

# Vitals Mobile User Manual

Version 7.0

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## 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.

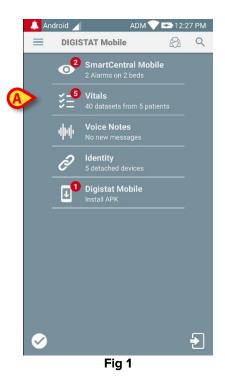
Examples:

- 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.

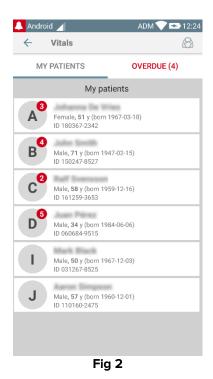
## 1.2 Vitals Mobile start-up

To start the Vitals Mobile module

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



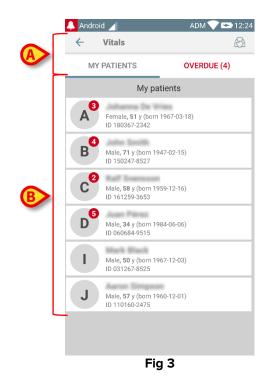
The Vitals Mobile screen, shown in Fig 2, will open.



## 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.



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.



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).



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**).



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.



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.



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

Android ∠			-	<b>X 🖙</b> 07:55
9 Mark Born 196 Sex Male	5 <b>7-12-03</b> , / e, ID <b>2000</b> 0	A		
Vital Parameters	- 1	07:2	07:27	
Respiratory Rate	bpm	21	21	
Oxygen Saturation (SPO2)	%	99	98	
Systolic BP	mmHg	78	78	
Temperature	C°	36	36.5	
Heart Rate	bpm	98	87	
B	X	Ô	â	)
	Fi	g 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.



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  $\bf{A}$  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).



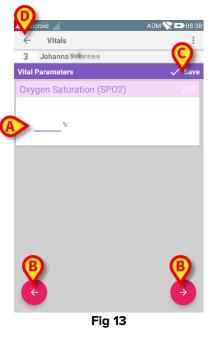
The data entry screen will be displayed.

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



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.



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.

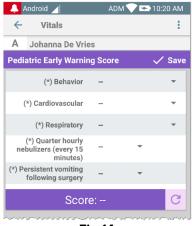
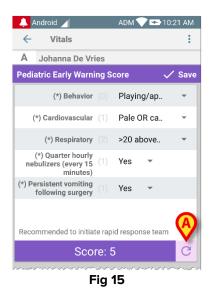


Fig 14

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:

👃 Android 🥖 🔋 ADM 💎 📼 10:20 AM	👃 Android 🔟 🛛 ADM 💎 📼 10:20 AM	ADM 💎 🖘 10:20 AM	👃 Android 🦯 🛛 ADM 💎 🖼 10:21 A
← Vitals :	← Vitals :	← Vitals :	← Vitals
A Johanna De Vries	A Johanna De Vries	A Johanna De Vries	A Johanna De Vries
Pediatric Early Warning Score 🗸 Save	Pediatric Early Warning Score 🗸 Save	Pediatric Early Warning Score 🗸 Save	Pediatric Early Warning Score 🗸 Sa
(*) Behavior (0) Playing/ap 👻	(*) Behavior (0) Playing/ap 🔻	(*) Behavior (0) Playing/ap 👻	(*) Behavior (0) Playing/ap 👻
(*) Cardiovascular 👻	(*) Cardiovascular (1) Pale OR ca 🔻	(*) Cardiovascular (1) Pale OR ca 💌	(*) Cardiovascular (1) Pale OR ca *
(*) Respiratory *	(*) Respiratory	(*) Respiratory (2) >20 above •	(*) Respiratory (2) >20 above
(*) Quarter hourly nebulizers (every 15	(*) Quarter hourly nebulizers (every 15	(*) Quarter hourly nebulizers (every 15	(*) Quarter hourly nebulizers (every 15 (1) Yes = minutes)
(*) Persistent vomiting following surgery	(*) Persistent vomiting following surgery	(*) Persistent vomiting following surgery	(*) Persistent vomiting following surgery
Not all data has been provided.	Not all data has been provided.	Not all data has been provided.	Not all data has been provided.
Score: – C	Score: – C	Score: – C	Score: -
n an an an ann an an ann an ann an ann an a		ويوجعهم وحربا فروان والحرف الجرام ورابن في فروان من المراجع الجوار فروان مراجع والمراجع المراجع المراجع والم	والاستعان المراجعة الراحية الراجع المستجرد المروان العرب المراجع والمواحية الراجع الراحية المراجع المراجع المراجع

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



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.

👃 Android 🔟	ADM 💎 🖘 10:48 AM
← Vitals	:
A Johanna De Vries	
Multivalue Test	🗸 Save
(*) Pressure	
3 0 Value must be between 5 ar of a phone of the first 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).

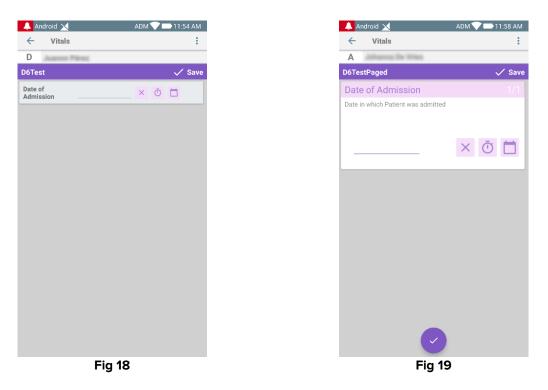
👃 Android 🔀	ADM 💎 🖿 1:35 PM
← Vitals	:
A1 Johanna De Wies	
Vital Parameters	🗸 Save
Data acquired: Apr 18	
Respiratory Rat 20.37 bp	m × C
Data acquired: Jun 15	
(*) Oxygen Saturation 98 %	×C
Systolic BP mr	nHg
C*	
(*) Heart Rate bp	n

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:



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

- > Touch the  $\bigcirc$  icon to insert the current date;
- > Touch the  $\square$  icon to insert a specific date;
- $\succ$  Touch the  $\stackrel{\scriptstyle{\scriptstyle{\times}}}{\scriptstyle{\scriptstyle{\times}}}$  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.

🐥 Android 🔀	ADM 💙 🖿 11:51 AM
← Vitals	:
D Juanne Pérez	
DT6	🗸 Save
Planned Intervention Date	×õ 🗖
Fig	20
Fig	20

- > Touch the  $\bigcirc$  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);

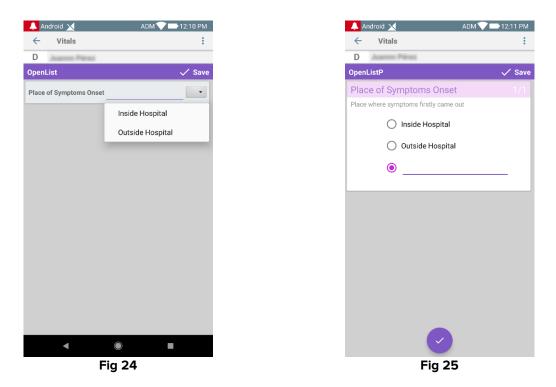


 $\succ$  Touch the  $\stackrel{\scriptstyle{\scriptstyle{\times}}}{\scriptstyle{\scriptstyle{\times}}}$  icon to cancel the inserted value.

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:



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:

👃 Android 🔀	ADM 💎 🖿 10:44 AM
← Vitals	:
A1 Johanna De Vries	
National Early Warning Score 2	Save
10-20	
(*) Breaths per Minut 17	bpm
> 95 %	
(*) Oxygen Saturatio 98	%
(*) Ventilation (2)	/entilation 👻
51 - 90 bpm	
(*) Heartbea	bpm
(*) Consciousness (3)	/erbal 👻
35.1 - 36.0 °C	
(*) Temperatur 36	°C
Score 6	C
Fig 2	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

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  $\bigcirc$  button:

🔔 Android 🗙	ADM 💙 🖿 12:12 PM	👃 Android 🔀	ADM 💎 🖿 12:12 PM	👃 Android 🗙	ADM 💎 📑 12:12 PM		
← Vitals	:	← Vitals	:	← Vitals	:		
D Juannn Pérez		D Juannn Pérez		D Juannn Pérez			
National Early Warning Score 2	🗸 Save	National Early Warning Score 2	🗸 Save	National Early Warning Score 2	🗸 Save		
(*) Breaths per Minute		(*) Oxygen Saturation		(*) Ventilation			
Breaths per Minute		Oxygen Saturation		Ventilation			
10-20		> 95 %		0 O Air			
16 bpm		98%		2      Ventilation			
	→	←	→	Example 1	$\rightarrow$		
• • • • • • • •							
Android 🗙	ADM 💎 📑 12:12 PM	Android X Vitals	ADM 💎 🖿 12:12 PM	Vitals	ADM 💎 🖿 12:12 PM	Android 🗙	ADM 💎 🖿 12:12 PM
D Juannn Pérez	•	D Juannn Pérez	•	D Juannn Pérez	•	D Juannn Pérez	•
National Early Warning Score 2	/ Save	National Early Warning Score 2	/ Save	National Early Warning Score 2	Save	National Early Warning Score 2	🗸 Save
	V 0470		V 0470	(	V 04VC		
(*) Heartbeat Heartbeat		(*) Consciousness Consciousness	5/7	(*) Temperature Temperature		Score	117
51 - 90 bpm				36.1 - 38.0 °C		-	
66 bpm		0 O Alert		37 °C		5	
<u> </u>		3 O Verbal		<u> </u>			
		3 💿 Pain					
		3 O Unresponsive					
¢	•	R	Ą	¢	<b>A</b>		
¢	€	¢	<b>→</b> Fig	¢	⇒	€ ⊘	

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):

	🐥 Android 🗙 🛛 ADM 💎	10:44 AM
	← Vitals	:
	A1 Johanna De Vries	
	National Early Warning Score 2	🗸 Save
B	Data acquired June 30 (*) Breaths per Minut	C
	> 95 % Data acquired: June 30 (*) Oxygen Saturatio 98 % X C	
	(*) Ventilation (2) Ventilation	-
	51 - 90 bpm Data acquired: June 30 (*) Heartbea	C
	(*) Consciousness (3) Verbal	• ·
	35.1 - 36.0 °C Data acquired June 30 (*) Temperatur 36 °C × (	1
	Score 6	G
	Fig 28	ידע דיין אין איין איין איין איין איין איין

> 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  $\times$  button (Fig 28 C) to delete the inserted value;
- > Touch the C 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:

🔔 Android 🔀	ADM 💎 📑 12:12 PM	👃 Android 🔀	ADM 💎 🖿 12:12 PM	🐥 Android 🔀	ADM 💎 📑 12:12 PM		
← Vitals	:	← Vitals	:	← Vitals	:		
D Juannn Pérez		D Juannn Pérez		D Juannn Pérez			
National Early Warning Score 2	🗸 Save	National Early Warning Score 2	🗸 Save	National Early Warning Score 2	🗸 Save		
(*) Breaths per Minute		(*) Oxygen Saturation		(*) Ventilation			
Breaths per Minute Data acquired June 30		Oxygen Saturation Late bogured June 30		Ventilation			
10-20		> 95 %		() 🔿 Air			
16 bpm		98 %		2      ventilation			
	→	÷	→	÷	→		
Android 🗙	ADM 💙 🚍 12:12 PM	Android 🗙	ADM 💙 🖿 12:12 PM	Android 🗙	ADM 💎 📑 12:12 PM	🔺 Android 🗙	ADM 💎 🖿 12:12 PM
← Vitals	:	← Vitals	1	← Vitals	1	← Vitals	1
D Juannn Pérez		D Juannn Pérez		D Juannn Pérez		D Juannn Pérez	
National Early Warning Score 2	🗸 Save	National Early Warning Score 2	🗸 Save	National Early Warning Score 2	🗸 Save	National Early Warning Score 2	🗸 Save
(*) Heartbeat	4/7	(*) Consciousness	5/7	(*) Temperature	6/7	Score	7/7
Heartbeat		Consciousness		Temperature Data soqured: June 20			
Data acculied: June 90 51 - 90 bpm		0 0 41-1		Cats sequred June 30 36.1 - 38.0 °C		5	
66 bpm		0 O Alert		37 °C		5	
		3 O Verbal					
		3 💿 Pain					
		3 O Unresponsive					
C	•	G	•	6	6		
¢	€	¢	⇒	¢ 29	<b>&gt;</b>	€ 🗸	

## **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.

🔔 Android 🔀		A	DM 💙 🗖	2:01 PM
<ul><li>Vitals</li><li>A1 TestSing</li></ul>	le		~	
/ital Parameters				+ Add
Time		9:13 AM 4/1/19	5:29 PM 6/6/19	1:26 PM
Respiratory Rate	bpm	15	23	21
Oxygen Saturation (SPO2)	%	86	82	88
Systolic BP	mmHg	121	121	121
Temperature	C°	38	37	37
Heart Rate	bpm	90	72	58
		30	/	1

- > 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  $\mathbf{B}$ ).

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

A1 TestSingle		
National Early Wa Time	rning Score 2	+ Add
Breaths per Minute	0	
Oxygen Saturation	0	
Ventilation	2	
Heartbeat	0	
Consciousness	3	
Temperature	1	
Score	6	

	Warnin	g Score 2	+
Time		10:44 AM	
Breaths per Minute	bpm	17	
Oxygen Saturation	%	98	
Ventilation		2	
Heartbeat	bpm	66	
Consciousness		3	
Temperature	°C	36	
Score		6	
		1	

### 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),



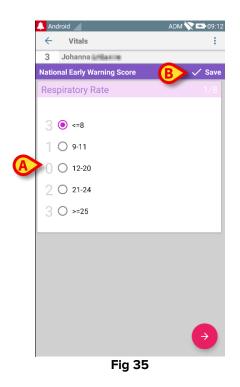
Fig 33

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

	+ Add
13:23 25-08	07:08
0	3
0	2
0	0
0	0
1	2
0	1
0	0
1	8

> Touch the "pen" icon corresponding to the set to be edited (Fig 34 A)

The data entry screen will open (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

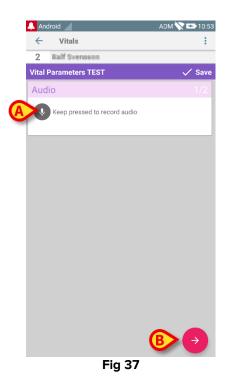
The Vitals Mobile module makes it possible to acquire audio recordings and pictures. This functionality can be configured both as a specific, independent dataset, and as a part of an existing "textual" dataset. In the latter case the functionality makes it possible to add an audio/visual commentary to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



The following screen will open, making it possible to record an audio file (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  $\bf{A}$  represents the recorded file.



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



> Touch the icon to listen to the audio file.

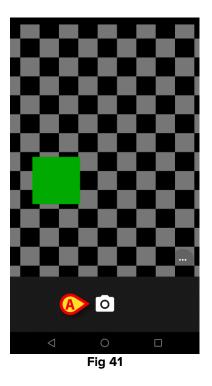
For pictures acquisition, go to the following screen, i.e.

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

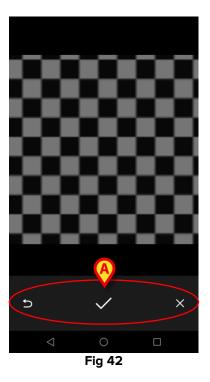
The following screen will open (Fig 40)

	🔔 An	droid				ADM 🚫 🗖	11:36
		V	itals				:
	2	$\mathbb{P}_{\mathbb{P}}$	Press.	1			
	Vital	Parar	neters TE	st		~	′ Save
	Ima	ige					
A	0	Clic	k to take a p	bicture			
		•		~			
				Fig 4	40		

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



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

Image	2/2
Click to take a picture	
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),

🔔 Android 🔟	ADM 🚫 🖙 08:09
← Vitals	:
2 12/12/12/12	
Vital Parameters TEST	🗸 Save
Image	2/2
Click to take a picture	
A	
← <	
Fig 44	
•	

Click the clicon (Fig 44 A).

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

💄 Android 🖌			ADM 🔪	08:1
← Vitals				
2 Born	Agi <b>Iale</b> , ID <b>2000000</b>	e	A	
Vital Parameter	rs TEST		V	+ Add
Time	23	08:21 13-09	10:42 02-10	08:14
Audio				
Image		_		_
			$\sim$	
			/	/
	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 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.

Silence	Systolic	mmHg	MAP/Cuff	Inflate/Stop
Narms	Diastolic 5	mmHg	imi	n Cyc/e
Menu	Pulse R	B ppm	BATTERY OK	Print On/Ott
CARESCAPE™	* 88		TE	V100 DINAMAP technology®

Fig 46 - General Electric V100 monitor

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

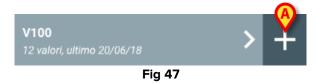
#### **1.5.1** Installation

Digistat OCR component is distributed as a standalone apk running on devices ranging from Android<sup>™</sup> 8 (API 26) to Android<sup>™</sup> 11 (API 30). After installation <u>no application icon will be</u> **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<sup>™</sup> 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).



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

👃 I TI			ADM 12:1
←	Vitals		
Α	Johanna De Vi	ries	$\smile$
V100			🗸 Sav
	Systolic		mmHg
	Diastolic		mm Hg
	MAP/cuff		mmHg
	Pulse Rate		bpm.
	SP02		%
	Temperature		°F
	_		
	F	ig 48	

 $\succ$  Touch the  $\Box$  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.

1



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):

🔔 I TI	м		ADM	▼∎ 12:16
←	Vitals	◙	**	
Α	Johanna De Vi	ies		$(\mathbf{c})$
V100				🗸 Save
	Systolic	120	mmHg	
	Diastolic	57	mm Hg	
	MAP/cuff	82	mmHg	
	Pulse Rate	68	bpm	
	SP02	<b>⁰</b>	%	A
	Temperature		°F	
	Value	is not accu	rate	
	F	ig 49		

If one of the values is not read or correctly recognized, the  $\triangle$  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  $\triangle$  icon) user confirmation is required (Fig 50):

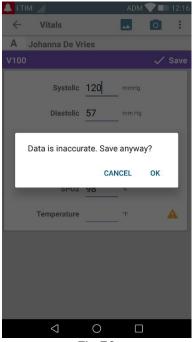


Fig 50

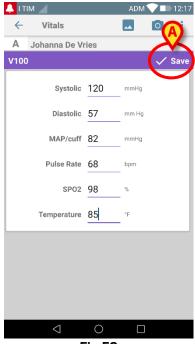
> Press **OK** to save anyway or **CANCEL** to manually insert the missing value.

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):

÷	Vitals			0
A Jo	ohanna De V	/ries		
V100				🗸 Save
	Systolic	120	mmHg	
	Diastolic	57	mm Hg	
	MAP/cuff	82	mmHg	
	Pulse Rate	68	bpm	
	SP02	98	%	
	Temperature		°F	▲
*	1	2	3	-
+	4	5	6	•
#	7	8	9	$\propto$
R	ABC	0		Fine
	$\bigtriangledown$	0		
		Fig 51		

When all fields are filled (Fig 52):



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

A summary screen is displayed (Fig 53):

12:44         14:50         12:17           Systolic         mmH         11         56         120           Diastolic         mmH          46         57           MAP/cuff         g          46         57           Pulse Rate         bpm           82           Pulse Rate         bpm           68           SPO2         %           98           Temperature         "F           1           Temperature         "C           1           Notes         (voi ce           85	12:44         14:50 2018-06-14         12:17           Systolic         g <sup>mmH</sup> 11         56         120           Diastolic         m <sup>mm</sup> 46         57           MAP/cuff         g <sup>mmH</sup> 82           Pulse Rate         bpm           88           SPO2         %           98           Temperature         "F           1           Temperature         "C           85           Notes         ce           85		(voi ce (cam			
12:44         14:50         12:17           Systolic         mmH         11         56         120           Diastolic         mmH          46         57           MAP/cuff         mmH          46         57           MAP/cuff         mmH           82           Pulse Rate         bpm           68           SPO2         %           98           Temperature         "F           1           Temperature         "C           85	M         Iiao 1967-03-18           V100         +         Add           Time         12:44         14:50         12:17           Systolic         gmH         11         56         120           Diastolic         Hg          46         57           MAP/cuff         gmH          46         57           Pulse Rate         bpm           68           SPO2         %           98           Temperature         "F           11           Temperature         "C           12		(voi			
12:44         14:50         12:17           Systolic         g         11         56         120           Diastolic         mm         11         56         57           MAP/cuff         g          46         57           Pulse Rate         bpm           82           SP02         %           98           Temperature         "F           82	M         12:44         14:50         12:17           Time         12:44         14:50         12:17           Systolic         mmH         11         56         120           Diastolic         mmH          46         57           MAP/cuff         mmH           82           Pulse Rate         bpm           68           SPO2         %           82           CapturedImage           85	Temperature	°C			85
Time     12:44     14:50     12:17       Systolic     g     11     56     120       Diastolic     Hg      46     57       MAP/cuff     g      82       Pulse Rate     bpm       68       SP02     %       98       Temperature     "F       85	M         Iiao 1967-03-18           V100         +         Add           Time         12:44         14:50         12:17           Systolic         gmH         11         56         120           Diastolic         Hg          46         57           MAP/cuff         gmH           68           SPO2         %           98           Temperature         "F           85					
12:44         14:50         12:17           Systolic         g         11         56         120           Diastolic         mm          46         57           MAP/cuff         g           82           Pulse Rate         bpm           68           SP02         %           98	Miao 1967-03-18           V100         + Add           Time         12:44         14:50         12:17           Systolic         g         11         56         120           Diastolic         Hg          46         57           MAP/cuff         gmH           82           Pulse Rate         bpm           68           SPO2         %           98	CapturedImage				1
12:44         14:50         12:17           2018-06-14         2018-06-14         12:17           Systolic         g         11         56         120           Diastolic         MMP          46         57           MAP/cuff         g          82           Pulse Rate         bpm           68	M         1360         1967-03-18           V100         + Add           Time         12:44         14:50           2018-06-14         2018-06-14         12:17           Systolic         g         11         56         120           Diastolic         Hg          46         57           MAP/cuff         g          82           Pulse Rate         bpm           68	Temperature	°F			85
Time         12:44 2018-06-14         14:50 2018-06-14         12:17           Systolic         mmH g         11         56         120           Diastolic         Hg g          46         57           MAP/cuff         mmH g           82	M         Iiao 1967-03-18           V100         +         Ado           Time         12:44         14:50           2018-06-14         12:17           Systolic         9         11         56         120           Diastolic         Hg          46         57           MAP/cuff         gH          82	SP02	%			98
Time         12:44         14:50         12:17           2018-06-14         2018-06-14         2018-06-14         12:17           Systolic         mmH         11         56         120           Diastolic         Hg          46         57           MAP/cuff         mmH          82	A Iiao 1967-03-18 V100 + Ado Time 12:44 14:50 2018-06-14 2018-06-14 Systolic 9 11 56 120 Diastolic mm - 46 57 MAP/cuff mm - 7 82	Pulse Rate	bpm			68
Time 12:44 14:50 12:17 2018-06-14 2018-06-14 Systolic mmH 11 56 120 Diactolic mm - 46 57	A iiao 1967-03-18 V100 + Ado Time 12:44 14:50 12:17 Systolic mmH 11 56 120 Diastolic mm - 46 57	MAP/cuff				82
Time 12:44 14:50 12:17 2018:06:14 2018:06:14 Systelic <sup>mmH</sup> 11 56 120	A iiao 1967-03-18 V100 + Ado Time 12:44 14:50 2018-06-14 2018-06-14 Systellic mmH 11 56 120	Diastolic			46	57
Time 12:44 14:50 12:17	A iiao 1967-03-18 V100 + Ado Time 12:44 14:50 12:17	Systolic		11	56	120
V100 + Ado	A iiao 1967-03-18	Time	20			12:17
		V100				+ Add

## 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.



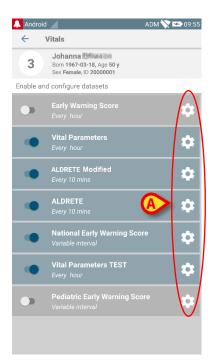
It is not possible to add or edit datasets for dismissed patients.

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

Touch the <sup>1</sup>/<sub>2</sub> icon (Fig 54 A).



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**).



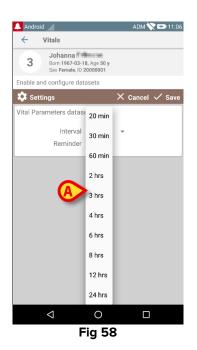
For each dataset the name and the current configuration settings are displayed.

> Touch the 2 icon to configure the dataset (Fig 56 **B**).

The following screen will open (Fig 57).



> Touch the "Interval" menu to decide the dataset timing (Fig 58).



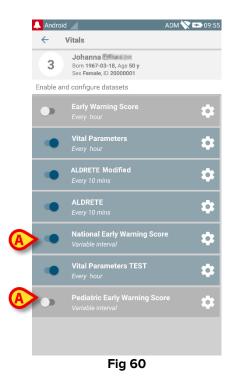
Select the "Reminder" checkbox to get automatic reminders on when the datasets acquisitions are due (Fig 59 **A**).



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**).



## 1.7 Widgets

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



## 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:

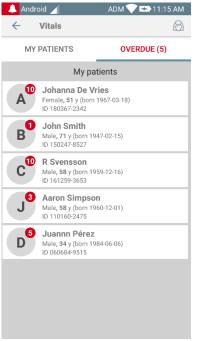
> Drag the icon shown in Fig 61 **A** and drop it on the device screen.

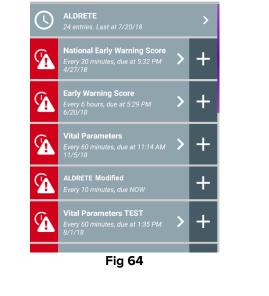
The Vitals Widget will be displayed on the device screen with the default size of 1 x 1 (Fig 62)



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

\$

Born 1967-03-18, Age 51 y Sex Female, ID 180367-2342

←

Α

Active Datasets

Vitals

Fig 63

## 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).





MY PATIENTS       OVERDUE (4         My patients       My patients         A <sup>®</sup> Female, 51 y (born 1967-03-18) (b)         B <sup>®</sup> Male, 71 y (born 1967-03-18) (b)         C <sup>®</sup> Male, 58 y (born 1967-03-18) (b)         D <sup>®</sup> Male, 59 y (born 1967-12-03) (b)         D <sup>®</sup> Male, 59 y (born 1967-12-03) (b)         D <sup>®</sup> Male, 59 y (born 1967-12-03) (b)         D       Male, 59 y (born 1966-12-01) (b)         D       Male, 57 y (b)         A       Male y (c)         Male y (c)       Fig. 4         Male y (c)       Fig. 4	And					0.
My patients         My patients         A <sup>3</sup> Female, 51 y (born 1967-03-18) II 180367/2342         B <sup>5</sup> Male, 51 y (born 1967-02-15) II 150247-8527         C <sup>6</sup> Male, 50 y (born 1964-06-05) II 000664-915         D <sup>5</sup> Male, 57 y (born 1964-06-05) II 000664-915         J       Male, 57 y (born 1960-12-01) II 101060-2475         J       Male, 57 y (born 1960-12-01) II 101100-2475         Vital Parameters       Fig. 4         Oxygen Saturation (SPO2)      %         Fig. 4       Android       Abdit 2         Vital Parameters       Fig. 4         Vital Parameters       Coron 1         C Vitals       Abdit 2       2         Vital Parameters       Coron 1       2         Vital Parameters       Coron 1       2         Mail (F)       Abdit 2       2         C Vitals       Apple       2         Mail (F)       Coron 1       2         Mail (F)       Abdit 2       2         Mail (F)       Apple       2         Mail (F)       Apple       2         Mail (F)       Apple       2         Mail (F)       Apple       2         Mail (F)       Apple <th><i></i></th> <th></th> <th>TS</th> <th>0</th> <th></th> <th>(4)</th>	<i></i>		TS	0		(4)
A <sup>®</sup> Female, 51 y (born 1967-03-18) ID 180567-2342         B <sup>®</sup> Male, 51 y (born 1967-02-15) ID 190247-6527         C <sup>®</sup> Male, 58 y (born 1967-12-16) ID 101259-3653         D <sup>®</sup> Male, 58 y (born 1969-12-16) ID 000684-9315         D <sup>®</sup> Male, 57 y (born 1960-12-01) ID 000684-9315         J       Male, 57 y (born 1960-12-01) ID 001267-8525         J       Male, 57 y (born 1960-12-01) ID 1011060-2475         Fig 2         Android       ADM N         ←       Vitals         3       Johanna         Visal Parameters         Oxygen Saturation (SPO2)		VITPATIEN			CRUUE	(4)
ID 18035-2242         B <sup>•</sup> Male, 57 y (born 1947-02-15)         D <sup>•</sup> Male, 58 y (born 1959-12-16)         D <sup>•</sup> Male, 50 y (born 1967-12-03)         D <sup>•</sup> Male, 57 y (born 1960-12-01)         D <sup>•</sup> D <sup>•</sup> Male, 57 y (born 1960-12-01)       D <sup>•</sup> D <sup>•</sup> D <sup>•</sup> Oxygen Saturation (SPO2)       P <sup>•</sup> P <sup>•</sup> Able       P <sup>•</sup> C <sup>•</sup> Fig 4         Android ▲       Able       P <sup>•</sup> A <sup>•</sup> Able       P <sup>•</sup> C <sup>•</sup> Trestinge       P <sup>•</sup> Vital Parameters       P <sup>•</sup> P <sup>•</sup> C <sup>•</sup> P <sup>•</sup> P <sup>•</sup> <td></td> <td></td> <td>ma De Vr</td> <td>ies.</td> <td></td> <td></td>			ma De Vr	ies.		
B       Male, 31 y (born 1947-02-15) in 150247-8527         C <sup>2</sup> Male, 58 y (born 1959-12-16) in 161259-3653         D <sup>3</sup> Male, 34 y (born 1984-05-06) in 0031267-8525         J       Male, 59 y (born 1967-12-03) in 0031267-8525         J       Male, 57 y (born 1960-12-01) in 10106-2475         Vital Parameters       Fig 4         Vital Parameters       Fig 4         Oxygen Saturation (SPO2)       *         *       *         *       *         Materia       Vital Parameters         Oxygen Saturation (SPO2)       *         *       *		ID 1803	67-2342	1907 00 10	,	
●       Male, 34 yrbrn 1984-06-06)         ●       Male, 55 yrborn 1967-12-03)         ●       Male, 57 yrborn 1967-12-03)         ●       J         Male, 57 yrborn 1960-12-01)       D10160-2475         ●       Fig 2         ▲ Android       ADM ▼         ✓       Vitals         3       Johanna ■         ✓       Vitals         3       Johanna ■         ✓       Vital Parameters         Oxygen Saturation (SPO2)         ▲       Addroid ▲	В	Male, 7 ID 1502	1 y (born 194	47-02-15)		
●       Male, 34 y born 1924-06-06) ID 0006649515         ●       Male, 50 y born 1967-12-03) ID 331257-8525         ●       Fig 2         ●       Fig 2         ●       Able, 57 y (born 1960-12-01) ID 110160-2475         ●       Fig 2         ●       Able, 57 y (born 1960-12-01) ID 110160-2475         ●       Fig 2         ●       Able, 57 y (born 1960-12-01)         ●       ID 10160-2475         ●       Yital Parameters         ●       Oxygen Saturation (SPO2)         ●       Fig 4         ●       Abdroid ●         ●       Fig 4         ●       Able ●         ●       Yital Parameters         ●       Yital Parameters         ●       11 Terestinge         Vital Parameters       011 Able ●         ●       12 Able ● <td< td=""><td>С</td><td>2 Male, 5</td><td>8 y (born 19</td><td>59-12-16)</td><td></td><td></td></td<>	С	2 Male, 5	8 y (born 19	59-12-16)		
I       Male, 50 y (born 1967-12-03) ID 031267-8525         J       Male, 57 y (born 1960-12-01) ID 10160-2475         Fig 2       Android         < Vitals						
Mele, 50 y Ocorn 1967-12.03) D 031267-8525         J       Mele, 57 y Ocorn 1960-12.01) ID 10160-2475         Fig 2         Android       ADM ▼         ✓ Vitals       3         3       Johanna ■         Vital Parameters       Image: Specific Stress         Øxygen Saturation (SPO2)       Image: Specific Stress         Fig 4       Android ▲       ADM ▼ 2         ✓ Vitals       ADM ▼ 2         ✓ Yatals       A	D	Male, 3 ID 0606	4 y (born 198 84-9515	34-06-06)		
Fig 2         Android       ADM ▼         ← Vitals       3         3       Johanna         7/tal Parameters       ●         0xygen Saturation (SPO2)       ●         ●       Fig 4         Android ▲       ADM ▼         ●       ●         ●       Fig 4         ●       Android ▲         ●       ● </td <td></td> <td>Male, 5</td> <td>0 y (born 19)</td> <td>57-12-03)</td> <td></td> <td></td>		Male, 5	0 y (born 19)	57-12-03)		
Fig 2 Android ADM Constraints Vital Parameters Oxygen Saturation (SPO2) Fig 4 Android Android ADM 2 Fig 4 Vitals Android Android ADM 2 Fig 4 Android Android ADM 2 Fig 2 ADM 2 Fig 2 ADM 2 Fig 4 Android Android ADM 2 Fig 2 ADM 2 Fig 4 Android Android Android ADM 2 Fig 4 Android Android Android ADM 2 Fig 2 Android Android Android ADM 2 Android Android Androi	J	Male, 5	7 y (born 19)			
Android         ADM         2           Vitals         ADM         2           Vitals         ADM         2           Vitals         ADM         2           Vitals         ADM         2           VitalParameters         Course         Course         Course           Respiratory Rate         Lpm         15         23           Orygen Saturation         %         86         82         Systolic BP         mmitg         121         121           Temperature         C*         38         37	3 Vital Pa	Johanna 🗈 arameters en Satura		202)	F	~
Android         ADM         2           Vitals         ADM         2           Vitals         Course         Course         Course           Time         9/13 AU         Course						
Vitals           Vital Parameters           Time         9:13 AM (7/1/9)           Respiratory Rate         bpm           15         23           Drygen Saturation (SPO2)         86           Systolic BP         mmilig         121           Temperature         C*         38         37						8
A1         TestSingle           Vital Parameters              • • • • • • • • • • • • •			Fig	g 4		8
Time         9:13 AM 4/17/19         0:0019 5         11           Respiratory Rate         bpm         15         23           Ovygen Saturation (SPA02)         %         86         82           Systolic BP         mm/tg         121         121           Temperature         C*         38         37		Vitals		A	DM	2201
Arr/19         CHPP19           Respiratory Rate         bpm         15         23           Oxygen Saturation (SPO2)         %         86         82           Systolic BP         mmHg         121         121           Temperature         C*         38         37	< A	Vitals TestSing		A	м	2:01
(SP02)         3         30         32           Systolic BP         mmHg         121         121           Temperature         C'         38         37	← A' Vital P	Vitals TestSing		AI	H	2:01
Systolic BP         mmHg         121         121           Temperature         C*         38         37	← A' Vital P Time	Vitals TestSing Parameters	gle	9:13 AM 4/1/19	H.	+
	← A <sup>•</sup> Vital F Time Respir Oxygei	Vitals TestSing Varameters atory Rate n Saturation	gle bpm	9:13 AM 4/1/19 15	6/6/19 23	+ 1:26 21
Heart Rate bpm 90 72	← A <sup>•</sup> Vital F Time Respir Oxyger (SPO2	Vitals TestSing Carameters atory Rate n Saturation	gle bpm %	9:13 AM 4/1/19 15 86 121	6/6/19 23 82 121	+ 1:26
	← Vital P Time Respir Oxyget (SPO2 Systoli	Vitals TestSing Parameters atory Rate n Saturation c BP	yle bpm % mmHg	9:13 AM 4/1/19 15 86 121	6/6/19 23 82 121	+ 1:2 : 1
	← Vital F Time Respir Oxygei (SPO2 Systoli Tempe	Vitals TestSing Parameters atory Rate n Saturation ic BP rrature	ppm bpm % mmHg C*	9:13 AM 4/1/19 15 86 121 38	676/19 23 82 121 37	+ 1:2 : 1 1 : 1 : 1 : : : : : : : : : : :
· *	← Vital F Time Respir Oxygei (SPO2 Systoli Tempe	Vitals TestSing Parameters atory Rate n Saturation ic BP rrature	ppm bpm % mmHg C*	A( 9.113.AM 4/1/19 15 86 121 38 90	676/19 23 82 121 37	+ 1:20 2 8