

Smart Monitor Web User Manual

Version 11.0

2024-01-03

Digistat Suite version 9.0

The Digistat suite is composed by the following products:

Digistat® Care version 2.0 Digistat® Docs version 2.0

Digistat[®] Care and Digistat[®] Docs are manufactured by Ascom UMS srl (http://www.ascom.com).

CE

Digistat $^{\circ}$ Care is $^{\circ}$ 0476 marked according to 93/42/EEC ("Medical Device Directive") amended by the 2007/47/EC.

Ascom UMS is certified according to EN ISO 13485:2016 with the following scope: "Design, production, installation, and servicing of stand-alone software for healthcare solutions for communication, information, and workflow management, including integration systems with medical devices and hospital information systems. Marketing and trade of medical devices for communication systems in healthcare".

Software License

The Digistat® Suite must be used only after obtaining a valid license from Ascom UMS or the Distributor

Licenses and registered trademarks

Digistat[®] is a Trademark of Ascom UMS. All other trademarks are the property of their respective owners.

No part of this publication can be reproduced, transmitted, copied, recorded or translated, in any form, by any means, on any media, without the prior written consent of Ascom UMS.

Contents

1. Smart Monitor Web	
1.1 Introduction	
1.2 Intended use	
1.2 Intended use	4
2. Wearables	5
3. Login	5
4. Global Dashboard	
4.1 Grid tab	
4.2 Cards tab	
4.3 Creating a search filter	
5. Patient Dashboard	
6. Associating a kit to a patient	
7. Detaching a device from a patient	18
8. Association check	20
9. Wearable Devices	21
10. User-Location Configuration	22
11. Patient admission mode	
11.1 Patient admission	
11.1 Patient Discharge	20

1. Smart Monitor Web



For general and detailed information about the Product environment and the intended use of the product, see the specific documents. The knowledge and understanding of these documents is mandatory for an appropriate and safe use of the Smart Monitor Web, described in this document.



Smart Monitor Web shall not be used for patient monitoring that could require immediate actions or direct clinical assistance. Smart Monitor Web shall be used for the clinical conditions of patients affected by diseases that require a daily or periodic monitoring of some vital parameters.



Smart Monitor Web is not intended to be used as part of a distributed alarm system,

nor is it intended to support workflows that require immediate awareness for potential clinical intervention.



The caregivers who are monitoring patient data should always verify and validate the measures (for ex. by requesting to repeat them, etc.) in order to minimize the risk of other family members and relatives using the same wearable device.

1.1 Introduction

Smart Monitor Web is a web application used to view data collected from medical devices, both wearables or devices directly connected to the beds of one or more patients, admitted to hospital facilities or remotely monitored for home therapy. The module provides a variously configurable dashboard that offers an overview of tens or hundreds of patients by displaying, for each patient, the latest available vital signs, and historical data.

Additional administrative functionalities are also available like the association between Gateway App and patients, the admission and discharge of patients.



In some configurations Smart Monitor Web is directly connected to the medical devices (i.e., Patient Monitor). In those cases, the Gateway App is not present, and the Patient-Kit association is not required.

1.2 Intended use

Smart Monitor Web is part of the Digistat Suite. Digistat Suite is split in two different products according to the functionalities implemented in the different modules (see the product manuals for a more detailed description). Smart Monitor Web is part of Digistat Care and inherits the same intended use.

Read the product manuals (*USR ENG Digistat Care MDR*) for a detailed description of the intended use and disclaimer notes.

The Digistat Suite can transfer the collected data to third party systems. Please, verify on the third-party system how the information provided by the Digistat Suite will be used.

2. Wearables

In addition to data from medical devices associated with hospital beds, the Smart Monitor Web can also display historical data coming from a set of "kits" connected to the patients. Every kit collects the data from a single patient.

A "kit" has the following components:

- Supported Android Smartphone (ex. Ascom Myco 3).
- Ascom Gateway App (see user manual USR ENG Gateway).
- One or more wearable devices (see above mentioned manual for the complete and updated list of supported wearable devices).

Once a kit has been assembled (a smartphone with the Gateway app installed and wearables) and configured, it is possible to associate it to a patient via Smart Monitor Web. After a kit is associated, it is possible to see the status of the collection of parameters in the main dashboard or in the patient detail dashboard.

Smart Monitor Web makes it also possible to disassociate the kit from the patient when data collection is no longer required.



The list of supported wearable devices is in the document "Digistat Drivers.xlsx".

3. Login

To access the Smart Monitor Web module either select:

- this icon from the Digistat ControlBar Desktop or this icon
 ControlBar Web;
- alternatively, from the Configurator Web > Web Modules page, copy on a browser or click on the configured URL for Smart Monitor Web for the browser navigation.

Perform the login entering the correct **username** and **password** and then, click **Login** to authenticate the user.

If an error is displayed, try again checking for typos. If the problem persists, contact system administrators. If authentication is successful, a Dashboard will be displayed to navigate the application.



Fig 1

Two different tabs can be independently configured and will be available on the main dashboard so that the user can choose the main view of the dashboard or switch between them by selecting them alternately. Obviously, in case only one of them is configured, the tab to access the other view will not be visible:

- Grid (Fig 1 A): it collects and displays the monitored patients' information in a single table. See chapter 4.1;
- Cards (Fig 1 B): it collects and displays the monitored patients' information in multiple and distinct cards. See chapter 4.2.

4. Global Dashboard

The global dashboard (Fig 2) displays the latest collected vital parameters for a set of patients connected to medical devices at the hospital bed or to wearable devices for home monitoring and admitted to configured locations.

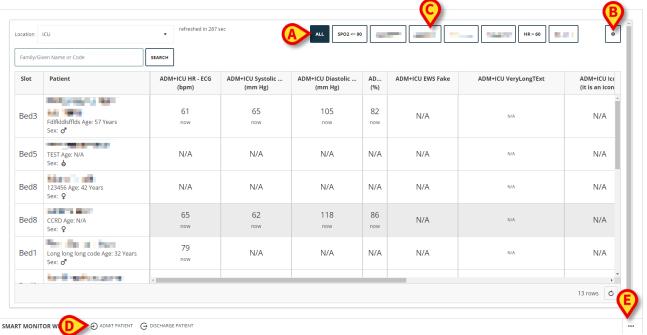
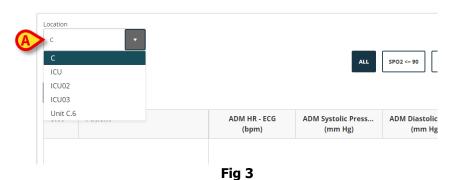


Fig 2

A logged user can display only the patients admitted to his "visible" locations (see chapter 10). If the user is associated to multiple locations, the displayed location can be selected on a drop-down menu (Fig 3 **A**). The drop-down menu contains all and only the locations associated to the logged user. Different data can be displayed for different locations, according to the configuration of Smart Monitor Web.



4.1 Grid tab

The Grid tab is selected by default, and it displays the information of monitored patients belonging to the selected Location in a table.

The main table (Fig 2) displays the following information:

- **Slot**: it represents a bed, or a virtual position (slot) used to virtually locate the patient.
- **Patient**: patient personal data, as name and surname, ID, age, and sex.
- List of vital sign parameters: a configurable list of columns displaying some vital signs parameters, with different icons and colors. Every vital parameter is displayed with the following information: value and collection time (ex. 1 min ago, 1 hour ago). The columns can be customized through the GridConfiguration system option. See the CFG ENG Digistat Suite MDR manual for details on the columns' configuration for the main Dashboard.

The table can be sorted clicking on any header.

It is also possible to filter the table using the buttons indicated in Fig 2 A.

> Click on a button to filter the table according to a "customized" rule (Fig 4) associated to the button.



Filter buttons can be added, edited, or deleted, using the **Manage filter** button (in the upper right corner of the table (Fig 2 **B** - see section 4.3).

It is possible to search for a specific patient using the search filter (Fig 2 \mathbf{C}) located in the upper part of the table:

- insert patient last name or first name, in full or even partially,
- > then click on the **Search** button.

On the bottom part of the screen, a command bar is provided with different possible buttons enabled according to the configuration of **NoDeviceAssignement** system option. If **NoDeviceAssignment** is set to true, the device assignment won't be available and the buttons for patient admission and discharge will be provided (Fig 2 **D**).

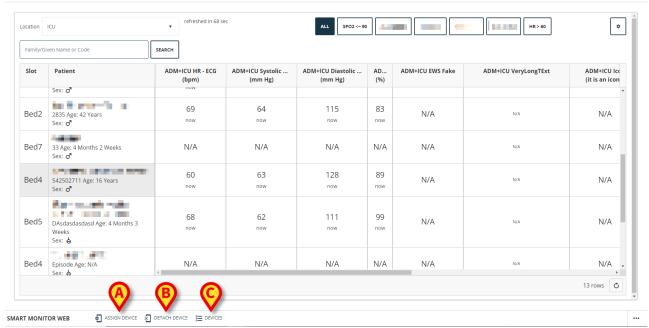


Fig 5

Otherwise, if the system option value is not flagged and it is set to false, three buttons are provided (**Fig 5**):

- **Assign Device** (Fig 5 **A**): to start the device assignment procedure.
- **Detach Device** (Fig 5 **B**): to start the device detachment procedure.
- **Devices** (Fig 5 **C**): to read the list of devices available for the assignment and those already attached to a bed/patient.

For more information on the configuration of the command bar, see the document *DSO ENG System Options*.

Clicking on the three dots button, available in both scenarios, a menu is provided with two options:



- **Verify device association** (Fig 6 **A**): to check the associated patient.
- **Configure User-Location** (Fig 6 **B**): to create, edit, delete, or just view available users and their associated locations.

In the following paragraphs, the actions and functions mentioned up to now will be reviewed and explained in detail.

4.2 Cards tab

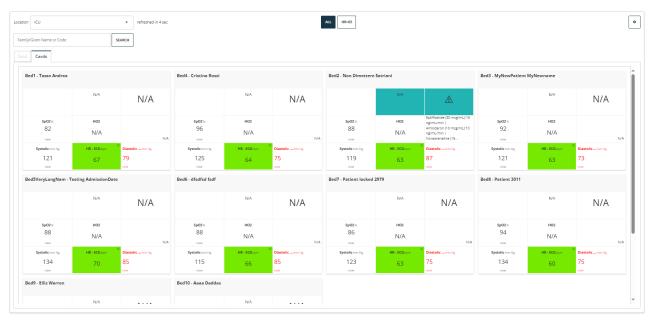


Fig 7

It is also possible to select the **Cards** tab to display the information of monitored patients belonging to the selected Location in multiple, distinct cards:

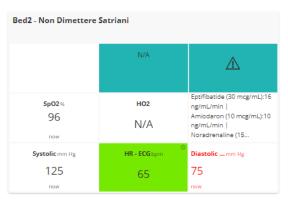


Fig 8

Each Card contains within it a configurable and variable number of panes/cells corresponding to the parameters specified in the *GridConfiguration* system option. They can be the same as or different from the columns configured and displayed in the **Grid** view (by selecting the **Grid** tab). Each pane/cell can display the name of the parameter, the unit of measurement, the value retrieved, and the time at which that value was recorded. The panes (and text) can be variously colored depending on the configurations performed.

To access the patient detail view:

Click on the Card Header.

4.3 Creating a search filter

Since different information/parameters can be displayed in columns and cells, both the **Grid** dashboard and the **Cards** dashboard can be equipped with different filters.

To create or edit the pre-defined search filters:

click on the Manage Filters (Fig 2 B) button-

The **Manage filters** window appears:



Fig 9

The existing filters are listed on a grid the left part of the window (Fig 9 $\bf A$) and each filter has an index number. The order of the filters can be edited, selecting one at a time and then moving it up and down through the list using the **up and down buttons** arrows provided (Fig 9 $\bf B$). The filters can also be deleted, selecting them and the red x button (Fig 9 $\bf C$) provided for each of them. They can be edited, modifying the fields available on the right side of the window (Fig 9 $\bf E$).

It is also possible to create a new filter and to do that:

- Click the + button (Fig 9 D) provided on top of the grid.
- > Customize the filter filling in the available fields.
- Press Save to save the filter and close the filters window.

A filter has the following properties:

- **Name**: the name of the filter. This text is displayed on the button in the main dashboard. Consequently, it is better to enter short names.
- Index: it is the sorting index, not editable.

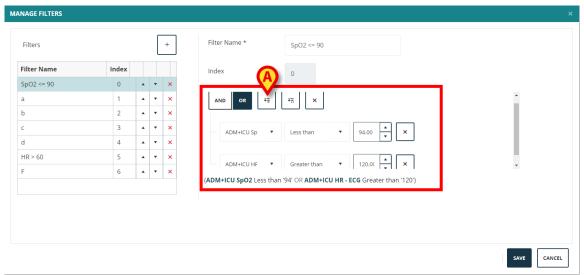


Fig 10

- **Expression**: it is possible to create a logical expression to specify the filter rules. It is possible to add as many logical constructs as needed (Fig 10 **A**). For example: the Test Filter displayed, once saved, and selected, will show only the patients with HR greater or equal to 120 bpm **and** SpO2 less or equal to 94%. A **textual summary** is provided under the expression fields.

5. Patient Dashboard

Double clicking on a patient card, the user can access the **Patient Detail Dashboard**. Two possible scenarios are given:

- If Online Web has been installed, a page has been correctly configured and the ID of that page has been indicated in the OnlinePageID system option of the WearableMonitor module, the patient detail dashboard coincides with that Online Web page and the user is redirected to the Online page. See CFG ENG Online Validation manual and the document DSO ENG System Options for details.
- If the **OnlinePageID** system option is set to 0 (the default value), the Smart Monitor Web patient detail page is given.



Fig 11

The patient detail dashboard page consists of several part that contains different information:

- A central section (Fig 11 A), that contains the charts returning and displaying
 the trends and history of the vital parameters retrieved over time for the
 selected patient. The charts display data in a 6-hour period by default. The xaxis represents the time while the y-axis represents the values. Click any chart
 to display the value at a certain time in a tooltip.
- On the top part (Fig 11 **B**), some buttons are given to change and customize the **time interval**. Use the buttons "6 hours", "12 hours" and "24 hours" to change the displayed time interval. It is also possible to manually specify a time value (number of hours) in the field provided and then press the **Search** button to apply the customization.
- On the right part of the page (Fig 11 **C**), all the **events** and **alarms** are listed, both those communicated by the patient (using the Gateway App) and those auto-generated (for example: "device disconnected").

- On the lower part, the command bar shows the Dashboard button (Fig 11 D), to go back to the main Dashboard view.
- Above the event table **four buttons** (Fig 11 **E**), are provided:



The grey buttons are disabled while the black ones are enabled. These buttons activate the following functionalities (left to right):

- Tracking (Fig 12 A): it displays on a map where the kit consisting of wearables devices, smartphone and Gateway app is located. To enable this functionality the Gateway app must be configured to read GPS coordinates.
- **Info** (Fig 12 **B**): it displays the assigned medical device data like the name and code/unique identifier.
- **Telephone** (Fig 12 **C**): it starts a telephone call with a configured phone number.
- Patient Privacy Document (Fig 12 D): it displays the Patient Privacy Document, generated during the association procedure (see chapter 6).

6. Associating a kit to a patient

In case the Gateway-Wearable kit combination is used, to start the patient-device association process, the smartphone must have been connected to the system at least once, in order to have it correctly registered. To start the association workflow:

Click Assign Device button on Smart Monitor Web command bar (Fig 5 A). The following window is displayed:

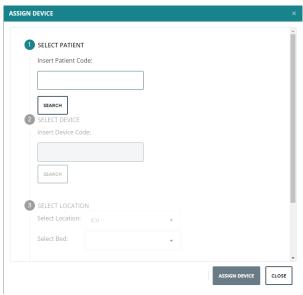


Fig 13

The association workflow can be completed in four steps:

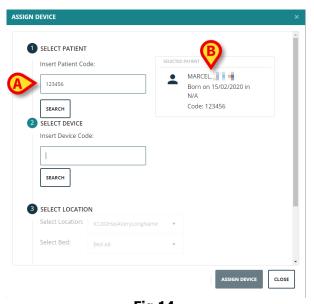


Fig 14

Step 1

Enter the **patient code** used in this specific installation and press the **SEARCH** button (Fig 14 **A**). If the patient already exists, then the related record is displayed in the **Selected Patient box** (Fig 14 **B**).



Fig 15

If the patient code is not retrieved, a red written message (Fig 15 **A**) appears warning the user that no patient has been found.



Fig 16

Step 2

Enter the ID of the gateway app (the kit ID) or the ID of the medical device to be associated (Fig 16 **A**). Click on **SEARCH** button and if the selected device is retrieved, its data are displayed in a new box. The status is set to **Available** (Fig 16 **B**).



The kit ID can be read on a label attached to the smartphone (if present) or in the Gateway app, selecting the nurse modality (see the relevant documentation for more instructions).

If the ID is not found, then it is necessary to check for typos. If no typos are detected, in case the ID of a kit is searched, it may be the case that the kit is new to the network. In this case, connect the kit to the network and try again.



If the device or kit are already associated to a patient, a red written message appears in the Status field (Fig 17), warning the user that they have been already assigned to a different patient, reporting their name, surname, and code. The detachment of the device from the original patient enables the subsequent assignment to the current patient.

Step 3

If a patient is not already admitted to a bed, it is possible to select the location where the user wants the patient to be admitted and one free slot. It is possible to choose only from those locations that are enabled for current user.

If the selected patient was already admitted to a bed, this section is disabled, and user can proceed to step 4.

Step 4

This step is not mandatory but configurable through the

MandatorySignatureOnDeviceAssignment system option. If the value of the system option is set to true, during the device assignment procedure, a signature will be mandatory in order to proceed with the association, otherwise it won't be mandatory, and the user will be able to associate a device without displaying the document.

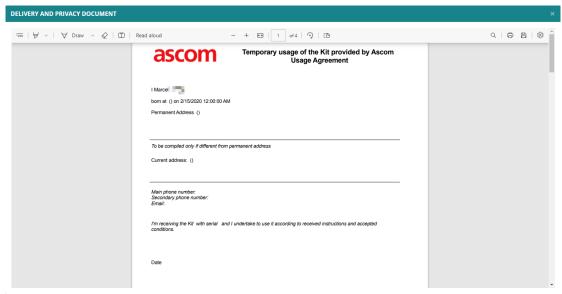


Fig 18

So, if the **MandatorySignatureOnDeviceAssignment** system option is set to true, as in the example provided, to complete the association workflow (and to activate the ASSOCIATE DEVICE button) it is necessary to press the **PRINT DOCUMENT** button (Fig 16 **C**). A privacy report is displayed. If the specific healthcare organization procedures require it, it is possible to print the document for patient signature. After the document has

been displayed, the **Assign Device** button enables. Click on it to confirm the association. See the document *DSO ENG System Options* for details on the configuration of the system option.

7. Detaching a device from a patient

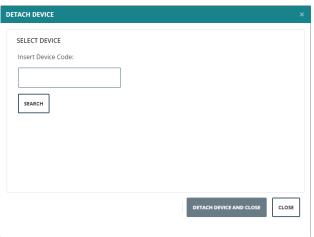


Fig 19

The procedure to detach a Gateway-Wearable kits or other medical devices from patients can be performed by clicking on **Detach Device** (Fig 5 **B**) button on Smart Monitor Web command bar. The **Detach Device** window is displayed:

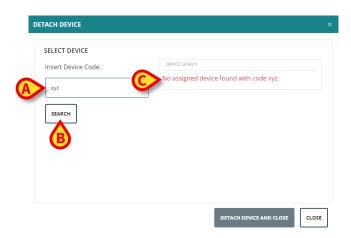


Fig 20

➤ Enter the **device ID** in the field provided (Fig 20 **A**) and press the **SEARCH button** (Fig 20 **B**). If the device is not found an error message (Fig 20 **C**) is displayed warning the user that no assigned device with the code entered has been retrieved, otherwise, the following window is displayed:

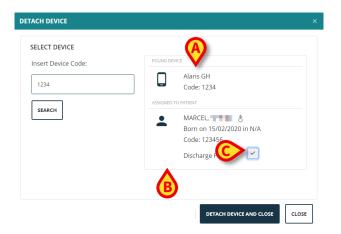


Fig 21

On the right section, a box that contains the **device information** (name and code, Fig 21 **A**) and the patient - to which it is assigned - **personal data** is displayed (Fig 21 **B**). Furthermore, a **checkbox** (Fig 21 **C**) is provided to discharge the patient at the same time as the finalization of the device detachment procedure.

Press Detach device and close button to complete the disassociation workflow.

The device is then available for another patient.

If that device is the only one associated to the previous patient, then the patient data disappears from the main dashboard.

8. Association check

The **Check device-patient association functionality** makes it possible to verify if a device is correctly associated to a patient. This workflow performs a double check in order to reduce risks of a wrong association. It can be performed, for example, in case the association workflow is performed before the actual "live" association to a patient.



To check the association:

Click on three dots button (Fig 22 A) on Smart Monitor Web command bar and then on Verify device association (Fig 22 B). The following window opens:



Fig 23

Type the device code in the field provided (Fig 23 **A**) and click on **Check associated patient** (Fig 23 **B**).

If an Android device (e.g., a smartphone) is used, it is possible to tap the **BARCODE scanner** button (Fig 23 **C**) to read the device barcode. To read the barcode it is necessary to install, on the smartphone, the "Barcode Scanner" third party app (by ZXing Team).

If the device is found and is already assigned to a patient, then the associated patient data is displayed (Fig 24 **A**), otherwise an error message appears.



Fig 24

9. Wearable Devices

It is possible to display the list of all medical devices that have been connected to the system. To do that, just:



Click on **Devices button** on Smart Monitor Web command bar (Fig 25 A). The following screen is displayed:

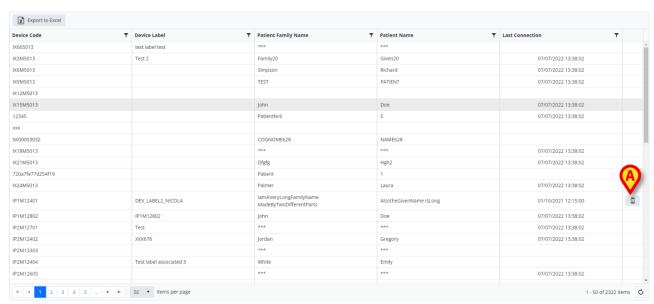


Fig 26

The table displays the list of all the medical devices and Gateway-Wearables kits that, at least once, have been connected to the system.

The "**Device Code**" column contains the devices IDs. If a device is already associated to a patient, the "**Patient Family Name**" and "**Patient Name**" columns contain respectively

the name and surname of the patient that is currently associated. **Device Label** and **Last Connection** columns are also provided, to respectively shows information on the Label used to customize the device with a simpler and more recognizable name, and, in case the device is currently in use, the date and time information about the last connection retrieved.

Icon buttons can also be provided (). Once clicked, the device details information is displayed in a pop-up window. In the example provided all the wearable devices that were connected to the Gateway App during the last communication of the Gateway with the system are listed.



The information provided in this view can be not updated if the kit is disconnected from the network and at the same time one or more wearables are detached from the gateway.

10. User-Location Configuration



It is possible to associate users to one or more locations using the functionality **User-Location Configuration**. This procedure can be performed only by users with specific permissions. To do that,

Click on three dots button (Fig 27 A) on Smart Monitor Web command bar and then on Configure User-Location button (Fig 27 B). The following window opens:

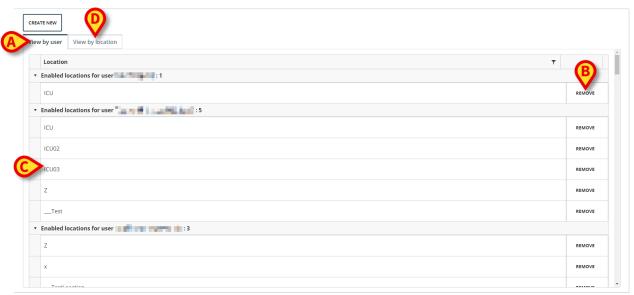


Fig 28

A grid is provided with the current associations between enabled locations and the active users. Locations can be shared between different users. The "View by user" (Fig 28 A) tab is selected by default and it shows, for every user, the list of associated locations (Fig 28 C). It is also possible to view the association by location, by selecting the "View by location" (Fig 28 D): for every location, the list of associated users is displayed. The existing associations can be removed:

- > clicking the **Remove** button (Fig 28 **B**) provided on the right of each entry. While to configure a new association or to edit an existing one:
 - > click on **Create New** button placed above the grid.

The following window is displayed:

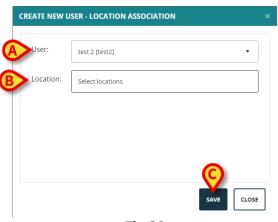


Fig 29

- > Select a user on the "User" drop-down menu (Fig 29 A).
- > Select the list of location(s) to be associated to the selected user on the "Location" drop-down menu (Fig 29 **B**).
- Click Save to confirm (Fig 29C).

From the version 8.1 of Digistat Suite package, the association between users and locations can be also configured through the Configurator Web > System Configuration > Locations.

11. Patient admission mode

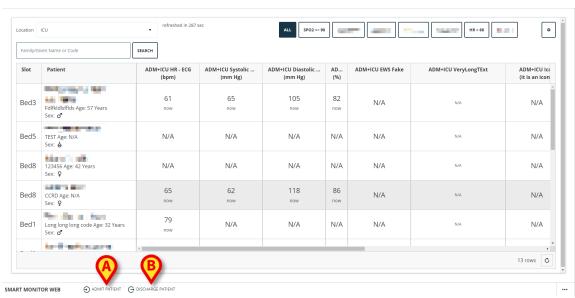


Fig 30

Smart Monitor Web can be configured to manage patients' admission and discharge instead of devices assignment and detachment.

In these cases, the devices assignment and detachment procedures are performed on an external system, depending on the specific choices of the healthcare organization.

When Smart Monitor Web is in "Patient admission" mode the Assign device/Detach device buttons on the Main Menu and on the toolbar drop down menu are replaced by the Admit Patient (Fig 30 **A**)/Discharge Patient (Fig 30 **B**) buttons.

11.1 Patient admission

To admit a patient:

Click the Admit Patient button on the Smart Monitor Web command bar.

The following screen opens:

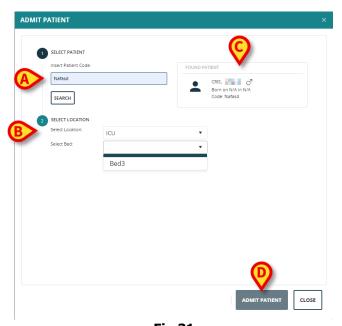


Fig 31

➤ Insert the **Patient Code** in the field indicated in Fig 31 **A** and click on **SEARCH** button.

If the patient is found, and they are not already admitted, the patient data is displayed on the right (Fig $31\ C$).

- > Select the destination **Location** and **Bed** (Fig 31 **B**).
- > Click the **Admit patient** button on the bottom-right corner of the screen (Fig 31 **D**), then confirm the patient admission.

11.2 Patient Discharge

To discharge a patient:

Click the **Discharge Patient** button on the Smart Monitor Web command bar (Fig 30 B).

The following screen opens:

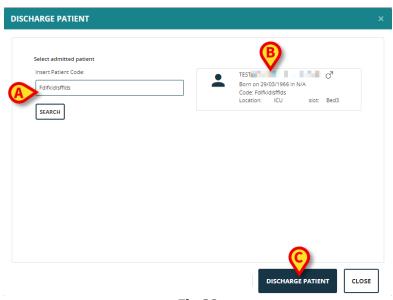


Fig 32

> Insert the **Patient Code** in the field indicated in Fig 32 **A** and click on **SEARCH** button.

If the patient is found the patient data is displayed on the right (Fig 32 B).

> Click on the **Discharge Patient** button (Fig 32 **C**) then confirm the patient discharge.