



Gateway User Manual

Version 8.0

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1. Ascom Gateway App



The present document must only be shared with either healthcare professionals or Ascom-authorized technicians. The document contains restricted information (for example technical credentials) that are not to be used by patients.

There are specific sections that are destined to patients. These sections should be extracted from this document and provided to patients separately.



For information about the Product environment, precautions, warnings and intended use see USR ENG Digistat Care (for the Digistat Suite EU) or USR ENG Digistat Suite NA (for Digistat Suite NA). The knowledge and understanding of the appropriate document are mandatory for a correct and safe use of the Gateway App, described in this document.

Ascom Gateway App is a standard android app that runs on selected android devices with the purpose of collecting data from a set of Bluetooth wearable devices and dispatches data to Digistat Connect.

Ascom Gateway App supports a set of wearable devices (see list in paragraph 2.2). New devices are constantly added. The supported parameters depend on the number and type of connected wearables.

Ascom Gateway App is part of the Digistat Care product in the EU (one of the two products forming the Digistat Suite for EU, the other one being Digistat Docs) and is part of the Digistat Connect product in the USA and Canada (one of the two products of the Digistat Suite NA, the other one being Digistat Smart Central). Ascom Gateway app expands the functionalities of the connectivity that are part of the Digistat Suite in order to support wearable devices and new workflows like home surveillance.

Ascom Gateway App is intended to be used only to “move” collected parameters from a location (the wearable device) to the server components without any modification to parameters.



Only the patient is allowed to use the associated kit (wearable devices + mobile device + Digistat Gateway app). No family member or relative is allowed to use the kit.

1.1 Installation and configuration

Ascom Gateway can be installed either using a Mobile Device Manager solution (MDM) or manually uploading the .apk file on the target device. At first execution the user will be prompted to grant some permissions; all permissions shall be granted to permit the application to work correctly. It is possible to install the app using a “provisioning” mode. Using “provisioning” the app will be executed in “kiosk-mode” meaning that the user cannot interact with the OS, but only with the app. For more information about MDM and kiosk mode, see section 2.3.

In order to configure the app an administrator password is required. The password is provided in an external document attached to this manual. The administrator password must be kept confidential.

When the application is executed the following view is displayed:

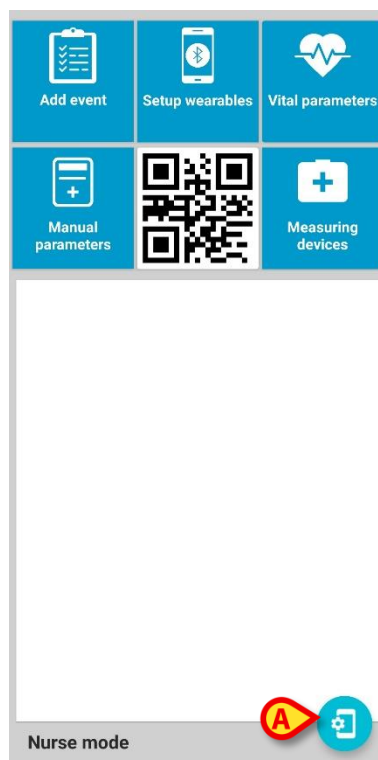


Fig 1 – Main View

- Press the “Settings” button (Fig 1 A) to open the settings page (Fig 2) and configure the application.

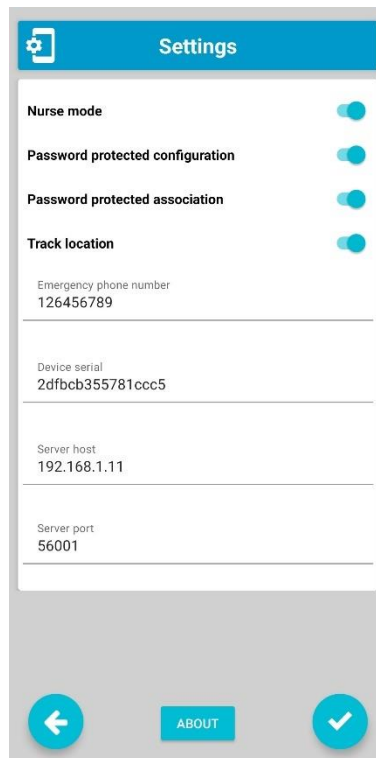


Fig 2

The following settings can be configured:

- **Nurse Mode:** switch between "Nurse mode" and "Patient mode". When in "Patient mode", some functionalities are not available.
- **Password protected configuration:** if enabled, a system password is required to open the settings page. Set to "enabled" when the device is used by patients.
- **Password protected association:** if enabled, a system password is required to pair wearables to the current gateway app.
- **Track location:** if enabled, this functionality tracks the user position. Please be aware of privacy issues. The organization must be entitled to collect this kind of information.
- **Emergency phone number:** when in "Patient mode", patients can click a specific button to call a configured phone number (for instance, the direct phone number of the department).
- **Device Serial:** the serial number of the device. It is suggested to assign names that make the device identification easier (ex: ICU-123). Use a unique identifier.



When running on Android 10, a random device serial number is used.

- **Server Host and Port:** hostname (or ip address) and port where the gateway shall be connected. If the gateway is intended to be used on a 4G connection, IT network shall be configured properly in order for the gateway to be able to reach the host where Digistat Connect is installed.

1.2 Main View

The “Main View” of the application changes according to the configured modality (either nurse or patient mode), as shown in Fig 3 and Fig 4.

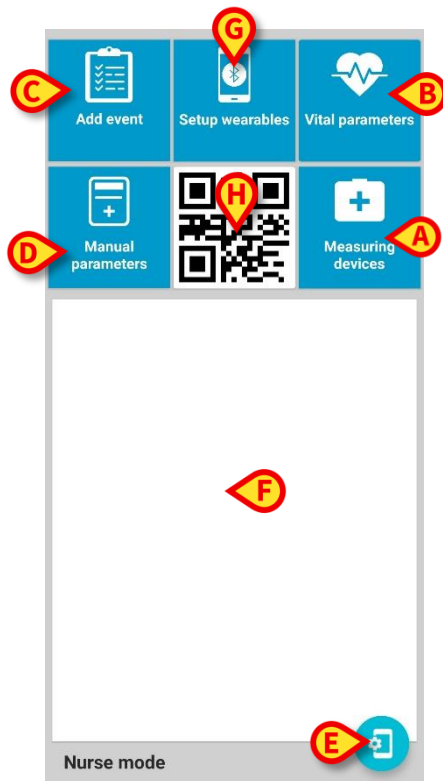


Fig 3

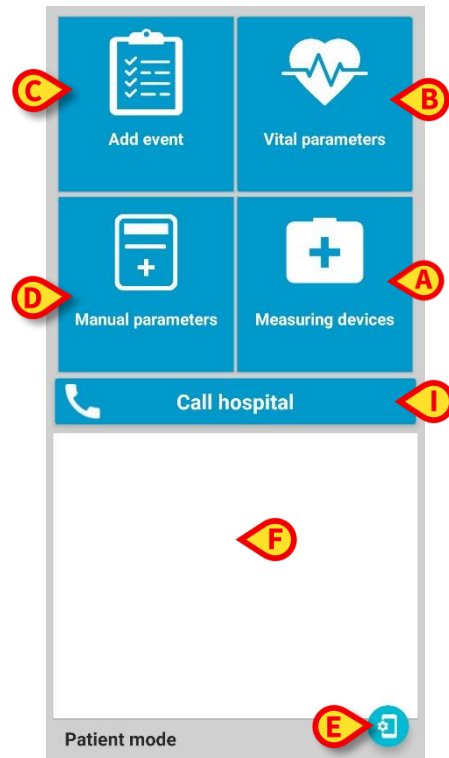


Fig 4

Nurse mode is intended to be used inside the hospital by nurses. Nurse mode supports additional functionalities as Setup Wearables (to pair Bluetooth wearables with the Gateway app) and the serial barcode on the front page, to be used for patient-app association.

Patient mode is intended to be used by patients, outside the hospital environment. Patients cannot pair/unpair wearables. Patient mode supports a “Call Hospital” button making it possible to call a configured phone number.

List of possible Actions (refer to Fig 3 and Fig 4):

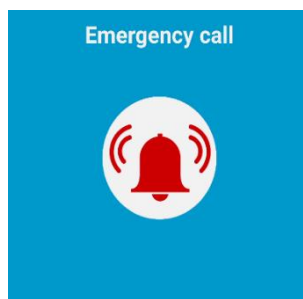
- A. Measuring devices.** Touch this button to open a dialog window and choose among the available wearable devices (if associated):



Fig 5

- Start to **measure SpO2** (if the appropriate wearable device is paired to the current phone). If a paired wearable retrieves SpO2 continuously, this button is disabled (no user action is required).
- Start to **measure Pressure** (if the appropriate wearable is paired to the current phone).
- Start to **measure spirometry** (if the appropriate wearable is paired to the current phone).
- Start to **measure weight** (if the appropriate wearable is paired to the current phone).
- Start to measure **glycemia** (if the appropriate wearable is paired to the current phone).
- Start to measure **Temperature** (if the appropriate wearable is paired to the current phone).
- Start to measure **ECG** (if the appropriate wearable is paired to the current phone).
- B. Verify the collection of data from paired wearables (Vital parameters).**
- C. Add an event.** Touch this button to add an Event to the patient history. See section 1.5 for more information.
- D. Add a manual parameter.** Touch this button to manually add a vital parameter to the patient history. See section 1.6 for more information.
- E. Open settings page.**
- F. Notification Area.** In this area the active notifications are listed (as, for example: "low battery", "disconnected from server", etc.)
- G. Pair/unpair wearables.** This button is displayed only in "Nurse Mode".
- H. Barcode** containing the gateway serial number. This button is displayed only in "Nurse Mode".
- I. Call the configured phone number.** The "Call Hospital" button is displayed only when in "Patient mode". The patients can call (only) the configured emergency telephone number.

When receiving a phone call, if the incoming phone number corresponds to the configured emergency telephone number a red bell is displayed. In all other cases a generic avatar is displayed.



This is true only if the Digistat Dialer app is set as the default phone app of the device.

The appearance of the buttons "**Measuring Devices**" and "**Manual Parameters**" (Fig 3 / Fig 4 **A** and **D**) can dynamically adapt, according to the wearables associated and to the configured events / manual parameters.

Example 1: only the "Add Event" button is configured; only two types of wearables are associated (Pressure and SpO₂). In this case, the "Manual Parameters" button is not displayed. The Pressure and SpO₂ measurement options are both displayed.



Example 2: only the "Add Event" button is configured; only one type of wearable is associated (Spirometry). In this case, the "Manual Parameters" button is displayed as disabled (grey).



1.3 Pair / Unpair Wearables

To pair/unpair wearables to the gateway:

- Tap "Setup wearables" (Fig 3 F). The following view is displayed (Fig 6).

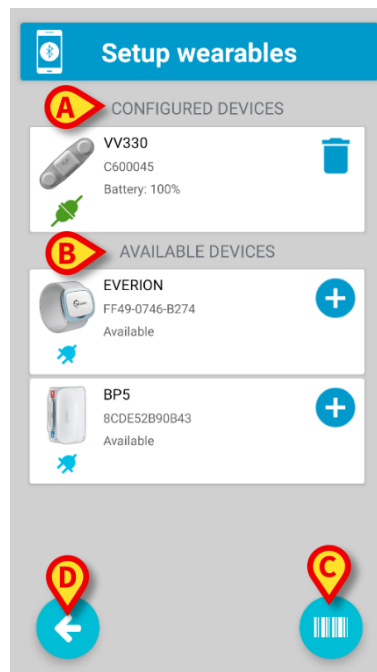


Fig 6

On the "Setup wearables" view (Fig 6) there are two areas:

- A. CONFIGURED DEVICES:** list of all paired devices. If a green plug icon is displayed, the wearable is currently connected, otherwise a grey disconnected plug icon is displayed.
 - Tap the **Trash** icon  to unpair the wearable. The unpaired wearables will be displayed in the AVAILABLE DEVICES section.
- B. AVAILABLE DEVICES:** list of all available devices. This list includes only devices that are turned on. If a wearable is not displayed, verify that wearable is turned on.

To pair a device:

- Tap on the **Plus** icon  placed alongside the device to be paired.



It can be difficult to distinguish between two devices of the same type. For correct pairing, either use the barcode feature (described below) or double-check the device serial number, comparing the serial number displayed on the app with the serial number printed on the wearable. If the serial displayed on the app is not printed on the wearable, it is necessary to turn on wearables one by one.

It is possible to pair a device using the barcode functionality. To do that:

- Tap the **Scan** button (Fig 6 C) to scan the barcode printed on the wearable device.

The device will be paired automatically. In this case, it is not necessary for the device to be turned on.

Barcodes printed on wearables need to be in a specific format and must be generated with a dedicated tool: "Ascom Wearable Barcode Generator", part of the Digistat Configurator. With the "Barcode Generator" it is possible to generate barcodes for every supported wearable with the purpose to print a label that can then be attached to the wearable itself. Note that this procedure can speed up the pairing process and reduce the risk of wrong association.



On Myco 3 devices, being the device provided with a "Scan" physical button, the button shown in Fig 6 C is not present.

After pairing, the Setup wearables screen changes as shown in Fig 7 (in the example displayed the Everion device passed from the "Available devices" area to the "Configured devices area").

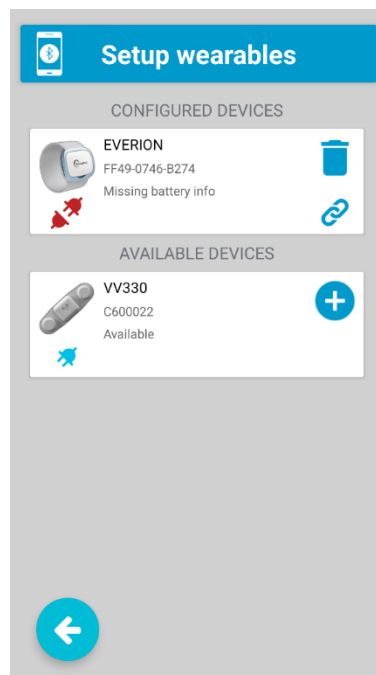


Fig 7

The link icon  (if present) represents the pairing status of the wearable device.



If the smartphone cannot connect to the wearable and still the link icon is displayed, then it is probably paired with another smartphone. For some wearables, explicit disassociation is required before pairing again to another smartphone. For detailed instructions, please refer to the specific wearable device manual.

A device performing continuous data acquisition, if not "sensed" by the smartphone, is displayed as follows on the message area (both Nurse and Patient mode):

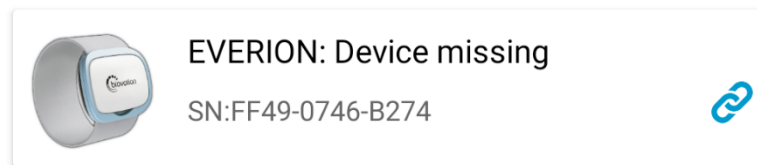


Fig 8

This message is displayed in the following cases:

- The wearable device is turned off.
- The battery of the wearable device is finished and the wearable device is off.
- The wearable device is not close enough to the smartphone and is therefore unable to communicate with it. This is likely with patients at home.



It is impossible to associate two devices of the same type at the same time in the Gateway app (i.e. two SpO₂ measurement devices, two Pressure measurement devices, etc.). To associate a new device of the same type it is necessary to first remove the old one.

Back button (Fig 6 D).

- Tap the **Back** button  (Fig 6 D) to go back to the main view (Fig 3).

1.4 Check collection of vital parameters

For the paired wearables it is possible to display, any moment, the collected parameters.

To do that:

- Tap **Vital parameters** (Fig 3 C) on the main view. The following view is displayed (Nurse mode: Fig 9 – Patient mode: Fig 10).

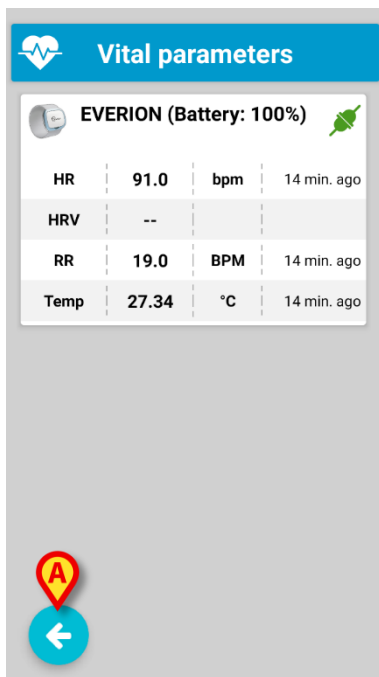


Fig 9

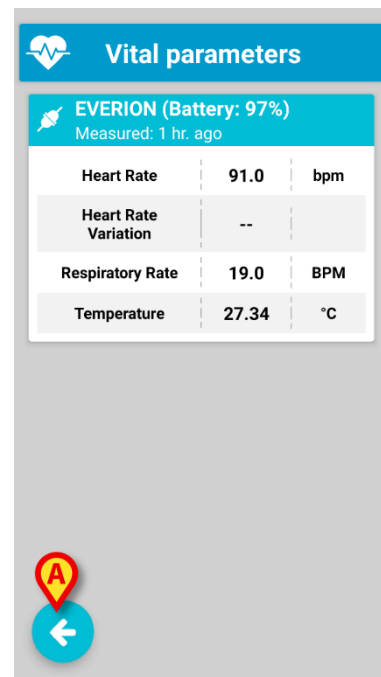


Fig 10

This view displays the wearables associated to current gateway device and, for each of them, the list of collected parameters. For each parameter the following information is provided:

- Name: name of the collected parameter (ex. HR, SpO₂, etc.);
- Value: latest collected value;
- Unit of measure;
- Refresh time (ex. 1 min ago): time of the latest collection.

If the value of the parameter is “—”, it means that the parameter has never been collected since the smartphone is on.

Nurse view differs slightly from Patient view (which is simpler).

- Tap the **Back** button  to go back to the main view (Fig 3).



When in Nurse mode, if a device supports ECG data, a button is displayed to open the ECG near-realtime view.

1.5 Add Event

- Tap **Add Event** (Fig 3 C or Fig 4 C) to insert a manual Event (Fig 11 is displayed).

An **Event** is an information which is relevant for clinical/diagnostic/administrative purposes. Some standard examples: "sleep start", "sleep end", "start walking", "eating", etc. An event can be inserted either as free text (via the android screen keyboard) or as a multiple choice item on a pre-configured list (pre-configured lists are compiled during configuration).

The following view allows to add a manual event (Fig 11).

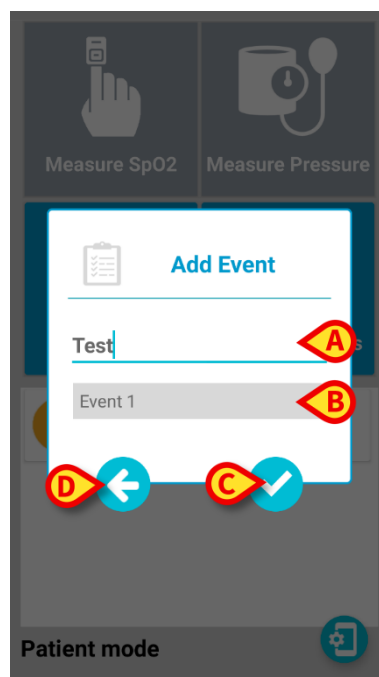


Fig 11

It is here possible to either enter a free text (Fig 11 A) or select an item on a list (Fig 11 B).

- Tap the **Confirm** button (Fig 11 C) to confirm and save the event.

A system-feedback is provided.

- Tap the **Left Arrow** button (Fig 11 D) to quit.



See section 3.4 for the events list configuration.

1.6 Add manual parameters

- Tap **Manual Parameters** (Fig 3 D or Fig 4 D) to insert manual parameters.

Fig 12 is displayed.

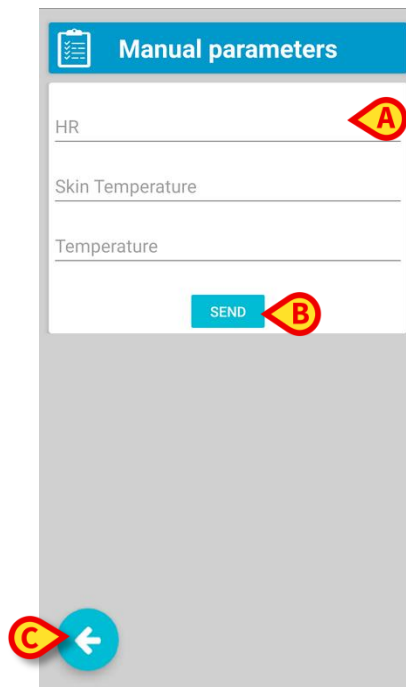


Fig 12

The list of available parameters changes according to the configuration (in the example: HR, Skin Temperature and Temperature). For data entry, tap any field to display the standard Android keyboard. All fields must be filled (Fig 12 A).

When done,

- Tap **Send** (Fig 12 B).

A system-feedback is provided.

Use the **Back** button (Fig 12 C) to quit.



See section 3.4 for the Manual Parameters configuration.

1.7 Measure SpO₂, Pressure, Spirometry, Weight, Glycemia, Temperature, ECG

To measure SpO₂, Pressure, Spirometry or Glycemia:

Measure SpO₂

- Tap **Measure SpO₂** (refer to Fig 3 and Fig 4 and Fig 5).
- Prepare the physical device and follow the instructions provided on screen.

The measurement process takes a few seconds.

Measure Pressure

- Tap **Measure Pressure** (refer to Fig 3 or Fig 4 and Fig 5).
- Prepare the physical device and follow the instructions provided on screen.

The measurement process takes 30-40 seconds.

Measure Spirometry

- Tap **Measure Spirometry** (refer to Fig 3 or Fig 4 and Fig 5).
- Prepare the physical device and follow the instructions provided on screen.

The measurement process takes 20-30 seconds.

Measure Weight

- Tap **Weigh** (refer to Fig 3 or Fig 4 and Fig 5).
- Prepare the physical device and follow the instructions provided on screen.

Measure Glycemia

- Tap **Glycemia** (refer to Fig 3 or Fig 4 and Fig 5).
- Prepare the physical device and follow the instructions provided on screen.

Measure Temperature

- Tap **Temperature** (refer to Fig 3 or Fig 4 and Fig 5).
- Prepare the physical device and follow the instructions provided on screen.

Measure ECG

- Tap **ECG** (refer to Fig 3 or Fig 4 and Fig 5).
- Prepare the physical device and follow the instructions provided on screen.

For all measurements:

A system notification is provided when the measurement is completed.

- Tap the **Back** button -  - to return to the main view.

1.8 Notification Area

The notification area on the application "Main view" (Fig 3 **G**) is a dedicated area where information messages and warnings are displayed. Notifications and warnings notify the user of possible issues that could occur during the collection of vital parameters.

The following notifications can be displayed:

- **Bluetooth unavailable:** Bluetooth antenna is not working properly. It is not possible to connect to wearable devices.
 - *RESOLUTION: check the device Bluetooth setting. Bluetooth must be enabled on the device.*
- **Bootstrap not completed:** gateway is not able to complete the startup procedure.
 - *RESOLUTION: verify the driver configuration and the network status on both client and server sides.*
- **Device Status:** contains the status of the paired wearables. There is one message per wearable. The status message can have the following values: connecting, connected, disconnected, battery low. If connected, the battery status is displayed.
- **Dialer Not Set:** there is not a dialer configured. It is not possible to make phone calls.
 - *RESOLUTION: click on the notification and assign to the application the requested permissions;*
- **Gateway Low Battery:** smartphone battery is low.
 - *RESOLUTION: connect the smartphone to the charger;*
- **Missing Permission:** gateway app has not all necessary permissions.
 - *RESOLUTION: click on the notification and assign to the application the requested permissions;*
- **Network quality low:** there are some network delays.
 - *RESOLUTION: check the Wi-Fi or 4G signal; try to move the smartphone in a position with a better network coverage;*
- **Network unavailable:** no connection to the network (4G or Wi-Fi).

- *RESOLUTION: check if Wi-Fi or 4G antennas are active and network signal is present, verify that server IP address/hostname and port are correct.*
- **Reminder Message:** these messages are displayed at configured times just as information or to remind the user to start a measurement. See section 3.4 for more information.
 - If the Reminder Message is related to a measurement, touch it to directly open the corresponding view (section 1.7).

2. Annex A – Technical Information

2.1 Administrative Credentials



When a password is required, it is necessary to enter one of the following system passwords: 20044 or 091091. The first one is valid for all Digistat Mobile modules, the second one is specific for the Digistat Gateway application.



Do not share these passwords with patients. They are administrative credentials, strictly reserved to the specifically trained administrative/clinical staff.

2.2 Supported Devices

Ascom Gateway App supports the following devices and parameters:

- **Everion Biovotion** (MD version): HR, SpO₂, Skin Temp, RR, Battery Level
- **iHealth PO₃** (Pulse Oximeter): spot SpO₂, Battery Level
- **iHealth BP₅ and BP_{5s}** (Blood Pressure): spot Blood Pressure Systolic and Diastolic, Battery Level
- **iHealth BT₅₅₀BT** (Blood Pressure): spot Blood Pressure Systolic and Diastolic, Battery Level
- **Gemini BP** (Blood Pressure): spot Blood Pressure Systolic and Diastolic, HR, Skin Temp (only device version C8) and Battery Level
- **VivaLNK ECG Monitor Patch**: HR, RRI, ECG (as near real time waveform), Battery Level
- **VivaLNK Fever Scout Patch**: continuous Axillary Temp, Battery Level
- **VivaLNK CheckMe**: continuous SpO₂ and HR
- **Oxitone Oxitone 1000M**: continuous SpO₂, HR and RR
- **GIMA TempSitter**: continuous Axillary Temp, Battery Level
- **Vitalograph Model 4000** (Spirometer): Spot Peak expiratory flow, Spot Forced expiratory volume (0.75s, 1s, 10s), Spot Forced expiratory volume ratio (1s/10s), Spot Forced expiratory flow (25% - 75%)
- **Seca 813bt** (Scale): Weight
- **Cosinuss c-med**: Body Temp, Blood Oxygenation, HR
- **iHealt BG₅S**: Glycemia
- **GIMA Suresync Glucometer**: Glycemia
- **Linktop HCO₃**: Blood Pressure, Temperature, SpO₂, ECG

2.3 Compatibility with certified MDMs

Digistat Gateway is compatible with Android Enterprise™ certified MDMs (Mobile Device Manager) and supports the following operations:

- Restrictions setting;
- Feedback;

- Lock task mode.

The suggested use mode is COSU (Corporate Owned, Single Use).



*Sharing between personal and work profiles is **NOT** supported and might result in an incorrect behavior of the app.*



Digistat Gateway installation and updates can be managed from a certified MDM without the need to support any Android Enterprise™ features.

2.3.1 Restrictions and “Managed Mode”

Digistat Gateway exposes the following restrictions:

Restriction	Format	Note
<i>EmergencyNumber</i>	<i>String</i>	<i>The emergency number</i>
<i>Host</i>	<i>String</i>	<i>The gateway driver hostname/IP address</i>
<i>Port</i>	<i>Integer</i>	<i>The port number the gateway driver is listening to</i>
<i>TrackLocation</i>	<i>Boolean</i>	<i>Set true to enable GNSS location tracking</i>

As soon as the MDM sets a restriction, the application turns to “managed mode”:

- When in managed mode, the user will not be able to change any of the restrictions: they will be greyed out in the settings view.
- When in managed mode, the user will not be able to modify the serial number.

In order to switch back to non-managed mode, the MDM shall set empty restrictions PLUS the MDM shall set an empty bundle. In other words: there must be no key/value pair associated with the app. When disabling managed mode, the current configuration is not affected (i.e. the gateway driver host and port will not change). If necessary, the user will be able to enter the settings view and modify whatever is required.

The application applies restrictions as soon as it is notified by the system. Only modified restrictions will affect the behavior of the app, this includes host and port. In this case, the current connection will be closed and a new one will be established with the new host/port values.

2.3.2 Feedback

Digistat Gateway supports sending feedback to the EMM (Enterprise Mobility Management). If the certified EMM solution supports it, proper feedback messages about which restrictions have been updated are provided.

2.3.3 Lock task mode

Digistat Gateway fully supports lock task mode when in managed mode. In order to be able to run the app in this mode, the EMM/MDM must be able to grant access to lock task mode to the Digistat Gateway app (package com.ums.app.digistatgateway). This will result in the following:

- app is permanently in foreground,
- all data are removed from the notification area,

- impossibility to exit the application.

Digistat Gateway must be restarted to enter lock task mode. To exit this mode the user must enter the settings view. Here a new specific button will be present making it possible to explicitly exit from "lock task mode".

Please note that reopening the app will enable again the "lock task mode" unless the app lock task access has been forbidden from the EMM/MDM. As a general rule, the application can enter "lock task mode" only when it is transitioning to the foreground state (this includes being opened from the recent app list).

3. Annex B – User Workflows

3.1 Configure the Digistat Gateway – Server Side

Applicable scenario: an installation of the Digistat Suite is already present in the Healthcare Organization, in which the feature "Digistat Gateway" is selected. In the installation folder the drivers requested by the Digistat Gateway Application are present. In case the Digistat Gateway installation on mobile devices is managed without using an MDM, in the installation folder of the Digistat workstation is also present the necessary apk file. See the Digistat Suite installation manual for more information.

- Go to the Configurator Web main page, access the **Drivers** page (Fig 13 **A**) and click **ADD NEW DRIVER** (Fig 13 **B**).

Driver Name	User Version	Version Build	Model	Manufacturer	Device Type	Notes	Alarm System Ty...
Carefusion_Demo	1.0	1.0	AGW	Carefusion	InfusionPump		DIS
Carescape_Demo	1.0	1.0	650	GE	PatientMonitor		DIS
CDSS Driver	1.3	1.0	CDSS Driver	ASCOM	OtherComplex		DIS
Evita_Demo	1.0	1.0	Evita XL	Draeger	PulmonaryVentilator		DIS

Fig 13

The **Edit Driver** window opens (Fig 14).

- Set the driver name as "Digistat Gateway" (Fig 14 **A**) and upload the files from the server workstation "C:\Digistat\Server\Drivers\DigistatGateway" folder by clicking the **Upload** button (Fig 14 **B**).

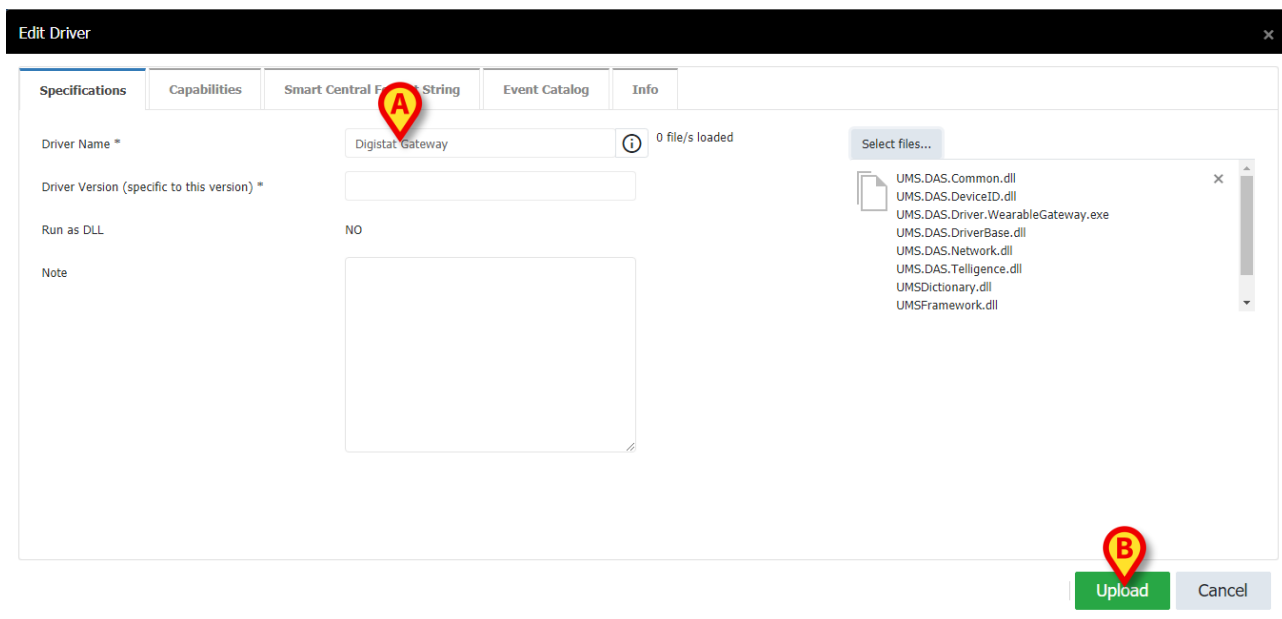


Fig 14

- Select the "Capabilities" tab (Fig 15 A) and enable all the capabilities of the driver (Fig 15 B). Click **Save** (Fig 15 C).

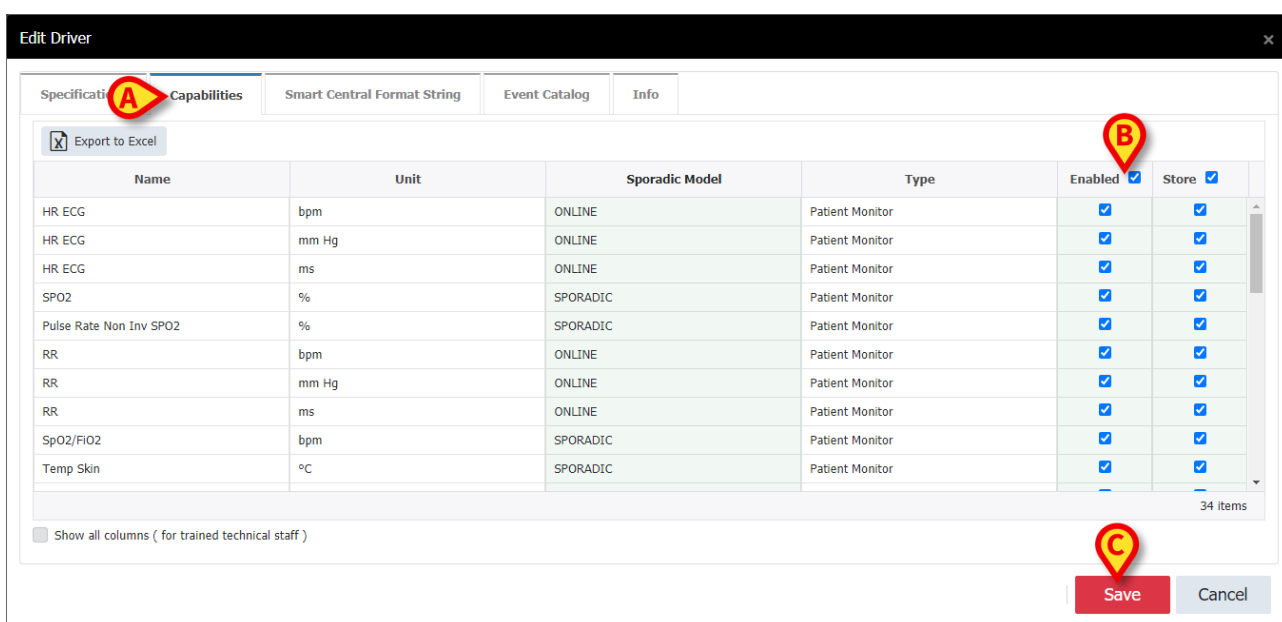
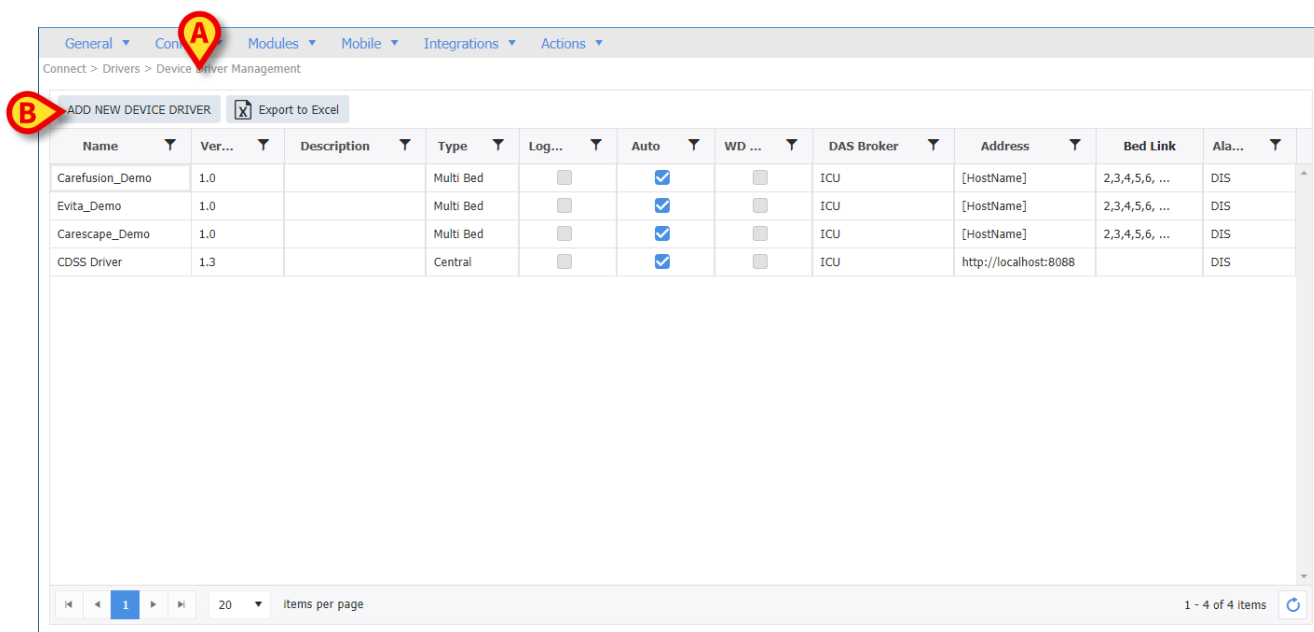


Fig 15

- Access the Configurator Web main page again. Access the **Device Driver Management** section (Fig 16 A) and click **ADD NEW DEVICE DRIVER** (Fig 16 B).

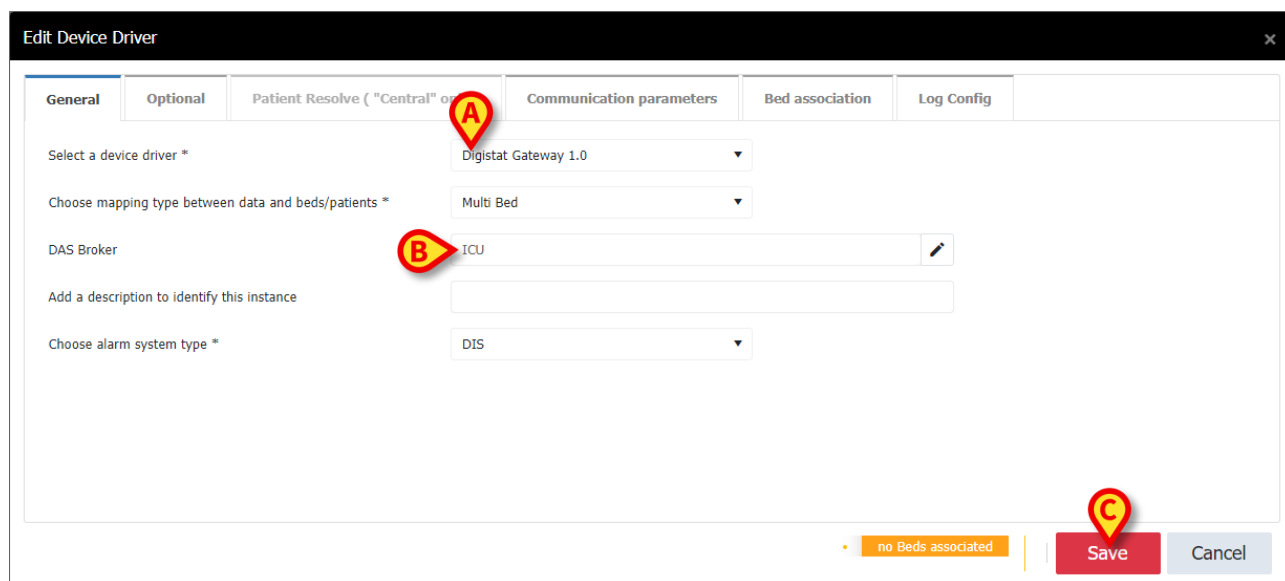


Name	Ver...	Description	Type	Log...	Auto	WD ...	DAS Broker	Address	Bed Link	Ala...
Carefusion_Demo	1.0		Multi Bed	☐	☒	☐	ICU	[HostName]	2,3,4,5,6, ...	DIS
Evita_Demo	1.0		Multi Bed	☐	☒	☐	ICU	[HostName]	2,3,4,5,6, ...	DIS
Carecape_Demo	1.0		Multi Bed	☐	☒	☐	ICU	[HostName]	2,3,4,5,6, ...	DIS
CDSS Driver	1.3		Central	☐	☒	☐	ICU	http://localhost:8088		DIS

Fig 16

The **Edit Device Driver** window opens (Fig 17).

- Select the recently entered Device Driver (Fig 17 **A**). Set the ICU in the “DAS Broker” field (Fig 17 **B**). Click **Save** (Fig 17 **C**).



Edit Device Driver

General | Optional | Patient Resolve ("Central" or) | Communication parameters | Bed association | Log Config

Select a device driver * Digistat Gateway 1.0

Choose mapping type between data and beds/patients * Multi Bed

DAS Broker ICU

Add a description to identify this instance

Choose alarm system type * DIS

no Beds associated

Save Cancel

Fig 17

The Digistat Gateway application is now configured on the Digistat server.

3.2 Configure the Digistat Gateway – Client Side

Applicable scenario: an installation of the Digistat Suite is already present (or is going to be performed) in the Healthcare Organization, in which the feature "Digistat Gateway" is selected. The Digistat Gateway application is already installed on the mobile device.

- Launch the Digistat Gateway application. The following view is displayed:

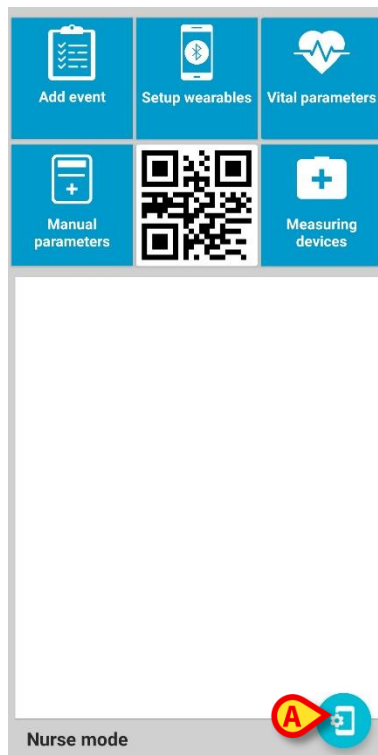


Fig 18

- Tap the "Settings" button (Fig 18 A) to open the settings page (Fig 19) and configure the application.



To access application settings an administrator password is required. The password is provided at the beginning of page 18.

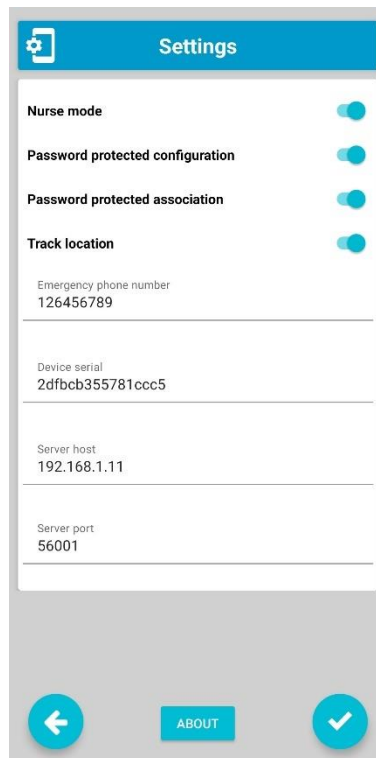


Fig 19

Configure the following settings:

- **Server Host and Port:** hostname (or IP address) and port where the gateway will be connected. If the gateway is to be used on a 4G connection, the IT network shall be configured properly to allow the gateway to reach the host where Digistat Connect is installed.
- **Nurse Mode:** switch between "Nurse mode" and "Patient mode". Some procedures are not available in "Patient mode".
- **Password protected configuration:** if enabled, a system password is required to open the settings page. This should be enabled when the device is used by a patient.
- **Password protected association:** if enabled, a system password is required to pair wearables to the current gateway app.
- **Track location:** if enabled, it tracks the user position. Be aware of privacy issues. The healthcare organization must be authorized to collect this kind of information.
- **Emergency phone number:** when in "Patient mode", a specific button makes it possible for the patient to instantly call a configured phone number (for example, the direct phone number of the ward).
- **Device Serial:** serial number of the device. It is suggested to use meaningful names to easily identify the owner of the device (ex. ICU-123). Use a unique identifier.



When running on Android 10, a random device serial number is used.

3.3 Associate Wearable devices to Digistat Gateway

Applicable scenario: an installation of the Digistat Suite is already present in the Healthcare Organization, in which the feature "Digistat Gateway" is selected. The Digistat Gateway driver was correctly loaded and configured. The Digistat Gateway application was properly installed on the mobile devices.

The goal is now to associate the relevant wearable devices and the mobile device in which Digistat Gateway is installed. This procedure can be performed via barcode. Use the dedicated tool provided in the Digistat Web Configurator to generate and print the appropriate barcodes for the wearable devices.

- Access the Configurator Web main page, click on **Mobile** and then on **Wearables Config** (Fig 20 A).

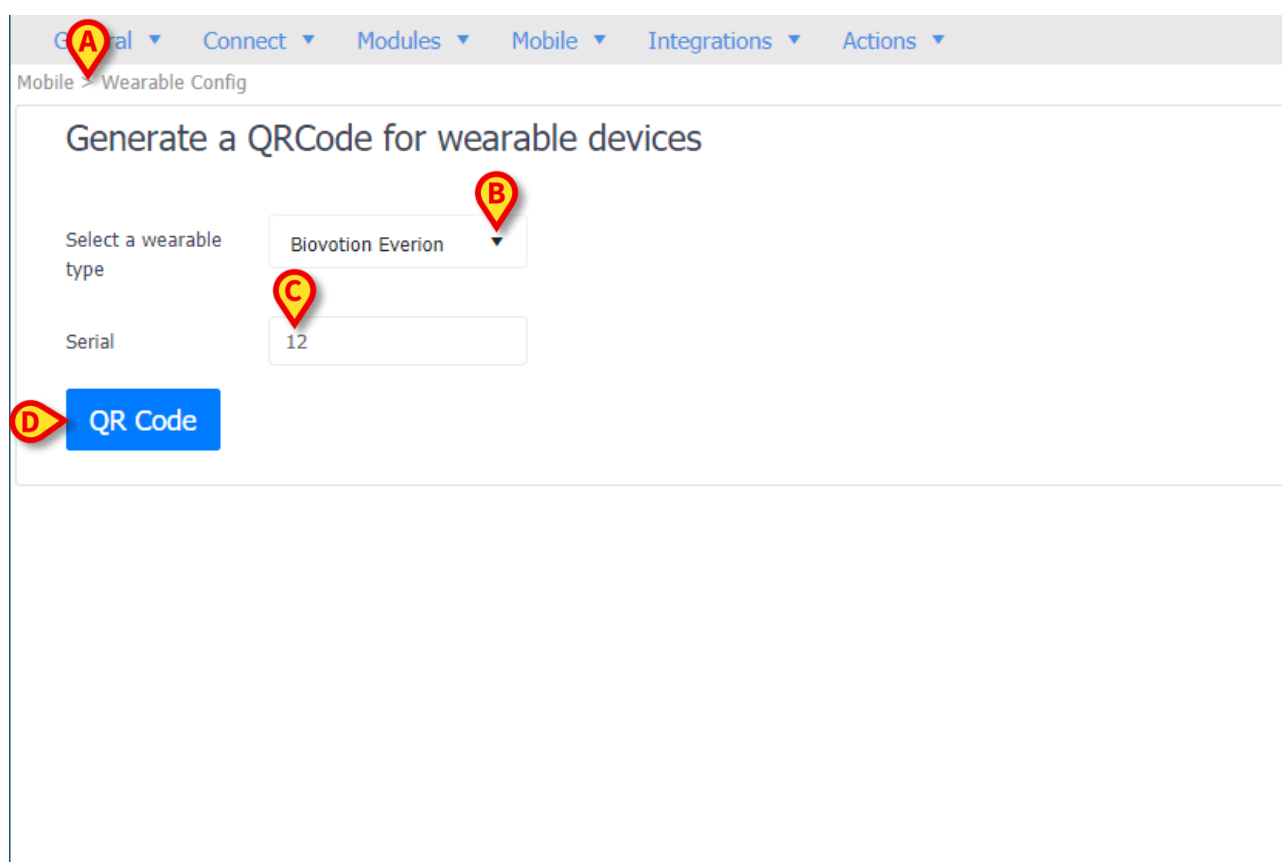


Fig 20

- In the drop-down menu "Select a wearable type" (Fig 20 B) choose the type of wearable to be associated.
- According to the wearable type, the field "Serial" or "MAC Address" or "Wearable version" are displayed. Fill it with the serial number or the MAC Address of the wearable to be associated (Fig 20 C).
- Click on **QR Code** button (Fig 20 D) to generate the code, download and print it (Fig 21).



Fig 21

- Open the Digistat Gateway application in "Nurse mode" on the mobile device. Tap the **Setup Wearable** button (Fig 22 A).

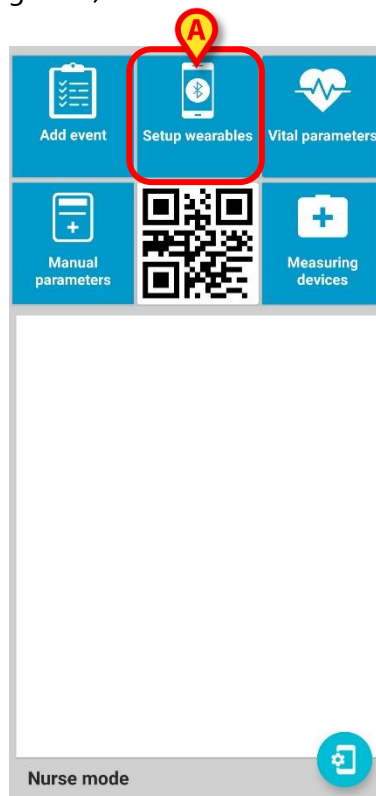


Fig 22

- Press the **Scan** button (Fig 23 A) to scan the barcode related to the wearable device to be paired (obtained via the procedure described above - Fig 20).

The wearable device will be paired automatically and included in the list of "Configured Devices" (Fig 23 B). User confirmation is required to complete the procedure.

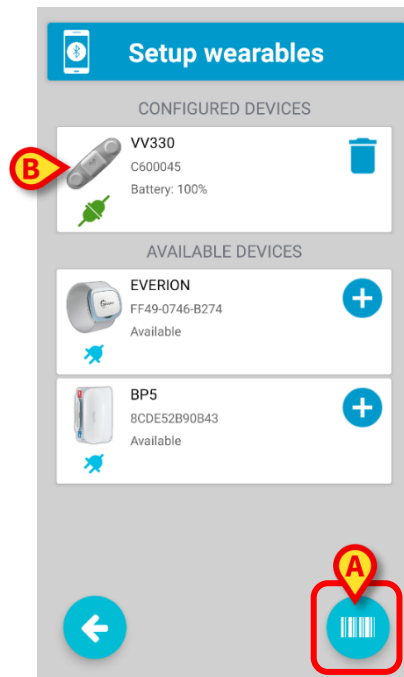


Fig 23



In case of unpairing, the device is moved to the "Available Devices" group.



The barcode functionality works slightly differently on Myco3 devices. Myco3 devices are equipped with a physical "Scan" button on the side. Therefore, the "Scan" icon (Fig 23 A) is not displayed on Myco3 devices.

3.4 Customize the Digistat Gateway driver

Applicable scenario: an installation of the Digistat Suite is present in the Healthcare Organization, in which the feature "Digistat Gateway" is selected. The Digistat Gateway drivers were successfully uploaded.

- Access the Configurator Web main page. Click on **Device Driver Management**. Double click the Gateway driver.

The **Edit device driver** window opens (Fig 24).

The screenshot shows the 'Edit Device Driver' window with the 'General' tab selected. The window has a title bar with a close button. Below the title bar are five tabs: 'General', 'Optional', 'Patient Resolve ("Central" only)', 'Communication parameters', and 'Log Config'. The 'General' tab contains the following fields:

- 'Select a device driver *': A dropdown menu showing 'Digistat Gateway 1.0'.
- 'Choose mapping type between data and beds/patients *': A dropdown menu showing 'Multi Bed'.
- 'DAS Broker': A text input field containing 'ICU'.
- 'Add a description to identify this instance': A text input field.
- 'Choose alarm system type *': A dropdown menu showing 'DIS'.

At the bottom right of the window, there is a status bar with a yellow bar indicating 'no Beds associated'. To the right of this bar are two buttons: 'Edit' (highlighted with a red circle 'A') and 'Close'.

Fig 24

- Click the **Edit** button (Fig 24 A). Select the "Communication parameters" tab (Fig 25 A) and then the "Custom" tab (Fig 25 B).

The screenshot shows the 'Edit Device Driver' window with the 'Communication parameters' tab selected. The window has a title bar with a close button. Below the title bar are five tabs: 'General', 'Optional', 'Patient Resolve ("Central" only)', 'Communication parameters', and 'Log Config'. The 'Communication parameters' tab contains the following elements:

- 'Connection Type': A dropdown menu showing 'Socket'.
- 'Socket', 'Serial Port', and 'Custom': Three tabs, with 'Custom' highlighted by a green bar and a red circle 'B'.
- 'Reload Default Settings': A button.
- 'ADD NEW PARAMETER': A button.
- A table with the following columns: 'Name', 'Value', and 'Description'. The table contains four rows of parameters:

Name	Value	Description
EventList	<Events></Events>	Xml list of events (<Events><Event text=" "></Event></Events>)
MobileTimeout	60	Timeout for mobile communication in seconds
DisconnectionAlarm	Wearable device {0}{1} disconnected from Myco{2}	Alarm text for disconnected device. {0} = source {1} = device serial {2} = Myco serial
DeviceDisconnectionAlarmDelay	60	Delay, in seconds, for the device disconnection alarm

At the bottom right of the window, there is a status bar with a yellow bar indicating 'no Beds associated'. To the right of this bar are three buttons: 'Delete', 'Save' (highlighted in red), and 'Cancel'.

Fig 25

- Customize as required. See some examples in the following sections.



After a custom parameter is changed, the Digistat Gateway driver is reloaded in order to allow the mobile devices to reload the updated custom parameter.

Configure the Event List / Manual Parameters in the Add Event section

- Modify in the “Event List” and in the “Manual Parameters” fields the XML file to set the list of parameters that will be requested to be manually entered once clicked on the **Event List / Manual Parameters** buttons in the Mobile Application (see sections 1.5 and 1.6).

The “Event List” parameter can be customized according to the following scheme:

```
<Events>
<Event text='TEXT'></Event>
</Events>
```

The field TEXT is a free text.

The “Manual Parameters” field can be customized according to the following scheme:

```
<ManualParameters>
<ManualParameter id='ID' label='LABEL' type='TYPE' ></ManualParameter>
</ManualParameters>
```

The field ID can be retrieved from the Standard Parameters tab.

Configure the Data Rate of wearables devices

The Data Rate parameter defines the time interval (in seconds) at which the Datasets collecting the parameters of the wearables devices will be sent from the mobile device to the Digistat Gateway driver. Two scenarios are possible:

- when Data Rate is greater than 0, the Dataset is sent once in the time interval, containing at most one value per parameter type for each wearable device;
- when Data Rate is not set (equal to 0), the Datasets are sent in real time.

Data Rate is considered only for non-ECG online parameters.

Schedule messages to be sent to every mobile device

- Modify in the “NotificationsScheduler” field the XML file to schedule a message to be sent to all mobile devices with the Digistat Gateway application at a specific time of the day.

The “NotificationsScheduler” parameter can be customized according to the following scheme:

```
<Notifications>
<Notification time='TIME'>
<NotificationMessage type='TYPE' text='MESSAGE'></NotificationMessage>
</Notification>
</Notifications>
```

TIME must be a valid timestamp in the format “hh:mm”. The MESSAGE is the text of the message. TYPE is the type of notification. Only one notification per type is displayed. Notifications can be

linked to a wearable device type: in this case, touching the notification redirects the user to the measurement page of the related wearable device (section 1.7).

The following values are supported:

PRESSURE; SP02; SPIROMETRY (All Devices)
KN-550BT; GEMINI; BP5; P03; M4000 (Single Device)
MANUAL (Manual Measure Reminder)
CUSTOM CATEGORY

Configure which parameters should be read from each device type.

- Modify in the "EnabledParams" field the XML file to set the parameters read by the Digistat Gateway application for each device type.

The "EnabledParams" parameter can be customized according to the following scheme:

```
<Devices>
<Device type="TYPE" params="PARAM"/>
</Devices>
```

TYPE is the type of wearable device. The following values are allowed:

EVERION; P03; BP5; VV330; VV200; WT1; 1000M; GEMINI; KN-550BT

PARAM is the specific parameter that the wearable device will acquire (if allowed: i.e. no blood pressure is expected from a thermometer):

SpO2; PRSpO2; HR; RR; SkinTemp; BodyTemp; Systolic; Diastolic; Mean; ECG; RRIArray;
HRV; RRI; Lat; Lon; Radius; Phone

Configure the battery level alarm of Wearable Devices / Mobile Device

- Set the "GatewayBatteryAlarmLevel" parameter to raise a warning for the user if the battery level of the mobile device on which Digistat Gateway is installed is lower than the specified value. Default value is 15%.
- Set the "WearableBatteryAlarmLevel" parameter to raise a warning for the user if the battery level of the configured wearable devices is lower than the specified value. Default value is 15%.
- Set the "XMLDeviceBatteryAlarms" field to customize more specifically the alarms provided in case of low battery level of the wearable devices. This field is an XML file having the following format:

```
<WearableBatteryAlarms>
<WearableBatteryAlarm device="WT1" lowpriority="50"
highpriority="30" step="10" />
</WearableBatteryAlarms>
```

The "device" is one of the supported devices:

When the battery of the specified wearable device is lower than "lowpriority", a low priority alarm is generated; when the battery of the specified wearable device is lower than "highpriority", a high priority alarm is generated. The variation step is specified in the attribute "step". The "step" defines the variation (in percentage points) that separates the different generation of alarms. For example, if:

```
<WearableBatteryAlarms>
<WearableBatteryAlarm device="WT1" lowpriority="50"
highpriority="30" step="10" />
</WearableBatteryAlarms>
```

Then:

Battery level=50 → no alarm
 Battery level=40 → low priority alarm
 Battery level=30 → low priority alarm
 Battery level=20 → high priority alarm
 Battery level=10 → high priority alarm

Configure the caching of data from wearable devices

Digistat Gateway supports data caching. I.e. the temporary storing of data coming from the wearable devices when the client (the Digistat Gateway application) temporarily disconnects from the server (Digistat Gateway driver).

- Set the "CachingType" parameter to enable data caching. Data can be stored either in the volatile memory of the mobile device or in the non-volatile memory of the mobile device: in the former case data are lost in case of mobile device reboot, in the latter case data are still available in case of mobile device reboot.
 The following values are possible:
 - 0 = disabled (default value);
 - 1 = volatile (data is saved in the mobile device volatile memory);
 - 2 = persistent (data is saved in the mobile device non-volatile memory).
- Set the "CachingInterval" field to define the time interval (in seconds) after which a value is cached per parameter type. When the client reconnects to the server, the last valid cached parameter is sent. Default value is 0.
- Set the "CachingExpiration" field to define the time interval (in minutes) after which a value that is still in the cache (and not sent to the server yet) is discarded. Default value is 5.

Customize the Mobile Disconnection Alarms and Timeout

The Digistat Gateway driver manages alarms in case of mobile device disconnection.

- Set the "MobileTimeout" parameter to define the time period (in seconds) after which the datasets coming from a mobile device are removed if the communication with the mobile

device fails. After that, if another MobileTimeout period elapses with no communication, the connection socket with the mobile device is closed. The default value is 10.

- Set the "DeviceDisconnectionAlarmDelay" parameter to define the delay time (in seconds) after which the disconnection alarm is sent by the driver in case of disconnection of the mobile device. Default value is 60.
- Set in the "DisconnectionAlarm" parameter the text of the alarm to be sent by the driver when one or more mobile devices are disconnected.
Three placeholders are allowed:
 - {0} = source of the alarm;
 - {1} = device serial number;
 - {2} = Myco serial number.
- Set the "PriorityDisconnectionAlarm" parameter to customize the priority of the disconnection alarm sent by the driver. The possible values are:
 - 0 → No alarm;
 - 10 → LogEvent;
 - 20 → UserEvent;
 - 30 → ClinicalEvent;
 - 40 → InformationAlarm;
 - 50 → LowPriorityAlarm;
 - 60 → MediumPriorityAlarm;
 - 70 → HighPriorityAlarm (default value).

The alarm is displayed in all Digistat Clients (e.g. Smart Central, Smart Monitor Web) according to the priority defined by this parameter. For example, if the mobile device disconnects and PriorityDisconnectionAlarm is set to 70 then a high priority alarm is displayed in the Digistat Smart Central clients.

Customize the User Alerts

- Set the "UserAlertDescription" parameter to configure the text of the alert message sent by the Digistat Gateway driver in case an alert condition is raised by the user. Myco 3 mobile devices are equipped with a physical button to trigger user alerts.
- Set the "UserAlertPriority" parameter to customize the priority of the alert message sent by the Digistat Gateway driver in case of an alert condition raised by the user. The possible values are:
 - 0 → No alarm (default value);
 - 10 → LogEvent;
 - 20 → UserEvent;
 - 30 → ClinicalEvent;
 - 40 → InformationAlarm;
 - 50 → LowPriorityAlarm;
 - 60 → MediumPriorityAlarm;
 - 70 → HighPriorityAlarm.

According to the priority defined by this parameter, the alert is displayed in all Digistat Clients (e.g. Smart Central, Smart Monitor Web). For example, if the user raises an alert and UserAlertPriority is set to 70, then a high priority alarm is displayed on the Digistat Smart Central clients.

- Set the "UserAlertDuration" parameter to customize the duration (in seconds) of the user alert message/alarm. After the UserAlertDuration, the user alert is automatically removed. If UserAlertDuration is set to 0, the alert message is not automatically removed. Default value is 0.

Enable the Digistat Gateway Demo mode

- Set the "DemoMode" parameter to 1 to activate the Demo Mode for Digistat Gateway.

Configure "AlgoMode" for Everion wearable devices

- Set the "EverionMode" parameter to configure the "AlgoMode" customization for Everion wearable devices. Refer to the manufacturer documentation for more information on the "AlgoMode" parameter.

3.5 Configure the Myco 3 button for barcode scanning

The Myco 3 device is equipped with a physical button that triggers the scan function. Therefore no barcode icon is present.

To configure this way the Myco 3 button:

- Set package or activity name as:
com.ums.app.digistatgateway/com.ums.app.digistatgateway.*
- Select the Digistat Gateway profile (or any other adopted by the user).
- Enable intent output.
- Set intent target as "Broadcast receiver".
- Set intent action as "gatewayscan".
- Set string intent extra as "scanstring";
- Set data intent extra as "scandata".

3.6 Configure the Myco 3 button for phone call

If properly configured, one of the physical buttons on the Myco3 device (usually the top button or one of the side ones when not used for barcode scan) will send a "user alarm" to the driver, to cover a case of a patient that needs immediate assistance. This action will result in an alert displayed on the Smart Central or the Smart Central Mobile. The Healthcare Organization can then trigger the alert and call the patient at home.

In a similar way, if properly configured, one of the physical buttons on the Myco3 device (usually the top button or one of the side ones when not used for barcode scan) can automatically trigger a phone call to a previously set emergency number.

To configure this way the Myco3 button:

- Set package or activity name as:
com.ums.app.digistatgateway/com.ums.app.digistatgateway.*
- Select the Digistat Gateway profile (or any other adopted by the user).
- Enable intent output.
- Set intent target as "Broadcast receiver".

Configuration to send an alarm message:

- Set intent action as "gatewayalert".

Configuration to start a phone call to an emergency number:

- Set intent action as "gatewaycall".