Vitals Mobile User Manual

Version 7.0

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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

➢ Touch the corresponding row on the handheld device screen (Fig 1).

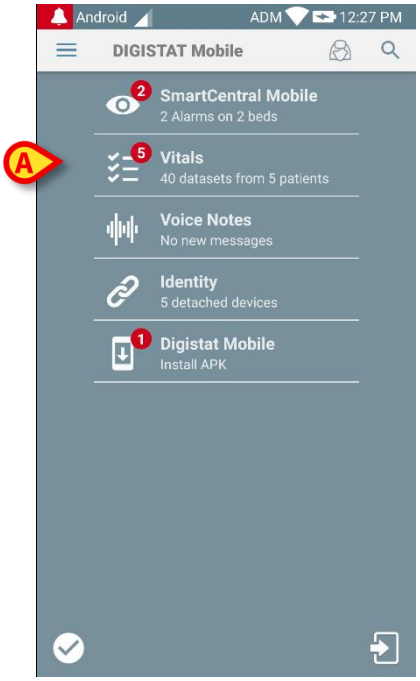


Fig 1

The Vitals Mobile screen, shown in Fig 2, will open.


Android
ADM
12:24
Vitals
MY PATIENTS
OVERDUE (4)
My patients
A
3
Female, 51 y (born 1967-03-18)
ID 180367-2342
B
4
Male, 71 y (born 1947-02-15)
ID 150247-8527
C
2
Male, 58 y (born 1959-12-16)
ID 161259-3653
D
5
Male, 34 y (born 1984-06-06)
ID 060684-9515
I
Male, 50 y (born 1967-12-03)
ID 031267-8525
J
Male, 57 y (born 1960-12-01)
ID 110160-2475

Fig 2

1.3 Patients list

The Vitals Mobile patient list screen (Fig 3) 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.

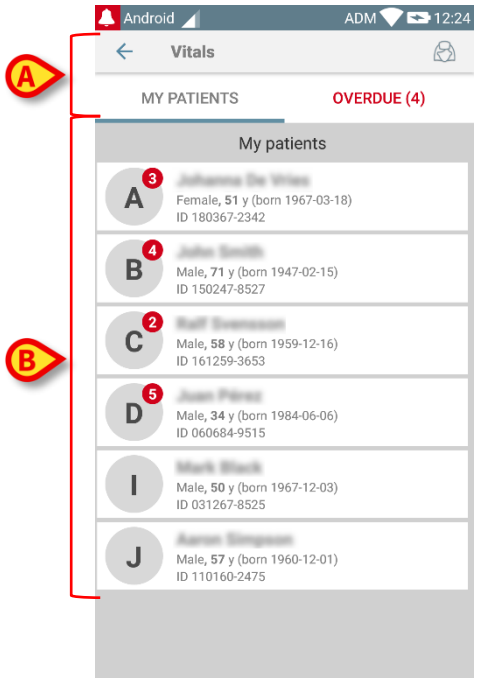


Fig 3

The patient list screen is formed of a heading (Fig 3 **A**) and the patients list (Fig 3 **B**).

1.3.1 Patient list heading

Fig 4 shows the heading of the patient list screen.

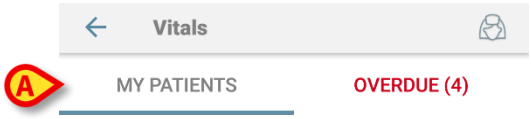


Fig 4

The filter indicated in Fig 4 **A** makes it possible to display either all the patients configured on the handheld device domain (**All Patients**) or only the patients for which there are notifications overdue (**Overdue**).

1.3.2 List of beds

Each bed is represented by a tile (Fig 5).

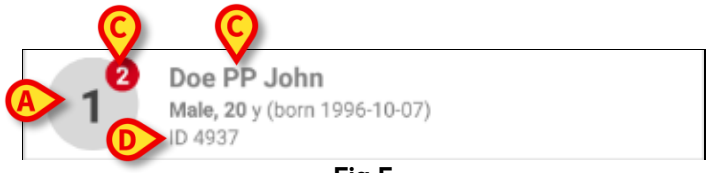


Fig 5

In the tile, the following information is displayed:

- bed number (Fig 5 **A**);
- number of notifications overdue (if any - Fig 5 **B**);
- name of patient on that bed (Fig 5 **C**);
- patient data (if available: sex, age, date of birth, patient ID - Fig 5 **D**).

➢ Touch one tile to access the list of datasets enabled for the corresponding patient (Fig 6).

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 6 **A**) and the list of datasets (Fig 6 **B**).

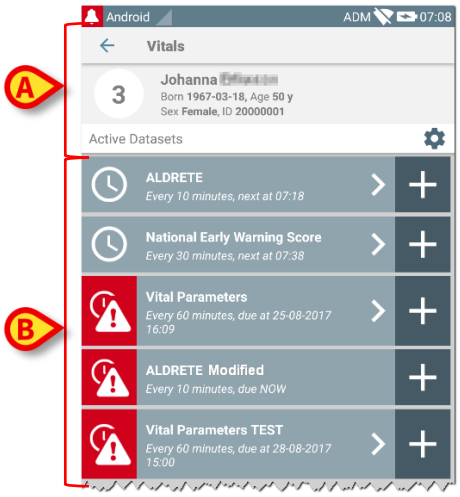


Fig 6

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).

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. See paragraph 1.5 for the dataset configuration functionalities.

Fig 7 shows an example.

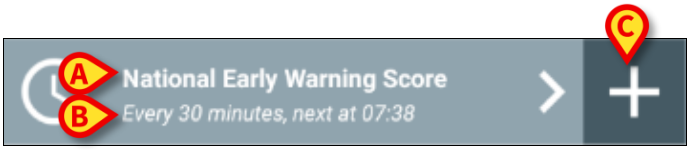


Fig 7

The dataset name is displayed inside the tile (“National Early Warning Score” - Fig 7 **A**).
Below the dataset name, information is displayed relating the data acquisition modalities (i.e. when the dataset shall be acquired, when is the next acquisition due etc. - all these data depend on how the dataset is configured - Fig 7 **B**).
The **+** button (Fig 7 **C**) makes it possible to insert new data (see paragraph 1.4.1).

If the **+** button is not present on the tile it means that the dataset is not enabled (see paragraph 1.5 for more information). The tile is still displayed because past data exists for that dataset, which can be still viewed. See for instance Fig 8.

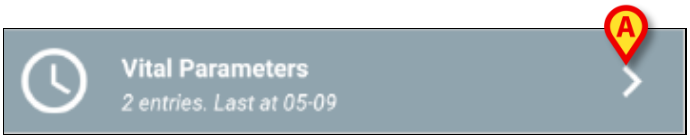


Fig 8

The arrow (Fig 8 **A**) makes it possible to display the past data. See for example Fig 9.

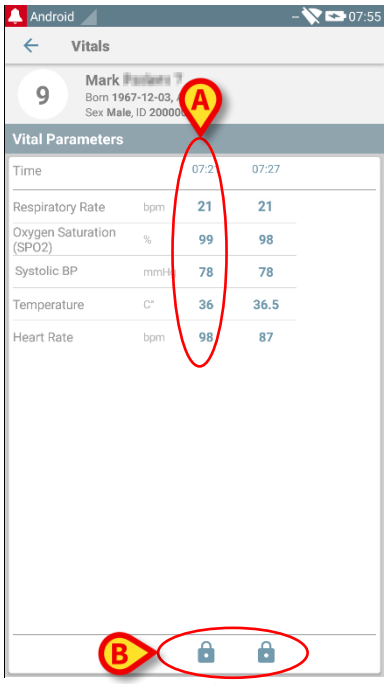


Fig 9

For each entry (i.e. a set of values), date and time are displayed on top. The recorded values are displayed below. See for instance the column indicated in Fig 9 **A**.

The “lock” icon indicated in Fig 9 **B** means that the corresponding score cannot be edited. Otherwise a “pen” icon is displayed (see for instance Fig 30).

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-light is purple.

See for instance Fig 10. The Aldrete score is here configured to be acquired every 10 minutes.

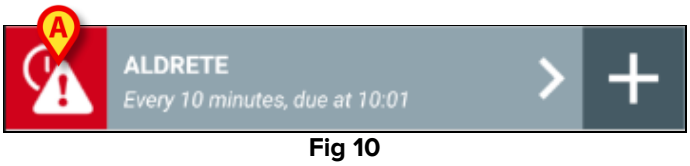


Fig 10

If the dataset is not acquired on time, the Product displays a notification, meaning that an action was due at a certain time but the action was not performed. The icon indicated in Fig 10 **A** is then displayed.
The handheld device in this case provides a specific sound/vibration. The notification is provided on the handheld device even if Vitals Mobile is not active. Also, a visual note is displayed on screen.

1.4.1 How to record a new set of data

To record a new set of data

- Touch the + icon on the tile corresponding to the wanted dataset (Fig 11).

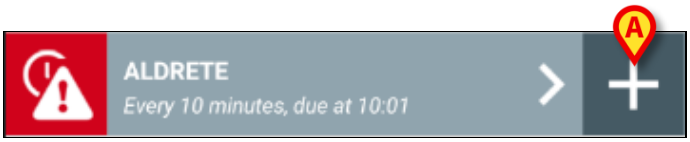


Fig 11

The data entry screen will be displayed.

The data entry screen features depend on the kind of dataset selected. See Fig 12 for an example.

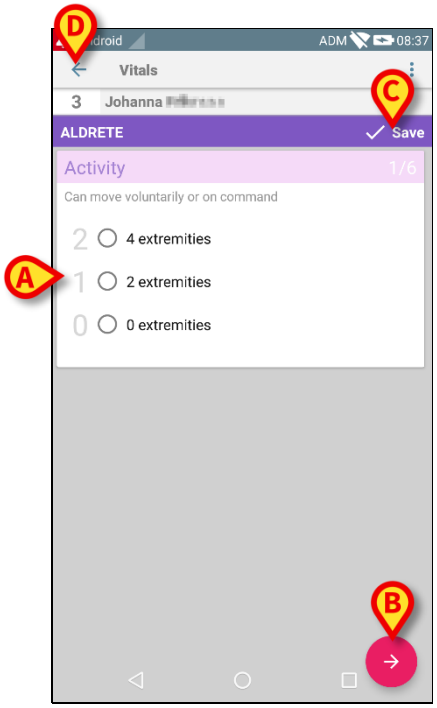


Fig 12

A score can be configured to indicate with a color code the degree of urgency/severity of the available values. The same color code will be then applied to the final result. Also, if so configured, a text indication about the therapy/treatment can be associated to a certain results range.

See Fig 13 for another example.

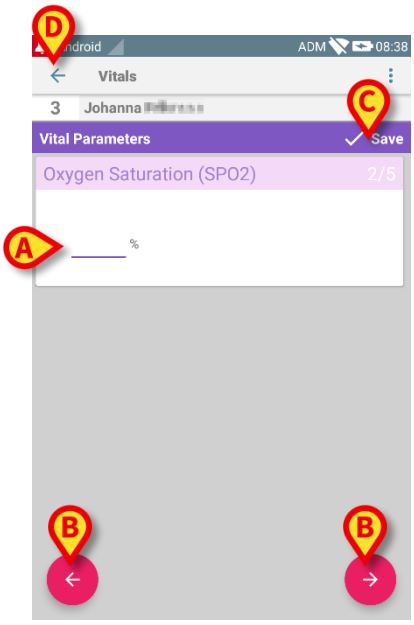


Fig 13

In general, data specification is divided in a number of different screens (one for each kind of data/question/parameter).

- Insert the required value/s on each screen (Fig 12 **A** and Fig 13 **A**).
- Move to next/previous screen using the arrows indicated in Fig 12 **B** and Fig 13 **B**.

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

- Touch **Save** to save the dataset (Fig 12 **C** and Fig 13 **C**). The **Cancel** option (Fig 12 **D** and Fig 13 **D**) closes the data entry screen.

It is also possible to configure the dataset in a way that shows all the requested parameters on a single page. Odd and even rows are colored differently (i.e. white or grey) to enhance readability.

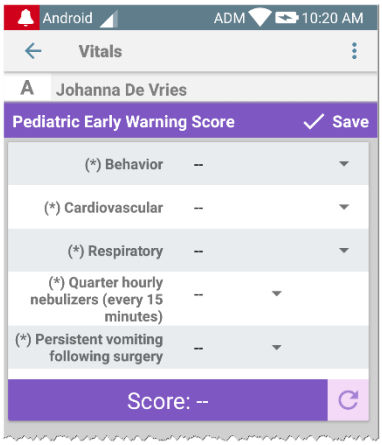
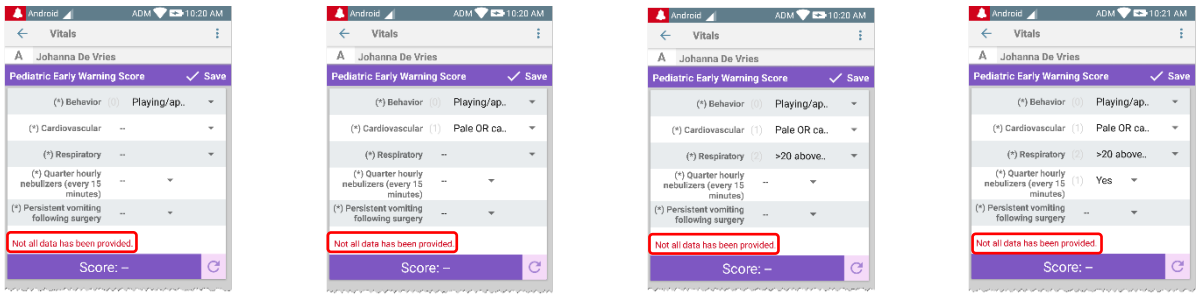


Fig 14

A score displayed on single page mode is calculated in real time i.e. at every data insertion the module tries to calculate it: if data is not enough, a notification is displayed:



Touch the button indicated in Fig 15 **A** to update the score (any moment):

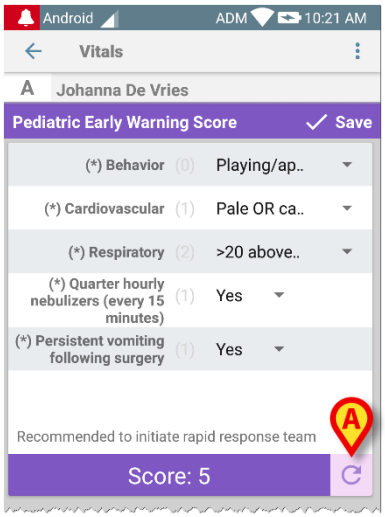


Fig 15

The module can be configured to consider as “Valid” only the values included in a configured range and to therefore not accept values outside the range.

If values outside the range are inserted, the module rejects them with a message informing the user about the range of acceptable values. See for instance Fig 16.

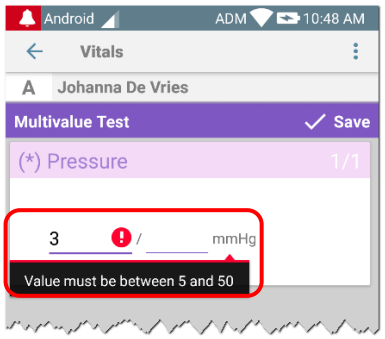


Fig 16

Certain parameters (as, for instance, Respiratory Rate or Oxygen Saturation) can be automatically acquired from the devices connected to the patient (and then edited by the user, if necessary).

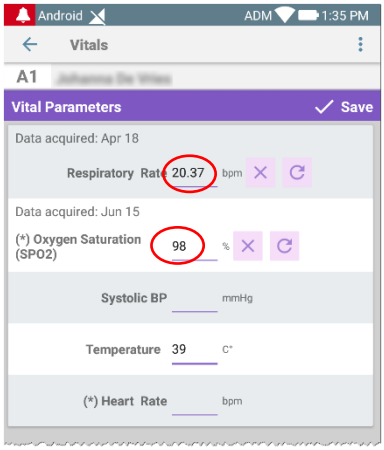


Fig 17

Date/time entry

Certain datasets require the user to entry date/time data.

The following pictures represent the same entry type “Date” in non-paged (Fig 18) and paged (Fig 19) datasets:

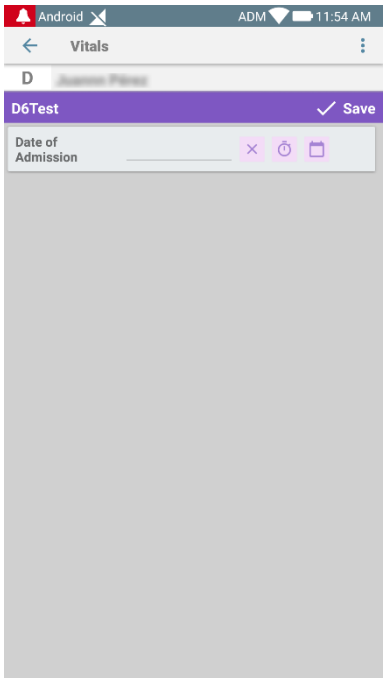


Fig 18

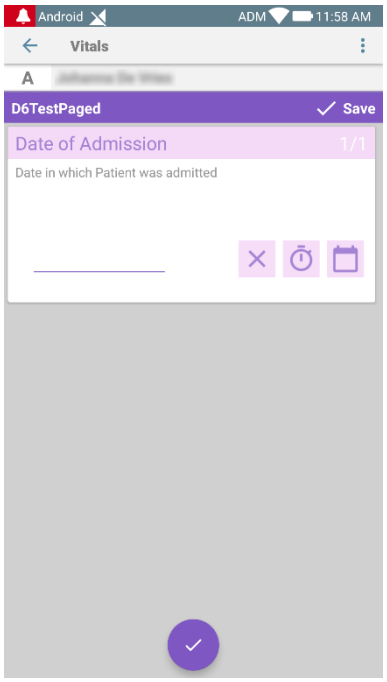


Fig 19

By means of “Date” entry type, the user can select and insert into the properly configured dataset the current date value.

- Touch the  icon to insert the current date;
- Touch the  icon to insert a specific date;
- Touch the  icon to cancel the inserted value.

By means of “Date-and-Time” data entry, the user can select and insert into the properly configured dataset a specific date and time value.

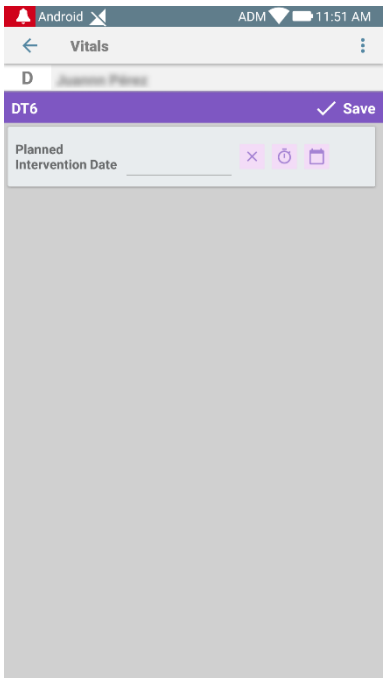


Fig 20

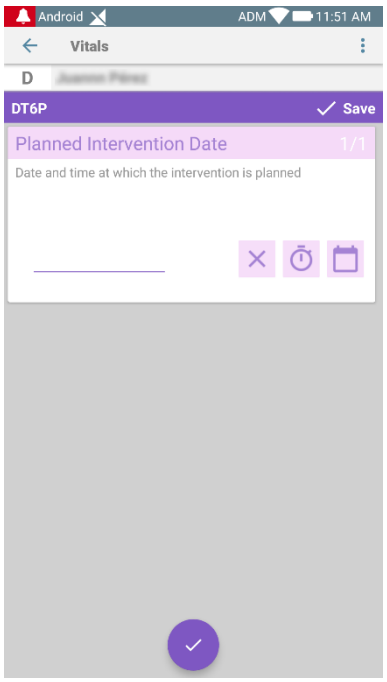


Fig 21

- Touch the  icon to insert the current date and time;
- Touch the  icon to insert a specific date and time, just as follows: the user firstly select the date (Fig 22) and after confirmation selects the time (Fig 23);

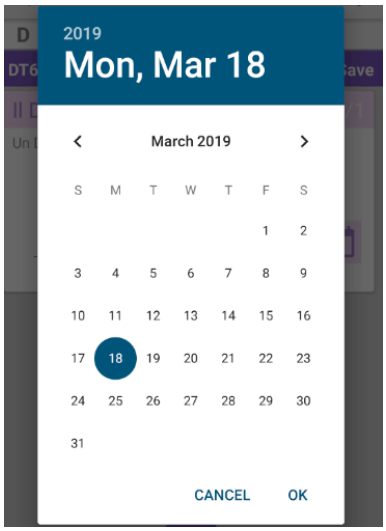


Fig 22

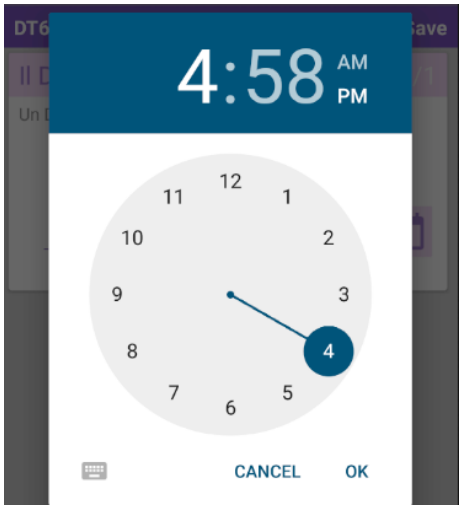


Fig 23

- Touch the  icon to cancel the inserted value.

Please note if the user inserts a date and time belonging to the current day, then only the time will be displayed.

The “OpenList” entry type collects elements usually not taken into account for scores. Some items of the list can be configured to be suggested: the user can however set a specific value different than the ones suggested.
The “OpenList” can be equally used in non-paged (Fig 24) or paged (Fig 25) datasets:

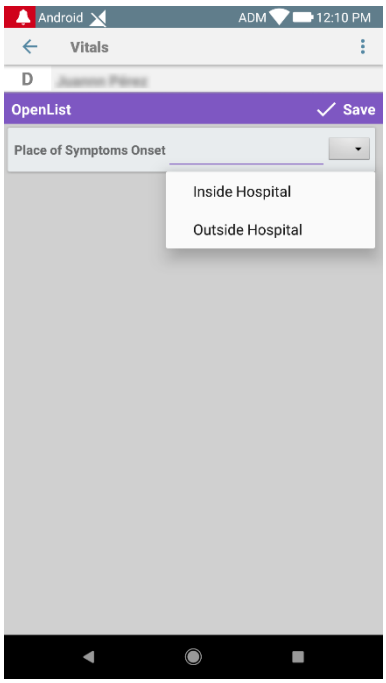


Fig 24

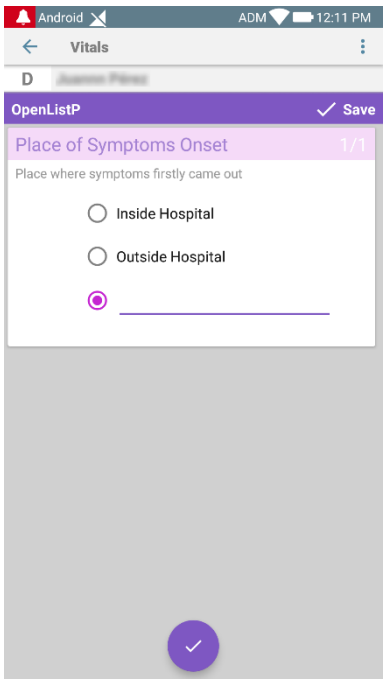


Fig 25

The “NumericList” entry type is related to score datasets. The user inserts a numeric value: such a value is mapped on an item label concurring to the calculation of the score itself. Let us consider the example below:

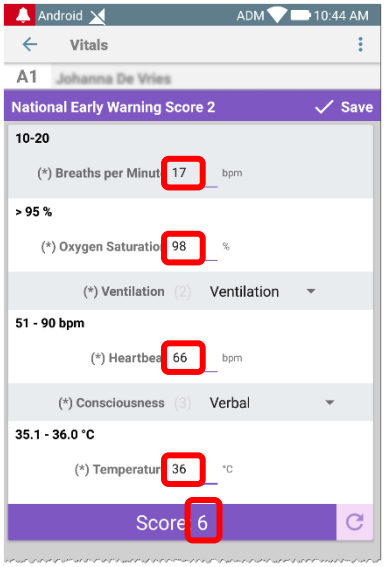


Fig 26

The same example with the same entry type can be also presented in paged datasets. One can pass from the first screen to the second one by touching the → button:

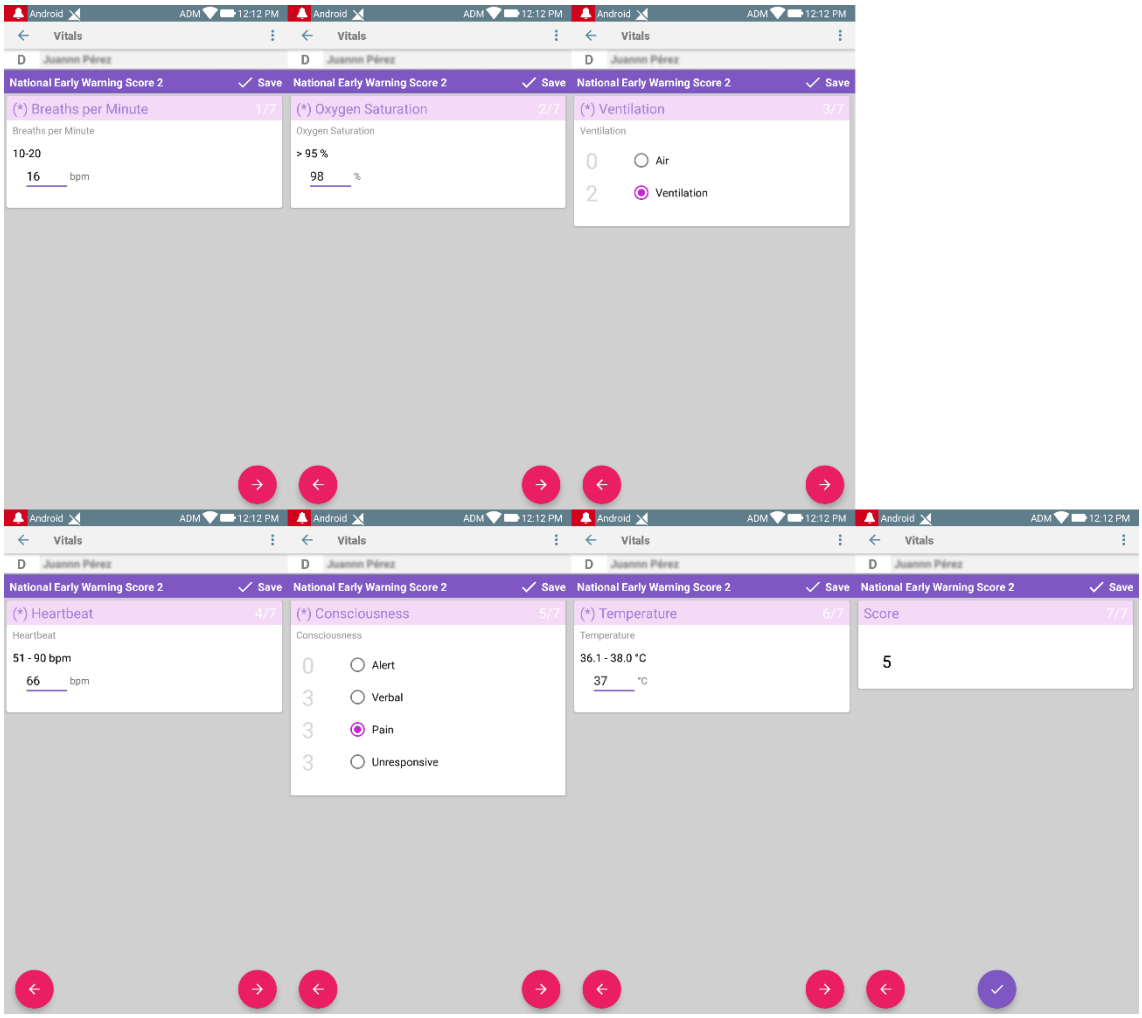


Fig 27

The “NumericList” entry type can be configured to read data from connected devices by means of installed drivers. See the example below (Fig 28):

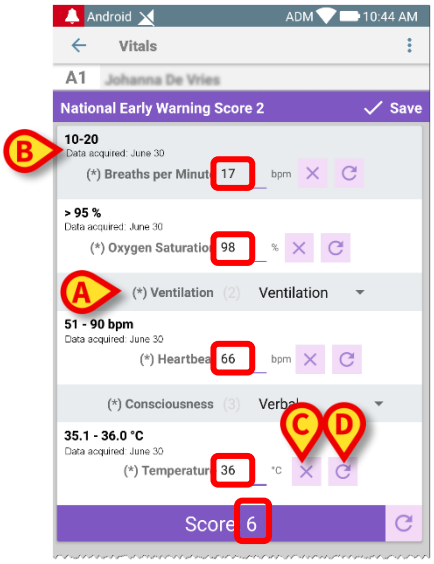


Fig 28

- The numeric value (Fig 28 **A**) is automatically read from the driver;

- A time counter (Fig 28 **B**) informs the user about the time elapsed since the last data reading;

- Touch the button (Fig 28 **C**) to delete the inserted value;

- Touch the button (Fig 28 **D**) to update the read value.

The same example with the same entry type can be also presented in paged datasets. Buttons to cancel or update data values from driver still have same meaning of above.
One can pass from the first screen to the second one by touching the button:

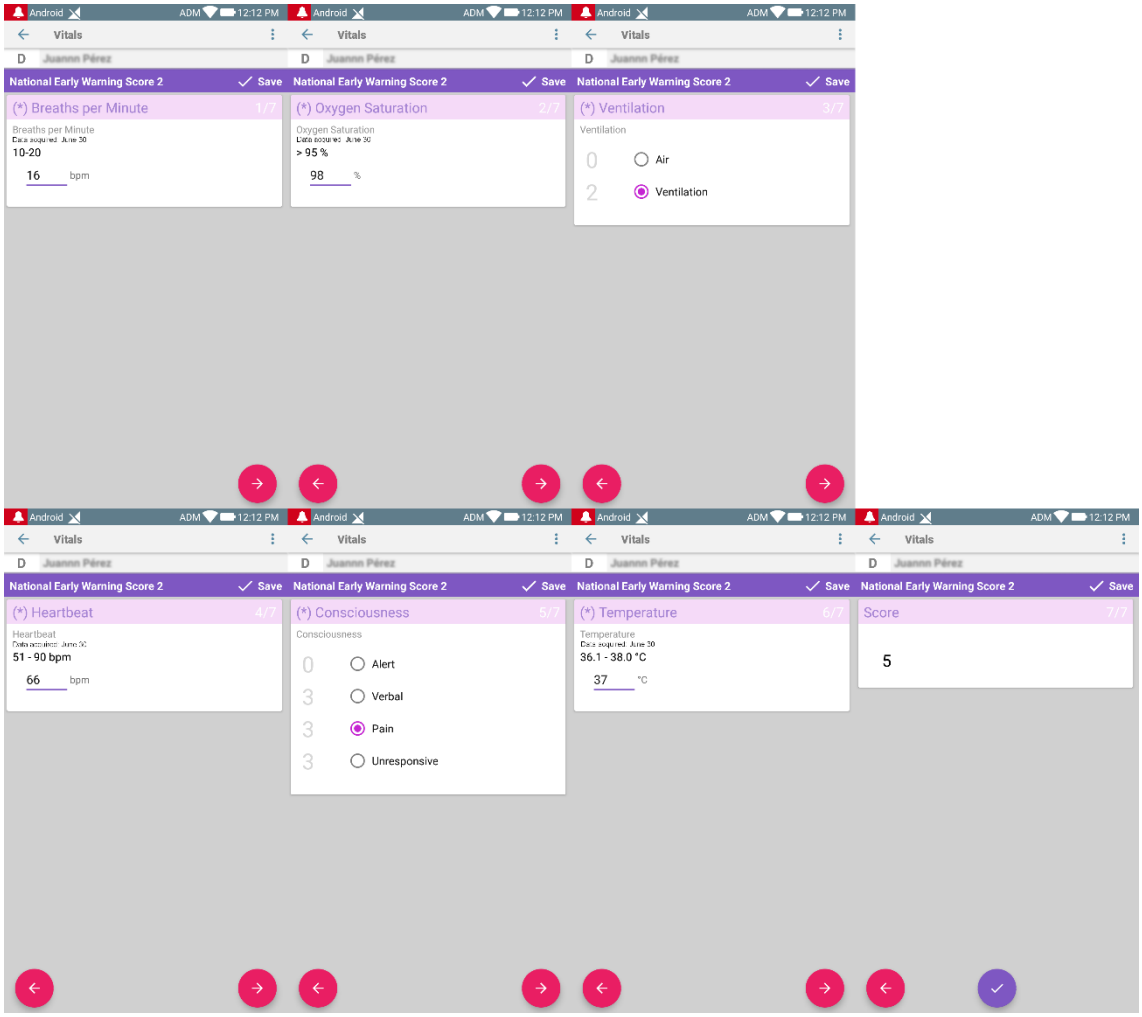


Fig 29

1.4.2 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. See Fig 30 for an example.

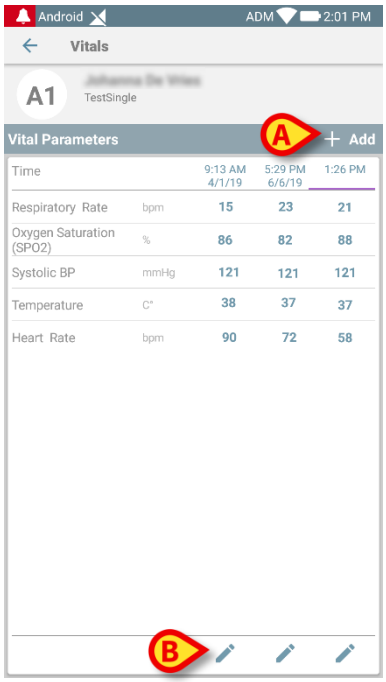


Fig 30

- On this screen, touch **Add** to add another set of data (Fig 30 **A**).
- Use the “Pen” icon to edit the data of an existing set (Fig 30 **B**).

In case of “NumericList” entry type, a specific button is displayed in the summary screen allowing the user to view the original numeric data or the associated label:

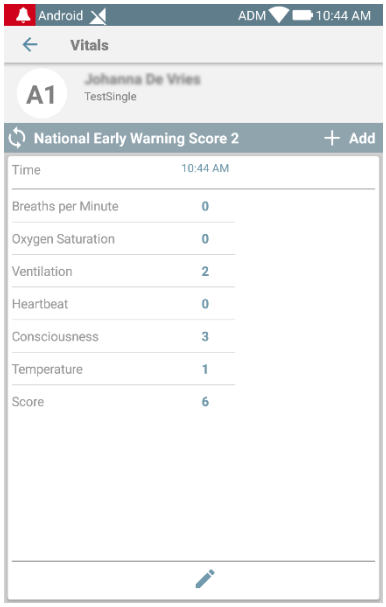


Fig 31

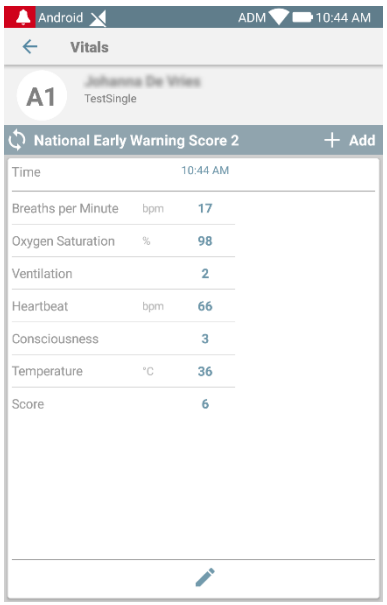


Fig 32

1.4.3 How to edit an existing set of data

To edit an existing set of data, on the datasets list screen (Fig 33),

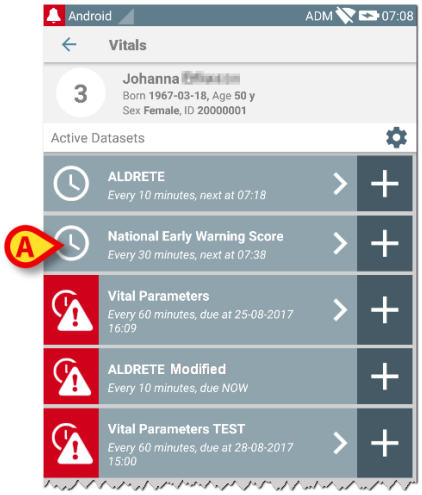


Fig 33

- Select the relevant dataset (Fig 33 **A**, for instance). The acquired datasets summary will open (Fig 34).

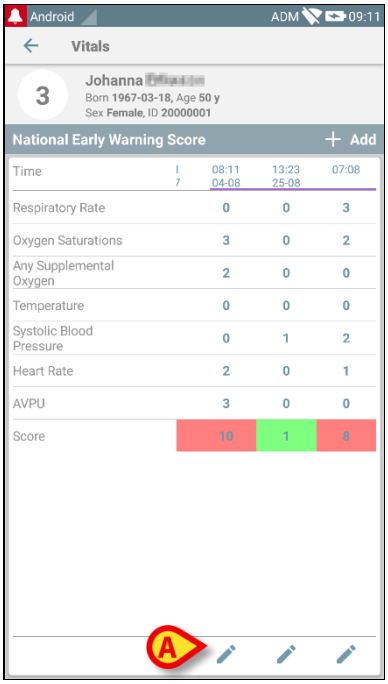


Fig 34

- Touch the “pen” icon corresponding to the set to be edited (Fig 34 **A**)

The data entry screen will open (Fig 35).

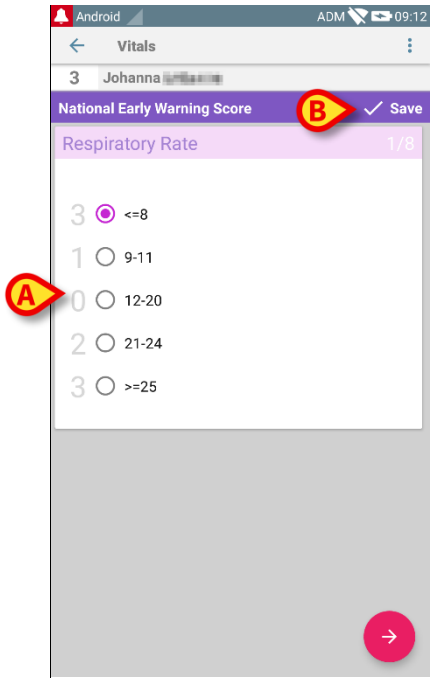


Fig 35

- Edit data (Fig 35 **A**).
- Touch **Save** (Fig 35 **B**).

The set is this way edited.

1.4.4 Pictures and audio acquisition

The Vitals Mobile module makes it possible to acquire audio recordings and pictures. This functionality can be configured both as a specific, independent dataset, and as a part of an existing “textual” dataset. In the latter case the functionality makes it possible to add an audio/visual commentary to the recorded values.

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

- Touch the “**+**” button placed on the right of the dedicated dataset (Fig 36 **A**).

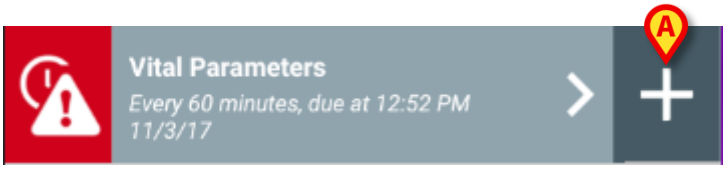


Fig 36

The following screen will open, making it possible to record an audio file (Fig 37).

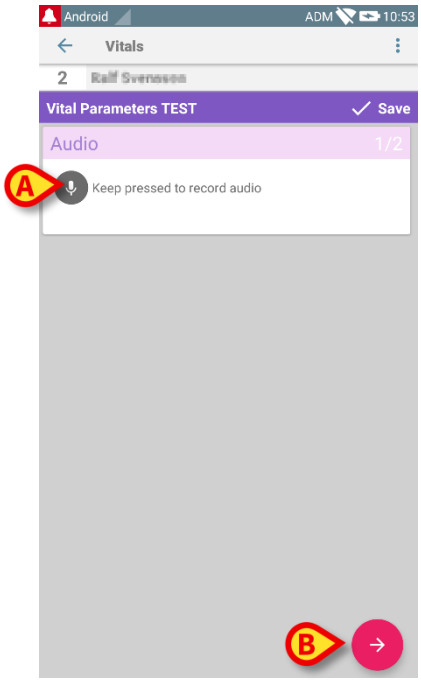


Fig 37

To record,

- Keep pressed the button indicated in Fig 37 **A**.

The button will turn red while recording. Recording ends when the button is released. After recording the audio acquisition page is displayed (Fig 38). The icon indicated in Fig 38 **A** represents the recorded file.

Fig 38

Multiple recordings are possible for a single dataset acquisition (Fig 39 **A**).

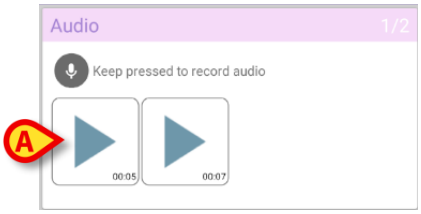


Fig 39

- Touch the icon to listen to the audio file.

For pictures acquisition, go to the following screen, i.e.

- Touch the icon on the lower-right corner of the screen (Fig 37 **B**).

The following screen will open (Fig 40)

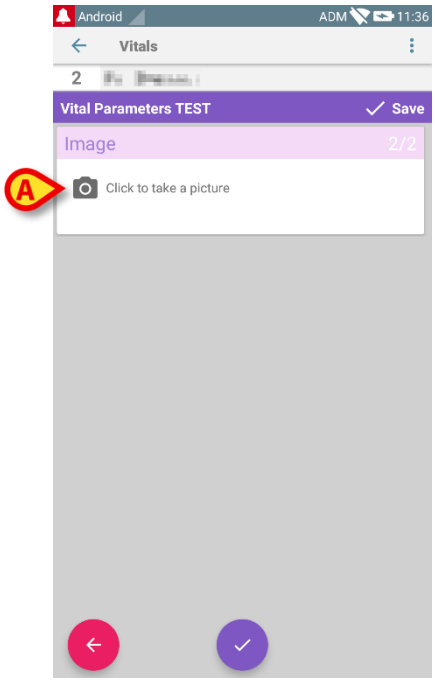


Fig 40

- Touch the icon indicated in Fig 40 **A** to activate the camera (Fig 41).

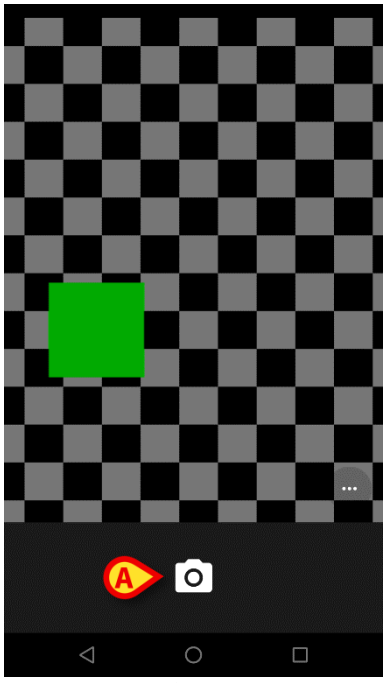


Fig 41

- Touch the icon to take the picture (Fig 41 **A**). A preview is displayed on screen (Fig 42).

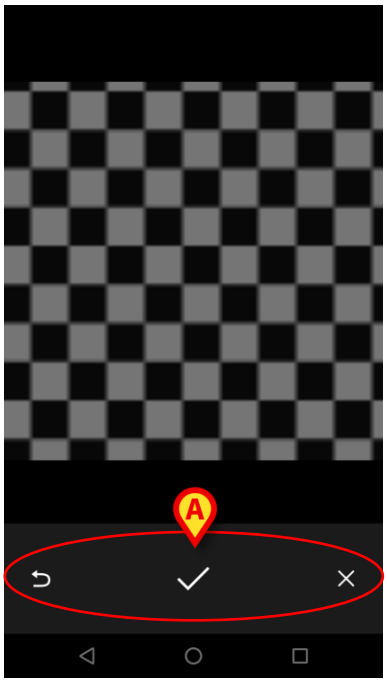


Fig 42

- Use the buttons indicated in Fig 42 **A** to:
  1. go back to the picture acquisition mode (Fig 41);
  2. keep the picture and go back to the photo acquisition page (Fig 40);
  3. discard the picture and go back to the photo acquisition page (Fig 40).

Once a picture is saved, a thumbnail is displayed on the photo acquisition page (Fig 43).

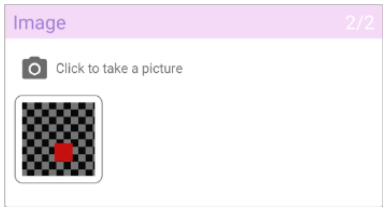


Fig 43

- Touch the thumbnail to display the picture again.

Multiple pictures can be acquired for the same dataset.

After audio and/or picture acquisition, to save the acquired data, on the photo acquisition page (Fig 44),

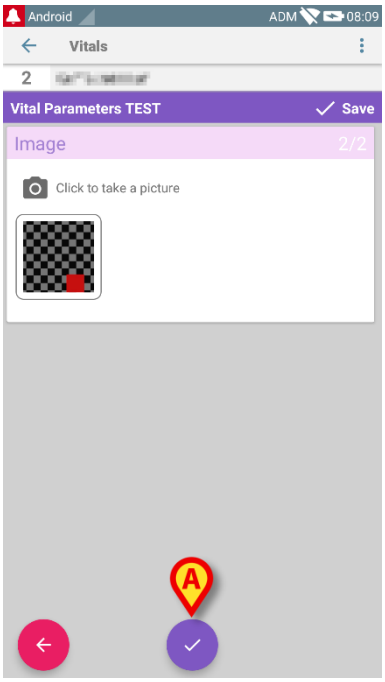


Fig 44

➢ Click the icon (Fig 44 **A**).

A summary screen is then displayed, listing all the acquired datasets (Fig 45).

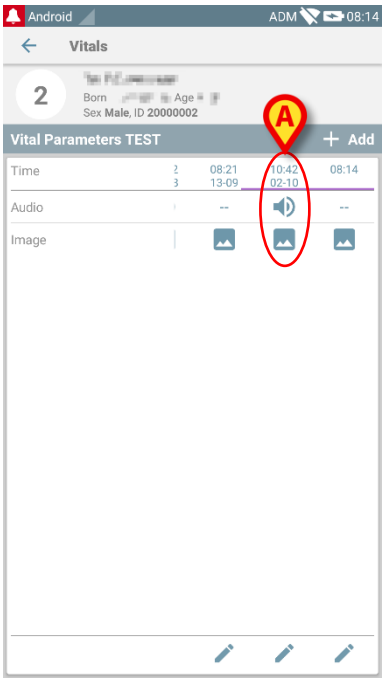


Fig 45

On this page, each column corresponds to a dataset (Fig 45 **A**). For each dataset the following information is provided:

- Date/time of acquisition.
- There is at least an audio recorded - icon.
- There is at least a picture saved - icon.

1.5 OCR functionality

The OCR functionality is not supported in general on devices with Android version 4.4.2 and lower; it is supported on the Myco 2 devices and in general on Myco devices with firmware version 10.1 and higher, or in general on Android devices with version 5.1 and higher.

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

Fig 46 - General Electric V100 monitor

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

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 shall be launched from Digistat. To verify the proper installation, please go to the list of applications in your Android™ device and verify “Digistat OCR” is present.

1.5.2 Usage

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

- Touch the + icon on the tile corresponding to the wanted dataset (Fig 47 **A**).

Fig 47

The data entry screen will be displayed (Fig 48).

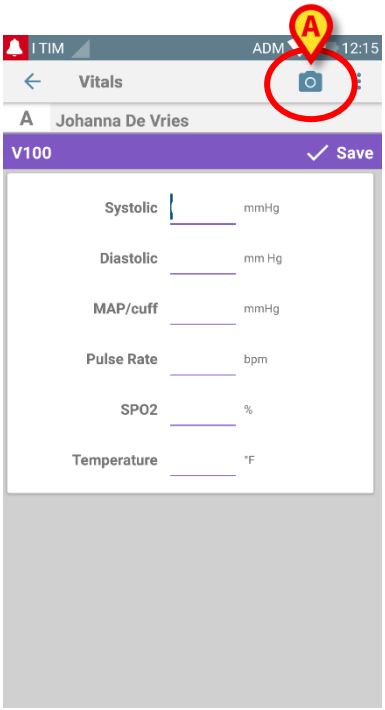


Fig 48

- Touch the icon indicated in Fig 48 **A**.

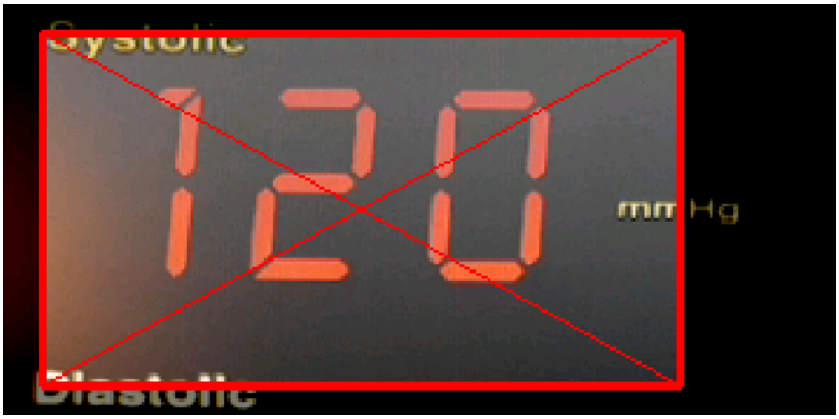
The screen for the image acquisition will appear.

A label in the upper part of the screen reports the medical device on which the OCR reading shall be done:

- Align the mask rectangles to the parameters on the device to read them. The OCR calculation will start automatically. The rectangles will be purple when calculating.

Once the value has been calculated, the rectangle will turn green with a “V” in the top right corner. Otherwise, the OCR will continue attempting to recognize the characters and the rectangle will continue to be purple.

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



- 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 modes by clicking on the sun/moon button.

- Once the calculation has been performed touch the confirm button in the bottom right of the screen to send back data. A picture representing the last image properly read for every green rectangle will also be returned.

Note that the user can always confirm the OCR reading despite are present red (stopped) or purple (ongoing) OCR calculation. In this case, only the data corresponding to calculated (green) rectangles are saved.

- On the main interface cancel the OCR operation with the back arrow on the bottom left part of the screen.

- In-app instructions are available by pressing the button in the top left part of the screen.

Touching the AF button will trigger an autofocus corresponding to the first area that has not been read yet. No operation will be performed if all parameters have been read. Please note touching the AF button will disable the device autofocus; to trigger a new one press AF button again.

Because the continuous autofocus is turned off when touching AF button, this feature should be used in those rare occasions in which the smartphone autofocus functionality is not properly focusing the medical device.
Before using this functionality, please give the smartphone time to properly adjust the focus: moving farther and closer to the medical device might be sufficient to trigger a new autofocus operation.

After confirmation, the acquired data (i.e. green rectangles) is automatically displayed in the dataset fields.

The following window is displayed (Fig 49):

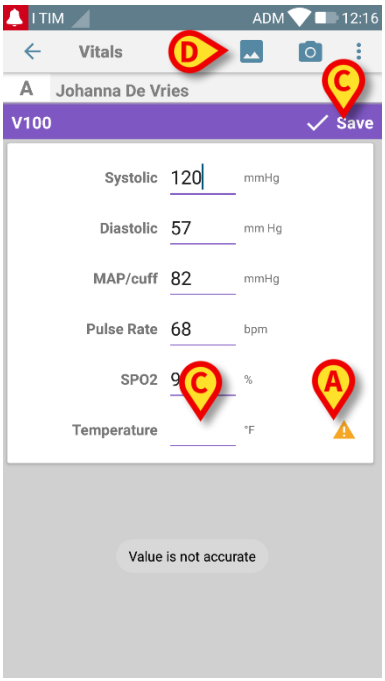


Fig 49

If one of the values is not read or correctly recognized, the ⚠ icon is displayed alongside the relevant parameter (Fig 49 **A)**.

- Tap the button indicated in Fig 49 **D** to display the picture representing the last image properly read for every green rectangle.

- Touch the **Save** button in the top right corner (Fig 49 **B**).

If not all the values are correctly acquired (i.e. there is the ⚠ icon) user confirmation is required (Fig 50):

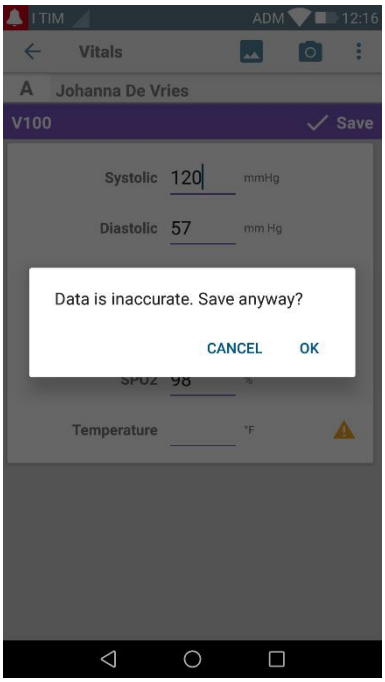


Fig 50

- Press **OK** to save anyway or **CANCEL** to manually insert the missing value.

To insert the value

- Touch the empty field (Fig 49 **C**). Since a numeric value is expected, a numeric keyboard to is displayed (Fig 51):

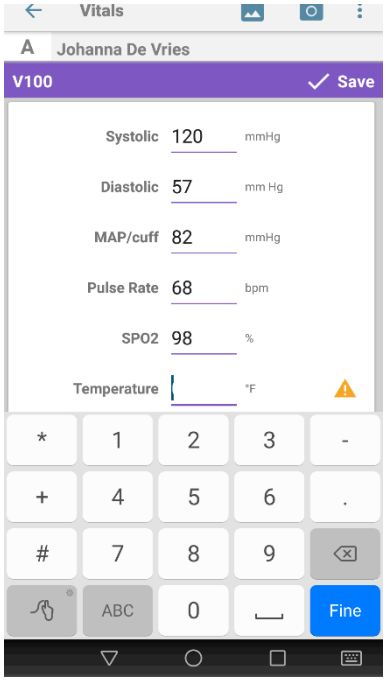


Fig 51

When all fields are filled (Fig 52):

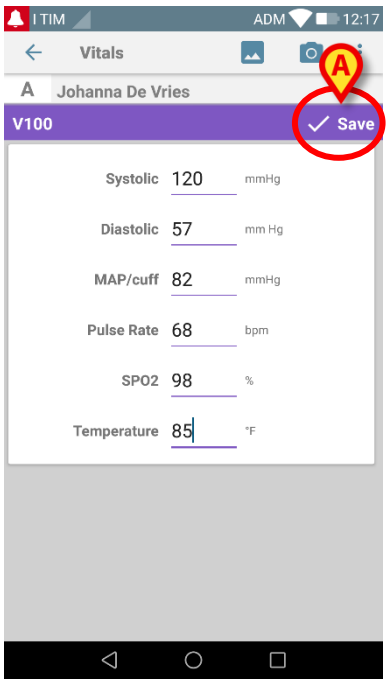


Fig 52

➢ Touch the **Save** button in the top right corner (Fig 52 A).

A summary screen is displayed (Fig 53):

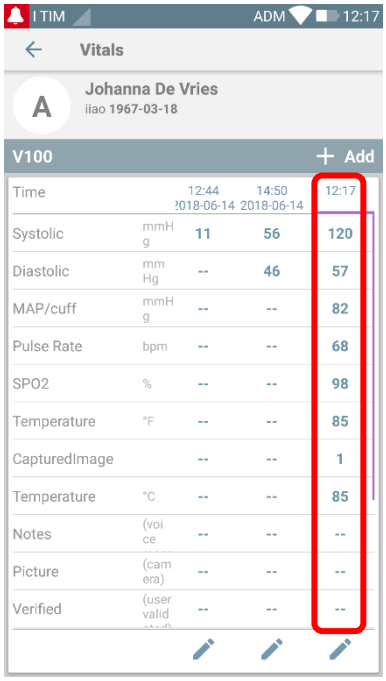


Fig 53

1.6 Enabling and configuring the existing datasets

The functionalities described in this paragraph are reserved to “super users” or system administrators and require therefore a specific permission level.

It is not possible to add or edit datasets for dismissed patients.

To access the dataset configuration options, after patient selection, on the datasets list screen (Fig 54),

- Touch the ⚙ icon (Fig 54 **A**).

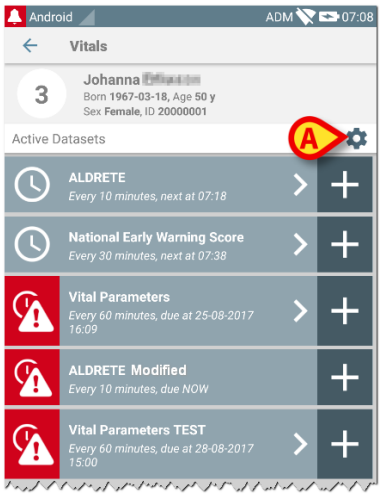


Fig 54

The list of all the existing datasets (defined by configuration) will open (Fig 55). The list of all existing dataset is configured.

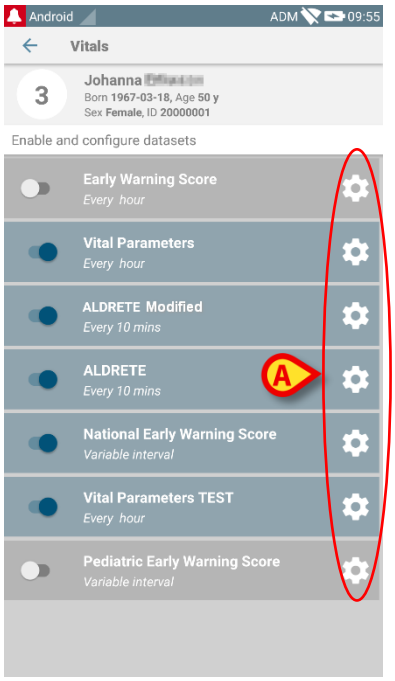


Fig 55

Use the switch on the left to enable/disable a dataset for the selected patient (Fig 55 **A**).
The switch is dark blue and positioned on the right when the dataset is enabled (Fig 56 **A**).

Fig 56

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

- Touch the icon to configure the dataset (Fig 56 **B**).

The following screen will open (Fig 57).

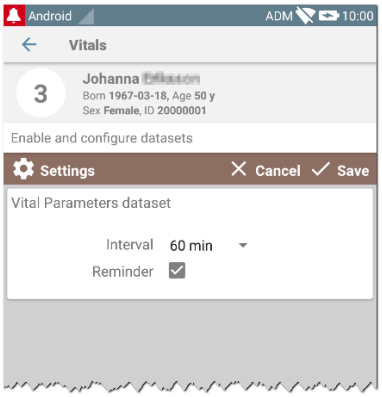


Fig 57

- Touch the “Interval” menu to decide the dataset timing (Fig 58).

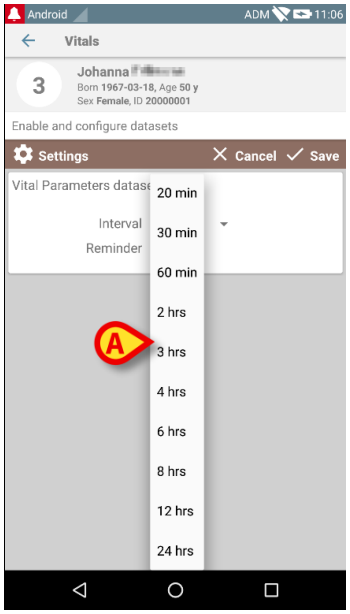


Fig 58

- Select the “Reminder” checkbox to get automatic reminders on when the datasets acquisitions are due (Fig 59 **A**).

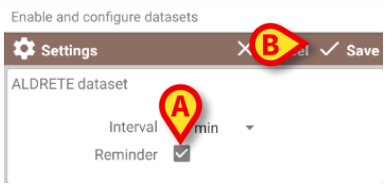


Fig 59

After configuring the dataset,

- Touch the **Save** option to save the changes made (Fig 59 **B**).

- Touch **Cancel** to go back to the datasets list.

Some datasets are pre-configured on a single timing option (i.e. “Once” or “Variable Interval” - see Fig 60 **A**).

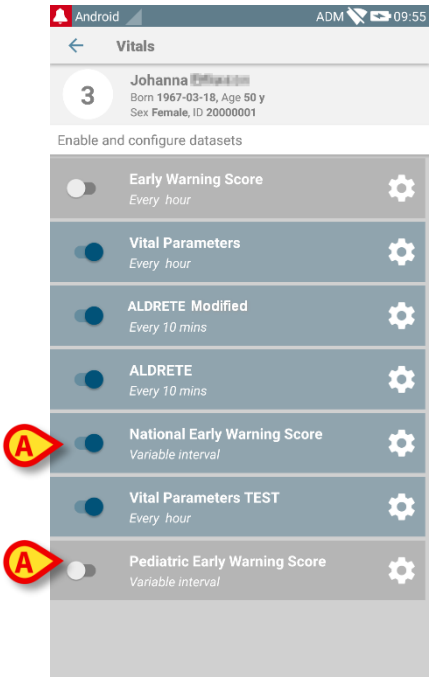


Fig 60

1.7 Widgets

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

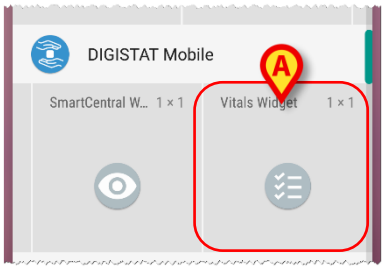


Fig 61

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 61 **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 62)

Fig 62

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

- Touch the Vitals Widget to access either the screen containing all datasets overdue (if no patient is selected - Fig 63), or the datasets overdue for a specific patient (if a patient is selected - Fig 64):

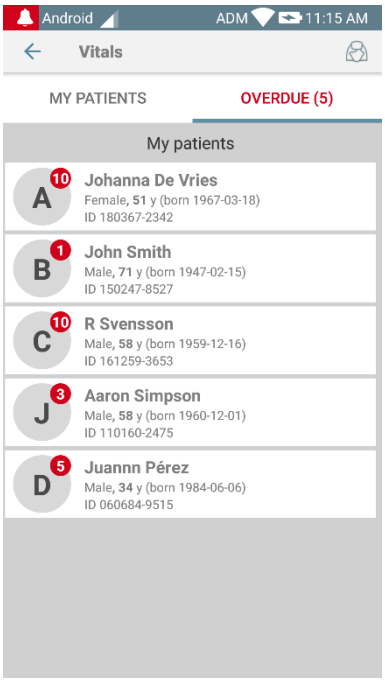

Android
ADM
11:15 AM
Vitals
MY PATIENTS
OVERDUE (5)
My patients
A
10
Johanna De Vries
Female, 51 y (born 1967-03-18)
ID 180367-2342
B
1
John Smith
Male, 71 y (born 1947-02-15)
ID 150247-8527
C
10
R Svensson
Male, 58 y (born 1959-12-16)
ID 161259-3653
J
3
Aaron Simpson
Male, 58 y (born 1960-12-01)
ID 110160-2475
D
5
Juannn Pérez
Male, 34 y (born 1984-06-06)
ID 060684-9515

Fig 63

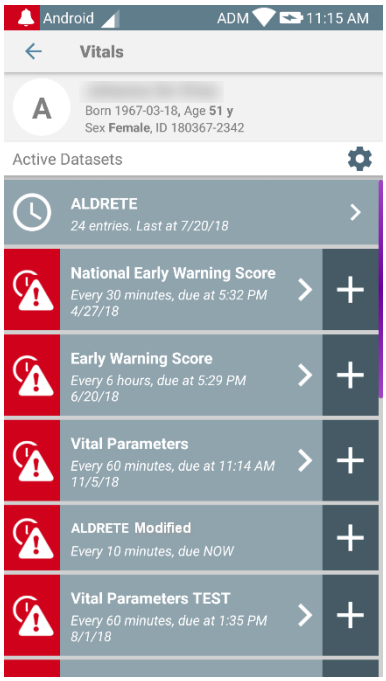

Android
ADM
11:15 AM
Vitals
A
Born 1967-03-18, Age 51 y
Sex Female, ID 180367-2342
Active Datasets
ALDRETE
24 entries. Last at 7/20/18
National Early Warning Score
Every 30 minutes, due at 5:32 PM
4/27/18
Early Warning Score
Every 6 hours, due at 5:29 PM
6/20/18
Vital Parameters
Every 60 minutes, due at 11:14 AM
11/5/18
ALDRETE Modified
Every 10 minutes, due NOW
Vital Parameters TEST
Every 60 minutes, due at 1:35 PM
8/1/18

Fig 64

1.8 Annex - Examples of user workflows

1.8.1 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.

1.8.2 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).

1.8.3 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.
Data specification is usually divided in a number of different screens (one for each kind of data/question/parameter).

- Insert the required value/s on each screen (Fig 4 - **D**).
- Move to next/previous screen using the arrows indicated in Fig 4 - **E**.

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

- Touch **Save** (Fig 4 - **F**).

The recorded sets of values are displayed in a specific summary screen.

1.8.4 Display the existing dataset summary

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

- Touch the corresponding tile (Fig 5 - **G**).

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

- On this screen, touch **Add** to add another set of data (Fig 6 - **H**).

1.8.5 Edit an existing set of data

- Use the “Pen” icon to edit the data of an existing set (Fig 6 - **I**).

Fig 1

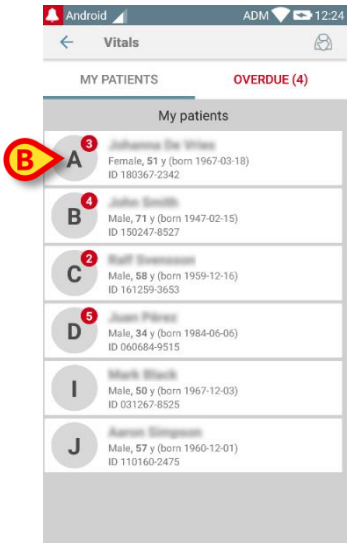


Fig 2

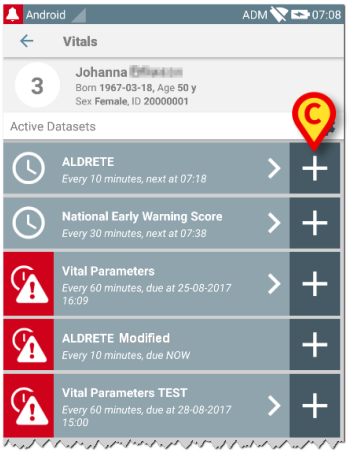


Fig 3

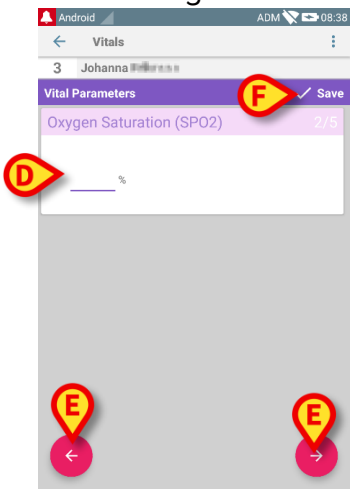


Fig 4

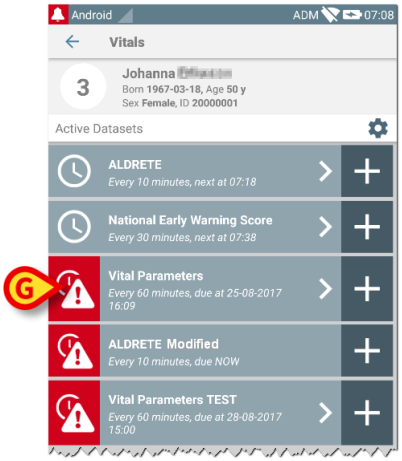


Fig 5

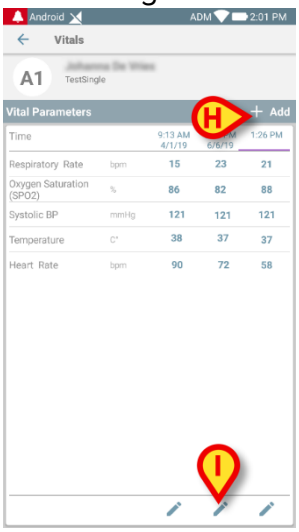


Fig 6