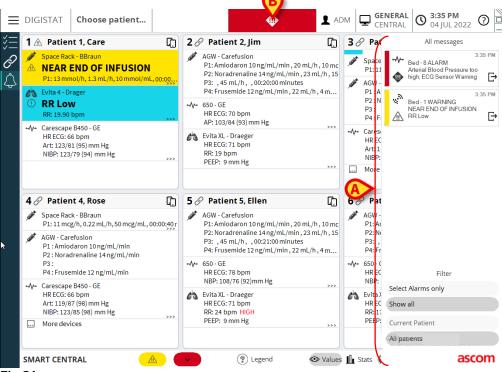


Fig 21

The notification area can be, by configuration:

- Always visible
- Automatically displayed when a new notification comes
- Only visible after user click on the notifications button on the Control Bar (Fig 21 B).

The different messages are displayed in chronological order (most recent on top) and by criticality (High priority alarms on top, then medium priority, then low priority).

Each notification is characterized by the colour corresponding to the priority level (red for high priority, yellow for medium priority, blue for low priority).

## 4. Alarms notification (summary)

By default, the Digistat Smart Central screen displays the device data on a bed only if there is an alarm notification coming from at least one of the devices connected to that bed.

In a condition of "No notifications" the "Smart Central" screen would appear as in Fig 22, where five connected "Beds" are displayed and no devices on any of the beds is in alarm state.



Fig 22

Each time an alarm occurs on one of the devices, the data relating to the bed to which the device is connected is displayed. In Fig 23, for instance, bed 3 is notifying a high priority alarm. A short text specifying the kind of alarm occurring is displayed on the "Bed Card".

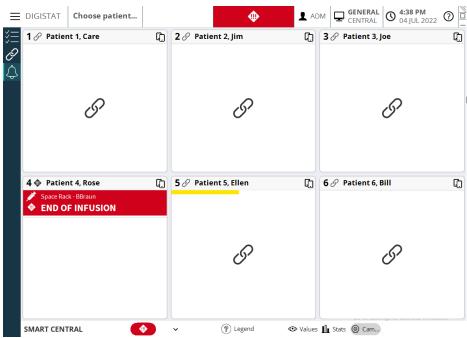


Fig 23

In addition, a sound notification is provided. Three different sounds exist, one for each alarm priority level. In case of multiple alarms, the sound corresponding to the one with highest priority is provided.

The occurrence of alarms is also notified on the command bar by the arrow-buttons indicated in Fig 24, Fig 25 and Fig 26.



An icon can be displayed between the arrow buttons (Fig 27). It indicates that there is an alarm on one of the "Bed Cards" currently displayed.



Fig 27

A visual feature on the upper bar on each "Bed Card" keeps temporarily track of the last alarm notified after the "Bed Card" has changed to a different priority level alarm (or no alarm). This makes it possible to be aware of alarms occurring and rapidly passing.

When the state of a "Bed Card" changes to a lower level alarm (or no alarm), the color relating to the previous alarm (Fig 28) remains on the heading bar for a certain configurable time.







Fig 28

#### 4.1 Alarms notification on Control Bar

Alarms are also notified on the Control Bar, so that they are always visible.



The button color depends on the alarm priority level (cyan=low; yellow=medium; red=high). For high and medium priority alarms, the button flashes.

Click the button to display the notification area (Fig 29 A)

The notification disappears when the alarm conditions no longer exist.

## 4.1.1 "Privacy Blind" mode on smart central video

If the Smart Central video functionality is activated for a patient, the "Privacy Blind" feature allows the user to turn off the webcam either permanently or for a certain time interval. If the Privacy Blind mode is enabled, then no video stream is viewed. The "Privacy Blind" mode is disabled by default. The "Privacy Blind" mode is indicated by the Frivacy Blind" permanently:

- 1 Click the relevant Bed Card to enter the patient detail screen.
- 2 Select On on the upper bar (A).



To activate the "Privacy Blind" for a pre-defined period:

2 – Select the wanted period on the upper bar (5 mins, 15 mins, 30 mins).

## 4.1.2 Display Waveforms

To display the Waveforms screen:

- 1 Click the relevant Bed Card to enter the patient detail screen.
- 2 Click **Waveforms** on the upper bar.

## 5. Sound Check procedure

When Smart Central is started, it provides a specific sound indicating that the sound notification of alarms is working properly.

If the sound is not provided the user can perform a "Sound Check" procedure. To perform the "Sound Check" procedure

Click the Menu button on Control Bar (Fig 30)



The following menu is displayed (Fig 31).



Fig 31

Click on Modules Configuration (Fig 31 A)

The following menu opens (Fig 32).

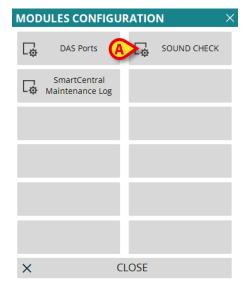


Fig 32

Click on Sound Check (Fig 32 A)

A pop-up window opens, asking whether a sound is heard or not from speakers.

If a sound is heard, then click **Yes**. The pop-up window disappears and nothing else happens (meaning that the Digistat Smart Central is working correctly).

If no sound is heard, then click **No**. The pop-up window disappears and a notification is displayed on the Control Bar, meaning that an error occurred while checking the sound notification system.

## 6. Patients management

To access the Patients management functionalities

Click the Patient button on Control Bar (Fig 33 A).



The screen displayed after clicking this button depends on the chosen configuration. If the list of admitted patients is not displayed by default, to display the list of admitted patients:

> Click the **In Bed** button on the command bar.

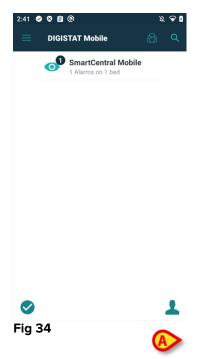
The list of beds configured in the domain is this way displayed.

## 7. Digistat Mobile

## 7.1 Login

To login to Digistat Mobile

> Touch **Login** on the lower-right corner of the "Applications list" screen (Fig 34 **A**)



The following screen will be displayed (Fig 35)



Fig 35

- Insert username and password (Fig 35 A).
- > Touch the **Login** button (Fig 35 **B**)

#### 7.2 General Notifications

Digistat Mobile provides short notifications when the application is not active as well (Fig 36  $\bf A$ ). The highest level notification indicates the overall alarm level of the Digistat Mobile application. Actually are implemented three levels of severity for the notifications, each of them corresponding to a different color (red = high priority – yellow = medium priority – cyan = low priority); in addition a purely informative notification is foreseen just as reminder for the user (purple).

For each module a row in the notification area is foreseen. Any change in the notifications is performed within the row related to the module triggering notification change.

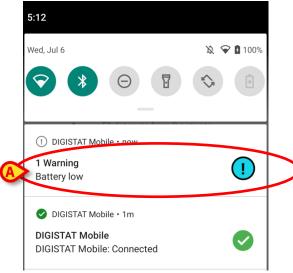


Fig 36

- Swipe the notification to make it disappear.
- > Touch the notification to directly access the relevant patient.

If the alarm notification from a module is related to one patient, then by touching it the alarmed patient tab is displayed; moreover, if the alarm notification is raised for more than one patient, by touching it the list of alarmed patient is displayed.

According to the device type, notifications concurrently coming from different applications of the Product mobile suite have a different LED color behavior

- Myco 3. The LED always reflects the higher priority alarm at any time;
- Non Myco 3. The LED reflects the latest notification color.

This means in case of multiple notifications, when swiping the higher priority one on a Myco3 device, the LED color is the one of the next notification. On non Myco3 devices, the LED is disabled after a swipe.

In addition to screen notifications, the Product can handle sound notifications by means of the device speaker and light notifications by means of the notification led.

In the case of sound notifications, the Product ever plays the notification with higher priority; if a notification is being executed and a new alarm has to be raised, then the Product restarts the notification with higher priority. Notifications with low priority level don't have any sound associated.

In case of service stop, a notification is provided to the user: it has the highest level of severity and it's not swipable.

In case of disconnection, the Product mobile client attempts to reconnect to the Product server. If this attempt fails, a not-swipable system notification is provided to the user, according to the following two different options:

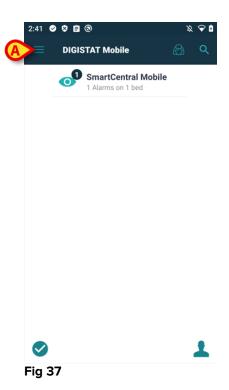
- Android previous than 8.0. One notification, non swipable, highest priority level. The user can
  mute it by pushing the Mute button;
- Android 8.0 and later. Two notifications, one non swipable without sound or LED color, the
  second one swipable with the highest priority level, reporting useful information about the
  cause of the disconnection. Moreover, the second notification will not be shown anymore
  since the user pushes the Mute button.

## 7.3 Sound Check procedure

The Sound Check Procedure makes it possible to verify if the sound and vibration notification of alarms is working properly.

To perform the "Sound Check" procedure

➤ On the home screen of the Digistat Mobile Application, touch the ≡ icon on the top-left corner of the screen (Fig 37 **A**)



The following menu will be displayed (Fig 38).

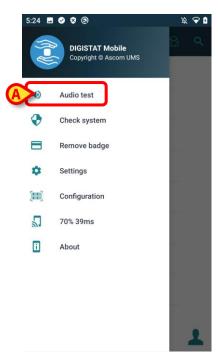


Fig 38

> Touch the **Audio test** option (Fig 38 **A**).
A test notification/sound will be this way provided (Fig 39 **A**).



Fig 39

#### 7.4 Patients search functionalities

The Product implements several patients search tools. These tools can be accessed from the Patients List screen. To access the search functionalities:

> Touch the icon indicated in Fig 40 A.



The following screen will open (Fig 41).

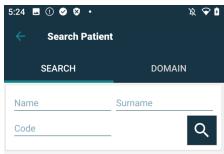


Fig 41

Three search options are available:

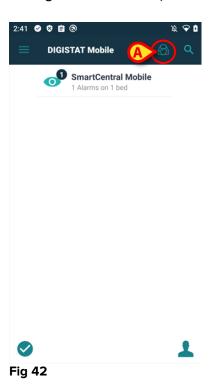
- 1. textual search (insert patient data, then click **Search**)
- 2. barcode scan (touch the 💻 icon and then scan the patient's barcode)
- 3. NFC code scan (position the device close to the patient's Tag).

## 7.5 Patients Assignment Functionality

Patient's assignment makes it possible for a user to select one or more patients and create a group of patients who are under his charge. The name of this group in the Digistat Mobile application is "My Patients".

Since the user assigns himself some patients, the following notifications can be displayed on the handheld device:

- a) The notifications related to the patients assigned (i.e. in the group "My patients");
- b) The notifications related to the patients assigned (i.e. in the group "My patients") and those related to the patients that no one has explicitly taken in charge;
- c) The notifications related to the patients assigned (i.e. in the group "My patients"), those related to the patients that no one has explicitly taken in charge and those related to other patients if the devices which had them in charge "lose" them (for any reason, low Wi-Fi signal for instance).



To select the list of patients a user assigns himself and forming "My patients" list, on Digistat Mobile Central screen,

> Touch the icon (Fig 42 A).

The following screen will be displayed (Fig 43 - "Setup My Patients").

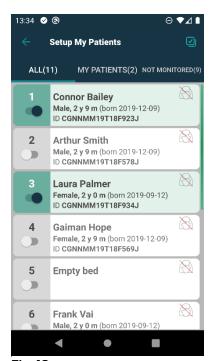


Fig 43

A patient can be selected/deselected by touching the corresponding "tile". Each tile corresponds to a bed. In addition, the user can select or deselect all the patients by checking the box on the top right corner (Fig 44 **D**).



Fia 44

The icons on the right of the patient names (Fig 44 A) have the following meanings:

- Patient is part of "My patients" of another user. It is still possible to select the patient. If two users select the same patient, the patient will be grouped under "My patients" for both users.
- Patient is not monitored. I.e. another user has him/her in charge, but at the moment, due (for example) to Wi-Fi connection failure, no one is monitoring him/her.

No icon means that no one has the patient in their "My patients" list, so the patient is not monitored.

The filters indicated in Fig 44 **B** make it possible to display:

- All patients;
- Only the assigned patients;
- Only the patients that are not monitored.

The back arrow icon indicated in Fig 44 C makes it possible to go back to "My Patients" list screen.

## 7.6 Single Patient Selection

To select a single patient:

> Touch the icon indicated in Fig 40 A. The following screen will appear (Fig 45 A):

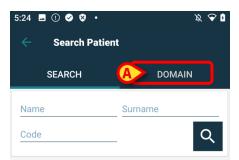


Fig 45

> Touch the "**DOMAIN**" tab. The following window shall appear (Fig 46)

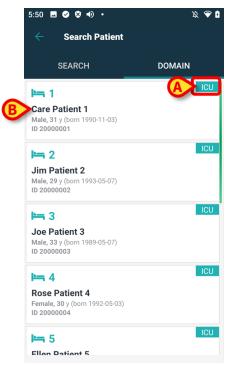


Fig 46

In Fig 46 all the patients are listed, without regard to their domain. The label on the top right corner of each tile highlights the domain of the patients (Fig 46  $\bf A$ ).

One single patient can be selected by touching the tile corresponding to his/her bed. Just for example:

> Touch the tile indicated in Fig 46 **B**. User confirmation is required (Fig 47).

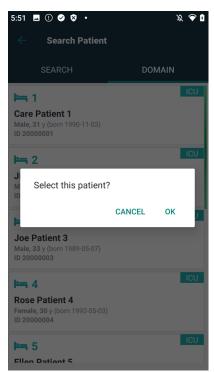
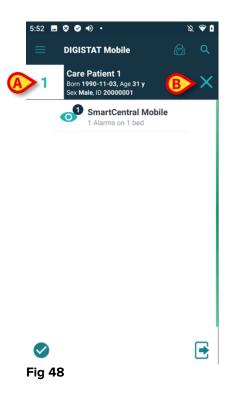


Fig 47

> Touch **Ok** to confirm. After confirmation, the following screen is displayed.



Patient data are on top of the page (Fig 48 **A**). All the data in all the Digistat Mobile modules are now filtered by patient (i.e. all and only the selected patient alarms/notifications are displayed).

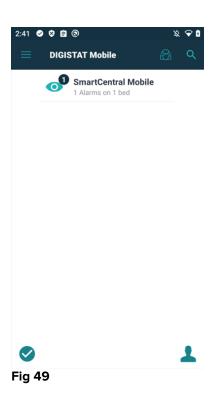
➤ Touch the symbol indicated in Fig 48 **B** to deselect the patient.

## 8. Smart Central Mobile Application

## 8.1 Application start-up

To start the Smart Central Mobile application

> Touch the corresponding row on the handheld device screen.



The Smart Central screen, shown in Fig 50, opens.



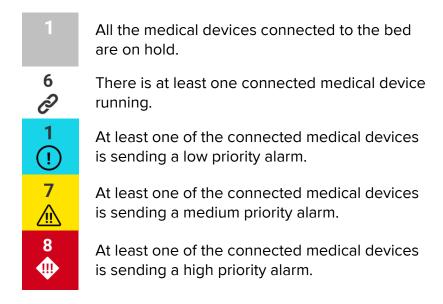
Fig 50

#### 8.2 "Smart Central" screen

The "Smart Central" screen displays a schematic summary of the status of the medical devices connected to each bed configured in the specific handheld device (Fig 50).

The numbered squares displayed on screen represent the beds configured in the handheld device (Fig 50  $\triangle$ ). The squares visible on a single screen form the "domain" of beds covered by the handheld device. The "domain" is defined by configuration.

The number displayed inside the square indicates the bed number. On each square, the status of the connected medical devices is indicated in graphic form by the background color and the related icon:



#### 8.3 Medical devices list

Touch one of the squares on the "Smart Central" screen to display the list of medical devices connected to the bed (Fig 51).

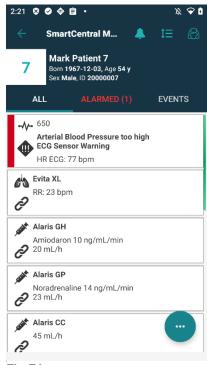


Fig 51

#### 8.4 Menu Button

The button indicated in Fig 52 **A** opens a menu allowing direct access to some specific functionalities.



Fig 52

> Tap the button to open the menu (Fig 53).



Fig 53

The actual options present on the menu depend on the configuration in use and the availability of the related functionalities.

The possible options are:

- Webcam display the video stream of a configured webcam.
- Waveforms Displays near real time waveforms collected by medical devices.

- Opens other Digistat Mobile modules, according to configuration and availability. For example CDSS Configurator Mobile or Online Mobile, with direct access to the currently selected patient data. A specific icon is displayed for each accessible module. See the related modules' User Manuals for operating instructions.
- Share it is a feature that allows the sharing of data with third parties applications (see the Smart Central Mobile user manual for instructions).
- > Tap the button to hide the menu.

## 8.5 Device events history

Each "device card" can be touched to access the list of all the events related to the medical device (Fig 54).

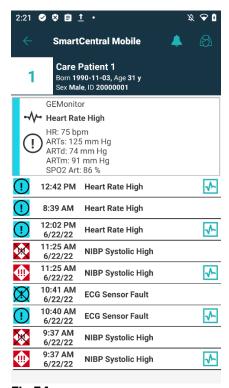


Fig 54

For each event, a short description and the time of occurrence are provided. For each alarm are displayed the beginning time and end time (black cross on the icon  $\times$ ).

## 8.6 Waveforms snapshot

➤ Tap the ♣ icon (if present - Fig 55 **A**) to display the snapshot of the waveform related to the corresponding event.

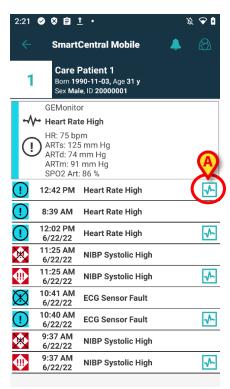


Fig 55

#### 8.7 Smart Central Video

The Smart Central application can be configured to support the video stream of a webcam. This feature enables the visual monitoring of the patient area.

If the Smart Central Video feature is enabled and properly configured for a selected patient, the webcam option is available on the menu button shown in Fig 56.



Fig 56

> Tap the "Webcam" option on the menu to view the webcam video stream (Fig 56 A).

#### 8.8 Waveforms

Smart Central Mobile can display near real time waveforms collected from medical devices. To enable this functionality it is necessary to enable at least one waveform parameter in the configuration section of the driver capabilities.

If the functionality is enabled, the "Waveforms" option is available on the menu button (Fig 57 **A**).



Fig 57

To display the Waveforms for a bed:

- > Tap the relevant bed card.
- Tap the menu button (Fig 57 A).
- > Tap the "Waveforms" option (Fig 57 **B**) on the menu.

A screen showing the trends of the acquired parameters is displayed.

## 9. Digistat Smart Central IFU

The Digistat Smart Central instructions for use (IFU) are provided with the Product. They can be displayed in digital format within the Product. To access the instructions for use

Click the Help button on the command bar (Fig 58)



A screen opens, making it possible to access:

- 1) the relevant user manuals;
- 2) possible quick reference guides referring to specific procedures.

The on line documentation is in PDF format.

## 9.1 On line update of the user manual

The user manuals can be downloaded on the dedicated Ascom site using any browser (eg. IExplorer, Chrome, Firefox).

To download the manuals, type the following address on your web browser address bar:

Host URL: https://confluence.ascom-ws.com

It is now required to enter username and password to access the User Manuals list.

**Username** – User name provided by the local distributor **Password** – Password provided by the local distributor

Select Digistat and then Digistat Smart Central (NA).

Select here the Product version. The relevant manuals are there available in PDF format.

## 9.1.1 How to display the Digistat Suite about box

To display the Digistat Smart Central about box

Click the **Menu** button on the Control Bar (Fig 59 **A**)



A menu containing different options opens (Fig 60).

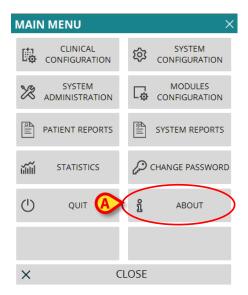


Fig 60

Click, on the menu, the **About** button (Fig 60 A).

The About Box opens. The labeling of the product is the About Box displayed on the client workstations and mobile devices where the Digistat Suite is installed.

## 9.2 Printed IFU

The customer can request a printed version of the user manuals of the purchased products. Ascom UMS will provide the requested manuals as soon as possible.

The request must be forwarded to the technical assistance. See paragraph 10 for the list of Ascom UMS contacts.

## 10. Manufacturer and Distributor Contacts

For any issue, please refer first to the Distributor who installed the Product.

Distributed in the U.S. by

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