Vitals Mobile User Manual

Version 12.0

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Contents

1. Vitals Mobile

For general and detailed information about the Product environment and the instructions for use of the Mobile Launcher software see the specific documents. The knowledge and understanding of these documents is mandatory for an appropriate and safe use of the Vitals Mobile software, described in this document.

1.1 Introduction

The Vitals Mobile module permits data entry and display for a variety of clinical workflows, procedures and protocols.
Examples:

- Patient vital signs data collection for normal wards.
- Patient data collection for clinical protocols associated to specific diseases, treatments or prevention of diseases.
- Generation of reminders for periodic data collection or patient examination and documentation of the activity performed and provided services.
- Documentation of patient conditions also by means of pictures and audio recordings.

1.2 Vitals Mobile start-up

To start the Vitals Mobile module

- Tap the corresponding row on the handheld device screen (Fig 1).

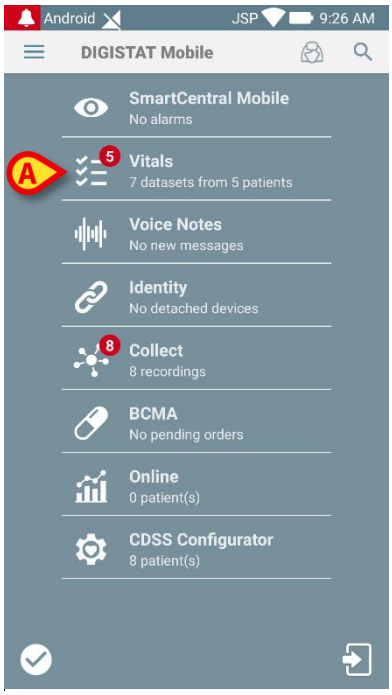

Fig 1

The Patient List screen, shown in Fig 2, opens.

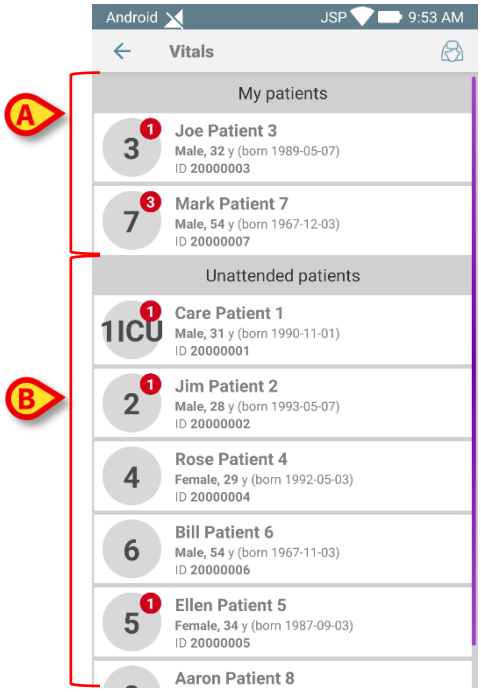

Fig 2

1.3 Patients list

The Vitals Mobile patient list screen (Fig 2) displays the list of beds configured on the handheld device (namely, the device "domain").
The domain of a specific handheld device is defined by configuration. In case there is no patient on one of the configured beds, then the bed is not displayed.
"My patients" and "Unattended patients" are separated (Fig 2 **A** - **B**). See the Digistat Mobile Launcher user manual for instructions on patient's management and "My patients" functionality.
Each bed is represented by a tile (Fig 3).

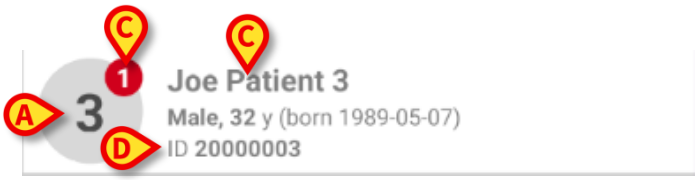

Fig 3

In the tile, the following information is displayed:

- bed number (Fig 3 **A**);
- number of expired datasets (if any - Fig 3 **B**);
- name of patient on that bed (Fig 3 **C**);
- patient data (if available: sex, age, date of birth, patient ID - Fig 3 **D**).

➢ Touch one tile to access the list of datasets enabled for the corresponding patient (Fig 4).

The term "Dataset" refers to a structured set of data, considered as a whole. It can be, for instance, a score calculation, a set of vital parameters etc.

1.4 Datasets list

The datasets list screen is formed of two areas: a heading area (Fig 4 **A**) and the list of datasets (Fig 4 **B**).

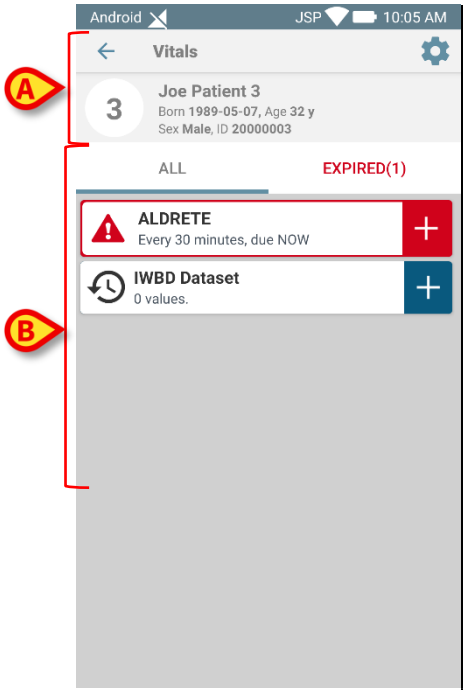

Fig 4

The heading area displays the following information:

- bed number;
- name of patient on that bed;
- patient data (if available: sex, age, date of birth, patient ID).

For each patient the appropriate list of datasets can be enabled. If the datasets are enabled, they are listed on screen (Fig 4 **B**). See section 1.6 for instructions on how to enable a dataset.
The datasets are displayed in tiles below the heading area. Each tile represents a dataset.

The information displayed inside the tiles depends on the kind of dataset and the way the dataset is configured.

Fig 5 shows an example.

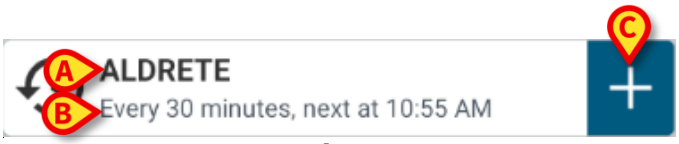

Fig 5

The dataset name is displayed inside the tile (Fig 5 **A**).
Below the dataset name, information is displayed relating the data acquisition modalities (i.e. when the dataset should be acquired, when is the next acquisition due etc. - this information depends on how the dataset is configured - Fig 5 **B**).

The **+** button (Fig 5 **C**) makes it possible to insert new data (see section 1.4.1).

If the + button is not present on the tile it means that the dataset is not enabled (see section 1.6 for more information). The tile is still displayed because past data exists for that dataset, which can be still viewed. See for instance Fig 6.

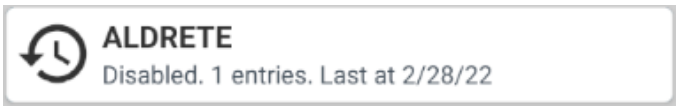

Fig 6

- Tap the tile to display the acquired data summary for that dataset (see section 1.4.3).

The datasets can be configured to provide a notification at scheduled times, as a reminder, when they should be acquired. When this notification occurs, the handheld device LED is purple.

In Fig 7 the dataset is configured to be acquired every 30 minutes.

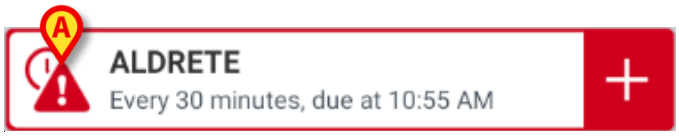

Fig 7

If the dataset is not acquired on time, the tile turns red and the icon indicated in Fig 7 **A** is displayed. If enabled by configuration, the application displays a notification, meaning that an action was due at a certain time, but the action was not performed.
The handheld device in this case provides a specific sound/vibration. The notification is provided on the handheld device also when Vitals Mobile is not active.

1.4.1 How to record a new set of data

To record a new set of data

- Tap the + icon on the tile corresponding to the wanted dataset (Fig 8).

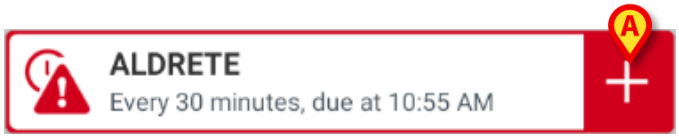

Fig 8

The data entry screen is displayed.

The data entry screen features depend on the kind of dataset selected. See Fig 9 for an example.

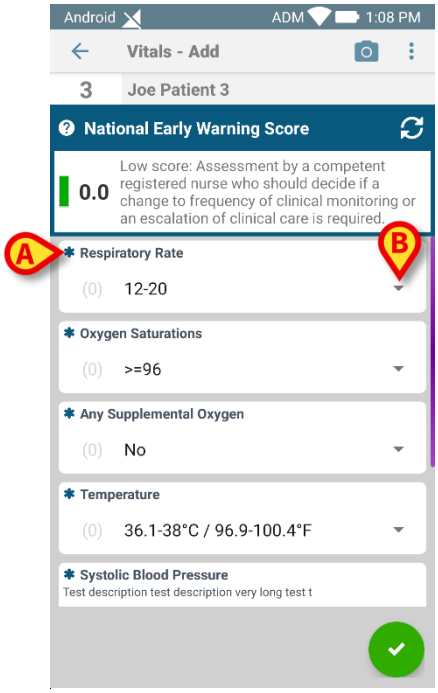

Fig 9

- Insert the required values according to the field type. The different types are described in section 1.4.2.

The fields indicated by the asterisk, as Fig 9 **A**, are mandatory. I.e.: the record cannot be saved if they are not specified.

A textual description can be displayed below the field as a guide to data entry.

- Tap the arrow button ▾ (Fig 9 **B**) to display the available options (Fig 10).

In Fig 10 the value in brackets is the score, the range displayed alongside the score refers to the actual value (respiratory rate in the example). The single choices can be associated to a color if required.

Fig 10

- Tap the window again to make it disappear.

Some of the values can be configured to be automatically acquired from the medical devices and inserted in the appropriate fields.

- If present, tap the ↻ icon placed alongside the field to refresh the values automatically acquired.

If the dataset is a "Score" type, when all the fields are filled, the total score is displayed in the data entry window (Fig 11 **A**). As shown in the figure, a dataset can be configured to highlight certain values as "critical" (usually red - the color is configurable) or "requiring attention" (usually yellow/orange). A textual description can be associated to those values (usually instructions and/or clinical procedures).

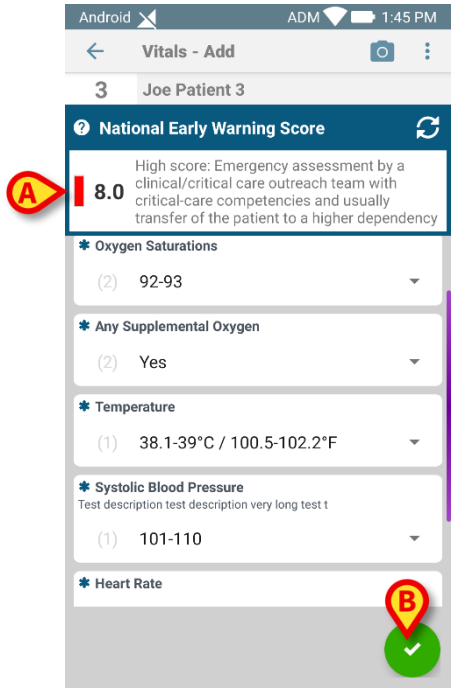

Fig 11

- Click  when done (Fig 11 **B**). The new record is added to the records table (Fig 12 **A**).

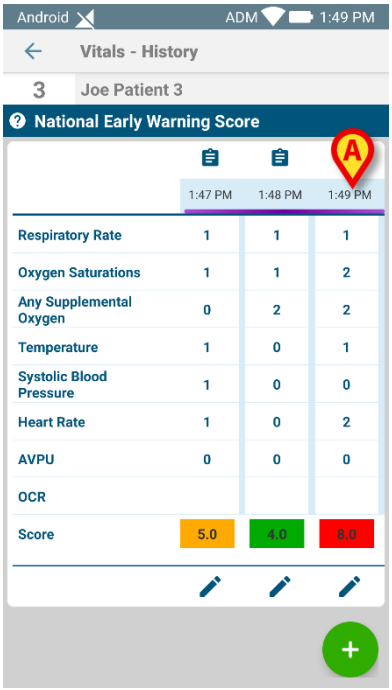

Fig 12

1.4.2 Data entry modes

The type of entered data and the entry mode depend on the kind of information that must be specified.
In all cases, if an incorrect type is inserted (for example a letter in a numeric field), a message error is displayed.
Also, acceptable ranges can be configured for a certain field. If a value outside of the allowed range is inserted, a message error is provided.

The possible data entry field types are:

- **Numeric**

Only numbers are acceptable values. Type the number in the field.

- **Numeric list**

Numeric value to be selected on a drop-down menu. The actual values are associated to another value for score calculation;

- **String**

Free alphanumeric string. Type the string in the field.

- **List**

Select an item from a pre-configured list of items to be selected on a drop-down menu.

- **Boolean**

Only "Yes" or "No" values are possible. Select a checkbox to indicate "Yes".

- **Image**

Image acquired by the user with the device camera. Can be acquired only on mobile devices, readable on any device.

- **Audio**

Recorded by the user with the device recorder. Can be acquired only on mobile devices.

- **String with presets**

Alphanumeric string with suggestions. It is possible to type a string or select the value on a drop-down list.

- **Date**

Insert a date.

- **Date/Time**

Insert date and time.

Fig 13

On "Date" and Date/Time" field types:

- Tap the empty field to display a calendar and/or clock allowing to select the required date and/or time.
- Tap the  icon to automatically insert the current date and/or time.
- Tap the  icon to clear the field.

- **Conditional**

A field can be configured to be displayed only if certain conditions are met. For example: a field is displayed only if the user selects a specific value from a previous list.

1.4.3 Inserted values summary

The recorded sets of values are displayed in a specific summary screen. The screen features depend on the kind of dataset acquired.

- Tap a tile on the list of enabled datasets (Fig 14) to access the summary for that dataset (Fig 15).

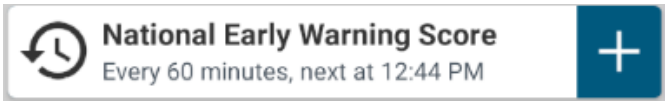

Fig 14

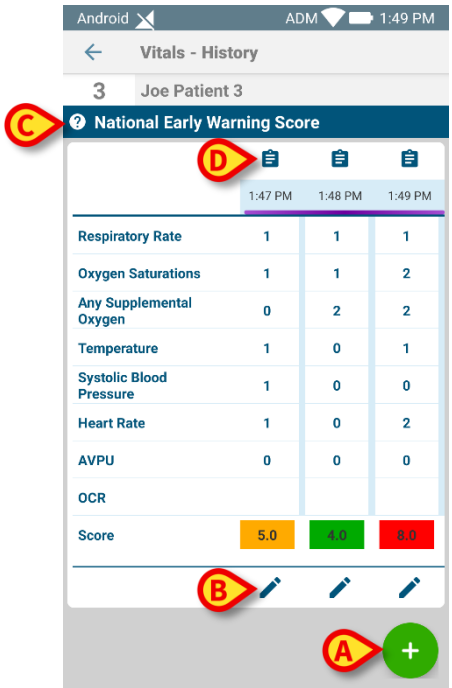

Fig 15

- On this screen, tap  (Fig 15 **A**) to add another set of data.

- Use the  icon (Fig 15 **B**) to edit the data of an existing set. If a  icon is displayed instead, it means that the corresponding set of data cannot be edited.

- If available, tap the **Help** icon (Fig 15 **C**) to open an online help page.

- The icon (Fig 15 **D** - available for "Score" type datasets) displays the original numeric data or the associated label (See Fig 16 for an example).

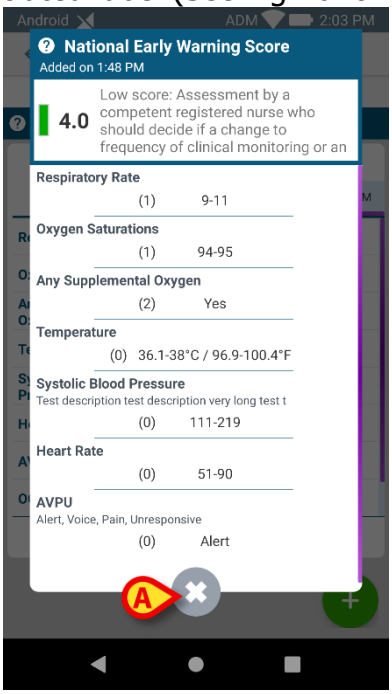

Fig 16

- Tap the icon to close the window (Fig 16 **A**).

1.4.4 How to edit an existing set of data

To edit an existing set of data, on the datasets list screen (Fig 17),

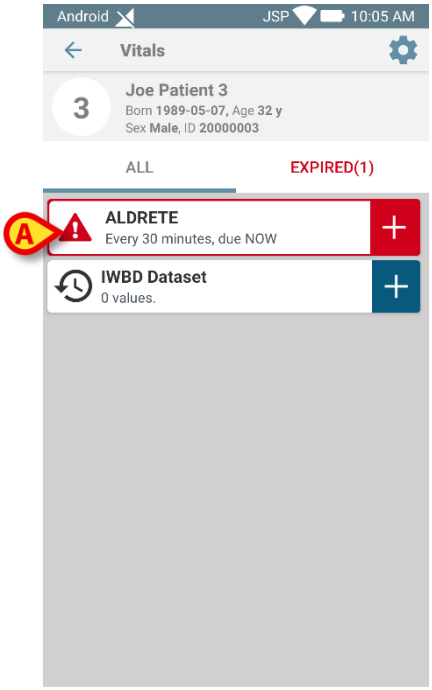

Fig 17

- Tap the relevant dataset (Fig 17 **A**, for instance). The acquired datasets summary opens (Fig 18).

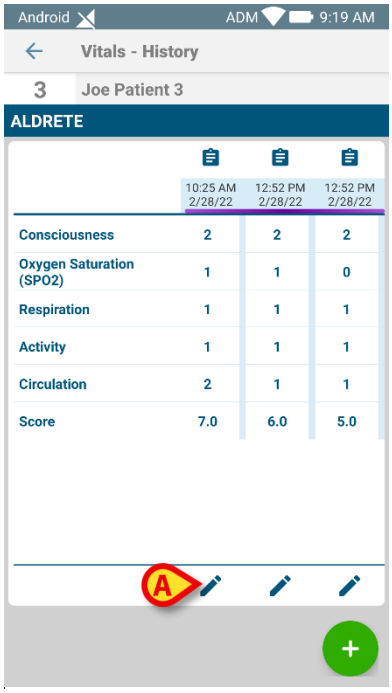

Fig 18

- Tap the "pen" icon corresponding to the set to be edited (Fig 18 **A**)

The data entry screen opens (Fig 19).

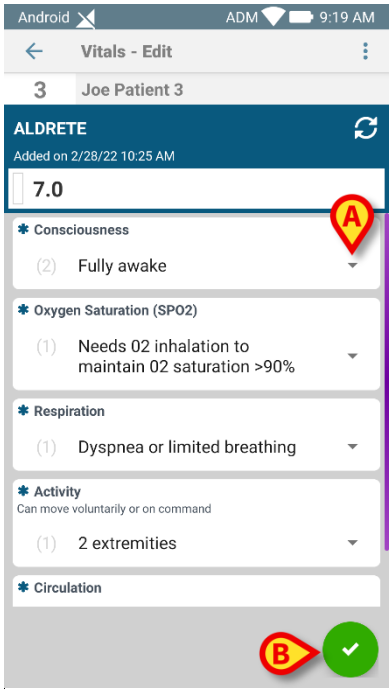

Fig 19

- Edit data (Fig 19 **A**).
- Tap  (Fig 19 **B**).

The set is this way edited.

1.4.5 Images and audio acquisition

The Vitals Mobile module makes it possible to acquire audio recordings and images as parts of a dataset.

To start the audio/image acquisition, on the datasets list

- Tap the "**+**" button on the right (Fig 20 **A**).

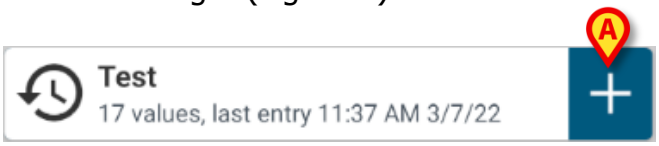

Fig 20

The data entry screen opens (Fig 21).

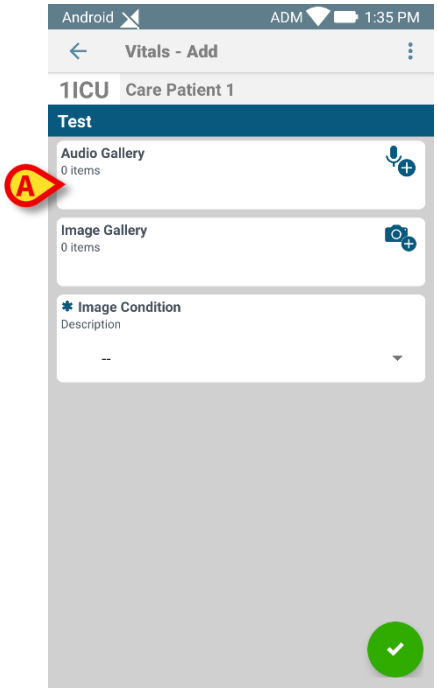

Fig 21

Audio acquisition

The audio acquisition item is indicated in Fig 21 **A**.

- Tap the  icon.

The following tool opens,

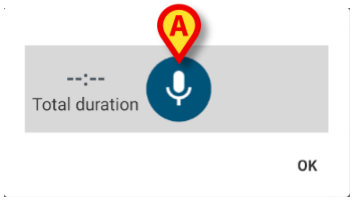

Fig 22

- Press the button indicated in Fig 22 **A** and keep it pressed.

Recording ends when the button is released. After recording, the following screen is displayed.

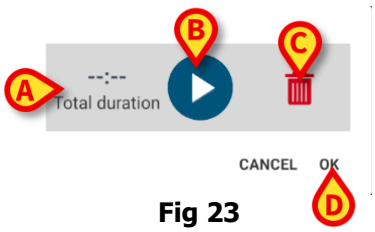

Fig 23

The recording duration is displayed on the left (Fig 23 **A**).

Tap the  icon to listen to the recording (Fig 23 **B**).

Tap the  icon to discard the recording (Fig 23 **C**).
Tap **Ok** to save the recording (Fig 23 **D**). An icon corresponding to the saved recording is then displayed on the data acquisition screen (Fig 24). Multiple recordings are possible for a single audio item in a dataset evaluation.

the data entry screen is displayed (Fig 24). The icon indicated in Fig 24 **A** represents the recorded file.

Fig 24

- Tap the icon to listen to the audio file.
- Tap the small cross -  - on top of the icon to delete the corresponding file.

Image acquisition

The image acquisition item is indicated in Fig 25 **A**.

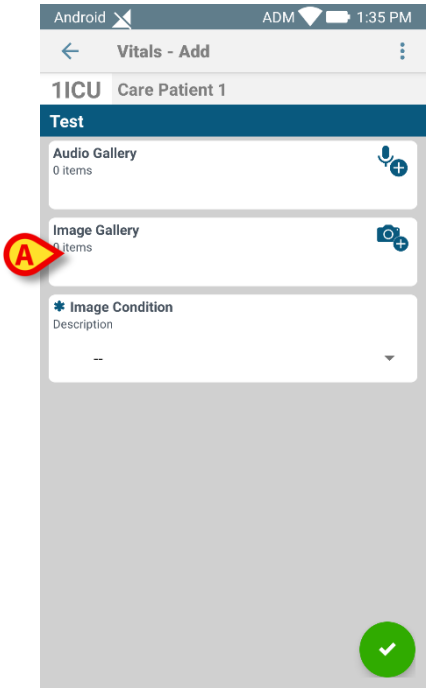

Fig 25

- Tap the  icon. The camera activates.

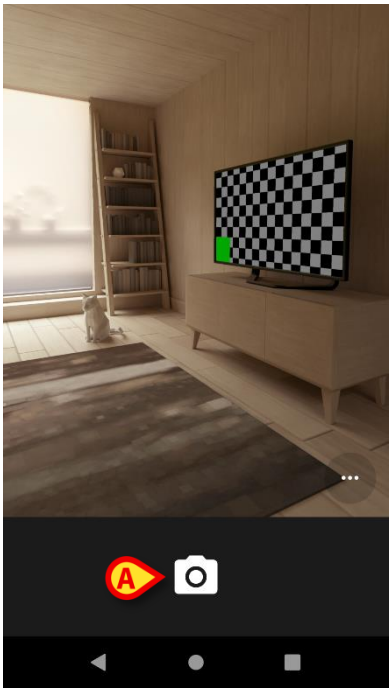

Fig 26

- Tap the icon to take the picture (Fig 26 **A**). A preview is displayed (Fig 27).

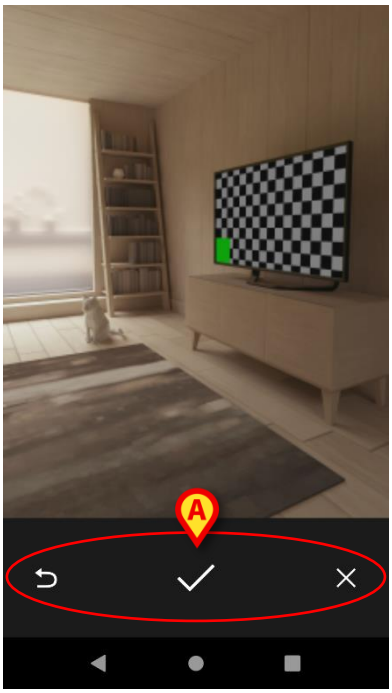

Fig 27

- Use the buttons indicated in Fig 27 **A** to:
  1. go back to the picture acquisition mode (Fig 26);
  2. keep the picture and go back to the data entry page (Fig 25);
  3. discard the picture and go back to the data entry page (Fig 25).

Once a picture is saved, a thumbnail is displayed on the data entry page (Fig 28).

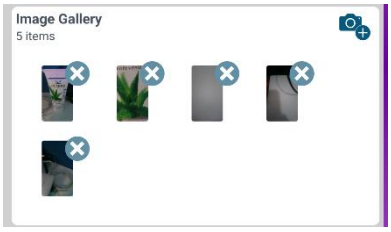

Fig 28

Multiple pictures can be acquired for the same "Image" item.

- Tap the thumbnail to display the picture again.
- Tap the small cross - - on top of the icon to delete the corresponding file.

After audio and/or picture acquisition, to save the acquired data, on the data entry page (Fig 29),

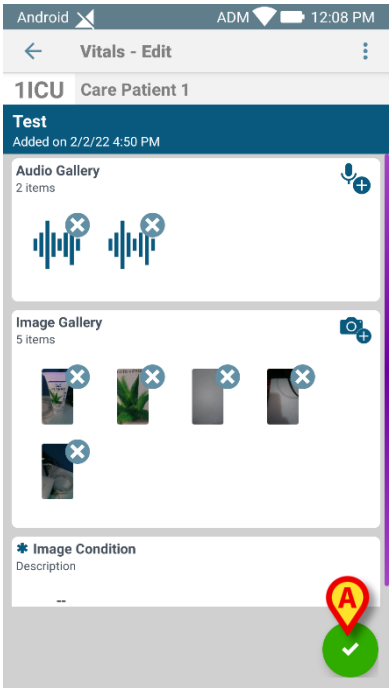

Fig 29

- Tap the  icon (Fig 29 **A**).

The dataset summary screen is displayed (Fig 30). On the datasets summary screen, images are indicated by the icon; audios are indicated by the icon (Fig 30 **A**).

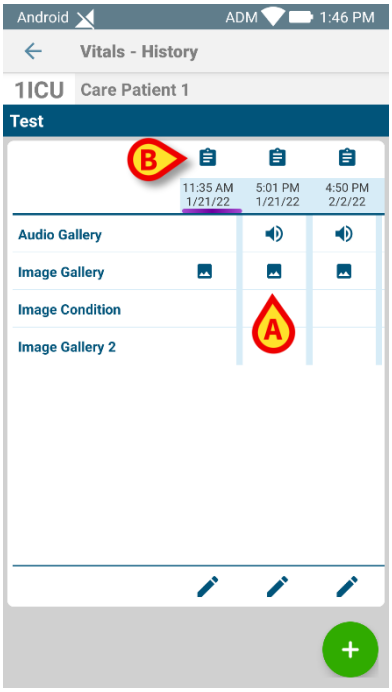

Fig 30

In Fig 30, the rows in the table represent the acquisition items, the columns represent the dataset evaluations.

- Tap the / icons to display a gallery (Fig 31) of all the audios/images acquired for the corresponding item.

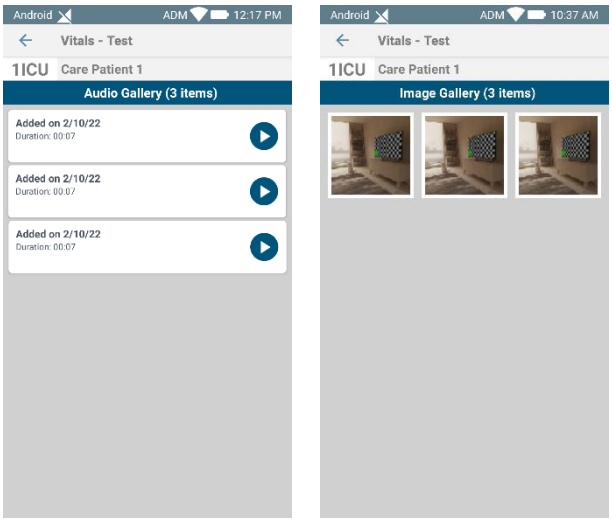

Fig 31 - Items: "Audio gallery" (left) and "Image gallery" (right)

- Tap the icon (Fig 30 **B**) to display an overview of all the audios/videos acquired for the same evaluation (Fig 32).

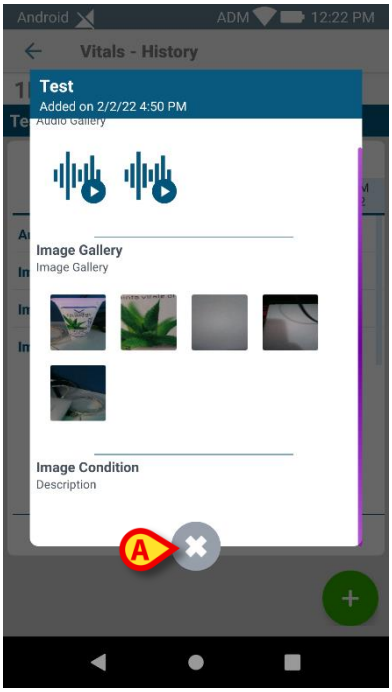

Fig 32 - Evaluation added at 4:50pm on the 2nd /2/22

- Tap the icon to close the overview (Fig 32 **A**).

In the audio and image galleries (Fig 31), an indication is provided if, for any reason, the audios/images cannot be played/displayed.

1.5 OCR functionality

The OCR (Optical Character Recognition) functionality is available when reading and recording data from the General Electric V100 monitor.

Fig 33 - General Electric V100 monitor

Only the General Electric V100 model of monitor is supported for the OCR functionality.

The OCR functionality requires an OCR-type Dataset properly configured. For more information read the document CFG ENG Vitals.

1.5.1 Installation

Digistat OCR component is distributed as a standalone apk running on devices ranging from Android™ 8 (API 26) to Android™ 11 (API 30). After installation **no application icon will be present on your device**, as the Digistat OCR component is launched from Vitals.

To verify the proper installation, please go to the list of applications in your Android™ device and verify that "Digistat OCR" is present.

1.5.2 Operativity

As explained in Section 1.4.1, to record a new set of data:

- Tap the **+** icon on the tile corresponding to the wanted dataset (Fig 34 **A**).

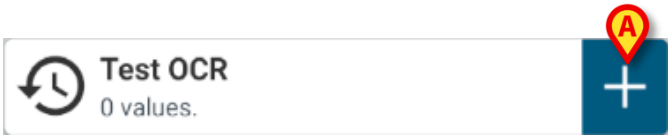

Fig 34

The data entry screen is displayed (Fig 35).

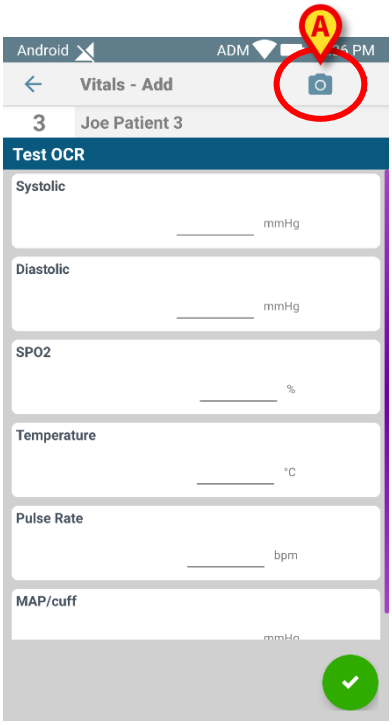

Fig 35

- Tap the icon indicated in Fig 35 **A**.

The acquisition screen is displayed (Fig 36).

Fig 36

A label in the upper part of the screen indicates the medical device to be read (Fig 37).

Fig 37

- Align the mask rectangles to the parameters on the device to read them. The OCR calculation starts automatically. The rectangles are purple when calculating.

Fig 38

When reading is completed, the rectangle turns green. A "V" is displayed in the top right corner. Otherwise, the OCR keeps attempting to recognize the characters while the rectangle remains purple.

Fig 39

- Tap on a calculating (purple) rectangle to interrupt the calculation. It will turn red with an X crossing the rectangle.

Fig 40

- Tap on a stopped (red) rectangle to restart the calculation.
- Tap again on a calculated (green) rectangle to restart the calculation (e.g. in case of incorrect reading).

In case parameters are hard to read, make sure there are little reflections on the device screen. It is possible to switch mode by clicking on the sun/moon buttons (Fig 41 ***A****).*

- After calculation, tap the "Confirm" button (Fig 41 **B**) to confirm data. A picture containing the latest correct acquisition for each value is also returned.

It is possible to confirm the OCR reading if red (stopped) or purple (ongoing) OCR calculations are present. In these cases, only the data corresponding to the calculated (green) rectangles are saved.

- Use the back arrow (Fig 41 **C**) to exit the procedure.
- Tap the button indicated in Fig 41 **D** to display in-app instructions.

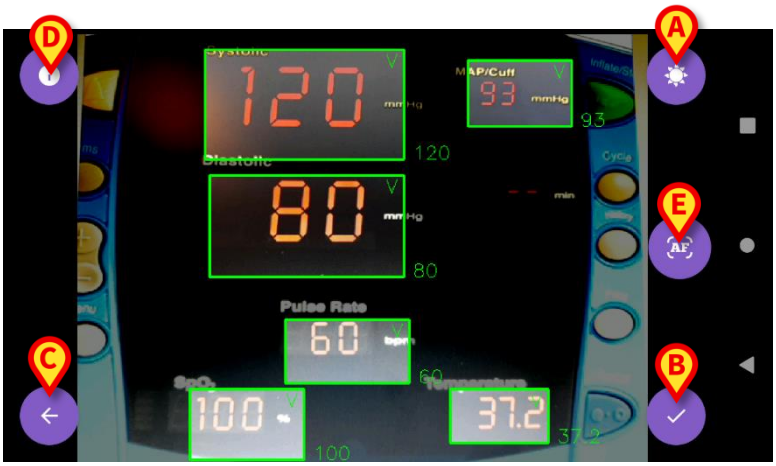

Fig 41

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*If some parameters are not read, the AF button (*Fig 41 **E***) triggers an autofocus aimed at the first unread area. The AF button disables the smartphone autofocus. For this reason, the AF feature should only be used when the smartphone autofocus is not enough.*

After confirmation, the acquired data is automatically displayed in the dataset fields (Fig 42):

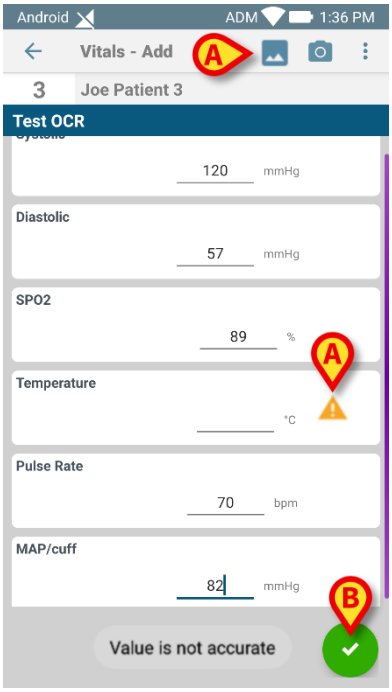

Fig 42

If the read data is not accurate enough, the ⚠ icon is displayed alongside the relevant parameter (Fig 42 **A)**.

- Tap the button indicated in Fig 42 **D** to display the picture representing the image containing the latest correct acquisition of each value.
- Tap the ✓ button to save the data (Fig 42 **B**).

If not all the values are correctly acquired (i.e. there is the ⚠ icon), user confirmation is required when saving (Fig 43):

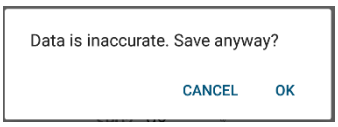

Fig 43

The missing value can be manually inserted. To do that:

- Tap the empty field (Fig 42 **C**) to display a numeric keyboard.
- Insert the value.
- Tap ✓.

1.6 Enabling and configuring the existing datasets

The functionalities described in this paragraph are reserved to "super users" or system administrators with specific permissions.

By default it is not possible to add or edit datasets for dismissed patients. This possibility can be enabled by the System Option *SearchDismissedPatient*. See the document DSO ENG System Options for more information.

To access the dataset configuration options, after patient selection, on the datasets list screen (Fig 44),

- Tap the icon (Fig 44 **A**).

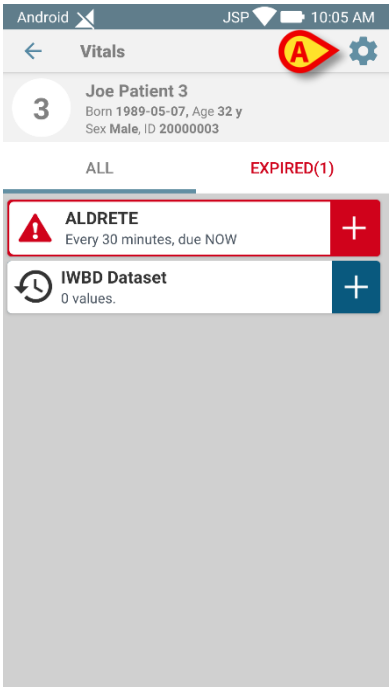

Fig 44

The list of all the existing datasets, defined during configuration, opens (Fig 45).

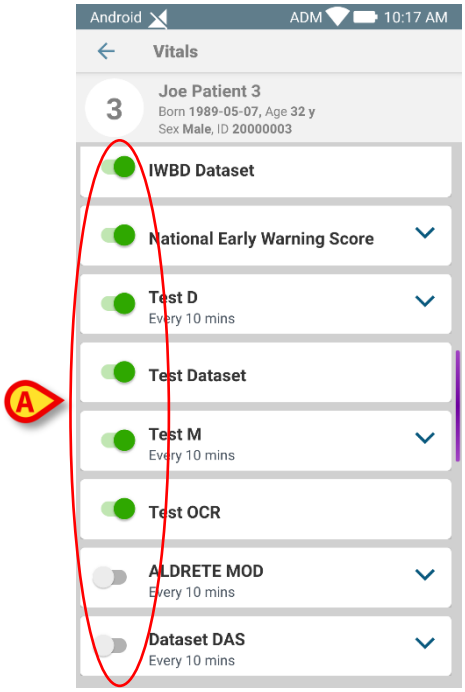

Fig 45

Use the switch on the left to enable/disable a dataset for the selected patient (Fig 45 **A**). The switch is green and positioned on the right when the dataset is enabled (Fig 46 **A**).

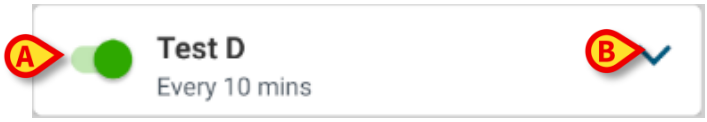

Fig 46

For each dataset the name and the current configuration settings are displayed.

- Tap the ⌄ icon to configure the dataset (Fig 46 **B**).

The dataset tile enlarges (Fig 47).

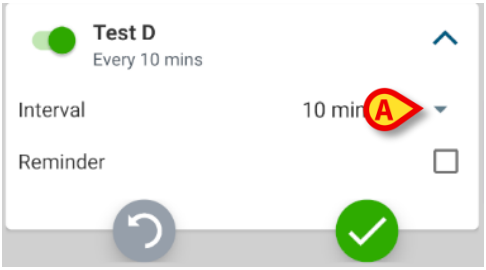

Fig 47

- Tap the "Interval" menu (Fig 47 **A**) to decide the dataset timing (Fig 48).

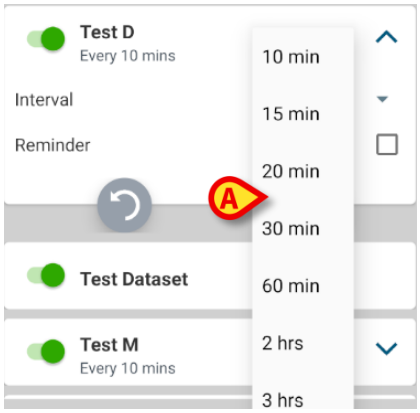

Fig 48

Three timing modes are possible:

- **Free** – whenever required. No evaluation interval is specified.
- **Fixed** – to be evaluated at fixed time intervals (for example: "every 15 minutes").
- **Variable** - to be evaluated at variable time intervals, depending on the patient state.

The timing mode is defined during configuration.

The "Interval" field sets the fixed time span after which the specific set of data must be collected. This field is enabled only for datasets with fixed timing.

➢ Select the "Reminder" checkbox to get automatic reminders on when the datasets acquisitions are due (Fig 49 **A**).

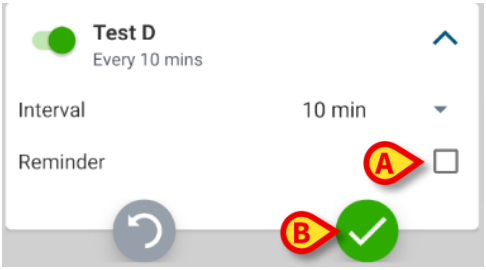

Fig 49

After configuring the dataset,

➢ Tap to save the changes made (Fig 49 **B**).

When a change is made in any of the dataset configuration parameters ("Interval", "Reminder" or both), the icon is displayed alongside the dataset name. This icon indicates that the configuration values were changed.

➢ Tap to go back to the original values.

For datasets with free and variable timing the only configurable option is "Reminder".

1.7 Widgets

The Product implements a set of widgets, i.e. graphic controls making it possible to speed up some user procedures.

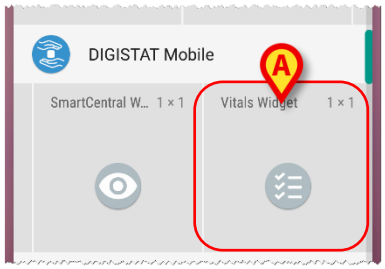

Fig 50

1.7.1 Vitals Widget

The Vitals Widget allows the user to access the Vitals Mobile module. To use this feature, it is necessary to:

- Drag the icon shown in Fig 50 **A** and drop it on the device screen.

The Vitals Widget will be displayed on the device screen with the default size of 1 x 1 (Fig 51)

Fig 51

User login is required. The number of expired datasets is represented as red number in widget.

- Tap the Vitals Widget to access either the screen containing all the expired datasets (if no patient is selected), or the expired datasets for a specific patient (if a patient is selected).

2. Annex - Examples of user workflows

2.1.1 Select Vitals Mobile

To select the Vitals Mobile module:

- Tap the corresponding row on the "Mobile Launcher" screen (Fig 1 - **A**).
- The Vitals Mobile screen opens (Fig 2). Each tile corresponds to a patient.

2.1.2 Select Patient

To select a patient and display their datasets:

- Tap the tile corresponding to the patient (Fig 2 - **B**).

The list of datasets existing for the selected patient is displayed (Fig 3).

2.1.3 Add a new set of data.

To acquire a new set of data, for a given dataset,

- Tap the **+** icon placed on the right (Fig 3 - **C**).

The data entry screen is displayed (Fig 4). The data entry screen features depend on the kind of dataset selected. The figure shows an example.

- Insert the required value/s (Fig 4 - **D**).

When all the (relevant/known) values have been specified,

- Tap  (Fig 4 - **E**).

The recorded sets of values are displayed in a specific summary screen (Fig. 6).

2.1.4 Display the existing dataset summary

To display a summary of all the acquired sets of data for a specific dataset:

- Tap the corresponding tile (Fig 5 - **F**).

A dataset summary screen is displayed (Fig 6). The screen features depend on the kind of dataset acquired. The figure shows an example.

- On this screen, tap  to add another set of data (Fig 6 - **G**).

2.1.5 Edit an existing set of data

- Use the "Pen" icon to edit the data of an existing set (Fig 6 - **H**).

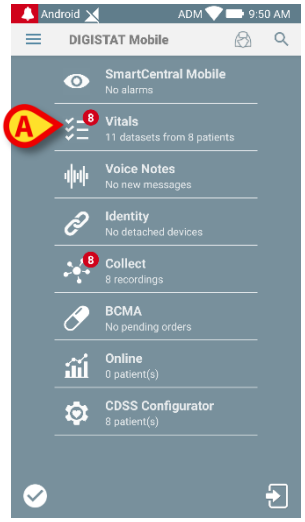

Fig 1

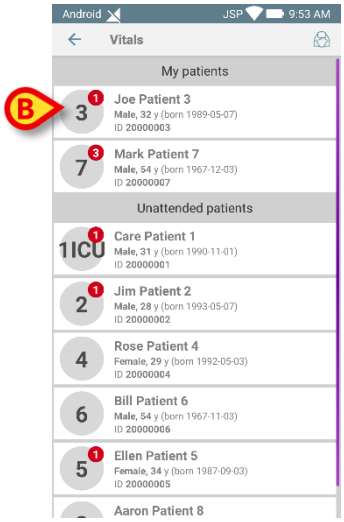

Fig 2

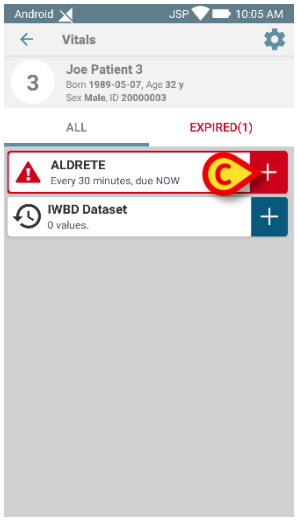

Fig 3

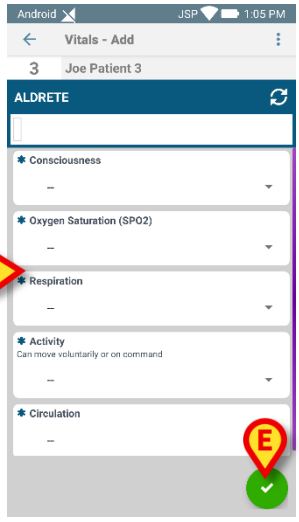

Fig 4

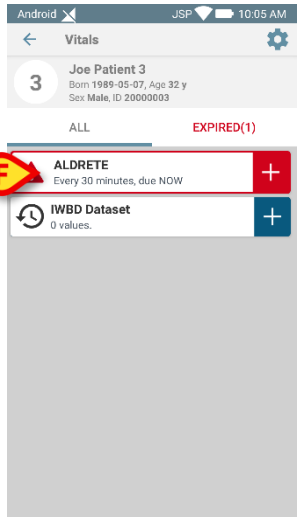

Fig 5

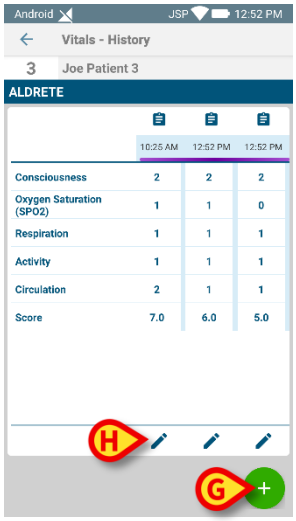

Fig 6