Digistat Smart Central User Manual

Digistat Smart Central V5.0

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Ascom UMS s.r.l. Unipersonale

Via Amilcare Ponchielli 29, 50018, Scandicci (FI), Italy

Tel. (+39) 055 0512161 – Fax (+39) 055 829030

www.ascom.com

Digistat Smart Central version 5.0

SOFTWARE LICENSE

Your Licence Agreement – provided with the product - specifies the permitted and prohibited uses of the product.

LICENSES AND REGISTERED TRADEMARKS

Digistat® Smart Central is produced by Ascom UMS s.r.l
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DIGISTAT® is a Trademark of Ascom UMS s.r.l
Information is accurate at the time of release.
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Ascom UMS is certified according to ISO 9001:2015 and ISO 13485:2003 standards.

Contents

1. Using the manual

1.1 Aims

The effort which has gone into creating this manual aims to offer all the necessary information to guarantee a safe and correct use of the Digistat Smart Central product and to allow the manufacturer identification. Furthermore, this document aims to describe every part of the Product, it also intends to offer a reference guide to the user who wants to know how to perform a specific operation and a guide for the correct use of the Product so that improper and potentially hazardous uses can be avoided.

The use of Digistat Smart Central requires a basic knowledge of information systems concepts and procedures. The comprehension of this manual requires the same knowledge.

1.2 Characters used and terminology

The use of Digistat Smart Central requires a basic knowledge of the most common IT terms and concepts. In the same way, understanding of this manual is subject to such knowledge.

Remember that the use of Digistat Smart Central must only be granted to professionally qualified and properly trained personnel.

When consulting the online version, cross-references in the document work like hypertext links. This means that every time you come across the reference to a picture (e.g. “Fig 7”) or to a paragraph / section (e.g. “paragraph 2.3”), you can click the reference to directly go to that particular figure or that particular paragraph / section.

Every time a reference is made to a button, this is written “**Bold**”. For example, in expressions like:

- Click the “**Update**” button,

“**Update**” is a button featured on the screen being described. Where possible, it is clearly indicated in a figure (with cross references as “See Fig 7 **A**”.

The character ➢ is used to indicate an action which the user must perform to be able to carry out a specific operation.

The character ● is used to indicate the different elements of a list.

1.3 Symbols

The following symbols are used in this manual.

	**Useful information** This symbol appears alongside additional information concerning the characteristics and use of Digistat Smart Central. This may be explanatory examples, alternative procedures or any “extra” information considered useful to a better understanding of the product.

	**Caution!** The symbol is used to highlight information aimed at preventing improper use of the software or to draw attention to critical procedures which might cause risks. Consequently, it is necessary to pay extreme attention every time the symbol appears.

The following symbols are used in the about box:

	Indicates the manufacturer’s name and address
	Attention, consult accompanying documents
℞ Only	Caution: US Federal and Canadian law restricts this device to sale by or on the order of a licensed medical practitioner
Unique Device Identifier (UDI)	Unique device identification. The unique device identification (UDI) system is intended to assign a unique identifier to medical devices within the United States.

2. Intended use

The intended use of the Digistat Smart Central is to provide an interface with clinical systems to forward information associated to the particular event to the designated display device(s). For medical, near real time alarms, the Digistat Smart Central is intended to serve as a parallel, redundant, forwarding mechanism to inform healthcare professionals of particular medical related events. The Digistat Smart Central does not alter the behaviour of the primary medical devices and associated alarm annunciations. The display device provides a visual, and/or audio and/or vibrating mechanism upon receipt of the alert.

The Digistat Smart Central is intended for use as a secondary alarm. It does not replace the primary alarm function on the medical devices.

2.1 Patient population

The product is a software application intended to be used on selected central stations and mobile devices. It is used to provide a secondary display of physiological and technical parameters and alarms from the connected medical devices and systems for remote monitoring and alarm surveillance.
The product is not in contact with the patient, it is intended to forward the information generated by the connected medical devices and systems, and it does not generate patient related alarms. As a consequence, the patient population and patient conditions are established by the medical devices and systems with which the product is connected.

2.2 “Off-label” use of the Product

Every use of the Product outside what explicitly stated in the “Intended use” (usually referred to as “off-label” use) is under the full discretion and responsibility of the user and of the healthcare organization.

The manufacturer does not guarantee in any form the Product safety and suitability for any purpose where the Product is used outside the stated “Intended use”.

2.3 Maintenance and technical support

ASCOM UMS declines all responsibility for the consequences on the safety and efficiency of the product determined by technical repairs or maintenance performed by personnel not explicitly authorized by ASCOM UMS and/or Distributor.

The attention of the user and of the healthcare organization is drawn to their responsibilities, in view of the local legislation regarding occupational safety and health and any additional local site safety policies.

The ASCOM UMS/Distributor Service is able to offer customers the support needed to maintain the long-term safety and efficiency of the devices supplied, guaranteeing the skill, instrumental equipment and spare parts required to guarantee full compliance of the devices with the original construction specifications over time.

2.4 Manufacturer's responsibility

Ascom UMS is responsible for the product's safety, reliability and performance only if:

- Use and maintenance comply with User Manual instructions;
- This Manual is stored in good conditions and all sections are readable;
- Configurations, changes and repairs are only performed by personnel trained and authorized by Ascom UMS ;
- The Product's usage environment complies with applicable safety regulations;
- The electrical wiring of the environment where the Product is used complies with applicable regulations and is efficient.

Should the Product be part of a "medical electrical system" through electrical and functional connection with medical devices, the healthcare facility is in charge of the required electrical safety verification and acceptance tests, even where Ascom UMS performed in whole or in part the necessary connections.

2.5 Product traceability

In order to ensure device traceability, the former Product owner is requested to inform Ascom UMS/Distributor about any ownership transfer by giving written notice stating the product, former owner and new owner identification data.

Product data can be found in the product labeling (the "About box" displayed within the product – see paragraph 5.10.4).
In case of doubts/questions about product labeling and/or product identification please contact Ascom UMS/Distributor technical assistance (for contacts see section 10).

2.6 Post-market surveillance

The device is subject to a post-market surveillance. Ascom UMS, its distributors and dealers must provide, for each marked copy, information concerning actual and potential risks, either for the patient or the User, during the Product's life cycle.

In case of deterioration of the Product characteristics, poor performance or inadequate user instructions that have been or could be a hazard to either the patient or User' health or to environmental safety, the User must immediately give notice to either Ascom UMS or its Distributor.

The product details can be found on its labeling.

On reception of a user feedback Ascom UMS will immediately start an investigation of the the reported nonconformity in order to take the required actions.

2.7 Product life

The life time of the product does not depend on wearing or other factors that could compromise safety. It is influenced by the obsolescence of the executing environment (e.g. computers, servers, operating system) and is therefore assessed as 5 years since the release date of the specific Product version. During this period, Ascom UMS is committed to fully support the Product.

3. Software/Hardware specifications

Digistat Smart Central must only be installed by trained authorized personnel. This includes Ascom UMS/Distributors staff and any other person specifically trained and explicitly authorized by Ascom UMS/Distributor. Without an explicit, direct authorization from Ascom UMS/Distributor, the healthcare organization staff are not authorized to perform installation procedures and/or to modify Digistat Smart Central configuration.

Digistat Smart Central must only be used by trained personnel. Digistat Smart Central cannot be used without having a proper training, performed by Ascom UMS/Distributors staff.

The information provided in this chapter covers the manufacturer's obligations identified by the IEC 80001-1:2010 standard (Application of risk management for IT-networks incorporating medical devices).

According to the IEC 60601-1 standard, in case where an electrical equipment is positioned close to the bed, the use of "Medical grade" devices is required. In these situations medical grade PANEL PCs are usually used. The hospital shall take into account any other local regulation that may supplement these requirements.

3.1 Central & Bedside

3.1.1 Hardware

Minimum hardware requirements:

- Intel® i3 processor (or faster)
- Memory: 4 GB RAM
- Hard Disk: at least 60 GB of available space
- Monitor: 1024 x 768 or higher (1920 x 1080 suggested).
- Mouse or other compatible device. Touch screen recommended.
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

3.1.2 Operating System

- Microsoft Corporation Windows 7 SP1 x86/x64 Professional
- Microsoft Corporation Windows 8.1 x64 Professional

- Microsoft Corporation Windows 10

3.2 Server

3.2.1 Hardware

Minimum hardware requirements:

- Intel® i5 processor (or faster)
- Memory: 4 GB RAM (8 GB recommended)
- Hard Disk: at least 120 GB of available space
- Ethernet interface 100 Mb/s (or higher). 1 GB recommended.
- CD/DVD Drive or possibility to copy the installation files

3.2.2 Operating System

- Microsoft Corporation Windows Server 2012 R2
- Microsoft Corporation Windows Server 2016

3.2.3 System Software

- Microsoft SQL Server 2008R2
- Microsoft SQL Server 2012
- Microsoft SQL Server 2014
- Microsoft SQL Server 2016
- Microsoft SQL Server 2017

3.3 Digistat Smart Central Mobile

Digistat Smart Central Mobile has been verified on the Ascom Myco SH1 Wi-Fi and Cellular Smartphone device, with Android version 4.4.2 (Myco 1) and 5.1 (Myco 2). It is therefore compatible with Myco 1 and Myco 2 mobile devices. The application is designed to be compatible with other Android devices with a minimum screen size of 3.5'', and compatibility with a specific device must be verified before clinical use.

Please contact Ascom UMS for the full list of devices that support Digistat Smart Central Mobile.

3.4 General warnings

To correctly use Digistat Smart Central, the Microsoft Windows Display Scaling must be set to 100%. Different settings may prevent the product from starting or cause malfunctions in the way Digistat Smart Central is visually displayed. Please refer to the Microsoft Windows documentation for instructions on the Display Scaling settings.

The minimum vertical resolution of 768 is supported only if Digistat Smart Central is configured to run in full-screen mode or if the Windows tray bar is in Auto-hide mode.

The computers and the other connected devices must be suitable for the environment in which they are used and must, therefore, comply with the relevant regulations.

It is mandatory to follow the manufacturer instructions for storage, transport, installation, maintenance and waste of third parties hardware. These procedures must be performed only by qualified and authorized personnel.

The use the Product together with any software other than those specified in this document may compromise the safety, effectiveness and design controls of the Product. Such use may result in an increased risk to users and patients. It is mandatory to consult an authorized Ascom UMS or Distributor technician before using together with the Product any software other than those specified in this document.

If the hardware on which the Product runs is a stand-alone computer, the user shall not install any other software (utilities or applications programs) on the computer. It is suggested to apply a permission policy that prevents users from performing procedures such as the installation of new software.

The healthcare organization shall implement for the Digistat Smart Central workstations a date/time synchronization mechanism to a reference source.

3.4.1 Cybersecurity controls

To protect the Digistat Smart Central from possible cyber-attacks, it is necessary that:

- the Windows© Firewall is active both on the client PCs and the server;
- antivirus software is installed and regularly updated both on the client PCs and the server.

The healthcare organization shall ensure that these two protections are activated. Ascom UMS tested the Product with F-Secure Antivirus but, considering the strategies and policies already existing in the healthcare organization, the actual choice of the antivirus is left to the healthcare organization. Ascom UMS cannot ensure that Digistat Smart Central is compatible with any antivirus or antivirus configuration.

Some incompatibilities have been reported between parts of Digistat Smart Central and Kaspersky antivirus. The solution to these incompatibilities required the definition of specific rules in the antivirus itself.

It is suggested to only keep open the TCP and UDP ports actually needed. These may change according to the Digistat Smart Central configuration. Please refer to the Ascom UMS/Distributor technical assistance for more information.

3.5 Local network features

This section lists the features of the local network on which Digistat Smart Central is installed in order to guarantee the Product's full functionality.

- Digistat Smart Central uses a TCP/IP traffic protocol.
- The LAN must not be congested and/or full loaded.
- Digistat Smart Central requires at least a 100 Megabit LAN available to the client workstation. 1 Gigabit Ethernet backbones would be worthwhile.
- There must not be filters in the TCP/IP traffic between workstations, server and secondary devices.
- If the devices (server, workstations and secondary devices) are connected to different subnets there must be routing in these subnets.

- It is recommended to adopt redundancy strategies to ensure network service availability in case of malfunction.
- It is recommended to schedule, together with Ascom/Distributors, the maintenance calendar in order to let Ascom or the authorized Distributor efficiently support the healthcare organization in managing the possible disservices caused by maintenance activities.

If the network does not match the requested features, Digistat Smart Central performance gradually deteriorates until timeout errors occur. The Product may finally switch to “Recovery” mode.

In case a WiFi network is in use, given the possible intermittency of the WiFi connection, network disconnections are possible, that cause the activation of the “Recovery Mode” and the consequent Product unavailability. The healthcare organization shall ensure an optimal network coverage and stability, and train the personnel in the management of these temporary disconnections.

3.5.1 Digistat Smart Central impact on the healthcare organization network

Digistat Smart Central impacts the local network of the healthcare organization. This section provides information on the traffic generated by Digistat Smart Central on the network in order to make it possible for the structure to evaluate and analyze the risks related to the introduction of Digistat Smart Central.

The bandwidth used by Digistat Smart Central depends on many different factors. The most important are:

- Number of workstations,
- Number of workstations configured as central stations,
- Number and type of devices dedicated to data acquisition
- Interfaces with external systems,
- Digistat Smart Central configuration and mode of use.

In a configuration with acquisition on 100 beds where every bed collects data from 1 ventilator, 1 patient monitor and 3 infusion pumps, and with 10 Digistat Smart Central workstations showing 10 beds each, the following bandwidth occupation values can be indicatively predicted.

Average: 0.8 – 6 Mbit/s

Pitch: 5 – 25 Mbit/s

4. Before starting

4.1 Installation and maintenance warnings

The following warnings provide important information on the correct installation and maintenance procedures of the Digistat Smart Central product. They must be strictly respected.

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Maintenance and repairs procedures shall be performed in compliance with Ascom UMS instruction only by Ascom UMS/Distributor technicians or personnel trained and authorized by Ascom UMS/Distributor.

Digistat Smart Central must be installed and configured only by specifically trained and authorized personnel. This includes Ascom UMS (or authorized Distributor) staff and any other person specifically trained and authorized by Ascom UMS/Distributor. Similarly, maintenance interventions and repairs on Digistat Smart Central must be performed according to Ascom UMS guidelines only by Ascom UMS/Distributor personnel or another person specifically trained and authorized by Ascom UMS/Distributor.

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Digistat Smart Central must be installed and configured only by specifically trained and authorized personnel. This includes Ascom UMS (or authorized Distributor) staff and any other person specifically trained and authorized by Ascom UMS/Distributor.

- Use third party devices recommended by Ascom UMS/Distributors.
- Only trained and authorized people can install third party devices.
- Incorrect installation of the third party devices can create a risk of injury to the patient and/or operators.
- Meticulously observe the manufacturer's instructions for the installation of third party hardware.
- Make provision for regular maintenance of the Product according to the instructions present in this manual and those provided with the third party devices.
- The Digistat Smart Central USB dongle must be stored and used in eligible environmental conditions (temperature, humidity, electromagnetic fields etc.), as specified by the dongle manufacturer. These conditions are equivalent to those required by common office electronic devices.

- Within the “Patient Area” (see Fig 1) it is recommended to use easily washable devices that are protected from liquids.

- Within the “Patient Area” (see Fig 1) it is recommended to use washable, sterilizable rubber keyboards and mouse devices. For “touch screens” it is recommended to adopt capacitive technology (insensitive if used with gloves) because it discourages using gloves (sometimes contaminated).

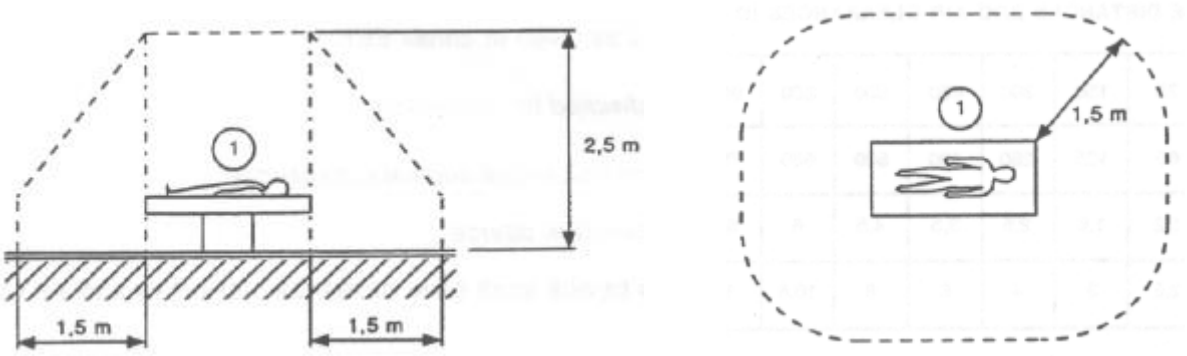

Fig 1 - Patient Area

4.1.1 Patient Area

The Patient Area is the space where there could be either intentional or unintentional contact between a patient and parts of the system (i.e. any device) or between a patient and other persons touching parts of the system (i.e. a physician who simultaneously touches a patient and other devices). The definition applies when the patient’s position is previously established; otherwise all possible patient positions must be taken into account.

According to IEC 60601-1 standard, every computer placed within the “Patient Area” must be a medical grade device.

According to the hardware license it is the responsibility of healthcare organization to perform all the required measurements on the electrical safety of the electro-medical system in use (PC, display and other possible connected devices) taking full consideration of the environment in which they are used.

Should the installation result in the establishment of a “medical electrical system” through electrical and functional connection of devices, the healthcare organization is in charge of the required safety verification and acceptance tests. This responsibility applies even where Ascom UMS/Distributor performed in whole or in part the wiring and the necessary connections.

4.2 Cleaning

Cleaning and disinfection procedures of hardware components must comply with the usual cleaning/disinfection procedures that the healthcare organization adopts for all the healthcare organization's equipment (both fixed and moveable).

Check the suggested cleaning procedures in the manuals of the hardware products that are used alongside Digistat Smart Central.

4.3 General precautions and warnings

To guarantee the reliability and security of the software during use, strictly observe the instructions given in this section of the manual.

Position all PCs appropriately to ensure adequate anterior and posterior ventilation. Failure to meet hardware ventilation requirements may cause equipment failure.

The healthcare organization shall ensure that the maintenance for the product and any third party device is implemented as requested to guarantee safety and efficiency and reduce the risk of malfunctioning and the occurrence of possible hazards to the patient and user.

The Product shall be used only by trained and authorized clinicians.

4.3.1 Electrical safety

The hardware devices (PC, display, barcode reader, etc...) used together with Digistat Smart Central must meet the requirements prescribed by the local legislation taking into consideration the environment in which they are used.

According to IEC 60601-1 standard, every computer placed within the “Patient Area” must be a medical grade device.

It is additionally recommended to perform all the relevant measurements on the leakage currents of the electro-medical system in use (PC, display and possible connected devices). The healthcare organization is responsible for these measurements.

The healthcare organization is responsible for all the required measurements on the electrical safety of the electro-medical system in use (PC, display and other possible connected devices) taking into consideration the actual environment in which the system is used.

4.3.2 Electromagnetic compatibility

The hardware devices (PC, display, barcode reader, etc...) used together with Digistat Smart Central must meet the requirements prescribed by the local legislation taking into consideration the environment in which they are used.

4.3.3 Devices eligibility

The hardware devices (PC, display, barcode reader, etc...) used together with Digistat Smart Central must meet the requirements prescribed by the local legislation taking into consideration the environment in which they are used.

4.4 Privacy Policy

Appropriate precautions should be taken in order to protect the privacy of users and patients, and to ensure that personal data is processed by respecting data subjects' rights, fundamental freedoms and dignity, particularly with regard to confidentiality, personal identity and the right to personal data protection.
Special attention shall be dedicated to Protected Health Information (PHI) in accord with the stipulations of the US Health Insurance Portability and Accountability Act (HIPAA).

Protected health information (PHI) under US law is any information about health status, provision of health care, or payment for health care that is created or collected by a Covered Entity (or a Business Associate of a Covered Entity), and can be linked to a specific individual.
According to the US Health Insurance Portability and Accountability Act (HIPAA), PHI that is linked based on the following list of 18 identifiers must be treated with special care:

1. Names
2. All geographical identifiers smaller than a state,
3. Dates (other than year) directly related to an individual
4. Phone numbers
5. Fax numbers
6. Email addresses
7. Social Security numbers
8. Medical record numbers
9. Health insurance beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers;
13. Device identifiers and serial numbers;
14. Web Uniform Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers, including finger, retinal and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code except the unique code assigned by the investigator to code the data

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The healthcare organization needs to assure that the use of the product is in line with the HIPAA requirements specifically respect the management of aforementioned information.

Digistat Smart Central manages the following PHI:

- First name and surname

- Birthdate
- Sex
- Patient code (MRN)
- Admission date
- Discharge date
- Patient weight
- Patient height

Digistat Smart Central can be configured to automatically hide the PHI on every application screen.
To do that, on the Digistat Smart Central Configuration Application, set the system option named “Privacy Mode” to “true” (see next chapters for the detailed procedure). Its default value is “true”.
If the “Privacy Mode” option is set to true, the following cases are possible:

- with no user logged in, no patient information is displayed.
- with a user logged in, and the user does not have a specific permission, no patient information is displayed.
- with a user logged in, and the user does have a specific permission, patient information is displayed.

The option can be applied to a single workstation (i.e. different workstations can be configured differently)

Please read the following precautions carefully and strictly observe them.

- The workstations must not be left unattended and accessible during work sessions. It is recommended to log out when leaving a workstation. See paragraph 5.5 for log out procedure.

- PHI saved in the product, such as passwords or users’ and patients’ personal data, must be protected from possible unauthorized access attempts through adequate protection software (antivirus and firewall). The healthcare organization is responsible for implementing this software and keep them updated.

- The lock function (paragraph 5.5.1) should be used only when strictly necessary. Automatic log out protects the Product from unauthorized accesses.

In some circumstances, sensitive data /PHI are transmitted in non-encrypted format and using a connection which is not physically secure. An example of this kind of transmission are the HL7 communications. The healthcare organization is responsible for providing adequate security measures to comply with the local privacy laws and regulations.

PHI can be present inside some reports produced by the Digistat Smart Central. The healthcare organization needs to manage these documents according to HIPAA regulation.

Client workstations (both desktop and mobile) do not store patient data on disk. Patient data is stored only inside database and database storage depends on the healthcare structure's procedures and choices (examples: physical machine, SAN, virtualization environment). Patient data shall be treated according all the current standards on privacy and personal data protection.

Patient data is not stored in proprietary files. The only place in which patient data is stored is database.

According to the HIPAA regulation, databases cannot leave the hospital without being encrypted.

4.4.1 User credentials features and use

This section explains the Digistat Smart Central user credentials (username and password) features, their use and recommended policy.

- Every precaution must be taken in order to keep personal username and password secret.
- Username and password must be kept private. Do not let anybody know your username and password.

- Each user can own one or more credentials to access Digistat Smart Central (username and password). The same username and password must not be used by more than one user.

- Authorization profiles must be checked and renewed at least once a year.

- It is possible to group different authorization profiles considering the similarity of the users' tasks.

- Each user account shall be linked with a specific person. The use of generic (for instance, "ADMIN" or "NURSE") must be avoided. In other words, for traceability reasons it is necessary that every user account is used by only one user.

- Each user has an assigned authorization profile enabling them to access only the functionalities that are relevant to their working tasks. The system administrator must assign an appropriate user profile when creating the user account. The profile must be reviewed at least once a year. This revision can also be performed for classes of users. The user profile definition procedures are described in the Digistat Smart Central installation and configuration manual.

- Password must be at least 8 characters.

- The password must not refer directly to the user (containing, for instance, user's first name, family name, date of birth etc.).

- The password is given by the system administrator at user account creation time. It must be changed by the user at first access in case this procedure is defined by configuration (see paragraph 5.10.3 for the password modification procedure).

- After that, the password must be changed at least every three months.

- If username and password are left unused for more than 6 months they must be disabled. Specific user credentials, used for technical maintenance purposes, are an exception. See technical manual for the configuration of this feature.

- User credentials must also be disabled if the user is not qualified anymore for those credentials (it is the case, for instance, of a user who is transferred to another department or structure). A system administrator can manually enable/disable a user. The procedure is described in the Digistat Smart Central installation and configuration manual.

The following information is reserved to system administrators:

The password must match a regular expression defined in the Digistat Smart Central configuration (default is ^.....* i.e. 8 characters). The password is assigned by the system administrator when a new account for a user is created. The system administrator can force the user to change the password at first access to the Digistat Smart Central. The password expires after a certain (configurable) period, after that period, the user must change the password. It is also possible (by configuration) to avoid password expiration.

See Digistat Smart Central installation and configuration manual for detailed information on user account creation procedures and password configuration.

4.4.2 System administrators

Ascom UMS/Distributor technical staff, when performing installation, updates and/or technical assistance may have access to personal data stored in the Digistat Smart Central database.

It is responsibility of the healthcare organization to adopt the necessary measures and provide instructions in order to comply with the local regulations.

4.4.3 System logs

Digistat Smart Central records the system logs on the database. These logs are kept for a configurable period of time. Also, logs are kept for different times depending on their nature. Default times are:

- information logs are kept for 10 days;
- logs of warning messages are kept for 20 days;
- logs of alarm messages are kept for 30 days.

These times are configurable. See Digistat Smart Central installation and configuration manual for the configuration procedures.

4.5 Backup policy

It is recommended to regularly perform system backups.

The healthcare organization using Digistat Smart Central must define a backup policy that best suits its data safety requirements.

Ascom UMS/Distributor is available to help and support in implementing the chosen policy.

The healthcare organization must ensure that backup files are stored in a way that makes them immediately available in case of need.

If data is stored on removable memory devices, the healthcare organization must protect these devices from unauthorized access. When these devices are not used anymore, they must be either securely deleted or destroyed.

According to the HIPAA standards, databases cannot leave the hospital without being encrypted.

4.6 Out of order procedure

Maintenance procedures and repairs shall be performed in compliance with Ascom UMS/Distributor procedures and guidelines and only by Ascom UMS/Distributor technicians or personnel specifically trained and explicitly authorized by Ascom UMS/Distributor.

This section describes the policy suggested by Ascom UMS in case a Digistat Smart Central workstation gets out of order. The goal of the procedure is to minimize the time required to successfully replace the out of order workstation.

Ascom UMS suggests the healthcare organization has substitute equipment and an additional PC on which Digistat Smart Central is already installed.

In case of a Digistat Smart Central workstation is out of order, the substitute equipment can promptly replace the Digistat Smart Central workstation.
Always remember that Digistat Smart Central must only be installed by trained authorized personnel. This includes Ascom UMS/Distributors staff and any other person specifically trained and explicitly authorized by Ascom UMS/Distributor. Without an explicit, direct authorization from Ascom UMS/Distributor, the healthcare organization staff are not authorized to perform installation procedures and/or to modify Digistat Smart Central configuration.

The risk related to the Digistat Smart Central workstation deactivation or substitution is that to associate the workstation with a wrong bed or room. This could lead to a “patient switch”, which is an extremely hazardous condition.

The risk related to the substitution and/or reconfiguration of network equipment involved in the Digistat Smart Central data acquisition (i.e. port server, docking station, etc...) is that of assigning the acquired data to a wrong patient. The patient-acquired

data relation is based on the IP address of the Digistat Smart Central workstation. Changing it could lead either to data flow interruption or, in severe cases, to assigning data to the wrong patient.

The out of order and replacement of a workstation is potentially hazardous. This is the reason why it must only be performed only by authorized and trained personnel.

The risk related to this procedure is that of associating a wrong bed/room/domain to the workstation, and therefore display data belonging to the wrong patients/beds.

In case a Digistat Smart Central workstation needs to be deactivated and replaced, the hospital staff must promptly call Ascom UMS (or authorized Distributors) and request the execution of this task.

Ascom UMS suggests the healthcare organization defines a clear, univocal operating procedure and to share this procedure with all the staff members involved.

In order to speed up replacement times, Ascom UMS suggests the healthcare organization has one or more substitution equipment with all the necessary applications already installed (OS, firewall, antivirus, RDP, ...) and with Digistat Smart Central already installed, but disabled (i.e. not executable by a user without the assistance of an Ascom UMS/Distributor technician). In case of out of order of a Digistat Smart Central workstation, the substitution equipment availability assures the minimization of restoration times (hardware substitution) and reduces the risk of associating patient data incorrectly.

In case of out of order of a Digistat Smart Central workstation we suggest to adopt the following procedure if a “substitution equipment” is available:

1) The healthcare organization’s authorized staff replaces the out of order PC with the “substitution equipment”
2) The healthcare organization staff calls Ascom UMS/Distributor and requests the “substitution equipment” activation
3) The Ascom UMS/Distributor staff disables the out of order workstation and correctly configure the “substitution equipment”
4) The out of order PC is repaired and prepared as “substitution equipment”

The instructions on how to enable/disable and replace a Digistat Smart Central workstation, reserved to system administrators, are in the Digistat Smart Central installation and configuration manual.

4.6.1 Reconfiguration/substitution of network equipment

In case it is necessary to either reconfigure or substitute a network device involved in the Digistat Smart Central data acquisition, the healthcare organization staff must promptly call Ascom UMS/Distributor and schedule the substitution/reconfiguration

procedure to allow Ascom UMS/Distibutor staff to either reconfigure Digistat Smart Central or provide all the necessary information to the healthcare organization. It is recommended, for this purpose, to define a clear procedure and share it with all the involved personnel. Some general indications about this are in the Digistat Smart Central installation and configuration manual.

4.7 Preventive maintenance

Maintenance procedures and repairs shall be performed in compliance with Ascom UMS/Distributor procedures and guidelines and only by Ascom UMS/Distributor technicians or personnel specifically trained and explicitly authorized by Ascom UMS/Distributor.

It is suggested to perform the maintenance of Digistat Smart Central at least once a year. Maintenance frequency is a function of system complexity. In case of high complexity, it is suggested to perform maintenance more often, typically up to twice a year.

See the Digistat Smart Central installation and configuration manual for the maintenance checklist.

4.8 Compatible devices

Digistat Smart Central is compatible with Digistat Connect 5.0.0 and it is able to display data from ventilators, patient monitors and infusion pumps. Please contact Ascom UMS/Distributor for the list of available drivers.

Purpose of Digistat Smart Central is to forward information from patient monitors, ventilators, infusion pumps to the designated display device(s).

4.9 Digistat Smart Central unavailability

If during start up there are problems connecting to the server Digistat Smart Central provides a specific information message (Fig 2).

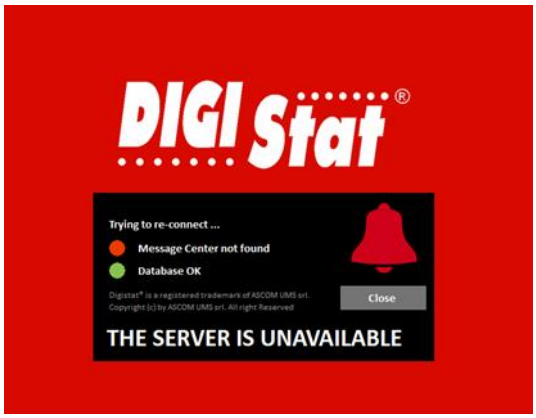


Fig 2

The connection problem is often automatically solved in a short time. If it does not happen, it is necessary to contact the technical assistance (see section 10 for the contacts list).

In rare, often extreme cases, it may be physically impossible to use Digistat Smart Central, for example cases of natural disasters, or long black outs.

It is responsibility of the healthcare organization using Digistat Smart Central to define an emergency procedure to put into effect in those cases. This is necessary to

1) Make it possible for the departments to keep on working
2) Restore as soon as possible the Product to full availability (back-up policy is part of this management. See paragraph 4.5).

It is responsibility of the healthcare organization using Digistat Smart Central to define an emergency procedure to put into effect in case of unavailability.

Ascom UMS/Distributor offers full support for the definition of such procedure.

See section 10 for the contacts list.

5. Digistat Smart Central “Control Bar”

5.1 Introduction

This section of the manual describes the features and functions of the Digistat Smart Central Control Bar.

5.2 Touch screen

Digistat Smart Central can run both on touch and non-touch workstations. The same procedures can be performed using fingers or mouse device. In this manual “mouse”, terminology is used throughout, with terms as “click” instead of “tap”, for instance. Here is a quick translation table making it possible to apply this manual to all kinds of workstations and user preferences. When specific gestures can be applied to specific screens/functionalities, it will be highlighted in the relevant context. In general, the main actions can be translated this way:

Mouse	Touch Screen
Click	Tap
Double click	Double tap
Drag	Flick
Use scrollbars	Scroll
Zoom in	Two fingers tap

5.3 Launching Digistat Smart Central

To launch Digistat Smart Central:

- Double click the desktop icon (Fig 3)

Fig 3

The following splash-screen appears while the Digistat Smart Central is loading.

Fig 4

5.4 Digistat Smart Central Work Area

The Digistat Smart Central Work Area is defined and enclosed by Control Bar, a tool that is common to all Digistat Smart Central installations (Fig 5).

Control Bar manages the patients and the users.
The Digistat Smart Central Control Bar is formed by a horizontal command bar (Fig 5 **A**), by a vertical selection bar on the left ("Lateral Bar" - Fig 5 **B**) and by a central Work Area. The different screens of the installed modules are displayed within the Work Area (Fig 5 **C**).

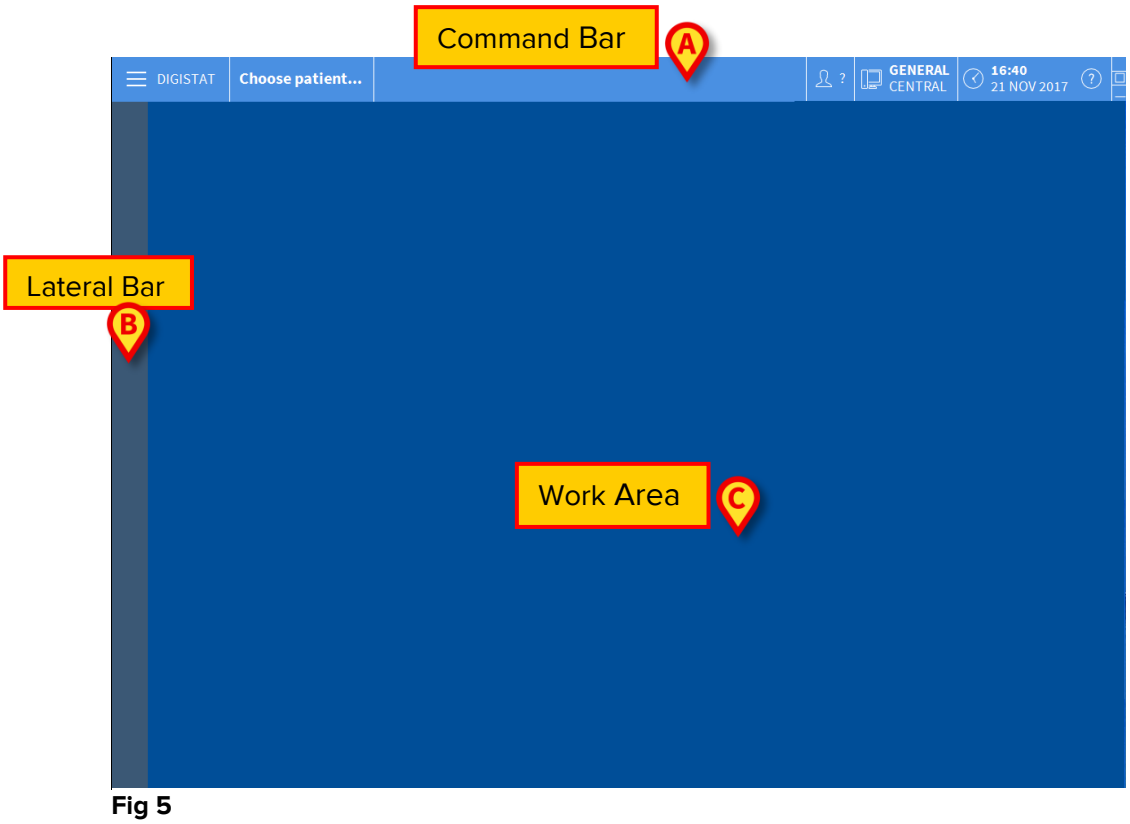


Fig 5

The command bar (Fig 5 **A**) will be described in paragraphs 5.4.1 and beyond.

The lateral bar displays the icons of the currently available modules. See Fig 6.

Fig 6

The module currently selected is highlighted (white).

5.4.1 Selecting a module

To select a module:

- Click the corresponding icon in the lateral bar

The icon will be highlighted and the module's functionalities will be displayed within the Work Area.

It is only possible to select a specific module after the user log in (see next paragraph).

5.5 Accessing Digistat Smart Central

Digistat Smart Central must be accessed by entering the username and password ("Log in" procedure).

For this reason, at the beginning of every work session, it is necessary to click the **User** button (Fig 7 **A**).

The following screen is displayed.

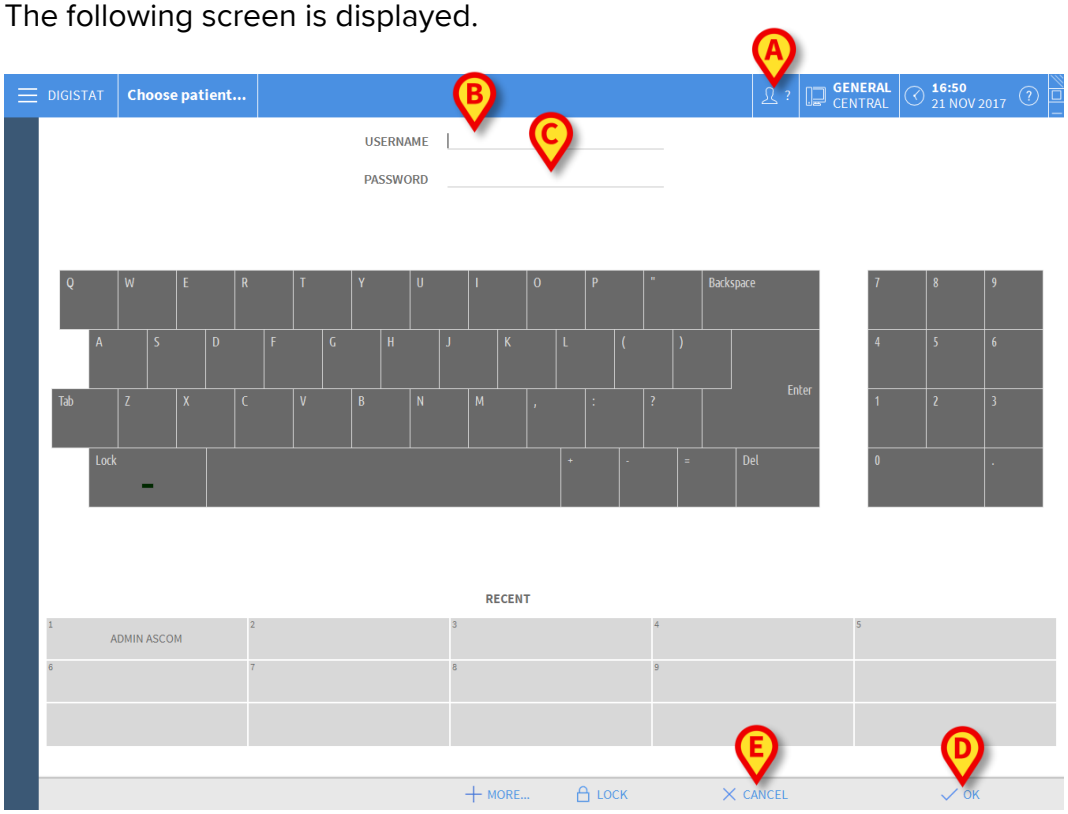


Fig 7

To access Digistat Smart Central:

- Enter your username in the "**Username**" field (Fig 7 **B**)
- Enter your password in the "**Password**" field (Fig 7 **C**)
- Click the **Ok** button (Fig 7 **D**)

The user is this way logged in. To cancel the operation:

- Click the **Cancel** button (Fig 7 **E**)

The username and password are issued by the system administrator. If you do not have a username and a password you are not authorized to use Digistat Smart Central .

The user can enter your username and password using either the virtual keyboard displayed on screen (clicking the letters with the mouse or touching them if using a touch screen) or the workstation keyboard.

After accessing the Digistat Smart Central, an acronym corresponding to the logged user appears on the **User** button on the control bar (the acronym is ADM in Fig 8 **A**).

Fig 8

The user whose credentials are displayed on the User button is responsible for all the actions performed on Digistat Smart Central . It is strongly recommended to log out before leaving the Digistat Smart Central workstation to avoid improper use.

To log out, click the **User** button during the work session. When this button is clicked, the user is disconnected and the acronym of the user disappears from the button.

To log in again, click the **User** button again. The screen shown in Fig 7 will appear again.

Digistat Smart Central does not support the Microsoft® Windows® "switch user" functionality.
This means that, for instance, if

a) User 1 launches Digistat Smart Central,
b) User 1 switches to User 2 without logging out User 1,
c) User 2 attempts to launch Digistat Smart Central again,

Then the second Digistat Smart Central instance cannot be launched because the first one is still running.

5.5.1 Disabling the automatic log out

If the Product is not used, or remains idle for a certain length of time, the user is automatically disconnected (automatic log out). This length of time depends on a configuration parameter.

To stop automatic log out from happening the user must click the lock button after entering the username and password but before clicking **Ok** (Fig 9 **A**).

Fig 9

If the user is locked, a padlock is shown at the bottom of the user icon (Fig 10).

Fig 10

The user is advised against the frequent use of the lock function. Automatic log out is implemented to protect Digistat Smart Central from unauthorized accesses.

5.5.2 Recent users

The “Recent” area of the “Login” screen (Fig 11 **A**) displays the names of users who have accessed Digistat Smart Central recently.

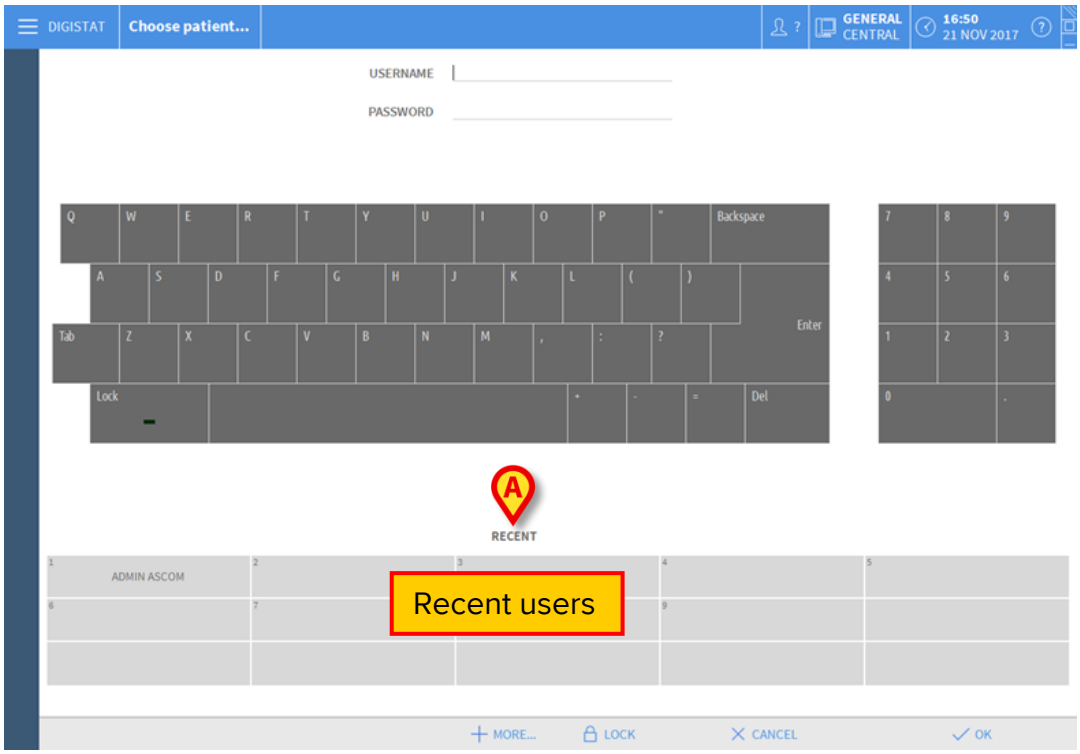


Fig 11

The area is divided into rectangles. The names of the users who accessed Digistat Smart Central recently appear inside the rectangles. When any of these rectangles is **clicked**, the “Username” field is automatically filled with the name appearing inside the rectangle.

5.5.3 How to use the “User List”

The **More** button on the control bar (Fig 12) makes it possible to display the complete list of possible users.

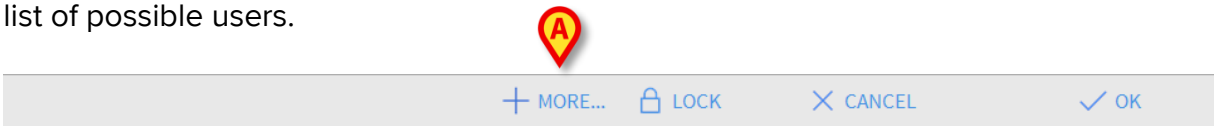


Fig 12

To display the “User List”:

- Click the **More** button

The following window is displayed (Fig 13).

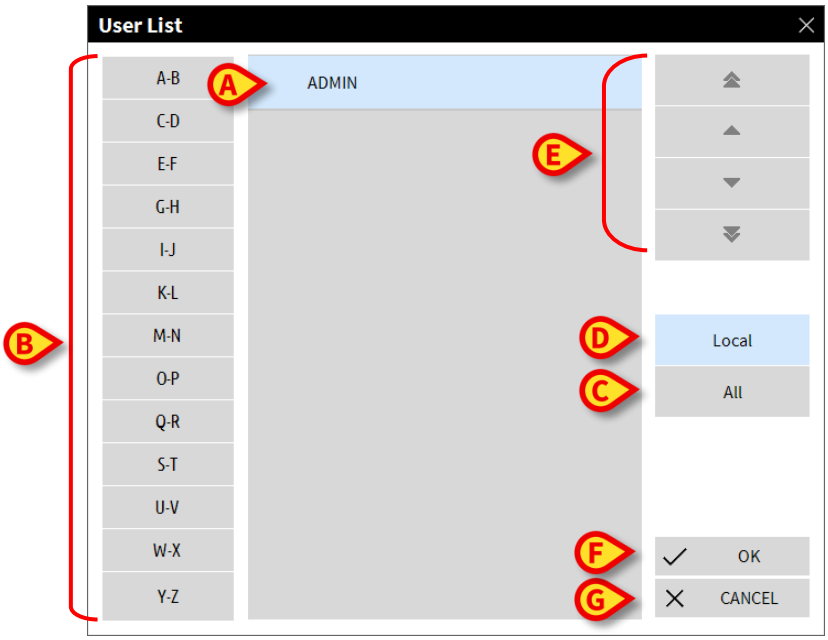


Fig 13

The window shown in Fig 13 can be used as an index book enabling the search and selection of a user in the list of all the possible users.

The central part of the window shows the names of possible users, in alphabetical order (Fig 13 **A**).

The letters on the left side of the window (Fig 13 **B**) work like an index and make it possible to see only the users whose names begin with a specific letter.
For example: click the **C-D** button to see the list of patients whose names begin with the letters C or D.

Use the **All** button (Fig 13 **C**) to see the list of all possible users.

Use the **Local** button (Fig 13 **D**) to see the list of users relating to the specific workstation on which you are currently working.

Use the arrows on the right side of the window (Fig 13 **E**) to scroll up and down the list of users.

To select a user:

- **Click** the name of the user

The name will be highlighted, then

- Click the **Ok** button (Fig 13 **F**)

Otherwise, you can:

- **Double-click** the row displaying the name of the user

After selection, the "**User list**" window closes and the name of the selected user appears in the "**Username**" field on the "**Login**" screen (Fig 7 **B**).

Use the **Cancel** button (Fig 13 **G**) to cancel the operation and close the "User list" window without selecting any user.

5.6 Digistat Smart Central Control Bar

The control bar that appears in the lower part of the screen is common to all Digistat Smart Central modules. Its main characteristics are listed below, with more detailed explanation of its functionalities provided in the following sections.

Fig 14

- The **Patient** button (Fig 14 **A**) will contain, after a patient has been selected, the patient's name and, if the patient has been admitted, their bed number.
- The User button (Fig 14 **B**) shows the name of the user connected.
- Use the Menu button (Fig 14 **C**) to open the following window (Fig 15).

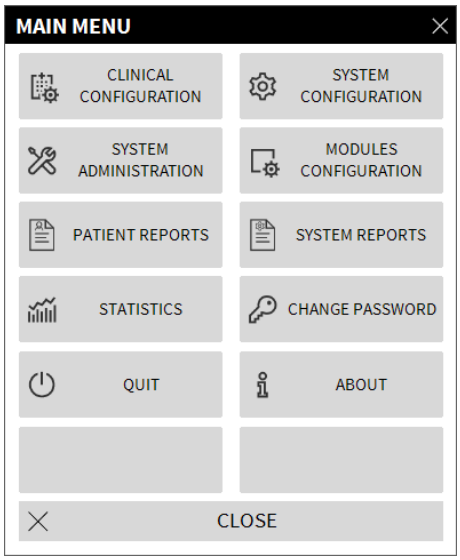


Fig 15

The buttons contained in this window give the user access to functionalities that will be described later.

- The button indicated in Fig 14 **D** is used by the Product to signal that there are notifications for the user.
- Date - time indication (Fig 14 **E**).

- Use the Help button (Fig 14 **F**) to access the documentation available.

- The small buttons highlighted in Fig 14 **G** can be used to:
  1) minimize the Digistat Smart Central window;
  2) select the full-screen display mode;
  3) select the window display mode.

These three buttons are present only if enabled by configuration.

5.6.1 How to read the "Patient" button

Patient selected

When a patient is selected, the **Patient** button displays the name of the selected patient (Fig 16 **A**). See the documentation of the specific modules for the patient selection procedure.

Fig 16

Patient admitted

When a patient is admitted, the bed number and the name of the department where he/she is admitted are displayed next to the **Patient** button (Fig 17).

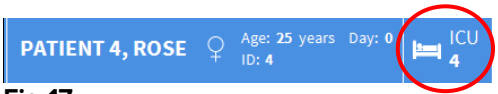


Fig 17

The box of the department name and the bed number are not highlighted if the patient belongs to the workstation domain (see Fig 17).
The box of the department name and the bed number are highlighted yellow if the patient is located in a domain that does not belong to the workstation domain (Fig 18 - the workstation domain is defined by configuration).

Fig 18

Every workstation is configured to be associated with a set of "beds" (domain). The user is enabled to perform certain actions only on the patients that are admitted to a bed belonging to this set. The red colour in the *PATIENT* button is used to advise the user that the patient selected is not in this set.

The signal "Other location" (Fig 19) appears when, at patient admission time, the user specified that the patient is not in one of the configured departments.

Fig 19

5.7 Help

Click the **Help** button on Control Bar (Fig 14 **F**) to access the online documentation available. The screen shown in Fig 20, or similar, depending on the available documentation, will open.

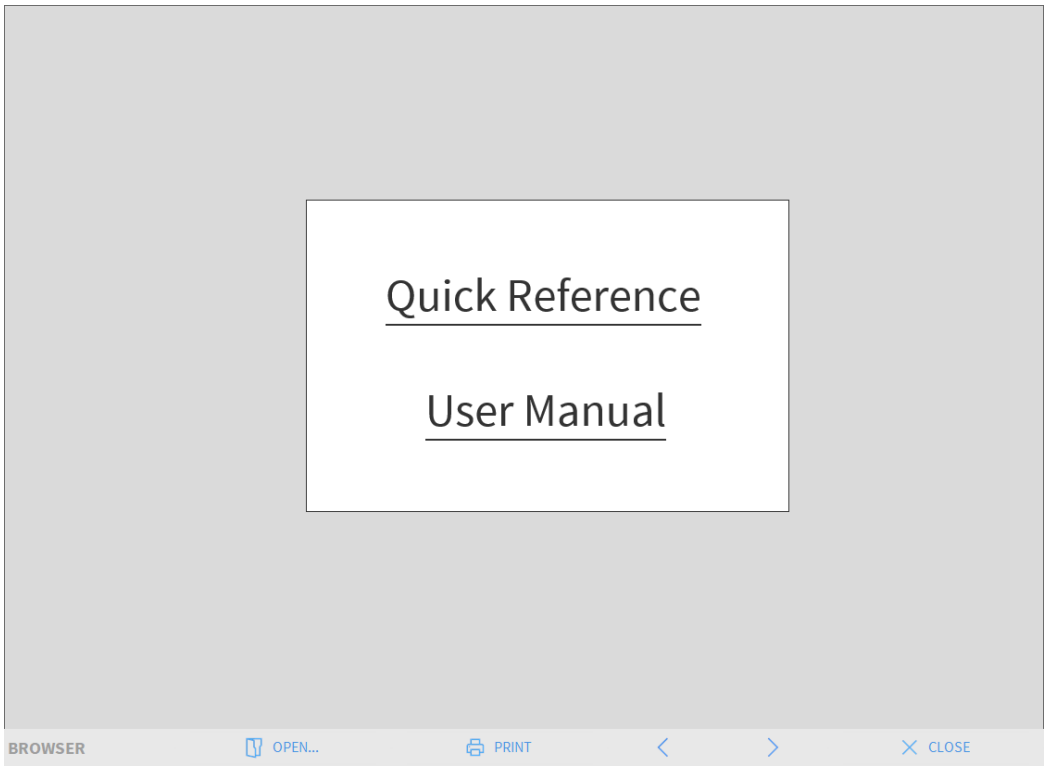


Fig 20

The command bar (Fig 21) offers some navigation possibilities.

Fig 21

- the **Open** button makes it possible to open other documents (if the user has the required permissions);
- the **Print** button prints the currently displayed document;
- the < and > buttons display either the previous or the next page of the document;
- the **Close** button closes the online help.

5.8 Digistat Smart Central Main Menu

The **Menu** button placed on the Digistat Smart Central Control Bar (Fig 22).

Fig 22

Opens a menu containing several options (Fig 23).

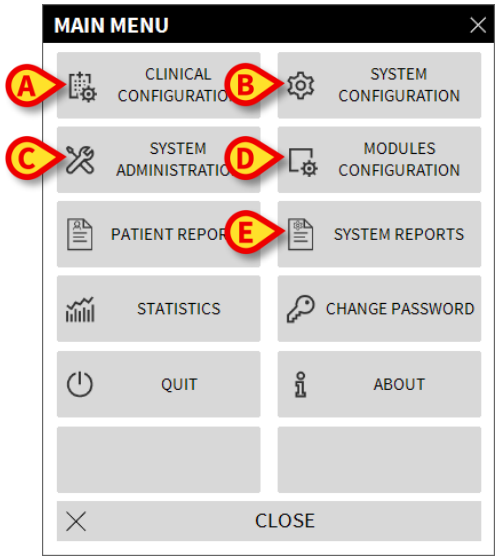


Fig 23

Each button on the menu accesses a specific set of functions.

The procedures associated with the following buttons relate to system configuration and are therefore reserved to the system administrators.

Clinical configuration - (Fig 23 **A**)

System configuration - (Fig 23 **B**)

System administration - (Fig 23 **C**)

Modules configuration- (Fig 23 **D**)

System reports - (Fig 23 **E**)

Contact your system administrator for the other procedures associated to these buttons.

The other buttons, indicated in Fig 24, make it possible to access features and functions that some users can perform (according to their permission level). These will be described in the following sections.

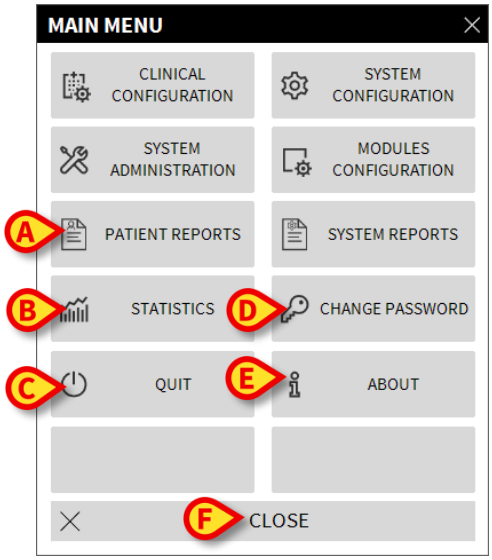


Fig 24

Patient reports - (Fig 24 **A**, paragraph 5.9)

Statistics - (Fig 24 **B**, paragraph 5.10.2)

Quit - (Fig 24 **C**, paragraph 5.10.5)

Change Password - (Fig 24 **D**, paragraph 5.10.3)

About - (Fig 24 **E**, paragraph 5.10.4)

The **Close** button (Fig 24 **F**) closes the “Main menu” window (Fig 24).

5.9 Patient reports

The "**Patient reports**" button (Fig 24 **A**) is not enabled in the present Smart Central configuration.

5.10 Print reports

This paragraph describes the Product's general print functionalities. Whenever the print functionality is accessible, it is indicated in the specific section/paragraph of the manual. Refer to this paragraph for general instructions.

To print a patient report:

- Click the relevant **Print** button

A print preview of the selected document will open (Fig 25).

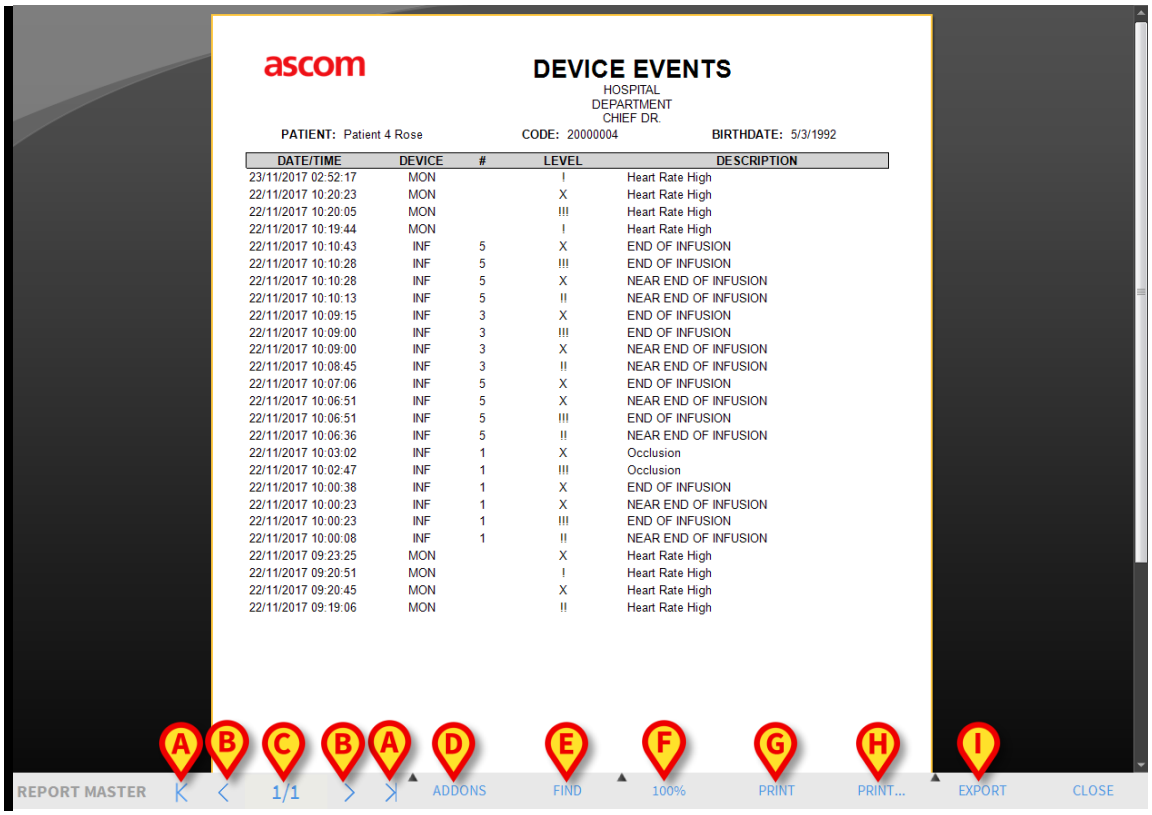


Fig 25

The buttons on the command bar of the "Print preview" screen make it possible to perform various actions, listed below.

Use the and buttons to reach the beginning and the end of the document.

Use the and buttons to go to the previous or the next page.

The display 1/1 indicates the current screen number.

The **Addons** button activates the possible additional print management options (in this configuration the “Watermarks” option is available - see paragraph 5.10.1.1 for a description of these options).

The **Find** button makes it possible to search the displayed document. See paragraph 5.10.1.2 for more instructions.

The button indicating the **100%** percentage is a zoom, making it possible to change the display mode. See paragraph 5.10.1.3 for more instructions.

Use the **Print** button (Fig 25 **G**) to print the report.

Use the **Print...** button (Fig 25 **H**) to display the print options window (Fig 31). See paragraph 5.10.1.4 for a description of this window and the related procedures.

Use the **Export** button (Fig 25 **I**) to export the document contents to different file extensions. See paragraph 5.10.1.5 for more instructions.

Use the **Close** button to close the “Print preview” screen.

5.10.1.1 Addons

The **Addons** button (Fig 25 **D**) activates the possible additional print management options.

To display the available options:

- Click the **Addons** button
- Click the button corresponding to the functionality you want to activate

Addons - Watermark

To add watermarks to the print report (either text or image, if the option is enabled by configuration),

- Click **Addons** and then **Mark**

The following window is displayed (Fig 26).

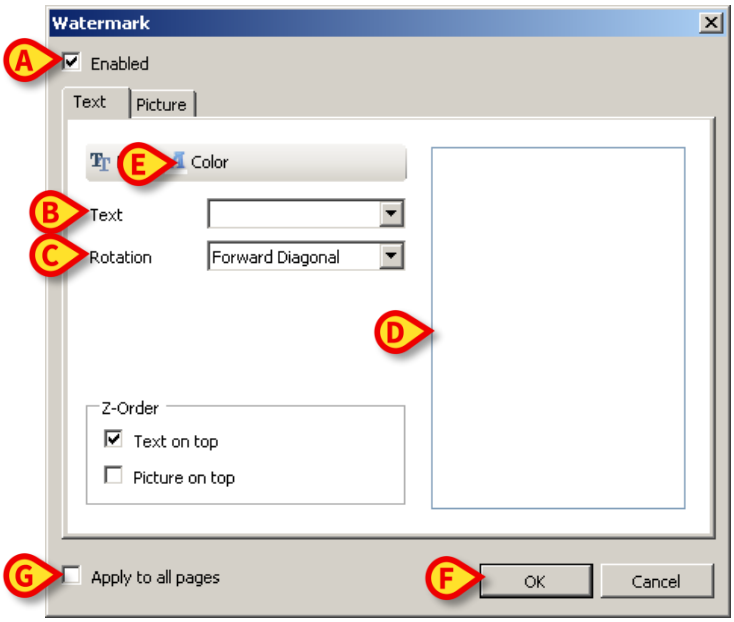


Fig 26

To add a textual watermark:

- Ensure that the "**Enabled**" checkbox is checked (Fig 26 **A**). If not, the window's contents cannot be edited
- Insert the text in the "**Text**" field (Fig 26 **B**)
- Use the "**Rotation**" menu (Fig 26 **C**) to specify the watermark orientation (diagonal, horizontal, vertical)

A print preview is displayed in the area indicated in Fig 26 **D**.

- Use the buttons indicated in Fig 26 **E** to select the watermark font and color
- Click the **Ok** button (Fig 26 **F**)

The text is this way inserted as watermark.

If the "**Apply to all pages**" checkbox is selected (Fig 26 **G**) the watermark is applied to each page in the document, otherwise it is applied only to the current page.

To insert a picture as watermark:

- Click the "**Picture**" tab indicated in Fig 27 **A**

The following window is displayed (Fig 27).

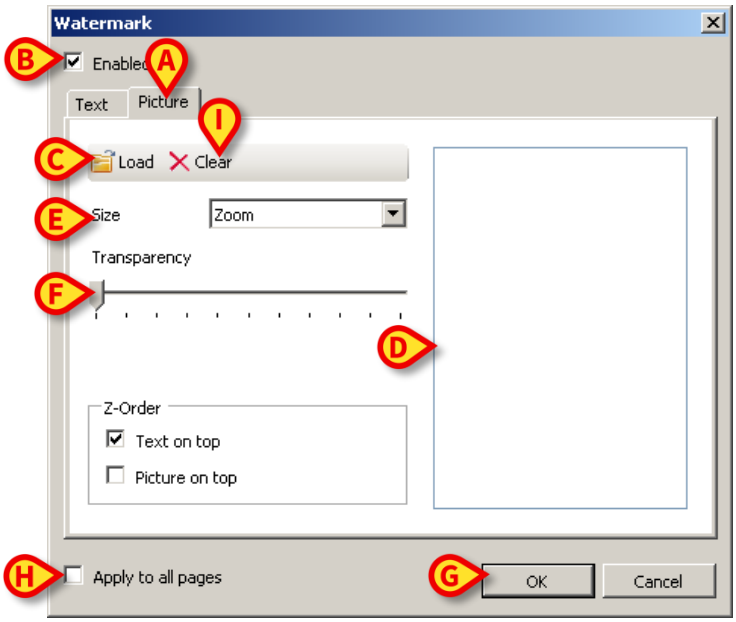


Fig 27

Follow these steps to insert an image as watermark:

- Ensure that the "**Enabled**" checkbox is checked (Fig 27 **B**). If not, the window's contents cannot be edited
- Click the "**Load**" button indicated in Fig 27 **C**

This opens the window making it possible to browse the computer contents.

- Search and select the image to be uploaded

The image is displayed in the area indicated in Fig 27 **D**.

- Use the "**Size**" drop-down menu to set the size of the image (Fig 27 **E**)
- Use the "**Transparency**" cursor to set the transparency level of the watermark image (Fig 27 **F** - maximum transparency when the cursor is on the left)
- Click the **Ok** button (Fig 27 **G**). The watermark image is this way inserted

If the "**Apply to all pages**" checkbox is selected (Fig 27 **H**) the watermark is applied to each page in the document, otherwise it is applied only to the current page.

To delete an already selected image:

- Click the "**Clear**" button indicated in Fig 27 **I**

5.10.1.2 Find

The **Find** button (Fig 25 **E**) makes it possible to search the print report currently displayed.

To search the print report:

- Click the **Find** button

The following window opens (Fig 28).

Fig 28

- Insert in the window the text to be found in the print report (Fig 29 **A**)

Fig 29

- Click the  button (Fig 29 **B**)

The text specified, if found, will be highlighted in the print report.

- Click the  button again to search for the other instances in the text

5.10.1.3 Zoom

The **Zoom** button (on which, by default, the **100%** size is displayed - Fig 25 **F**) is a zoom, making it possible to change the display size and mode.

To change the display mode:

- Click the **Zoom** button. The following menu is displayed (Fig 30)

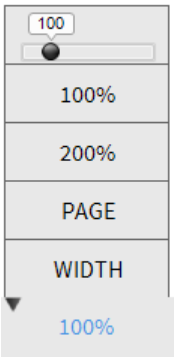


Fig 30

➢ Click the required zoom option on the menu

The page is displayed accordingly. The mode currently selected is indicated on the button.

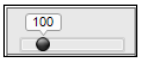
The following options are available:

The **Width** button makes it possible to display the page using the full screen width;

the **Page** button displays the whole page;

the **200%** button doubles the page size (200% zoom);

the **100%** button displays the page in its actual size (100% zoom);

the 

area contains a cursor that can be used to zoom the page contents (left is zoom out, right is zoom in). The percentage value corresponding to the page size is displayed above the cursor. Values range from 25 to 500 %. The selected value is also displayed on the **Zoom** button on the command bar after selection.

5.10.1.4 Print

The **Print...** button opens a window offering several print options.

➢ Click the **Print...** button (Fig 25 **H**) to display the print options window (Fig 31)

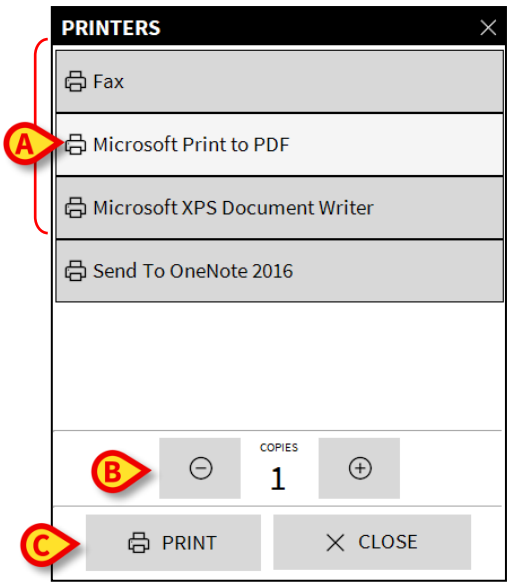


Fig 31

This window makes it possible to select the printer and the number of copies to be printed.

➢ Click the appropriate printer on the menu to select the printer (Fig 31 **A**)

- Use the ⊖ (one less copy) and the ⊕ (one more copy) buttons to specify the number of copies (Fig 31 **B**)

- Click the **Print** button (Fig 31 **C**) to print the report

5.10.1.5 Export

The **Export** button (Fig 25 **I**) makes it possible to export the displayed document contents to different file extensions.

- Click the **Export** button to open the “Export” menu

The menu displays all the file formats currently supported.

- Click the option corresponding to the required file format

The document is exported to the corresponding file format.

5.10.2 Statistics

The **Statistics** button on the main menu (Fig 32) makes it possible to access the Product’s statistical calculation tools.

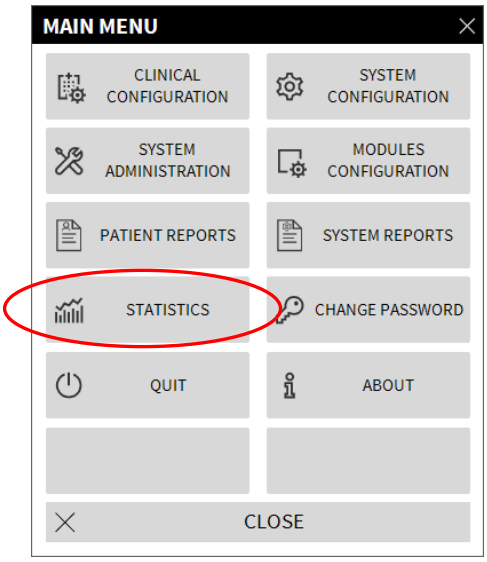


Fig 32

The button opens another menu (Fig 33) that enables access to various distinct tools. The type and number of accessible tools depend on the configuration in use and the specific modules installed.

These tools are mainly reserved for the system administrators. Please see the specific technical documentation for a description.

The “Query assistant” tool, which is accessible for users having specific permissions, is described in the next section.

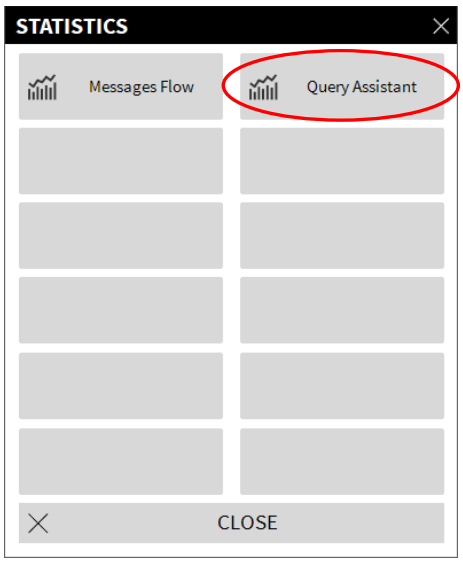


Fig 33

5.10.2.1 Query Assistant

The **Query Assistant** button (Fig 33) accesses a tool to create, save and execute queries on the Digistat Smart Central database (Fig 34).

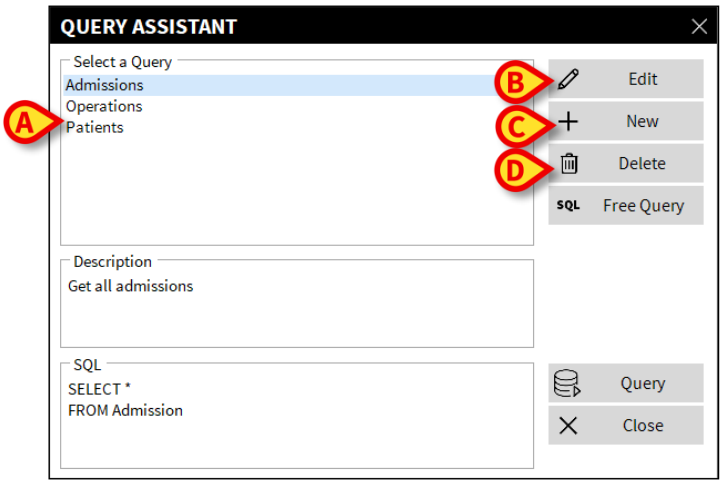


Fig 34

The user can select a query from a list of pre-defined queries, which will execute the query and display the results in a specific window.

The “Select a Query” area displays the list of all the pre-defined queries (Fig 34 **A**).

To run a query:

- Click the corresponding name on the list.

The name will be highlighted (Fig 35 **A**).

A textual description of the query is displayed in the “Description” area (Fig 35 **B**).

The “SQL” area (indicated in Fig 35 **C**) displays the content of the query in SQL language (Structured Query Language).

The **Edit** button placed on the right of the “Query Assistant” window (Fig 34 **B**) makes it possible to edit an existing query.

The **New** button placed on the right of the “Query Assistant” window (Fig 34 **C**) makes it possible to create a new query.

The **Delete** button placed on the right of the “Query Assistant” window (Fig 34 **D**) makes it possible to cancel an existing query.

The “edit”, “delete” and “new” query options are reserved for the system administrators.

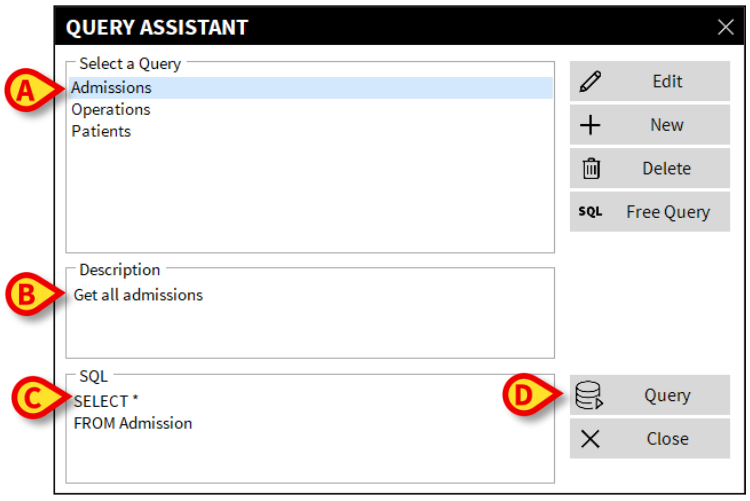


Fig 35

To run the query:

- Click the **Query** button (Fig 35 **D**).

The results are displayed in a new window, as a table (Fig 36).

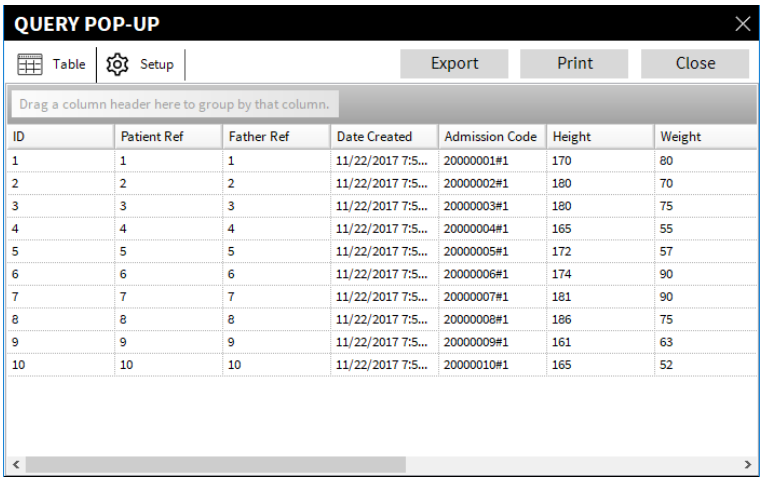


Fig 36

5.10.3 Change password

The **Change Password** button on the Digistat Smart Central main menu (Fig 37 **A**) opens a window making it possible to change the password of the user currently logged to the Digistat Smart Central.

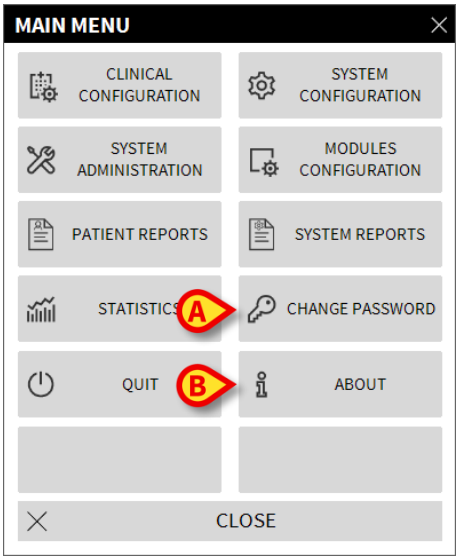


Fig 37

To change the user password:

- Click the **Change Password** button (Fig 37 **A**). The “Change password” window will open.

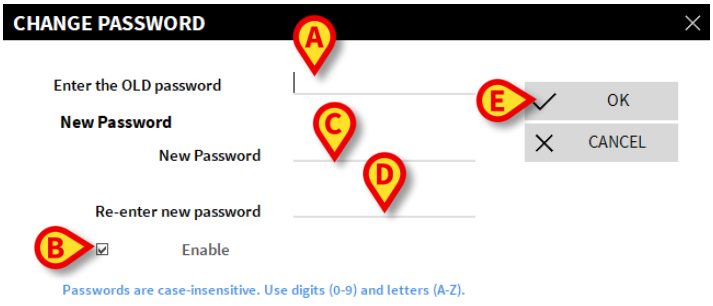


Fig 38

- Type the current password in the "**Enter the OLD password**" field (Fig 38 **A**).
- Verify that the "**Enable password**" checkbox (Fig 38 **B**) is selected.
- Type the new password in the field indicated in Fig 38 **C**.
- Type again the new password in the field "**Re-enter new password**" (Fig 38 **D**).
- Click the **Ok** button (Fig 38 **E**).

The passwords are not sensitive to uppercase and lowercase. The passwords can only be formed by numbers (0 to 9) and letters (A-Z).

5.10.4 About Digistat Smart Central

The **About** button on the Digistat Smart Central main menu (Fig 37 **B**) displays a window containing information on the Digistat Smart Central version installed and the related licenses (in Fig 39 an example).

Fig 39

5.10.5 Quit Digistat Smart Central

The **Quit** button on the Digistat Smart Central main menu (Fig 41 **A**) makes it possible to quit the Digistat Smart Central environment.

To quit Digistat Smart Central:

- Click the **Menu** button on the control bar (Fig 40)

Fig 40

The Digistat Smart Central main menu will open (Fig 41).

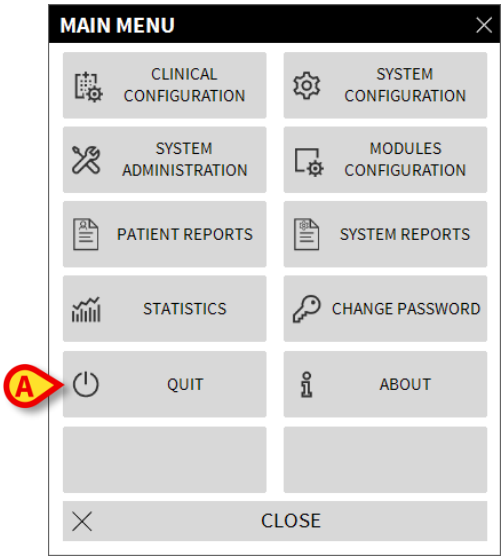


Fig 41

- Click the **Quit** button (Fig 41 **A**)

Another menu is displayed (Fig 42).

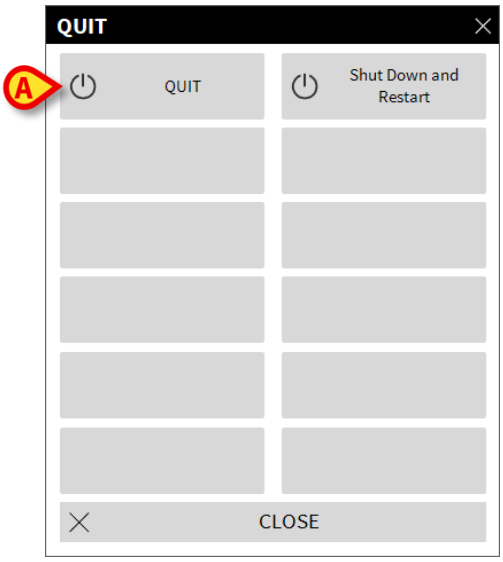


Fig 42

➢ Click the **Quit** button again (Fig 42 **A**)

User confirmation is required (Fig 43).

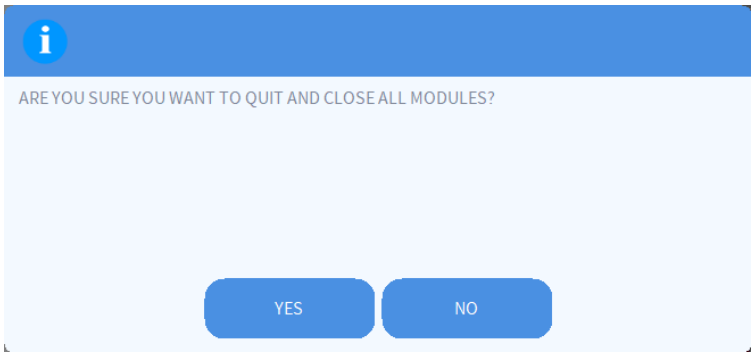


Fig 43

➢ Click **Yes** to exit Digistat Smart Central.

Specific permissions are required to exit Digistat Smart Central. Not all Digistat Smart Central users are enabled to close Digistat Smart Central.

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6. Digistat Smart Central

6.1 Information for the user

Please read carefully the following warnings.

The purpose of Digistat Smart Central is to help with alarm management and shall not be used as a remote alarm system or as an alarm replicator.

Digistat Smart Central must not be used to replace the monitoring of the device alarms.

Digistat Smart Central is not designed to verify that connected devices are working correctly but rather to acquire and catalog clinical data.

Disconnecting a device while it is running causes the interruption of data acquisition on Smart Central. Device data that is lost during the disconnection period are not recovered by Smart Central after reconnection.

Digistat Smart Central does not replace a Nurse Call system.

In case a “Nurse call” system is in use, it is recommended to never disable the “Nurse call” system.

Never disable the alarm systems on the medical devices unless explicitly allowed by the usual healthcare organization procedures.

The correctness of each message notified by Digistat Smart Central must always be double-checked on the actual device that supposedly generated it.

Never disable the audio on the workstations on which Digistat Smart Central is running.

The operator shall be positioned at a maximum distance of 1m (3,28 ft) to be able to read the notifications on the Smart Central. Within a maximum distance of 4m (13,12 ft) it is possible for the Operator to see that there is an alarm.

This is true if:

- the Operator has a visual acuity of 0 on the logMAR scale or 6-6 (20/20) vision
  (corrected if necessary),
- the viewpoint is at the Operator's position or at any point within the base of a cone
  subtended by an angle of 30° to the axis horizontal to or normal to the center of the plane
  of display of the monitoring display or visual indication,
- the ambient illuminance in the range of 100 lx to 1 500 lx.

For reasons that are outside the control of the software, for instance, the way the actual physical devices are installed/cabled, delays are possible between the alarm generation and the actual alarm display.

!	The Product acquires the information generated by the primary medical devices and displays them. Therefore, the Product always reports what the primary medical devices communicate. The assignment of alarm priorities is decided according on the primary medical device. On Digistat Smart Central it is possible to decide the order of the medical devices, for every bed, in accordance to the customer preference: per device type, model / manufacturer. The ordering of alarms is setup in Smart Central during deployment of the product according to the user request/preference. The color of every bed card is always the color of the highest priority alarm between all alarms occurring on that bed.

!	The update of data displayed on screen caused by device connection, power off, disconnection and change of status depends on the time required by the device itself to communicate the changes. This time depends on various factors. Among them is the device type and type of connection. For some devices, there are conditions in which the delay in communicating changes might be important. Since they might change depending on devices configuration and operational conditions, it is not possible to provide an indication of the delays for all the possible devices

!	Check that the medical devices are correctly connected by verifying that their data are displayed on the Digistat Smart Central.

!	Use the sound check procedure to verify if the audio on the workstation/handheld device is correctly working (see paragraph 6.10 for the procedure).

!	On the connected medical device where it is possible, generate an artificial alarm condition to verify that the corresponding alarm notification is correctly displayed on the Digistat Smart Central (it is suggested to perform this check at least once per shift).

Within the Digistat Smart Central the alarms are grouped in “physiological alarms”, “technical alarms” and “other”. This kind of differentiation has no impact on the way the alarms are displayed on the Digistat Smart Central interface.

The drivers used to read the data from the connected medical devices have a reading-cycle of less than 3 seconds (i.e. all the data from the devices is read every 3 seconds at maximum). However, there are devices that communicate the information less frequently (5-10 seconds interval). Refer to the specific driver documentation for details on the reading-cycle.
As soon as a driver detects an alarm, it takes maximum 1 second to transfer it to the Digistat Smart Central.

In case of electrical black-out, it takes a few minutes for Digistat Smart Central to be fully operative again and therefore generate alarm notifications (usually this time is less than 3 minutes, however it depends on the configuration of the used computers).

6.2 Module selection

To open the Digistat Smart Central:

- Click the corresponding icon on the lateral bar (Fig 44)

Fig 44

The Digistat Smart Central screen, shown in Fig 45, opens.

6.3 Digistat Smart Central functionality

The Digistat Smart Central screen displays an overview of the situation of each patient in the ward (Fig 45).

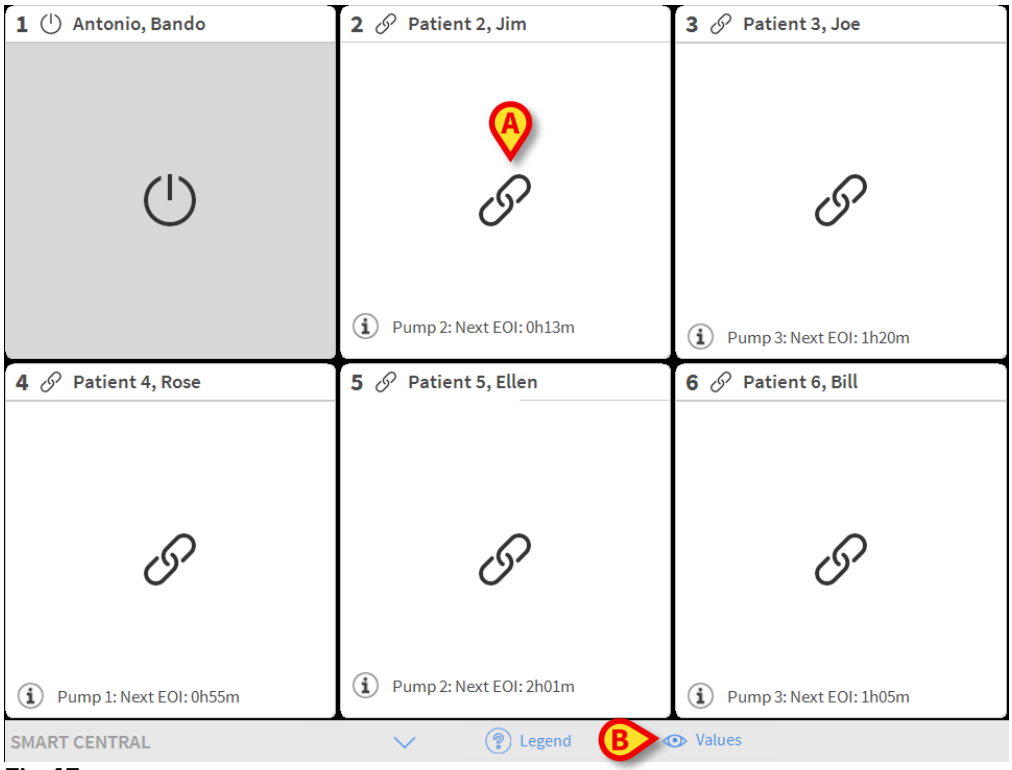


Fig 45

The screen is divided into rectangular areas, named “Bed areas” (Fig 45 **A**). Every area refers to a bed and displays information on the devices connected to the patient admitted to that bed. By default, only the data referring to alarmed beds is displayed (Fig 47), and only data relating to alarms is displayed. A bed is alarmed if at least one of the devices connected to the bed is alarmed. If multiple alarms occur at the same time on the same bed, the alarm with the highest priority is notified.
It is possible to display all the available data (both referring to the non-alarmed beds and referring to the non-alarmed devices on the alarmed beds) by clicking the “VALUES” button on the command bar (Fig 45 **B**).

To display all the available data:

- Click the **Values** button on the command bar (Fig 45 **B**)

The button will be selected. The available information will be displayed as in Fig 46.

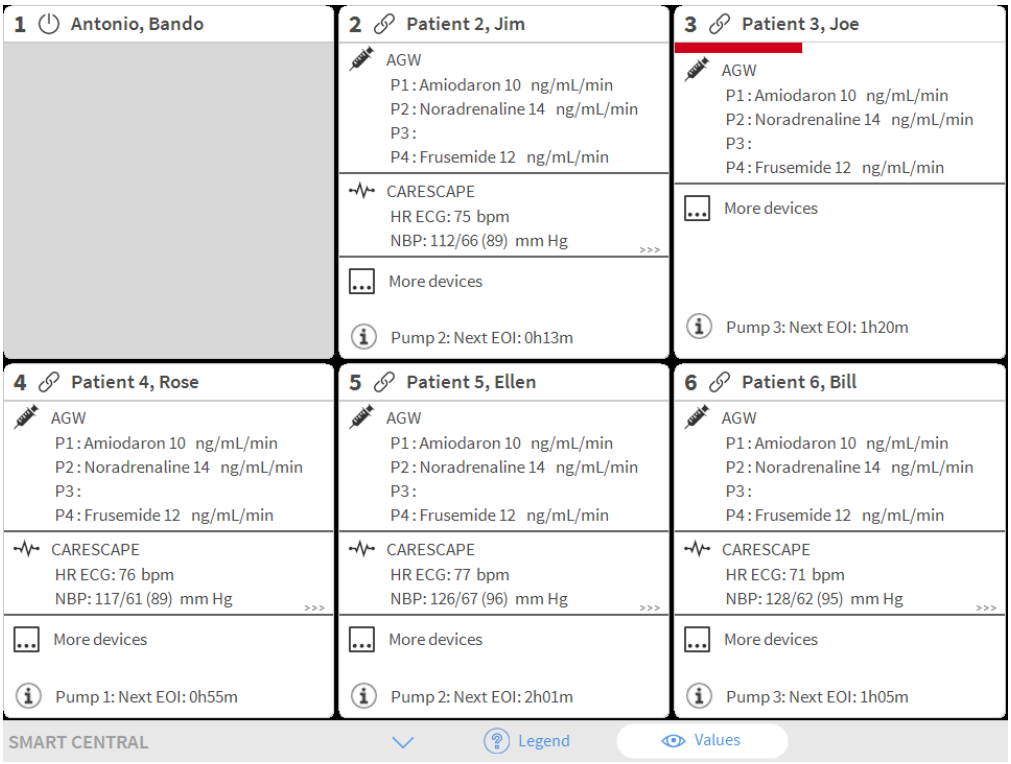


Fig 46

6.4 Bed areas

Each “Bed area” displays some of the data provided by the devices connected to the patient (Fig 47). The kind of data displayed depends on the design and configuration of the device.

If the “Bed area” is light blue, as in Fig 47, it means that there is at least one low priority alarm, and no medium and/or high priority alarms, coming from the connected devices.

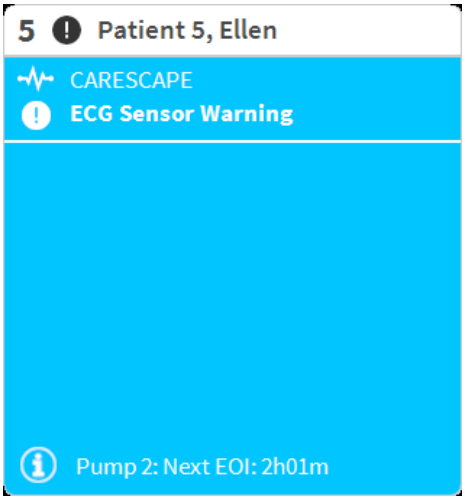


Fig 47

If the “Bed area” is yellow, as in Fig 48, it means that there is at least one medium priority alarm, and no high priority alarms, coming from the connected devices.

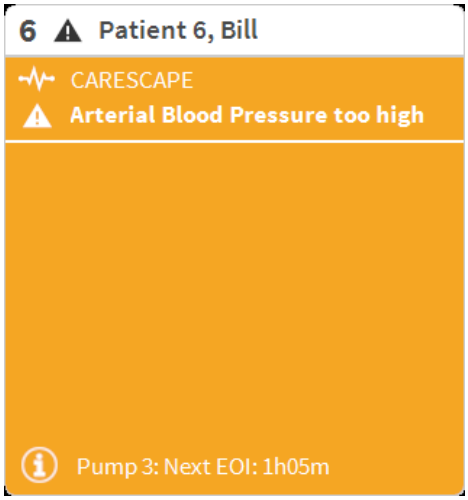


Fig 48

If the “Bed area” is red, as in Fig 49, it means that at least one of the connected devices is in high priority alarm state.

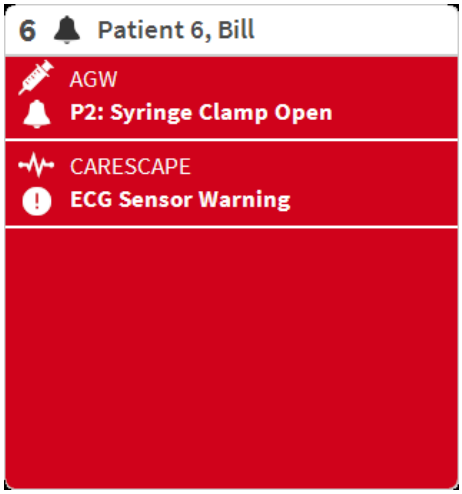


Fig 49

The connected beds from which no alarms are received appear as in Fig 50. No device data is displayed as this might distract the reading of possible alarms occurring on the other beds.

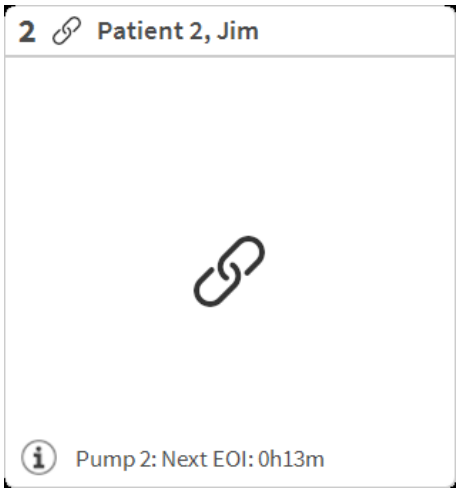


Fig 50

To display device data on these devices “pump” click the **Values** button on the command bar (Fig 45 **B**). The “Bed area” will appear as in Fig 51.

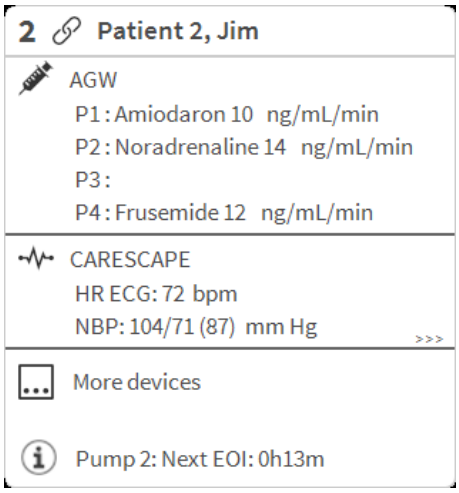


Fig 51

Disconnected beds are displayed as in Fig 52.

Fig 52

6.4.1 Bed area description

This section provides a detailed description of the way information is displayed on every “Bed area”.

On top of the “Bed area” the bed number and the patient name are displayed (Fig 53). The icon means that the bed is connected to Digistat Smart Central and that Digistat Smart Central is currently receiving device data from the bed. If one of the devices connected to the bed is notifying a low priority alarm the icon is displayed instead. If one of the devices connected to the bed is notifying a medium priority alarm the icon is displayed instead. If one of the devices connected to the bed is notifying a high priority alarm the icon is displayed instead.

Fig 53

The information in the bed area is divided by “Device type”. Each device type is characterized by a specific icon (Fig 54 **A**).

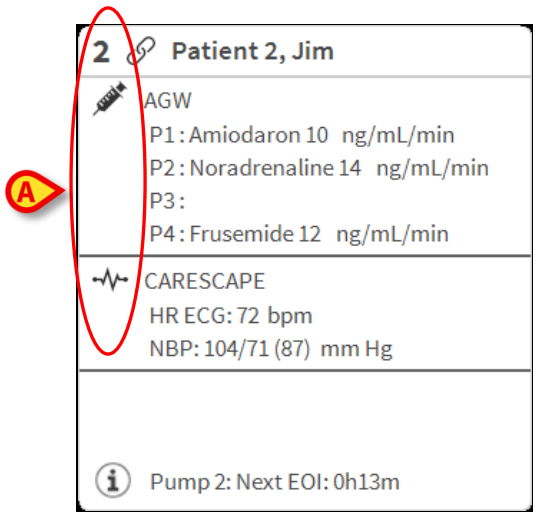


Fig 54

A legend is available showing which device type a specific icon refers to.

To display the legend:

- Click the **Legend** button on the command bar. See paragraph 6.5.1 for a detailed description

Data coming from the same kind of devices are grouped together. In Fig 55, for instance, two groups are indicated: infusion pumps and patient monitor.

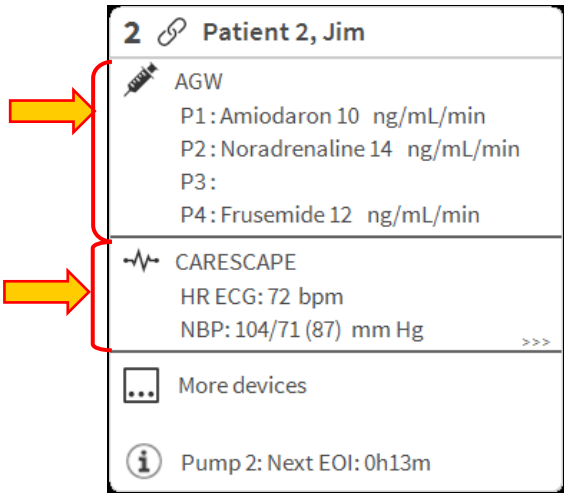


Fig 55

It is possible that not all the data coming from the devices is displayed in the box. If there is hidden data the >>> signal is displayed at the end of every group (see Fig 56 **A**).

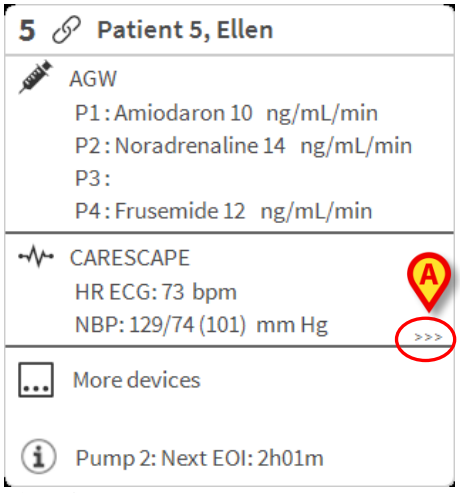


Fig 56

Hidden data can be displayed by clicking the “Bed area”, which is enlarged to full-screen mode (Fig 57). All the available information is displayed.

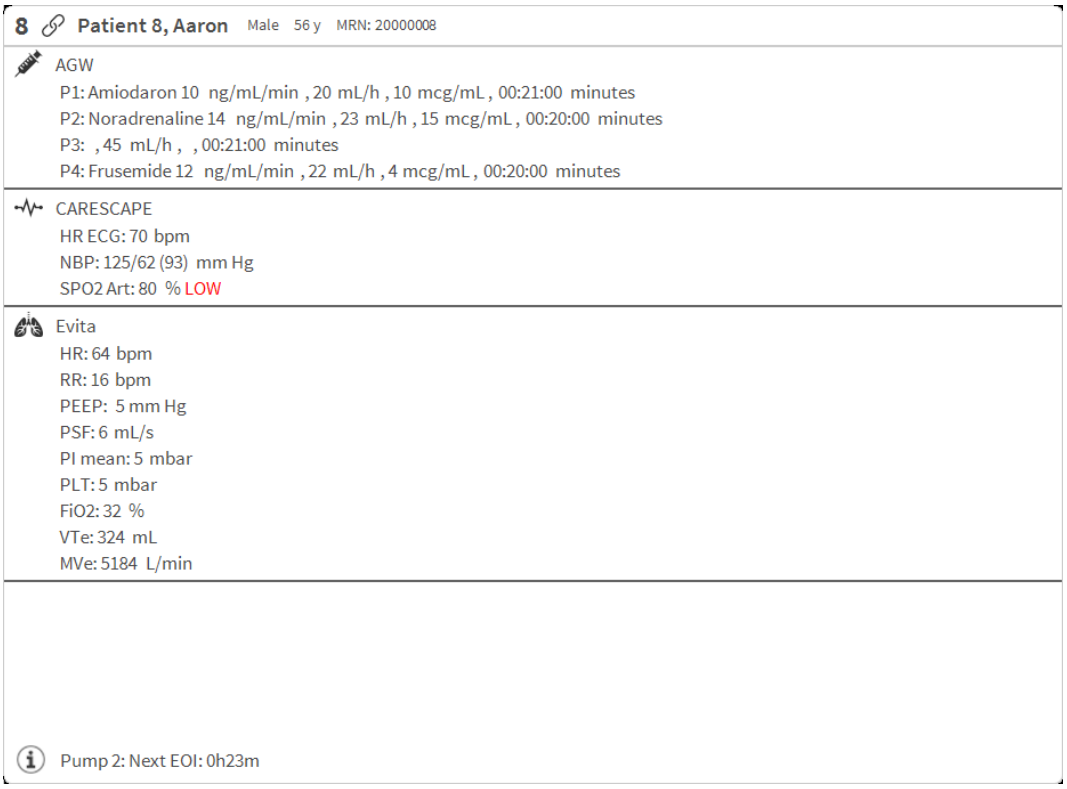


Fig 57

Additional information about the connected devices and the list of the possible disconnected devices are displayed at the bottom of the “Bed area” (Fig 58 **A**). Disconnected devices are indicated by the icon. Additional information is indicated by the icon.

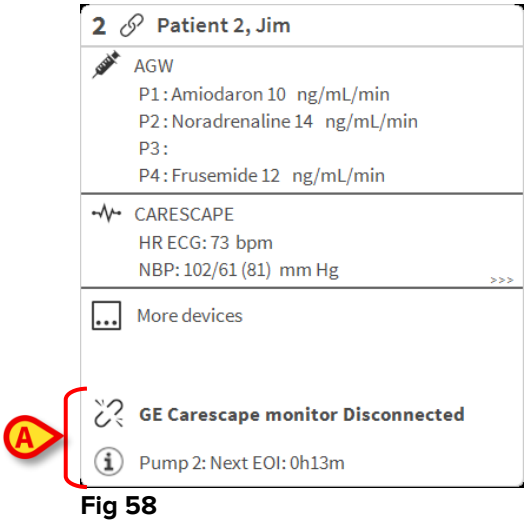


Fig 58

It is possible, by configuration, to associate messages to the displayed values. For instance it is possible to define a range of values that are “normal” and configure the Product to inform the user if the collected values are outside this range. See for instance Fig 59 **A**, in which the values are defined as “Low”.

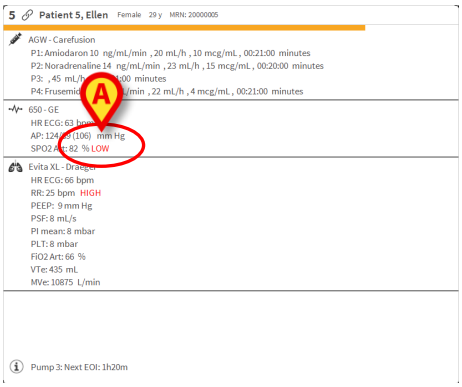


Fig 59

A visual feature on the upper bar on each “Bed area” keeps temporarily track of the last alarm notification provided after the “Bed area” has changed to a different priority alarm (or no alarm). This makes it possible to be aware of alarms occurring and rapidly passing (Fig 60).

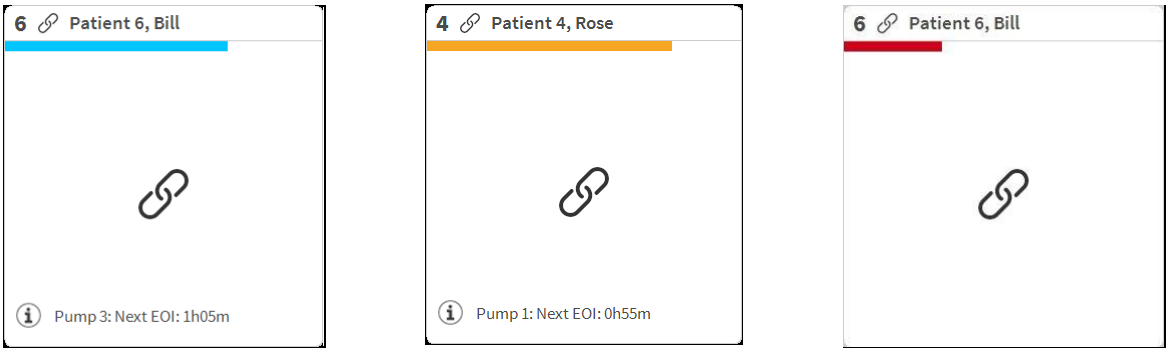


Fig 60

6.5 The Digistat Smart Central command bar

The buttons on the command bar of the Digistat Smart Central make it possible to perform different actions.

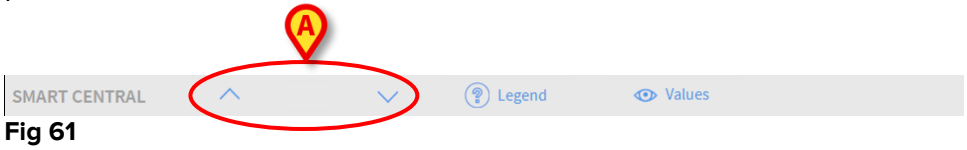


Fig 61

The arrow buttons (Fig 61 **A**) make it possible to scroll up and down the screen when it is not possible to display all the configured “Bed areas” at the same time.

When one (at least) of the non-displayed “Bed areas” is notifying an alarm, the corresponding button takes the color corresponding to the alarm priority level (blue = low; yellow = medium; red = high).

In case of multiple alarms the arrow color corresponds to the highest priority notified.

An icon can be displayed in the box between the arrow buttons (Fig 62). It indicates that there is an alarm on one of the “Bed areas” currently displayed.

Fig 62

The **Legend** button displays a window with the meaning of all the different icons that can be found while using the software (See paragraph 6.5.1).

The **Values** button displays all the available data (both referring to the non-alarmed beds and referring to the non-alarmed devices on the alarmed beds).

The **ICU** button contains an acronym indicating the ward currently displayed. If the Product is configured to cover more than one ward, the button can be clicked to open a menu displaying all the configured wards.

6.5.1 Legend

The **Legend** button opens a window explaining the meaning of all the different icons that can be found while using the software.

To display the “Legend”:

- Click the **Legend** button

The following window is displayed (Fig 63).

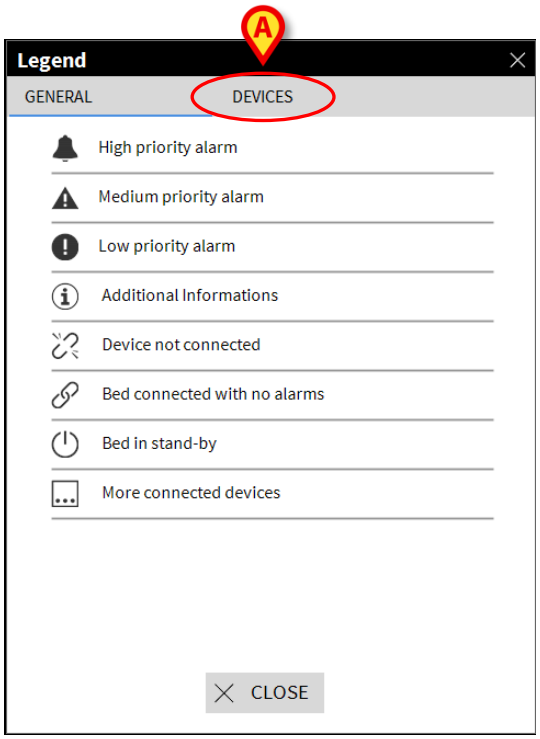


Fig 63

The window lists the “General” icons that can appear in different contexts. Another list of icons, those indicating the connected devices, can be displayed by clicking the “DEVICES” button indicated in Fig 63 **A**.

To see the “Devices”:

- Click the **Devices** button indicated in Fig 63 **A**

The “Devices” legend is this way displayed (Fig 64)

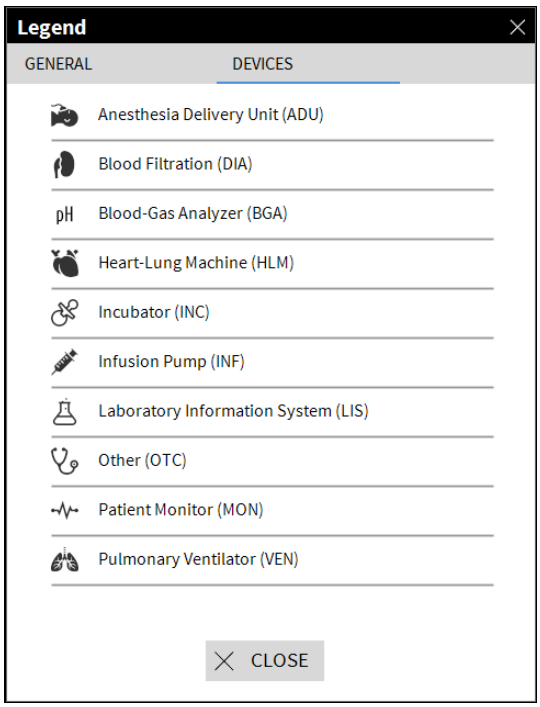


Fig 64

On this window all the possible icons are listed. Alongside the icon the device name is specified, with the corresponding abbreviation / acronym (e.g. INF refers to infusion pumps, MON to patient monitors and so on).

6.6 Events list

It is possible to display a detailed list of all the events occurred for a patient. To display the events list:

➢ Click the “Bed area” referring to the bed to be displayed (Fig 65)

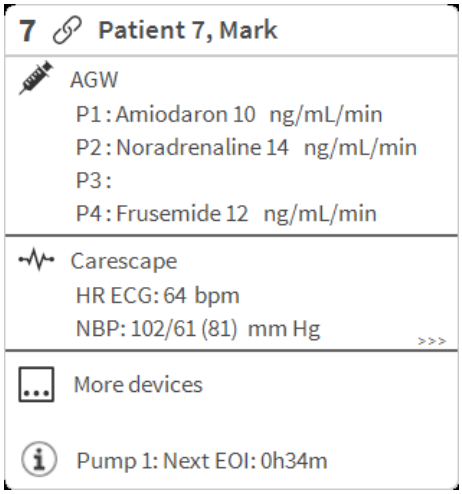


Fig 65

The events list will be displayed on the right (Fig 66).

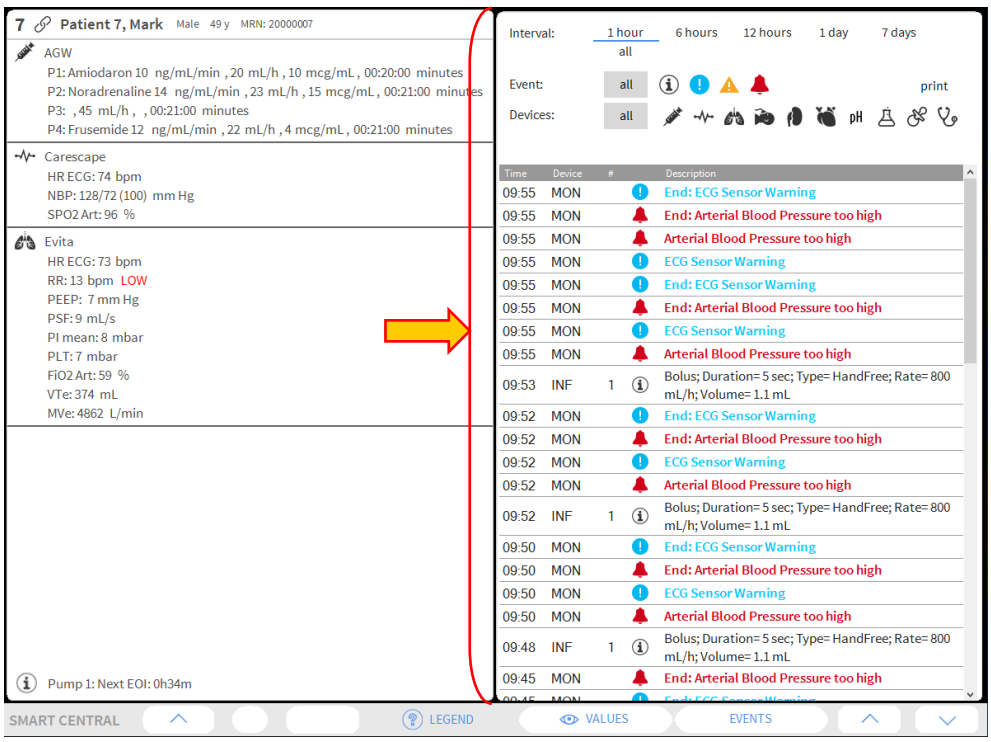


Fig 66

The vertical bar indicated in Fig 66 delimiting the Events area, can be dragged left/right to resize the area.

6.6.1 Events list description

The table shown in Fig 67 contains the list of all the events occurred on all the devices connected to the selected patient during their stay.

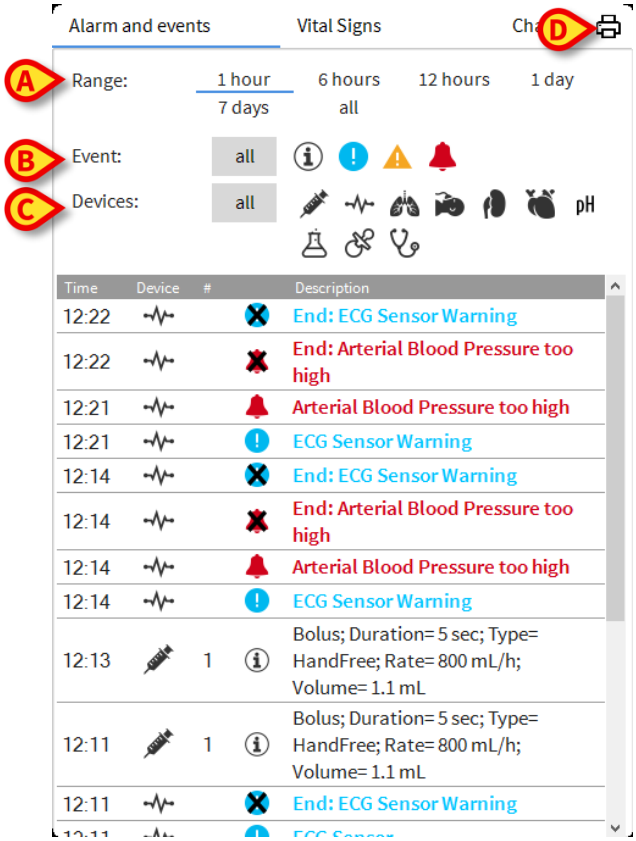


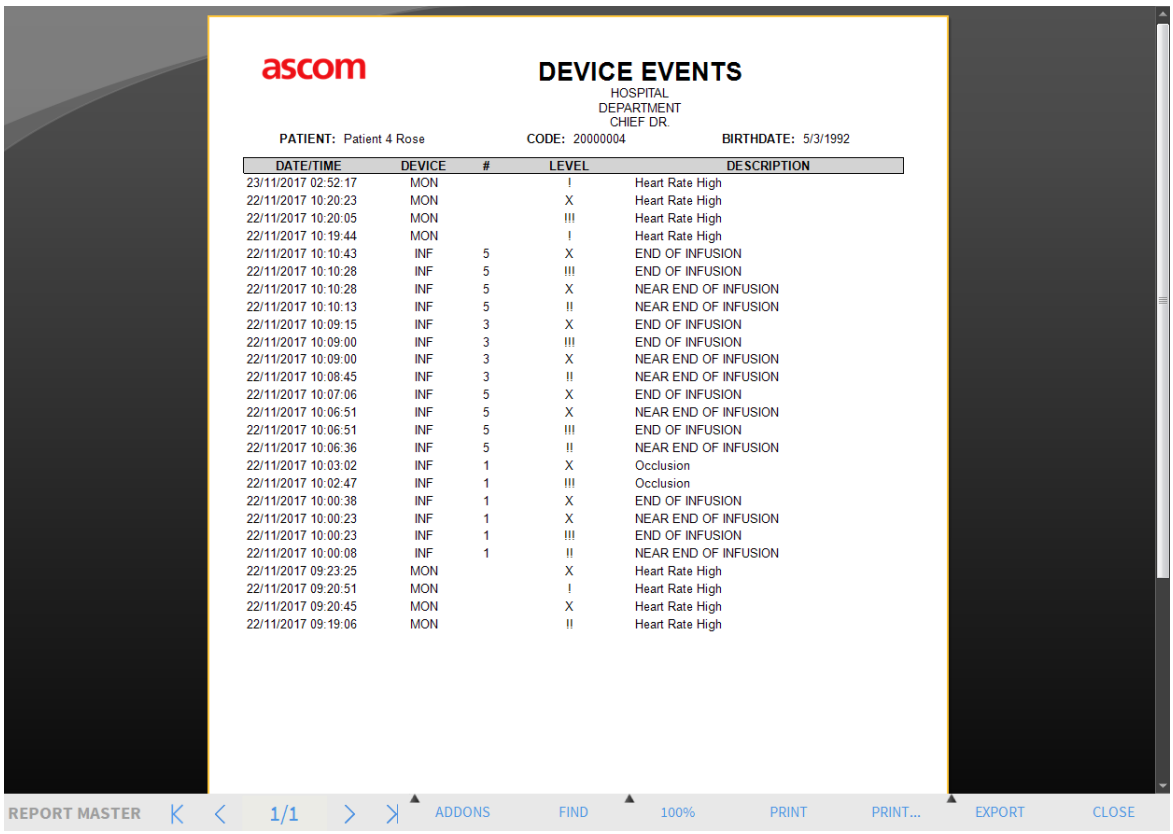
Fig 67

The time period to which the events list refers can be selected using the "**Range**" filters (Fig 67 **A**).

The "**Event**" buttons indicated in Fig 67 **B** are also filters making it possible to display only certain types of events. The **All** button, selected by default, displays all the events occurred in the selected time period. The button only displays the "Information" events; the buttons only display the low and medium priority alarms; the button only displays the high priority alarms. Multiple selections is possible to display two kinds of events at the same time (i.e. only low and medium priority alarms).

The "**Device**" buttons indicated in (Fig 67 **C**) are also filters making it possible to display only the events referring to a specific device. The **All** button, selected by default, displays all the events occurred in the selected time period; the button only displays the events referring to the infusion pumps; the button only displays the events referring to patient monitors and so on... The full list of icons with their explanation can be found in the "**Legend**" window (see paragraph 6.5.1). Multiple selection is possible to display the events referring to two or more devices at the same time.

The **Print** button indicated in Fig 67 **D** makes it possible to print the list of events displayed (Fig 68).



ascom

DEVICE EVENTS

HOSPITAL
DEPARTMENT
CHIEF DR.

PATIENT: Patient 4 Rose **CODE:** 20000004 **BIRTHDATE:** 5/3/1992

DATE/TIME	DEVICE	#	LEVEL	DESCRIPTION
23/11/2017 02:52:17	MON		I	Heart Rate High
22/11/2017 10:20:23	MON		X	Heart Rate High
22/11/2017 10:20:05	MON		III	Heart Rate High
22/11/2017 10:19:44	MON		I	Heart Rate High
22/11/2017 10:10:43	INF	5	X	END OF INFUSION
22/11/2017 10:10:28	INF	5	III	END OF INFUSION
22/11/2017 10:10:28	INF	5	X	NEAR END OF INFUSION
22/11/2017 10:10:13	INF	5	II	NEAR END OF INFUSION
22/11/2017 10:09:15	INF	3	X	END OF INFUSION
22/11/2017 10:09:00	INF	3	III	END OF INFUSION
22/11/2017 10:09:00	INF	3	X	NEAR END OF INFUSION
22/11/2017 10:08:45	INF	3	II	NEAR END OF INFUSION
22/11/2017 10:07:06	INF	5	X	END OF INFUSION
22/11/2017 10:06:51	INF	5	X	NEAR END OF INFUSION
22/11/2017 10:06:51	INF	5	III	END OF INFUSION
22/11/2017 10:06:36	INF	5	II	NEAR END OF INFUSION
22/11/2017 10:03:02	INF	1	X	Occlusion
22/11/2017 10:02:47	INF	1	III	Occlusion
22/11/2017 10:00:38	INF	1	X	END OF INFUSION
22/11/2017 10:00:23	INF	1	X	NEAR END OF INFUSION
22/11/2017 10:00:23	INF	1	III	END OF INFUSION
22/11/2017 10:00:08	INF	1	II	NEAR END OF INFUSION
22/11/2017 09:23:25	MON		X	Heart Rate High
22/11/2017 09:20:51	MON		I	Heart Rate High
22/11/2017 09:20:45	MON		X	Heart Rate High
22/11/2017 09:19:06	MON		II	Heart Rate High

Fig 68

See paragraph 5.10 for the Product's print functionalities.

The events table is displayed below (Fig 69).

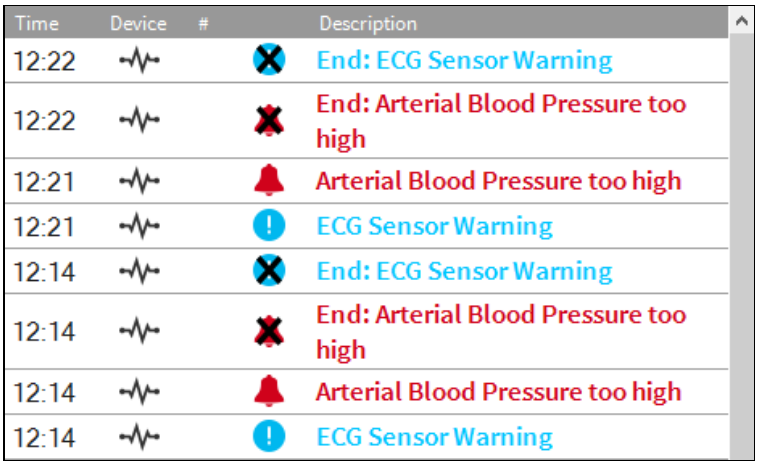


Fig 69

The events table provides the following information:

- Event time (indicated as hh:mm)
- Type of device in which the event occurred
- Number (in case of infusion pumps it indicates the pump number)
- Alarm priority level
- Event description
- The black cross on the alarm symbol indicates the end of the corresponding alarm

6.7 Dashboard configuration

If the Digistat Smart Central is configured as a “Dashboard” Smart Central, some additional functionalities are available. These are the “Vital Signs” and “Charts” functionalities, described below (Fig 70 **A**).
Both functionalities are accessible from the “Notification area”.

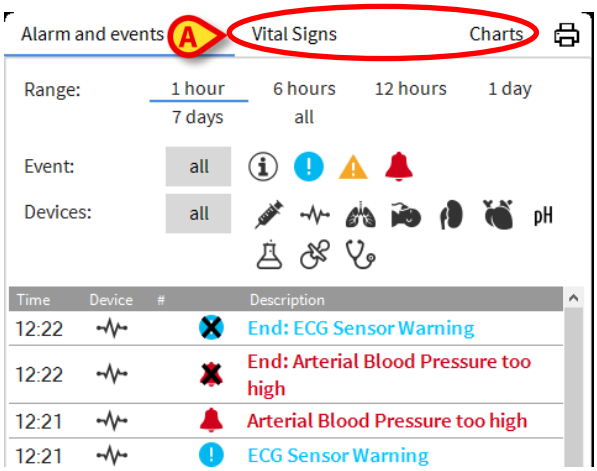


Fig 70

6.7.1 Vital Signs

Click the Vital Signs button to activate the “Vital Signs” functionality (Fig 71 **A**).

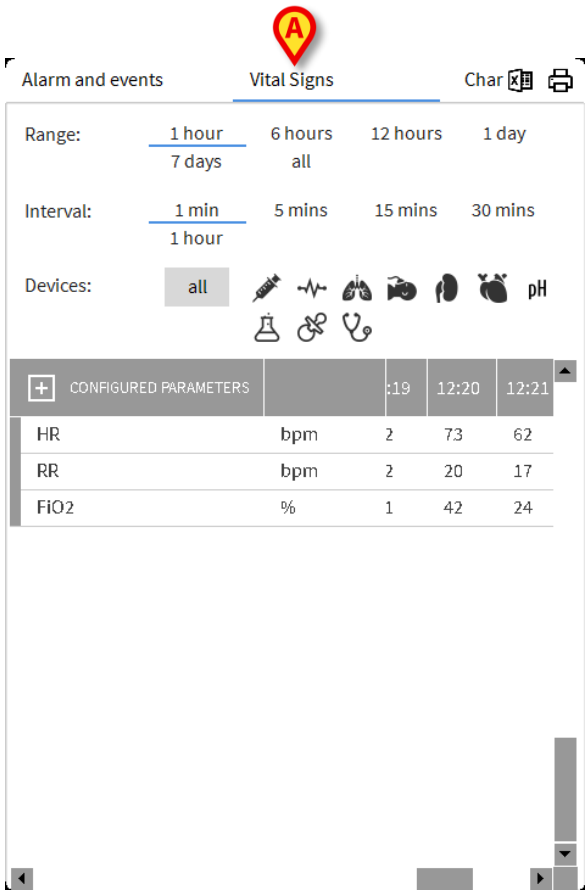


Fig 71

“Vital signs” makes it possible to display in a table some selected patient parameters (Fig 72). The displayed parameters are defined by configuration. In the table they are grouped by acquisition device.

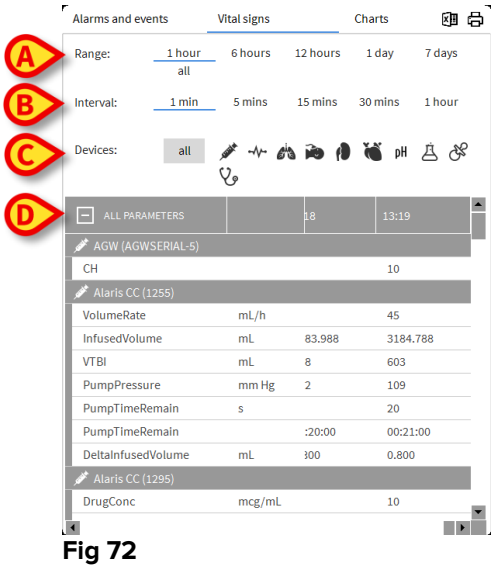


Fig 72

Use the “Range” filter (Fig 72 **A**) to display the time span within which the parameters are acquired. For instance: if **1 hour** is selected the table displays the parameters acquired from one hour in the past to the present time; if **6 hours** is selected the table displays the parameters acquired from six hours in the past to the present time, and so on.

Use the “Interval” filter (Fig 72 **B**) to define the values acquisition interval (i.e., depending on the interval selected, the values displayed in the table are acquired each minute, every 5 minutes, every 15 minutes, and so on).

Use the “Devices” filter (Fig 72 **C**) to display only the values acquired by the selected devices.

Click on “Configured Parameters” (Fig 72 **D**) to display all the acquired parameters (1 minute interval).

The “all” option displays all the acquired parameters (1 minute interval).

A task in the database deletes the previous data at a set time.

Click the print button  to create a print report of the displayed parameters.

Click on the excel icon  to export the data to an XLS file.

6.7.2 Charts

Click the **Charts** button to activate the “Charts” functionality (Fig 73 **A**).

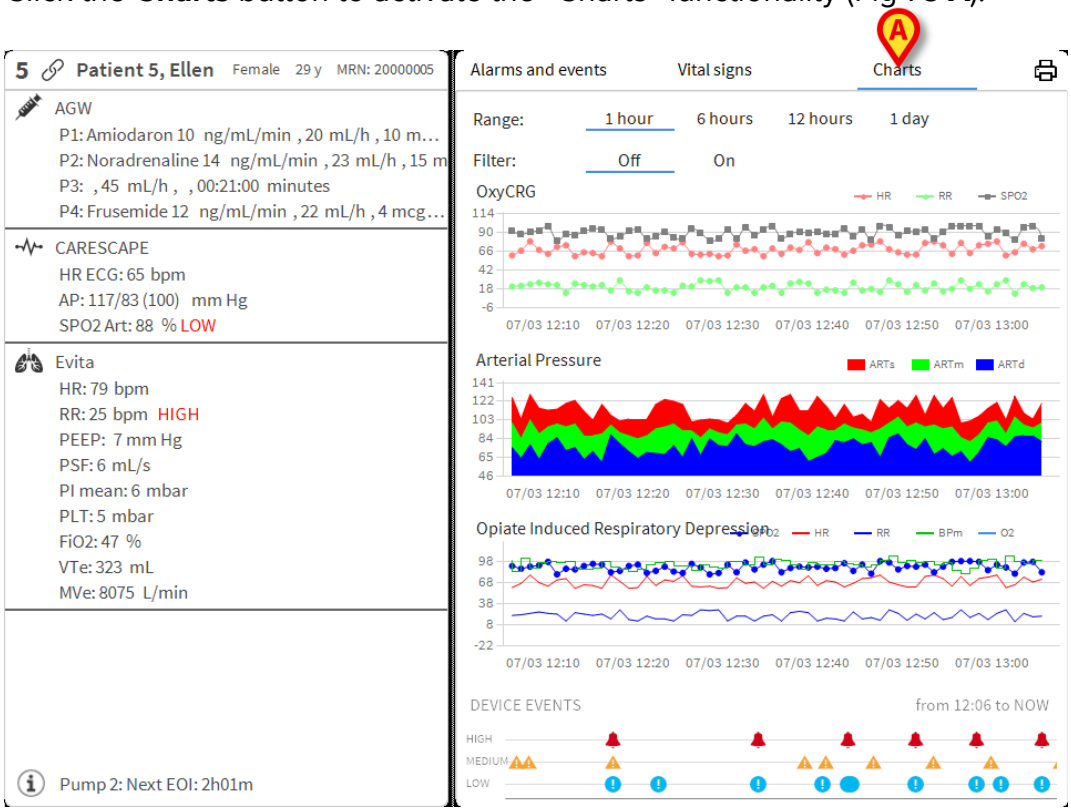


Fig 73

“Charts” makes it possible to display different charts drawn from the acquired parameters (Fig 74). The charts show the configured parameters as trends. The number of charts, their contents and names are defined by configuration.

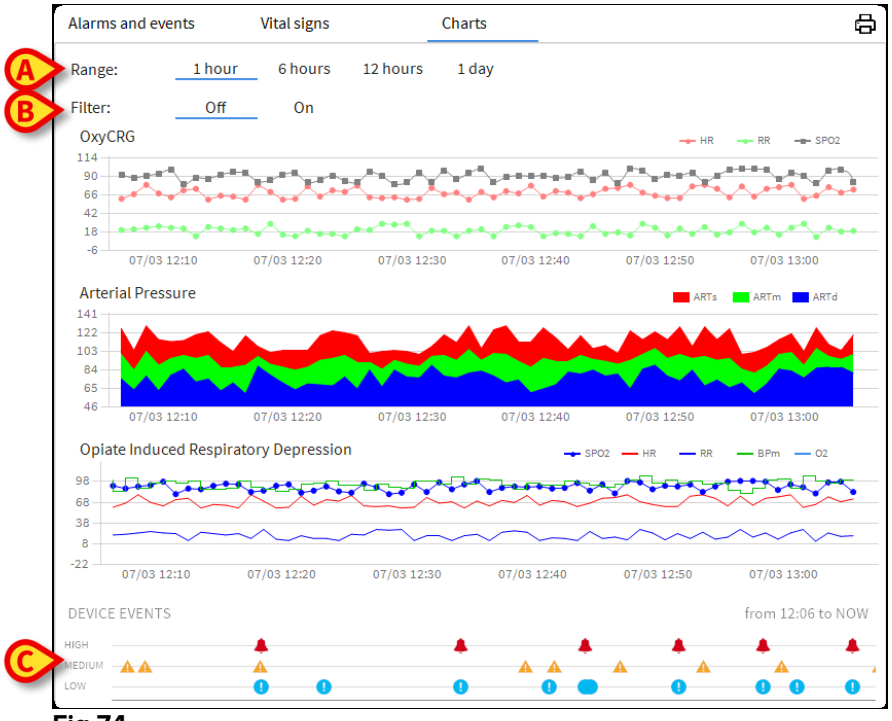


Fig 74

Use the “Range” filter (Fig 74 **A**) to define the time span to which the charts refer. For instance: if **1 hour** is selected the charts display the trends starting one hour in the past until present time; if **6 hours** is selected the charts display the trends starting six hours in the past until present time, and so on.

Use the “Filter” option (Fig 74 **B**) to activate an algorithm that approximates the charts values in a way making it possible to better display and evaluate the trends. If this option is activated the acquired data are grouped five by five. Each group of five is then ordered. Then only the middle value of five is kept, while the other four are discarded. This procedure eliminates the lowest and highest values (i.e. artefacts) and provides a “normalised” chart.

The chart indicated at the bottom of the page (Fig 74 **C**) is always present and displays on three rows the device events. Each event is positioned according to its priority level and time of occurrence.

Click any chart to display a vertical cursor making it possible to display the values of all charts at a given time (Fig 75 **A**).

Fig 75

6.7.3 Alarms statistics

A printed report of the alarm statistic history can be generated by accessing the System Report menu, displaying graphical statistics inclusive of event summaries and event details.

To print an Alarm statistic report:

- Click the **Menu** button on the control bar

➢ Click on **System Reports**

➢ Click **Smart Central Dashboard**

From the prompted window it will be possible to select the data source (All available patients or the selected patient) and the date range.

➢ Click the **Generate** button

A print preview of the selected Event statistics will open.

Once the Event Statistic preview is displayed, the buttons on the command bar make it possible to perform various actions, as listed in paragraph 5.10.

6.8 Notification area

A notification area is displayed on the right of the Digistat Smart Central screen, reporting various notifications sent by the connected devices (Fig 76 **A**).

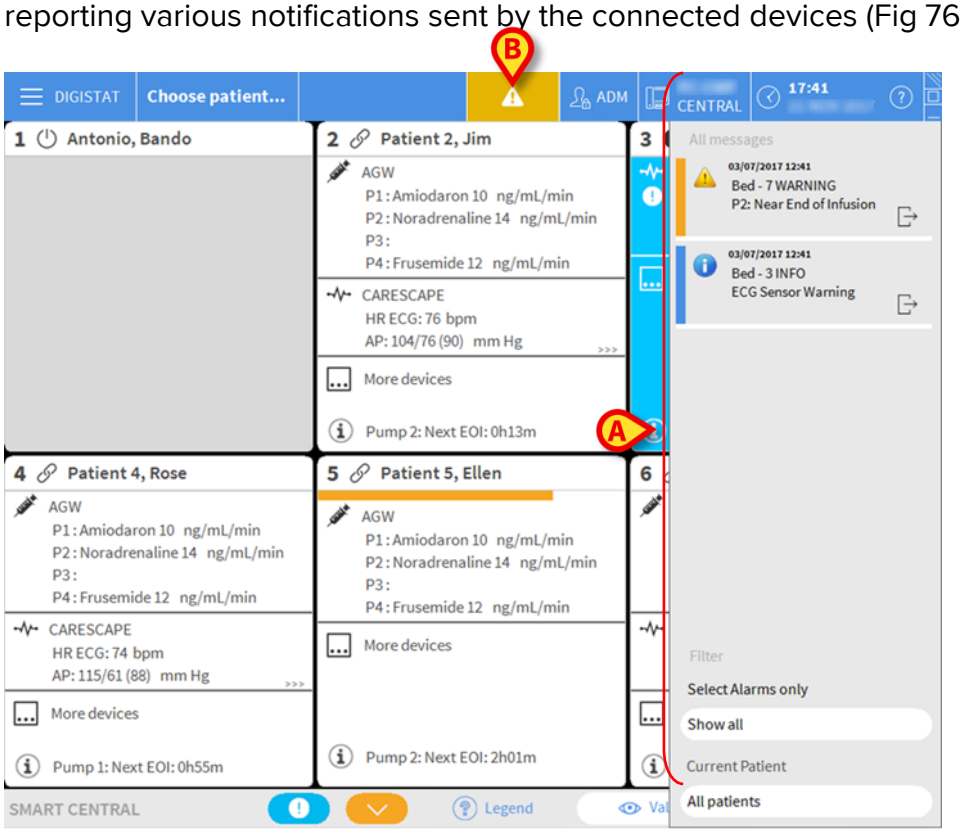


Fig 76

The notification area can be, by configuration:

- Always visible

- Automatically displayed when a new notification comes
- Only visible after user click on the Notification button on Control Bar (Fig 76 **B**).

The different messages are displayed in chronological order, (most recent on top - Fig 77 **A**) and by criticality (High priority alarms on top, then medium priority, then low priority).

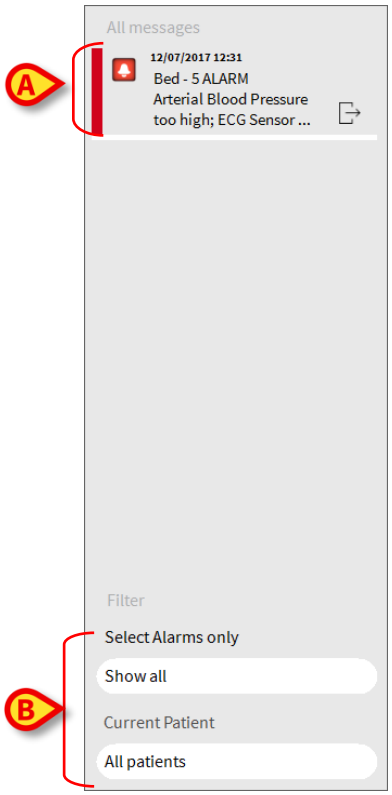


Fig 77

Each notification is characterized by the colour corresponding to the priority level (red for high priority, yellow for medium priority, blue for low priority).

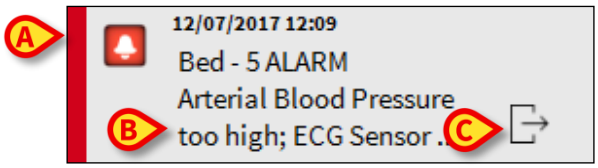


Fig 78

In the message box (Fig 78), the following information is displayed:

- Date-time of occurrence
- The number of the bed from which the message comes
- The actual message text
- An icon characterizing the message type (Warning, Alarm, Info - Fig 78 **A**)
- An icon indicating the message category (Fig 78 **B**)
- A “Callback” button. Click the button to access the patient station on which the notification occurred (Fig 78 **C**)

At the bottom of the area, four different filters are available, making it possible to choose the type of message to be displayed (Fig 77 **B**). The available filters are:

- Only alarms
- All messages
- Messages relating only to the selected patient
- Messages relating to all patients

6.9 Alarms notification

! Digistat Smart Central shall not be used as a remote alarm system or as an alarm replicator.

By default, the Digistat Smart Central screen displays the device data referring to a bed only if there is an alarm notification coming from at least one of the devices connected to that bed.

In a condition of “No notifications” the Digistat Smart Central screen would appear as in Fig 79, where five connected “Beds” are displayed and where no devices on any of the beds is in alarm state.

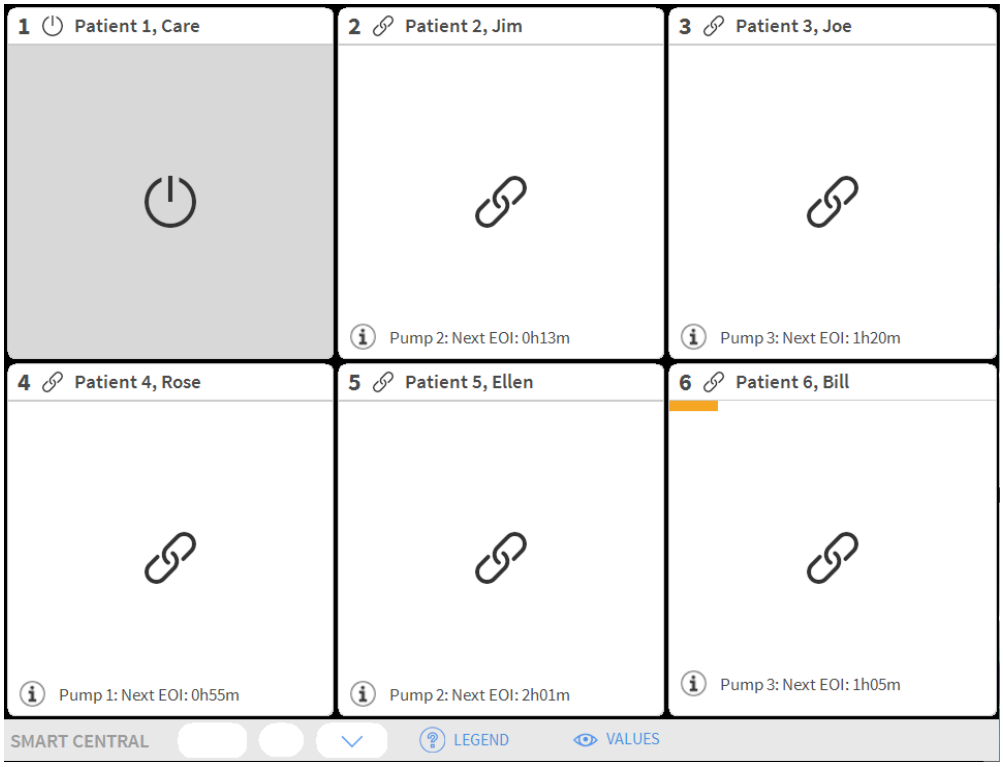


Fig 79

Each time an alarm occurs on one of the devices, the data relating to the bed to which the device is connected is displayed. In Fig 80, for instance, bed 3 is notifying a high priority alarm. A short text specifying the kind of alarm occurring is displayed on the “Bed area”.

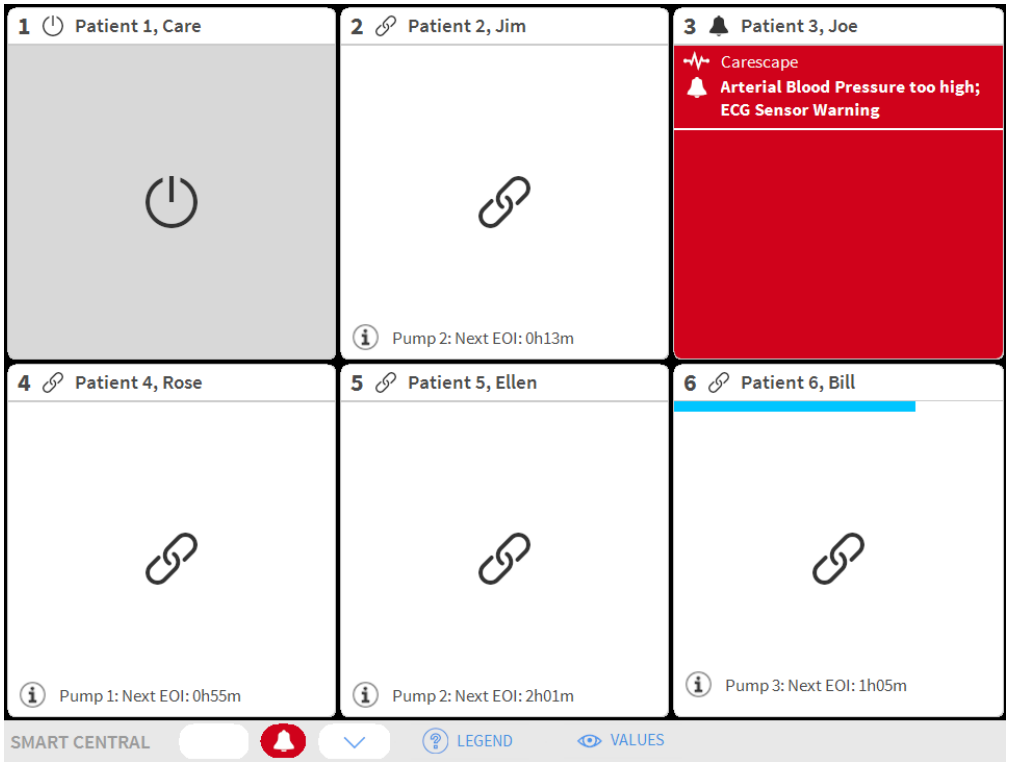


Fig 80

In addition, a sound notification is provided. Three different sounds exist, one for each alarm priority level. In case of multiple alarms, the sound corresponding to the one with highest priority is provided.

The occurrence of alarms is also notified on the command bar by the arrow-buttons indicated in Fig 81, Fig 82 and Fig 83.

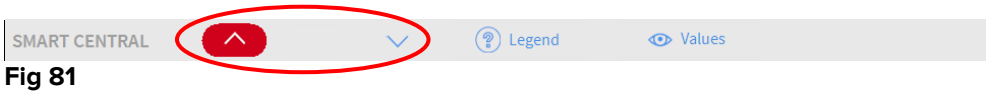


Fig 81

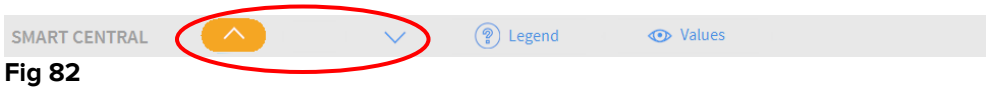


Fig 82

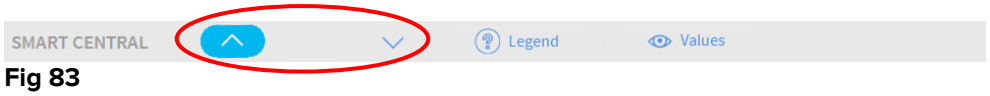


Fig 83

These buttons make it possible to scroll up and down the screen when it is not possible to display all the configured “Bed areas” at the same time.

When one (at least) of the non-displayed “Bed areas” is notifying an alarm, the corresponding button takes the color corresponding to the alarm priority level (blue = low; yellow = medium; red = high).

In case of multiple alarms the arrow color corresponds to the one with the highest priority.

An icon can be displayed within the box between the arrow buttons (Fig 84). It indicates that there is an alarm on one of the “Bed areas” currently displayed.

Fig 84

A visual feature on the upper bar on each “Bed area” keeps temporarily track of the last alarm notified after the “Bed area” has changed to a different priority level alarm (or no alarm). This makes it possible to be aware of alarms occurring and rapidly passing.
When the state of a “Bed area” changes to a lower level alarm (or no alarm), the color relating to the previous alarm (Fig 85) remains on the heading bar for a certain configurable time.

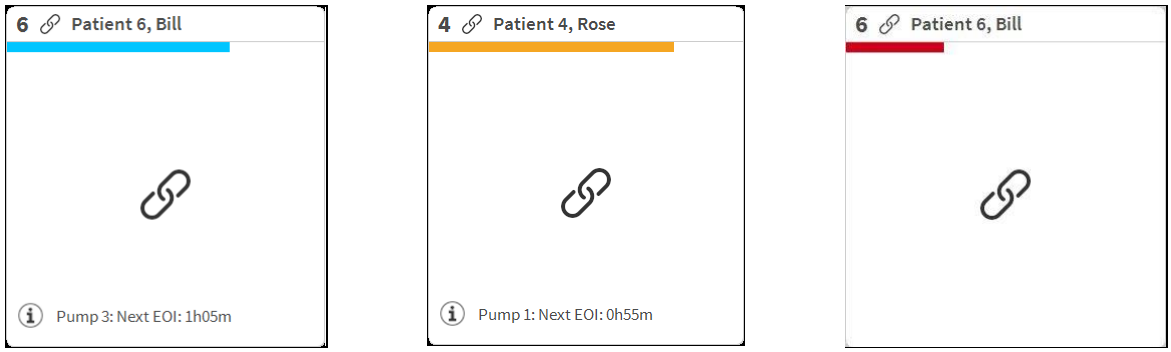


Fig 85

6.9.1 Alarms notification on Control Bar

Alarms are also notified on the Control Bar, so that they are always visible.

Fig 86

The button color depends on the alarm priority level (cyan=low; yellow=medium; red=high). For high and medium priority alarms, the button flashes.

- Click the button to display the notification area (Fig 86 **A**)

The notification disappears when the alarm conditions no longer exist.

6.10 Sound Check procedure

The Sound Check procedure shall be performed at least once per shift.

When Digistat Smart Central is started, it provides a specific sound indicating that the sound notification of alarms is working properly.

If the sound is not provided the user can perform a “Sound Check” procedure. To perform the “Sound Check” procedure

- Click the **Menu** button on Control Bar (Fig 87)

Fig 87

The following menu is displayed (Fig 88).

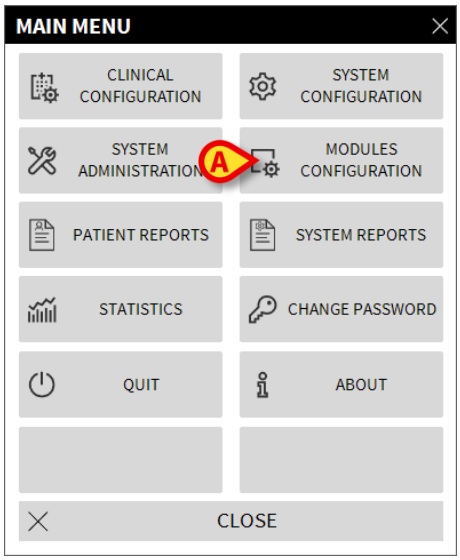


Fig 88

- Click on **Modules Configuration** (Fig 88 **A**)

The following menu opens (Fig 89).

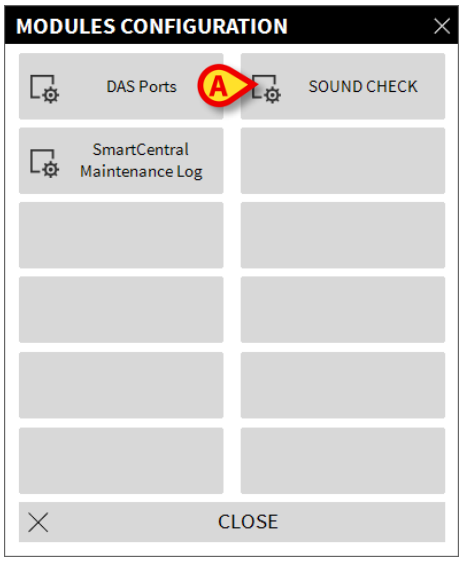


Fig 89

- Click on **Sound Check** (Fig 89 **A**)

The following pop-up window opens, asking whether a sound is heard or not from speakers (Fig 90).

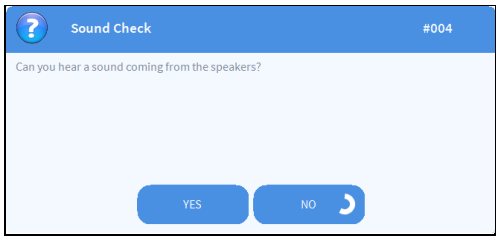


Fig 90

If a sound is heard, then click **Yes**. The pop-up window disappears and nothing else happens (meaning that Digistat Smart Central is working correctly).

If no sound is heard, then click **No**. The pop-up window disappears and a notification is displayed on Control Bar, meaning that an error occurred while checking the sound notification system (Fig 91).

Fig 91

The notification remains while working with Digistat Smart Central. It disappears when another “Sound Check” procedure is performed and a “YES” answer is provided in the end.

The  button can be clicked to display a more detailed explanation of the error occurred (Fig 92).

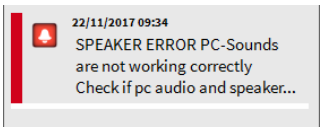


Fig 92

6.11 Patient admission, selection and search

In some Digistat Smart Central configurations it is possible, for users having specific permissions, to use patient admission, search and selection tools.

To access these functionalities:

- Click the **Patient** button on Control Bar (Fig 93 **A** and Fig 94)

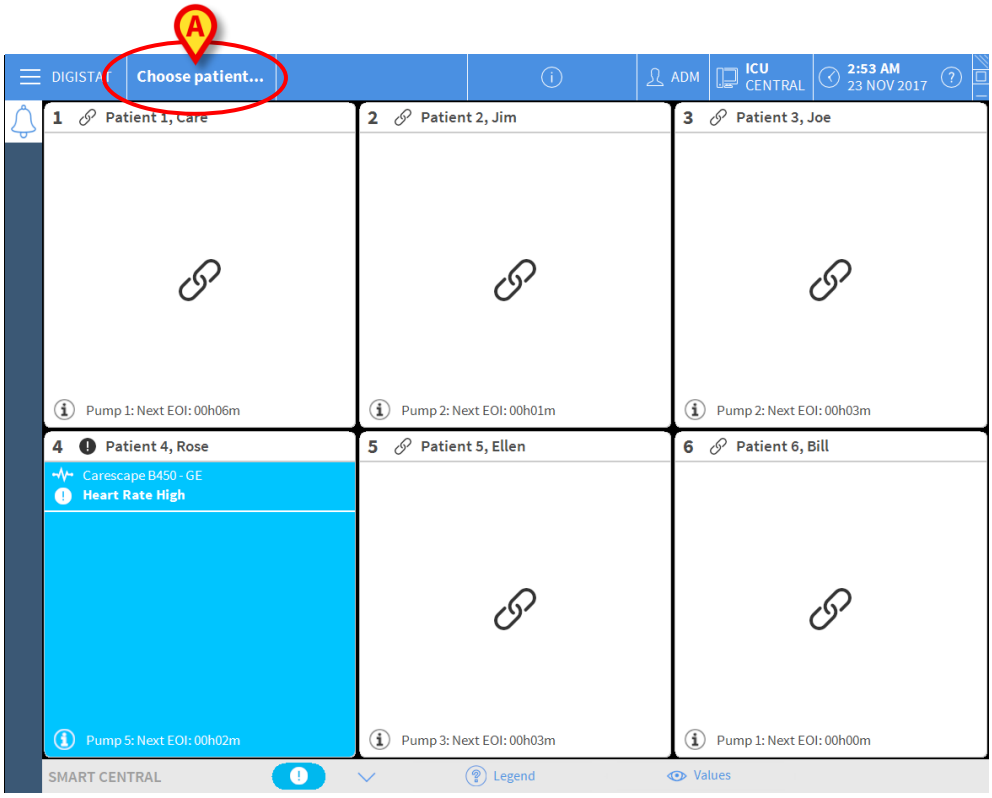


Fig 93

Fig 94

The “Anonymous Patient” screen is displayed by default (Fig 94).

6.11.1 The “Anonymous Patient” screen

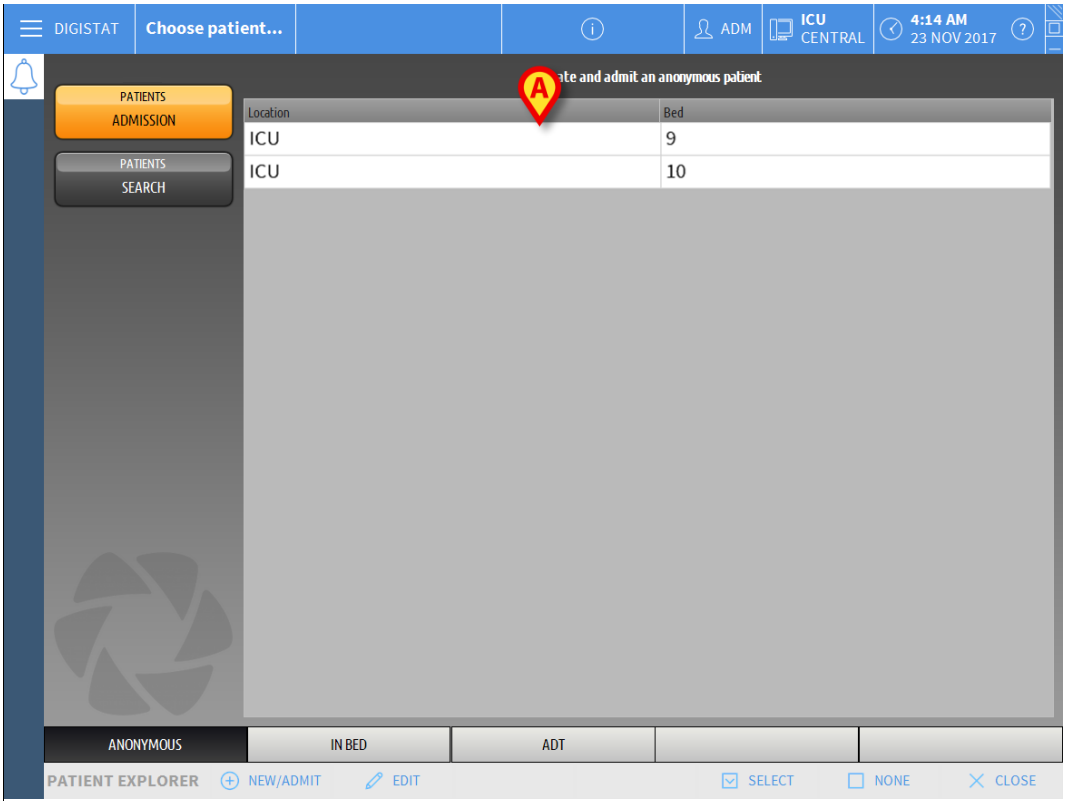


Fig 95

The “Anonymous Patient” screen makes it possible to admit a patient whose data are not yet available. In the area indicated in Fig 95 **A** all the available beds are listed.

To admit an anonymous patient to a bed,

- Double click the row corresponding to the wanted bed

User confirmation is required (Fig 96).

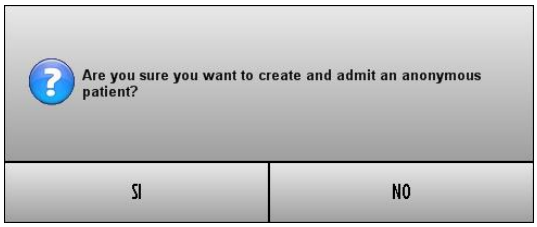


Fig 96

- Click **Yes** to admit the patient. The Digistat Smart Central screen related to that patient is then displayed. A temporary name is automatically assigned (Patient 10 - Fig 97 **A**)

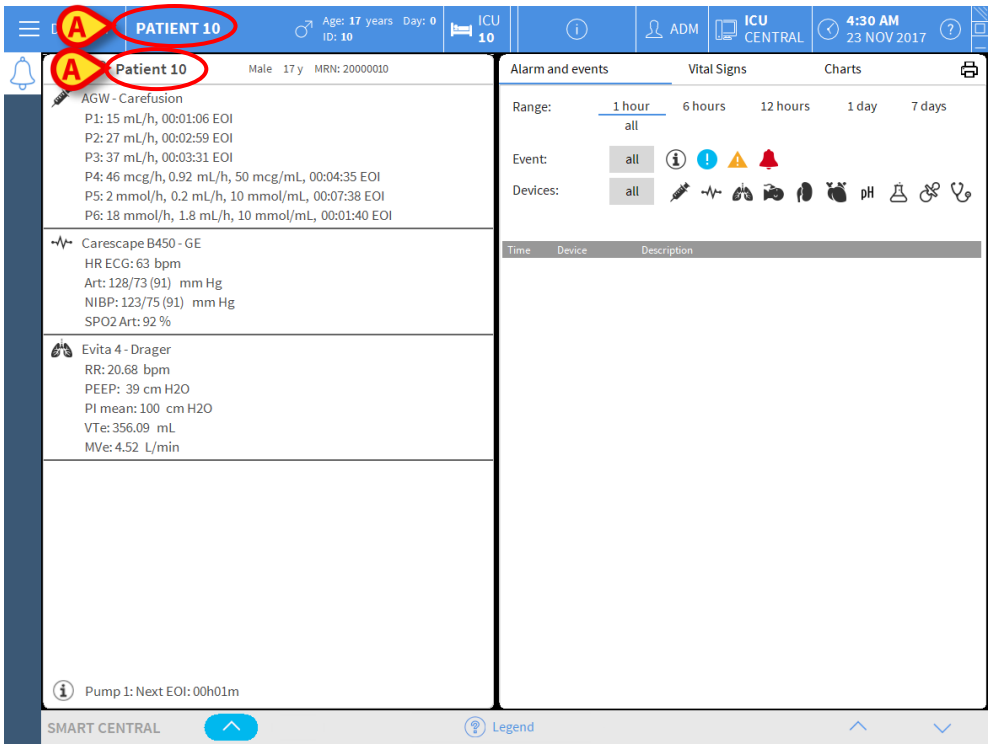


Fig 97

➢ Use the “Edit patient” functionalities to later complete the patient data (see paragraph 6.13.2)

6.11.2 Admitted patients list

To display the list of admitted patients:

➢ Click the **In Bed** button on the command bar (Fig 98 **A**)

The list of beds configured in the domain is this way displayed (Fig 98 **B**).

Fig 98

The rectangular buttons on the screen (Fig 98 **A**) represent the beds configured in the workstation domain (usually the beds of a specific ward). If a patient is admitted to a bed, the patient name is displayed on the area (Fig 99 **A**). Below the patient name you can read the admission date. Areas with no name correspond to empty beds (Fig 99 **B**).

Fig 99

- Click one of the areas to select the corresponding patient

The name of the selected patient is displayed on the **Patient** button on Control Bar (Fig 100).

Fig 100

The current situation of the selected patient (i.e. the corresponding “Bed area”) will be displayed in full-screen mode (Fig 101).

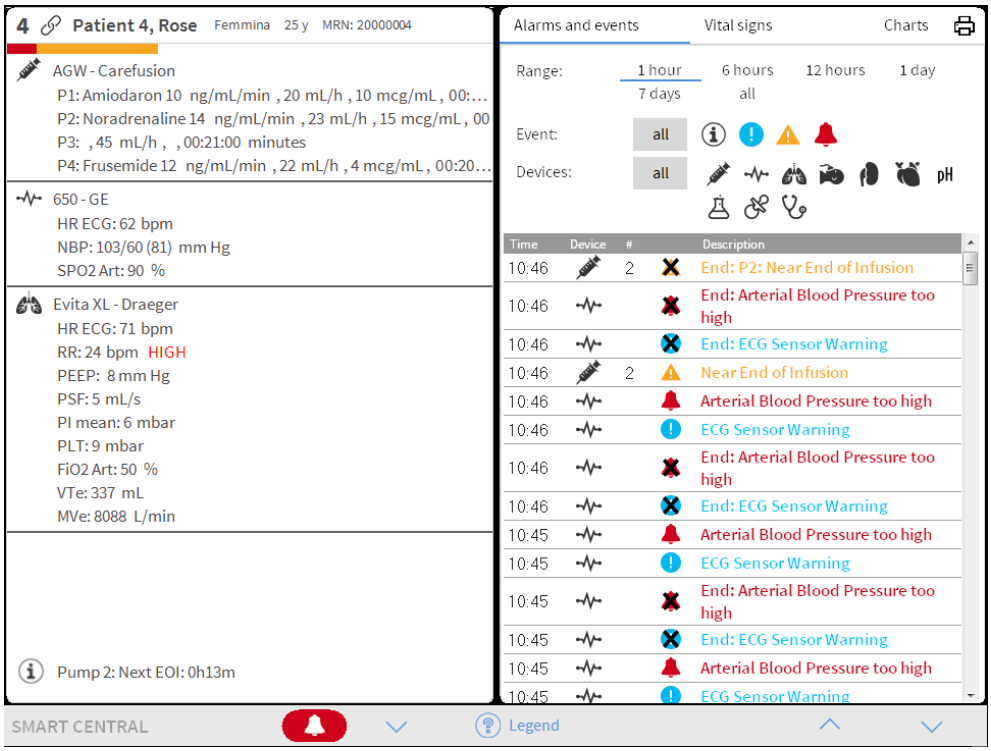


Fig 101

6.11.3 Patients from ADT

If a specific software component is installed server-side, the Digistat Smart Central can acquire patient data from the hospital ADT.
If the software is so configured, and if bed information is provided, then the patient can be directly admitted to bed by the ADT. In this case the ward staff will automatically see the new patients on the list of admitted patients (Fig 98).
Otherwise, the patients assigned to the department by the ADT will be listed on a specific screen. To access this screen:

- Click the ADT button on the command bar (Fig 107 **A**)

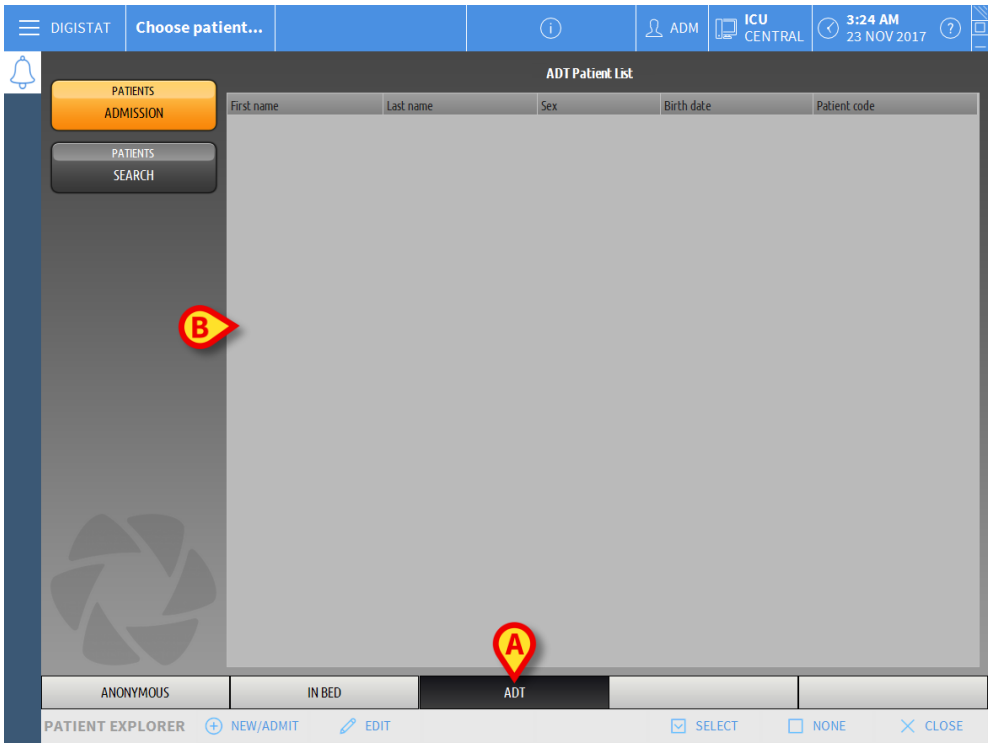


Fig 102

Patients assigned by the ADT are listed on the area indicated in Fig 107 **B**.
For each patient the following information is provided:

- First name
- Last name
- Sex
- Birthdate
- Patient Code

To select a patient

➢ Double click the row corresponding to the patient

The **New/Admit Patient** window, containing the available patient data will be displayed (Fig 103).

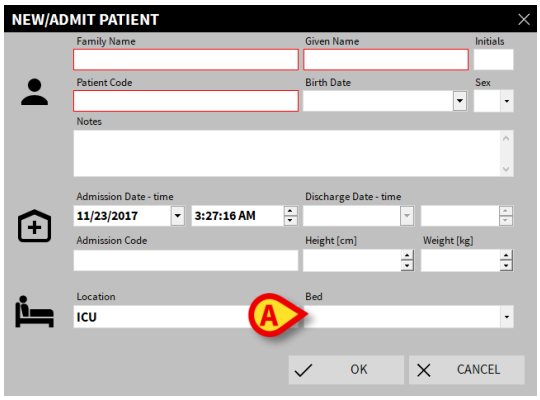


Fig 103

➢ Specify the bed number in the field indicated in Fig 103 **A**

6.11.4 Direct patient admission

It is possible to directly admit a patient to a bed by entering patient data. To do that, use the New/Admit patient functionality, which is described in paragraph 6.13.1.

6.12 Patient search

To search for a patient's data on the Digistat Smart Central database:

➢ Click the PATIENTS SEARCH button indicated in Fig 104 **A**

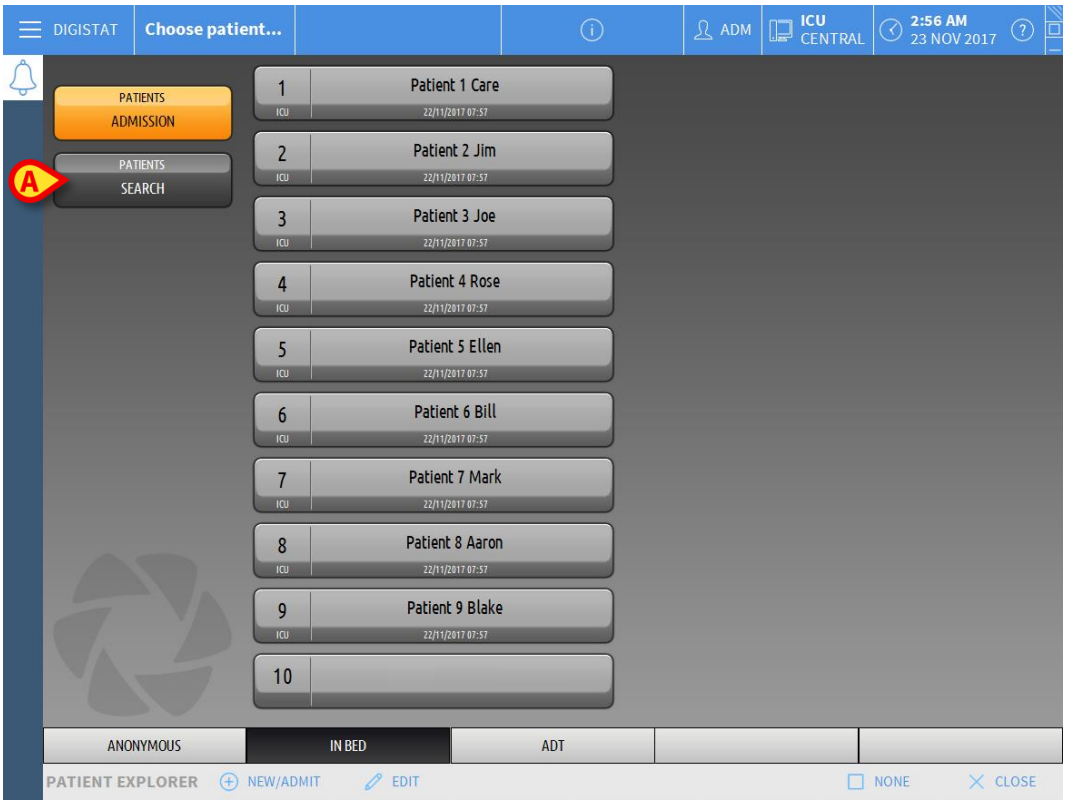


Fig 104

The following screen will open (Fig 105).

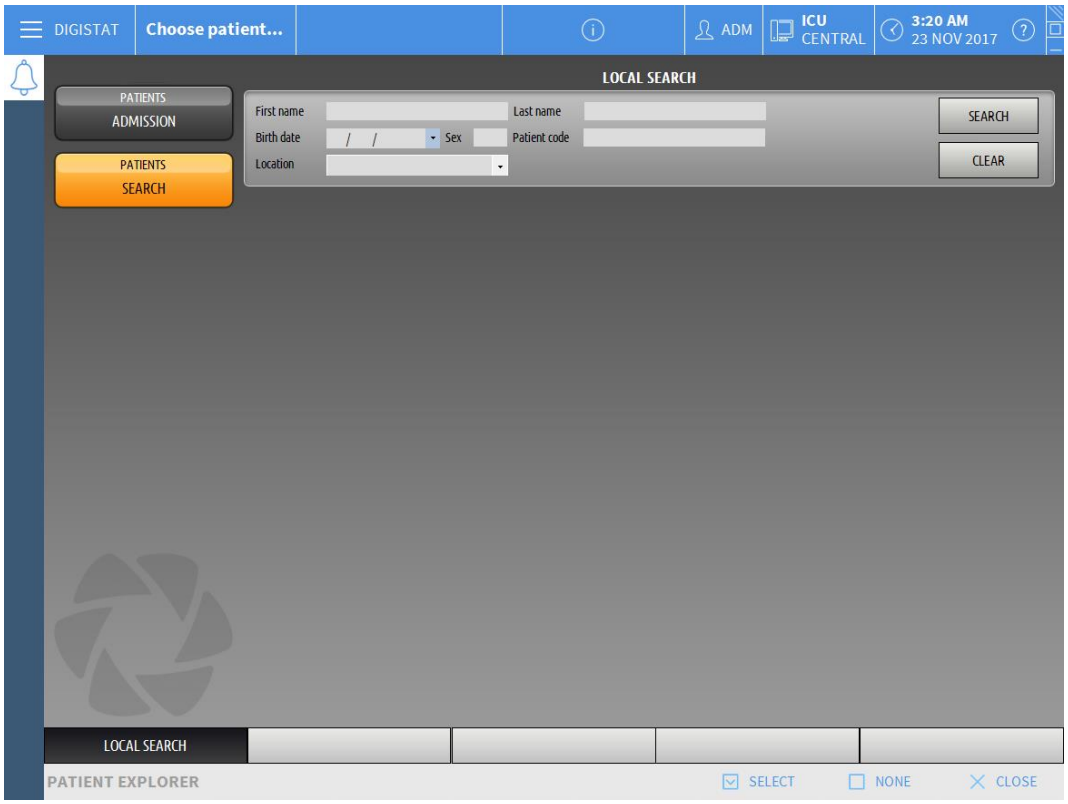


Fig 105

The search fields in the upper area make allow relevant patient's information to be searched (Fig 106).

Fig 106

To search for a patient:

- Enter the data of the patient you are searching for in one or more fields (Fig 106 **A**)
- Click the **Search** button (Fig 106 **B**)

The central area displays in a table the list of all the patients whose data match those specified.

The system displays the list of patients who satisfy all the search parameters entered.

For example: if a search is performed by entering the patient's date of birth, the result will list all patients born on that date. If a search is performed by entering the patient's date of birth **and** sex the result will list only the men or women born on that date.

- Click the **Search** button without entering any value in the search fields to display the list of all the patients registered in the database

- Use the **Clear** button to clear the search filters

6.12.1 The search results

The search results are shown in the central part of the screen (Fig 107).

First name	Last name	Sex	Birth date	Patient code	Admission date	Admission code
Care	Patient 1	M	03/11/1990	20000001	22/11/2017	20000001#1
Claire	Patient 10	M	02/05/2000	20000010	22/11/2017	20000010#1
Jim	Patient 2	M	07/05/1993	20000002	22/11/2017	20000002#1
Joe	Patient 3	M	07/05/1989	20000003	22/11/2017	20000003#1
Rose	Patient 4	F	03/05/1992	20000004	22/11/2017	20000004#1
Ellen	Patient 5	F	03/09/1987	20000005	22/11/2017	20000005#1
Bill	Patient 6	M	03/11/1967	20000006	22/11/2017	20000006#1
Mark	Patient 7	M	03/12/1967	20000007	22/11/2017	20000007#1
Aaron	Patient 8	M	01/12/1960	20000008	22/11/2017	20000008#1
Blake	Patient 9	M	15/07/1957	20000009	22/11/2017	20000009#1

Fig 107

The results are displayed in alphabetical order of the family name. The information provided for each result depends on the configuration in use. In the example shown in Fig 107 the columns indicate the family name, first name, sex, patient code and date of birth of every patient. It is possible that not all the data will be available for a patient, in which case the area corresponding to the missing information is empty.

To select a patient on the list:

- Double click the row corresponding to that patient

6.13 The Command bar

The command bar (Fig 108) contains buttons making it possible to perform different actions.

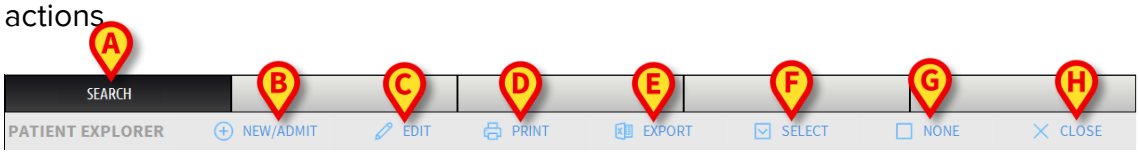


Fig 108

1) **Search** (Fig 108 **A**) – This button, if configured, can be used to indicate the current ward or department.

2) **New/Admit Patient** (Fig 108 **B**) – This button makes it possible to enter a new patient in the database and to admit him/her to a bed (see paragraph 6.13.1 for the detailed procedure).

3) **Edit Patient** (Fig 108 **C**) – This button makes it possible to edit the patient's data (see paragraph 6.13.2).

4) **Print** (Fig 108 **D**) - This button, when enabled, prints the grid currently displayed on screen.

5) **Export** (Fig 108 **E**) - This button, when enabled, makes it possible to export the current data to an XLS file.

6) **Select** (Fig 108 **F**) - This button makes it possible to select a patient.

7) **None** (Fig 108 **G**) – This button makes it possible to deselect a patient when he/she is selected. After clicking the **None** button, the name of the previously selected patient disappears from the **Patient** button (see paragraph 6.13.8).

8) **Close** (Fig 108 **H**) – This button closes the search screen (see paragraph 6.13.9).

6.13.1 New/Admit patient

The **New/Admit Patient** button (Fig 109) makes it possible to enter a new patient in the database and to admit them into a bed.

Fig 109

To enter a new patient:

- Click the **New/Admit Patient** button

The following window opens (Fig 110).

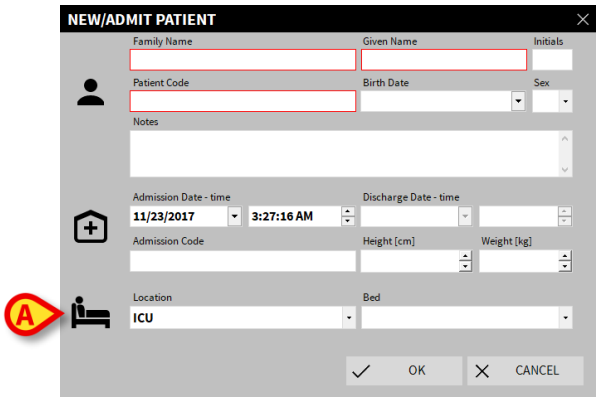


Fig 110

- Enter the new patient's data. The fields highlighted in pink are mandatory
- Click **Ok** to confirm

The new patient is registered in the database and admitted to the bed/department specified in the "Location" and "Bed" fields (Fig 110).

6.13.2 Edit patient

The **Edit Patient** button (Fig 111) makes it possible to edit the data of a selected patient.

Fig 111

Remember that this button can only be used if a patient is selected. The name must appear on the **Patient** button of the Digistat Smart Centra+l Control Bar (Fig 112).

The "edit" operations performed are always for the patient whose name appears on the **Patient** button (Fig 112).

Fig 112

To edit the patient's data:

- Select the patient whose data must be edited
- Click the **Edit Patient** button

A menu containing different options opens (Fig 113).

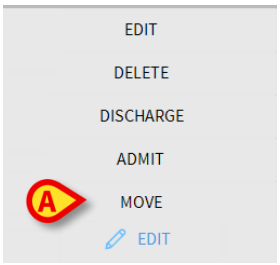


Fig 113

Each of these options makes it possible to perform a different operation. The functions of the different buttons on the menu are described in the following sections.

6.13.3 Move

The **Move** button (Fig 113 **A**) makes it possible to register the transfer of the patient selected to a different bed and/or a different location.

To transfer a patient:

- Select the patient

The name of the selected patient is displayed on the **Patient** button.

- Click the **Edit Patient** button

A drop-down menu containing various options opens (Fig 113).

- Click the **Move** button (Fig 113 **A**)

The following window opens (Fig 114).

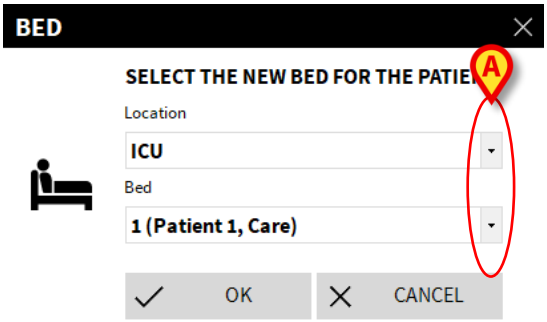


Fig 114

- Use the arrow buttons (Fig 114 **A**) to select the bed to which the patient will be transferred

The upper button opens a list of all the locations available.
The lower button opens a list of all the beds available in the location selected.

If the name of a patient appears alongside the bed number, the bed is already occupied.

- Click **Ok** to confirm

If an occupied bed is selected and the **Ok** button is clicked, a pop-up message is provided, asking whether we want to exchange the patients in the two beds.

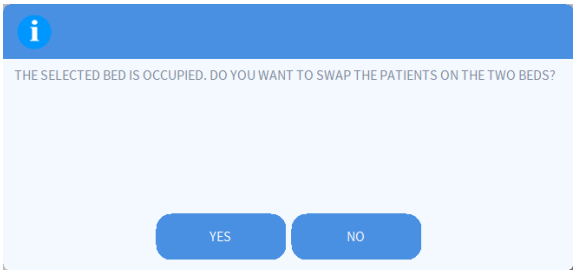


Fig 115

6.13.4 Admit

The admission button is disabled. The admission procedure is performed together with the “New patient” recording procedure. See paragraph 6.13.1.

6.13.5 Discharge

The **Discharge** button makes it possible to register the discharge of a patient.

To discharge a patient

- Select the patient

The name of the selected patient is displayed on the **Patient** button.

- Click the **Edit Patient** button

A menu containing various options opens (Fig 116).

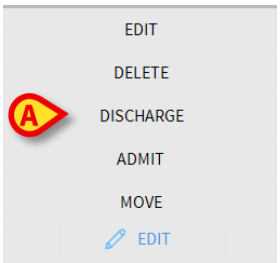


Fig 116

- Click the **Discharge** button (Fig 116 **A**)

A pop-up message requesting confirmation of the operation opens (Fig 117).

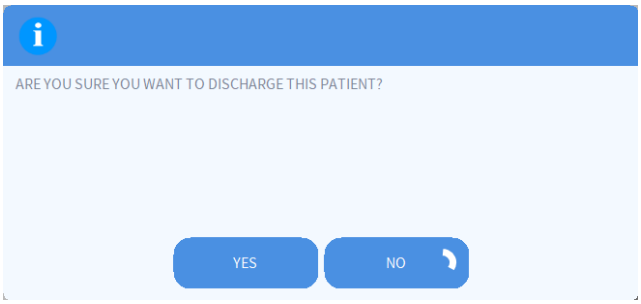


Fig 117

- Click **Yes** to proceed with the discharge of the patient

This action opens the window containing the patient's data (Fig 118 – unlike the window shown in Fig 110, here you can change the date and time of discharge).

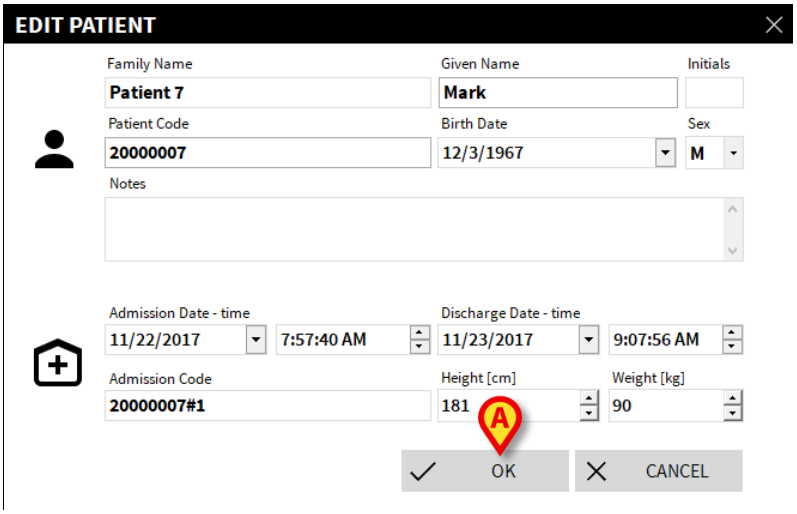


Fig 118

- Click **Ok** to complete the discharge procedure (Fig 118 A)

6.13.6 Delete

The **Delete** button makes it possible to delete all data of a patient from the database.

To delete a patient's data:

- Select the patient

The name of the selected patient is displayed on the **Patient** button.

- Click the **Edit Patient** button

A menu containing various options opens (Fig 119).

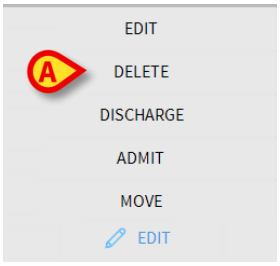


Fig 119

- Click the **Delete** button (Fig 119 **A**)

A pop-up message requesting confirmation is provided (Fig 120).

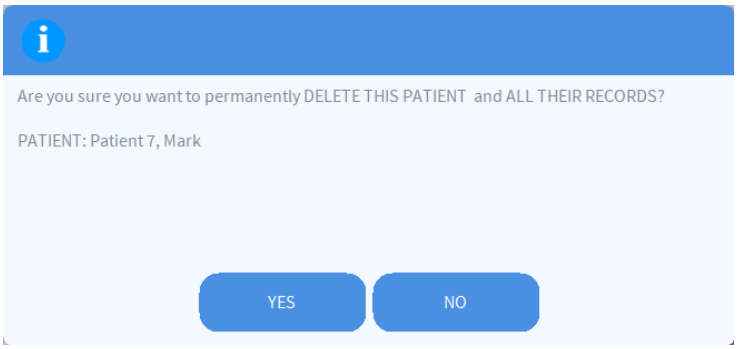


Fig 120

- Click **Yes** to proceed with the deletion procedure

Once a patient has been deleted it is no longer possible to access any document regarding him/her acquired through the Digistat Smart Central.

Therefore, it is necessary to perform this operation with extreme caution.
Only users with specific permissions are enabled to delete a patient.

6.13.7 Edit

The **Edit** button makes it possible to edit data of a selected patient.

To edit a patient's data:

- Select the patient.

The name of the selected patient is displayed on the **Patient** button.

➢ Click the **Edit Patient** button

A menu containing various options opens (Fig 121).

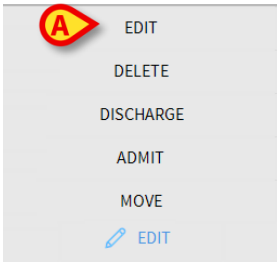


Fig 121

➢ Click the **Edit** button (Fig 119 **A**)

A window containing the patient's data opens (Fig 122).

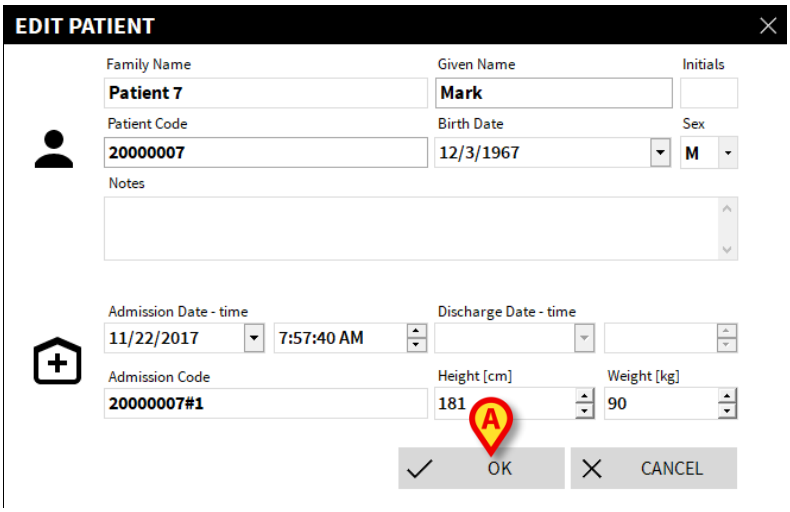


Fig 122

➢ Edit the patient's data

➢ Click **Ok** to confirm (Fig 122 **A**).

6.13.8 Deselect patient

The **None** button (Fig 123) makes it possible to deselect the selected patient (whose name is shown on the PATIENT button).

Fig 123

To deselect a patient:

➢ Click the **None** button (Fig 123)

The patient's name disappears from the **Patient** button.

6.13.9 Close

The **Close** button (Fig 124) makes it possible to close the search screen.

Fig 124

To close the patient search screen:

- Click the **Close** button on the screen (Fig 124)

7. Bedside configuration

The Digistat Smart Central can be configured to be “locked” to a single bed. In this case the screen displays the data of the connected bed in full-screen mode. In Fig 125 the workstation is locked to bed 2.

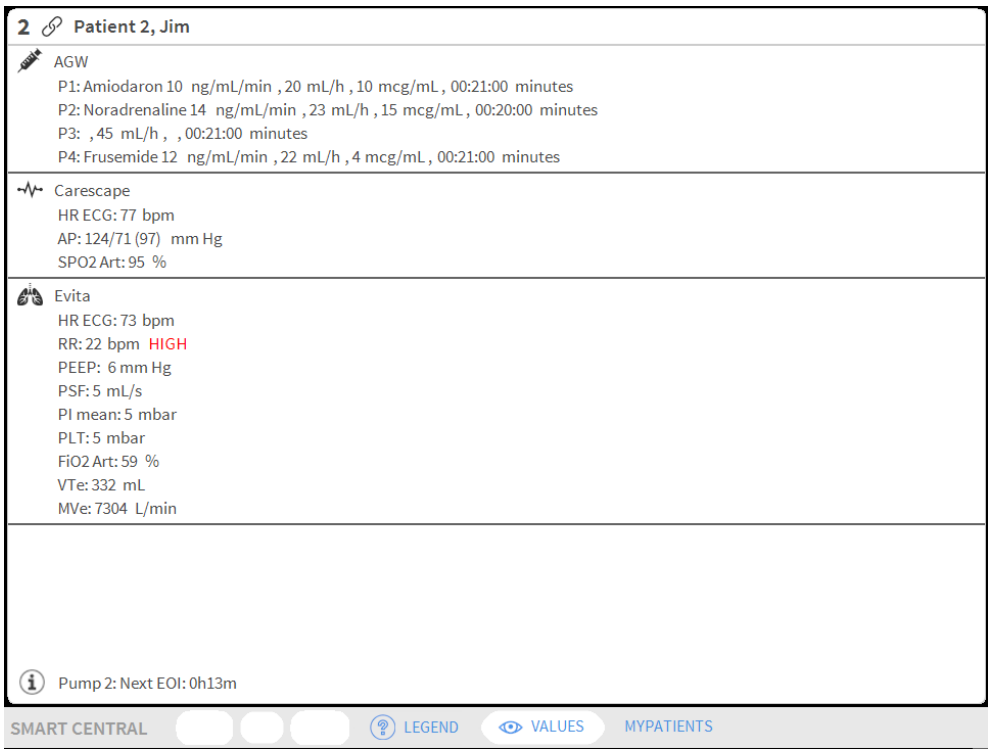


Fig 125

The “Bed area” is the same as described above.

Three buttons are in the command bar.

Use the **Legend** button to display the “Legend” window explaining the meaning of the different icons (see paragraph 6.5.1).

Use the **Values** button to display the device values when no alarm is provided (see paragraph 6.4.1).

Use the **MyPatients** button to select other beds to be displayed on the screen (see next section).

7.1 My Patients

The “My patients” functionality makes it possible to display up to 4 additional “Bed areas” on a “Bedside” workstation (maximum 5 in total, depending on configuration).

To use this functionality:

- Click the **MyPatients** button on the command bar

The following window opens (Fig 126).

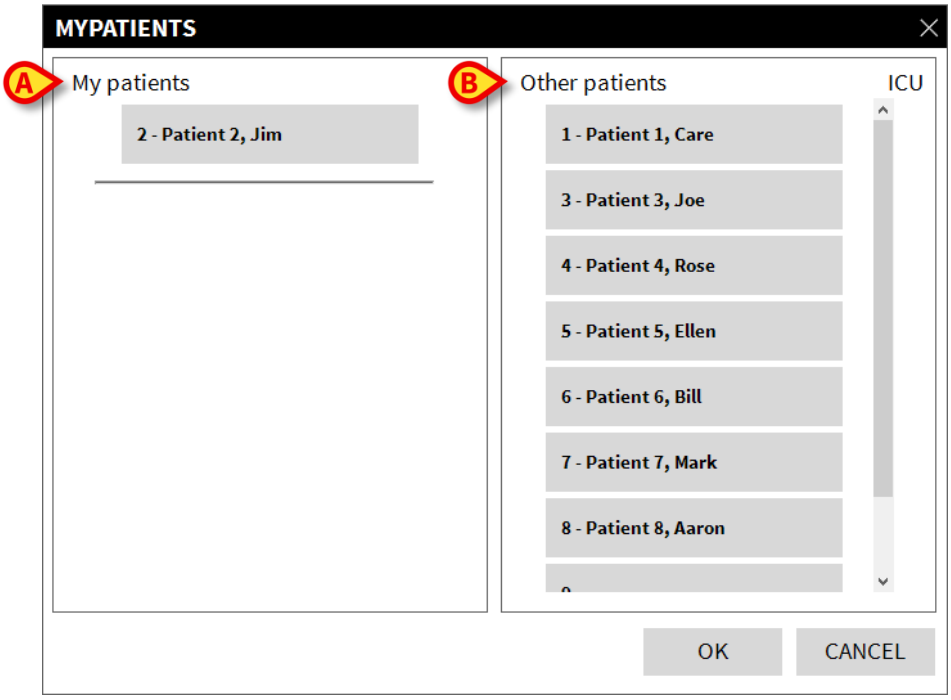


Fig 126

On the left, in the “My patients” column, is the list of “Bed areas” currently displayed (Fig 126 **A**). Each box represents a “Bed area”. The box on top represents the patient to which the workstation is locked.

On the right, in the “Other Patients” column, all the existing “Bed areas” are listed (Fig 126 **B**).

To select a “Bed area” to be displayed on screen,

- Click the corresponding box for the patient in the “Other Patients” column

The box disappears from the “Other Patients” column (right) and is displayed on the “My Patients” column (Left). A maximum of 4 additional “Bed areas” can be selected (depending on configuration).

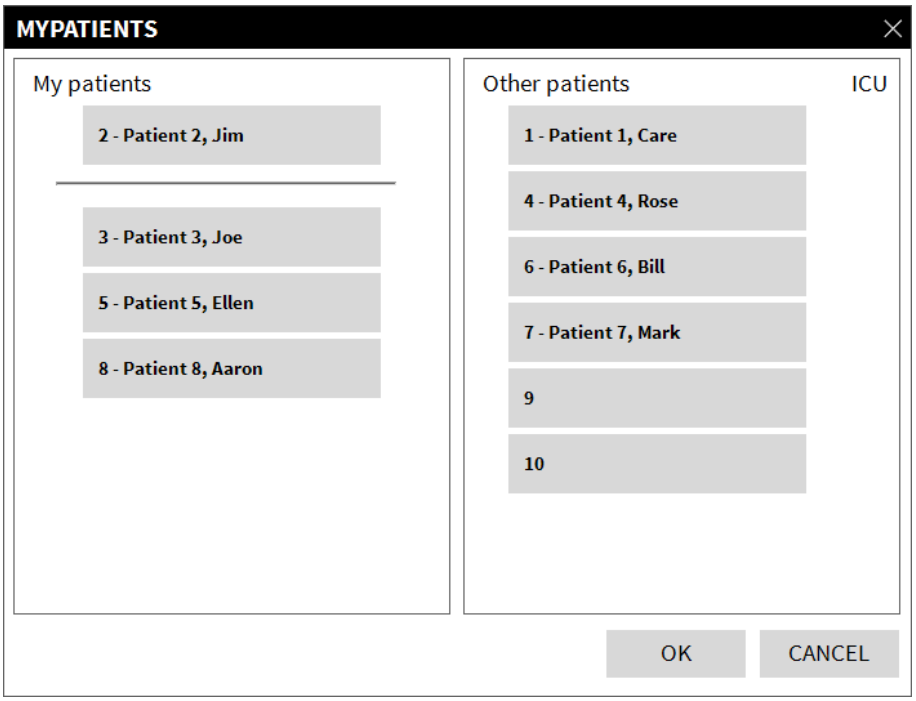


Fig 127

In Fig 127 “Bed areas” 3, 5 and 8 are selected.

➢ Then click the **Ok** button

The Digistat Smart Central screen is displayed as shown in Fig 128.

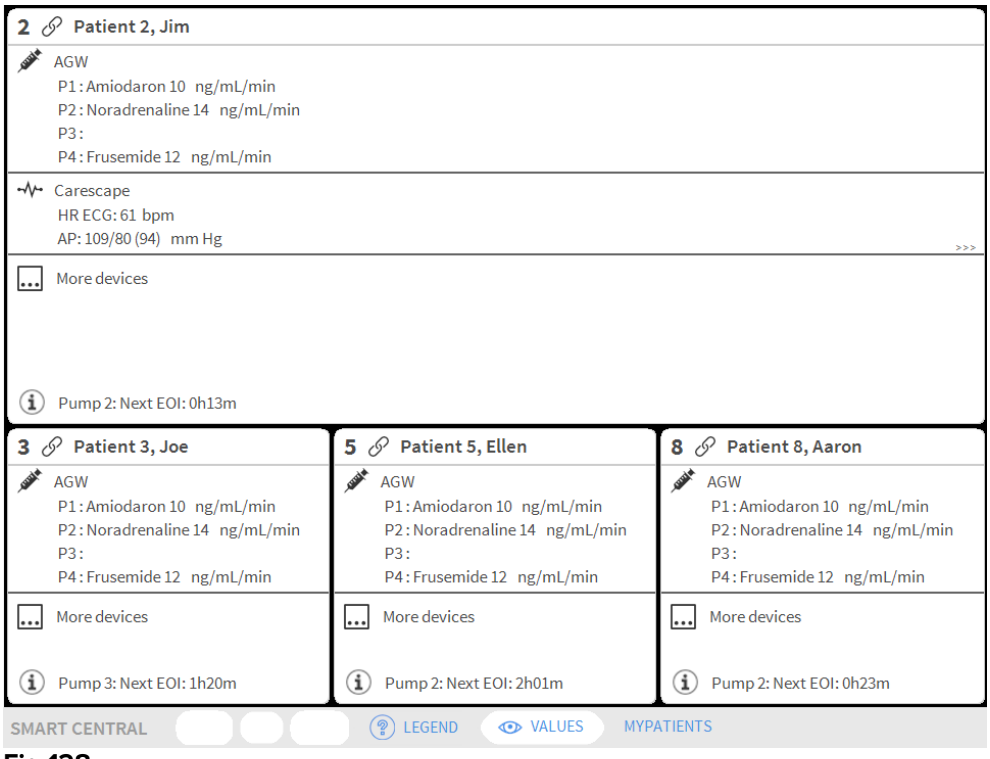


Fig 128

The “Bed area” to which the workstation is locked is number 1 (large, on top). “Bed areas” 3, 5, 8 are displayed underneath the locked “bed area” and are smaller.

The additional “Bed areas” can be enlarged.

- Click on one of the additional “Bed areas” to enlarge it. Click again to bring it back to the original proportions

In order to remove one or all the additional “Bed areas”,

- Click the **MyPatients** button on the command bar

The “My Patients” window is displayed (Fig 127).

To remove an additional “Bed area”,

- Click the box corresponding to the “Bed area” to be deselected in the “My Patients” column

The box disappears from the “My Patients” column (left) and is displayed on the “Other Patients” column (Right). The deselected “Bed area” will not displayed anymore.

8. Digistat Smart Central Mobile

Digistat Smart Central Mobile is a mobile application designed to bring some the Digistat Smart Central functionalities directly “in the hands” of nurses and clinicians.

8.1 Information for the user

Please read carefully the following warnings.

!	Disconnection from server is possible. In case of disconnection of the Digistat Smart Central Mobile application a specific notification is generated, consisting of a characteristic and persisting sound and vibration. Sound duration is configurable. The sound is repeated until the connection is reestablished. Connection is automatically reestablished as soon as possible.
!	The mobile device shall always be kept by the user either in direct contact or close enough to be clearly audible.
!	The Digistat Smart Central Mobile application may display personal and/or confidential information. It is therefore recommended to not leave unattended the handheld device on which the Digistat Smart Central Mobile application runs or, in case, to always logout before leaving it unattended.
!	Digistat Smart Central Mobile can be closed by the user. After which time the application will not send any other notification.
!	Because of the Android architecture, in exceptional cases, which are hard to foresee, the operating system can close the Digistat Smart Central Mobile application. After such event, the application will not send any other notification.

!	The update of data displayed on screen caused by device connection, power off, disconnection and change of status depends on the time required by the device itself to communicate the changes. This time depends on various factors. Among them is the device type and type of connection. For some devices, there are conditions in which the delay in communicating changes might be important. Since they might change depending on devices configuration and operational conditions, it is not possible to provide an indication of the delays for all the possible devices

!	The mobile device shall support the vibration mode.

!	Check that the medical devices are correctly connected by verifying that their data are displayed on the Digistat Smart Central Mobile.

!	Use the sound check procedure to verify if the audio and the vibration on the handheld device is correctly working (see paragraph 8.7 for the procedure). The procedure should be performed once per shift.

!	On the connected medical device where it is possible, generate an artificial alarm condition to verify that the corresponding alarm notification is correctly displayed on the Digistat Smart Central Mobile (it is suggested to perform this check at least once per shift).

!	Within the Digistat Smart Central Mobile Application the alarms are grouped in “physiological alarms”, “technical alarms” and “other”. This kind of differentiation has no impact on the way the alarms are displayed on the Digistat Smart Central Mobile interface.

The drivers used to read the data from the connected medical devices have a reading-cycle of less than 3 seconds (i.e. all the data from the devices is read every 3 seconds at maximum). However, there are devices that communicate the information less frequently (5-10 seconds interval). Refer to the specific driver documentation for details on the reading-cycle.
As soon as a driver detects an alarm, it takes maximum 1 second to transfer it to the Digistat Smart Central Mobile.

In case of electrical black-out, it takes a few minutes for the system to be fully operative again and therefore generate alarm notifications (usually this time is less than 3 minutes, however it depends on the configuration of the used computers).

8.2 Start-up

Although the contents are the same, start-up and layout are slightly different on the Ascom Myco device (if integrated with Ascom Unite) and other Android handheld devices (or Ascom Myco not integrated with Ascom Unite).
The layout displayed in Fig 129 is referring to a scenario where the Ascom Myco is integrated with UNITE.

8.2.1 Ascom MYCO (w/ Unite) Start-Up

On the Ascom Myco device, when integrated with Ascom Unite, the Digistat Smart Central Mobile application is already running on the rightmost page of the Myco's Unite launcher.

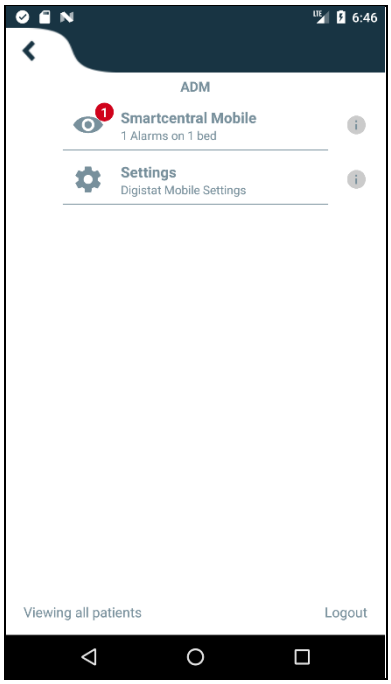


Fig 129

The available functionalities are listed on the page. Touch the row corresponding to the functionality to open it.

The **Settings** option makes it possible to access some configuration options. A specific password is required to access this area (Fig 130).

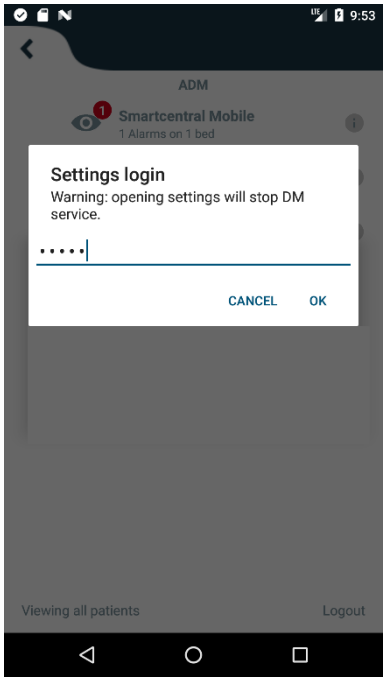


Fig 130

➢ Insert password and touch **OK** to access these options. The following screen will be displayed.

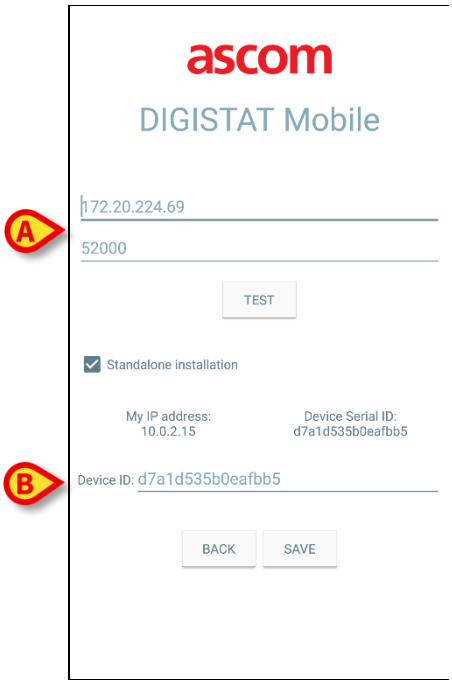


Fig 131

It is here possible to specify the IP address of the server and the server port (Fig 131 **A**).

After editing:

- touch the **Test** button to test the new settings
- touch the **Save** button to save the changes made,

The lower field (Device ID - Fig 131 **B**) makes it possible to change the device id code.

8.2.2 Android device start-up

On the handheld device,

- Touch the  icon.

The following screen will be displayed (Fig 132).

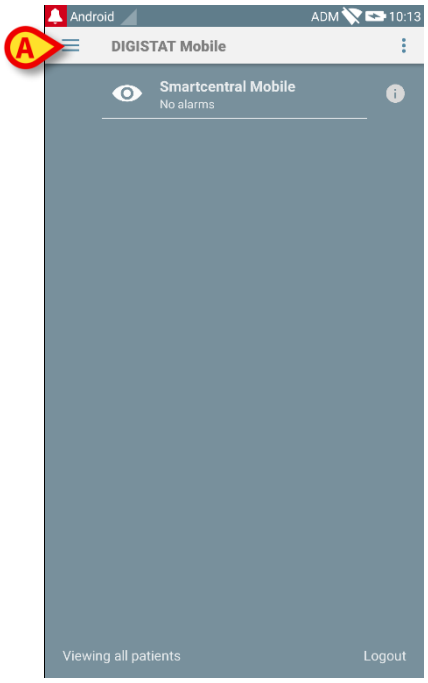


Fig 132

The available functionalities are listed on the page. Touch the row corresponding to the module to open it.

- To access the “Settings” area, touch the  icon on the top-left corner.

The following options will open (Fig 133 - see paragraph 8.3 for the full list of options).

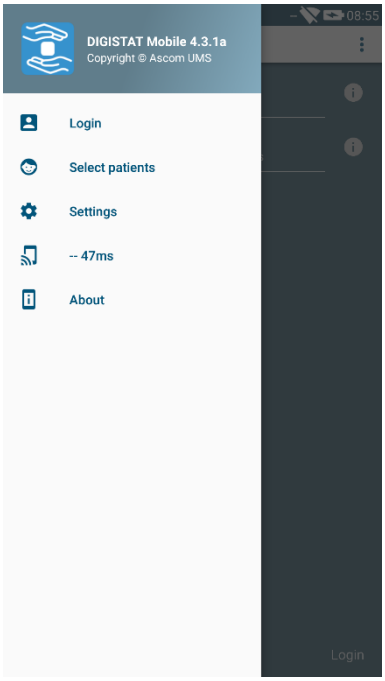


Fig 133

- Touch **Settings** to access the settings management screen. A specific password is required to access this area.

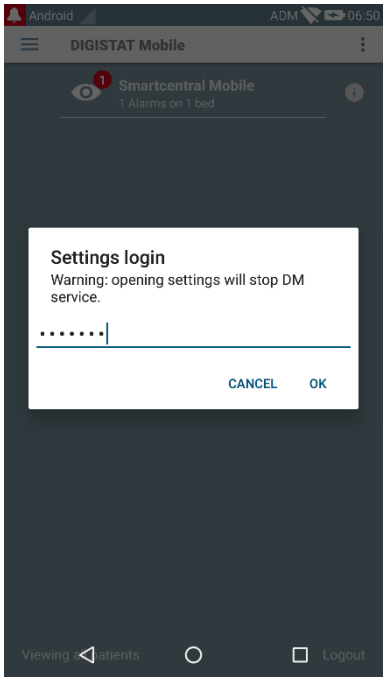


Fig 134

➢ Insert password and touch **OK** to access these options. The following screen will be displayed.

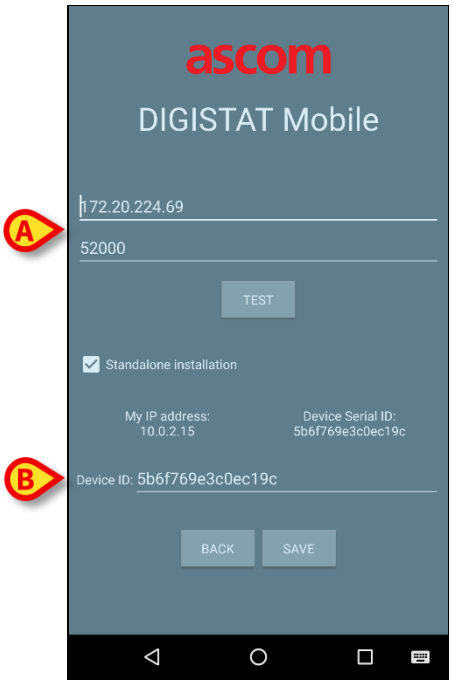


Fig 135

It is here possible to specify the IP address of the server and the server port (Fig 131 **A**).

After editing:

➢ touch the **Test** button to test the new settings

➢ touch the **Save** button to save the changes made,

The lower field (Device ID - Fig 135 **B**) makes it possible to change the device id code.

8.2.3 Updates installation (APK files)

Whenever a software update is available, an additional row is displayed on the start page.

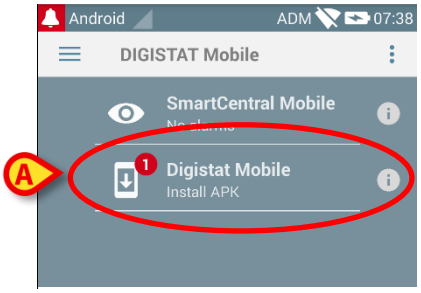


Fig 136

To install the software updates

➢ Touch the row indicated in Fig 136 **A**.

8.3 Lateral Menu

The  icon on the top-left corner opens a menu containing different options (Fig 137).

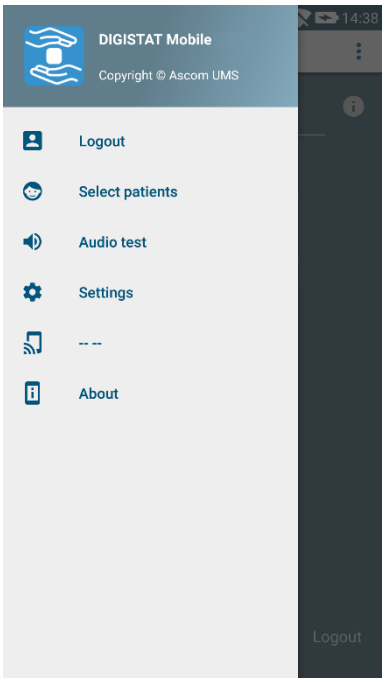


Fig 137

These are:

Login
Touch this option to access the login screen (described below - Fig 140).

Select Patients
Touch this option to access the Patients List (see paragraph 8.8).

Audio Test
Touch this option to perform an Audio Test (see paragraph 8.7).

Settings
Touch this option to access the Settings screen (see previous paragraph 8.2.2).

Wireless connection status
Indicating the wireless connection status.

About
Touch this option to open a screen containing general info about Digistat Smart Central Product and Manufacturer. Touch **Licenses** on this screen (Fig 138 **A**) to display the licenses associated with the Product.

Fig 138

8.4 Login

To login to Digistat Smart Central Mobile

- Touch **Login** on the lower-right corner of the “Applications list” screen (Fig 139 **A**)

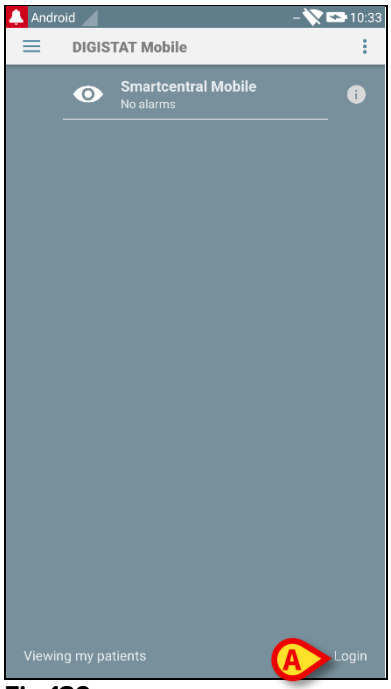


Fig 139

The following screen will be displayed (Fig 140)

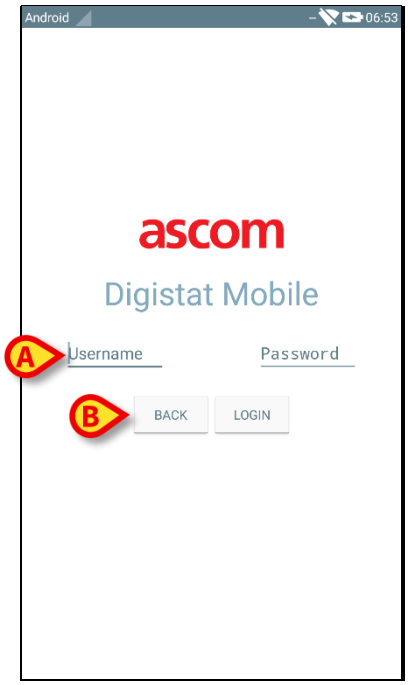


Fig 140

- Insert username and password (Fig 140 **A**).
- Touch the **Login** button (Fig 140 **B**)

The acronym indicating the logged user will then be displayed either on the "Applications list" screen (for Myco/UNITE version - Fig 141 **A**),

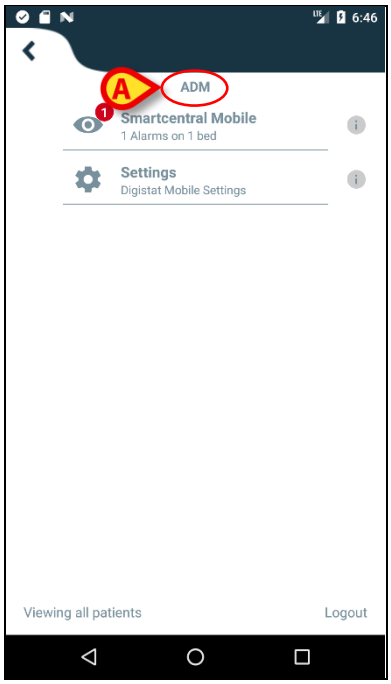


Fig 141

or on the upper notification bar (for other android handheld devices - Fig 142 **A**).

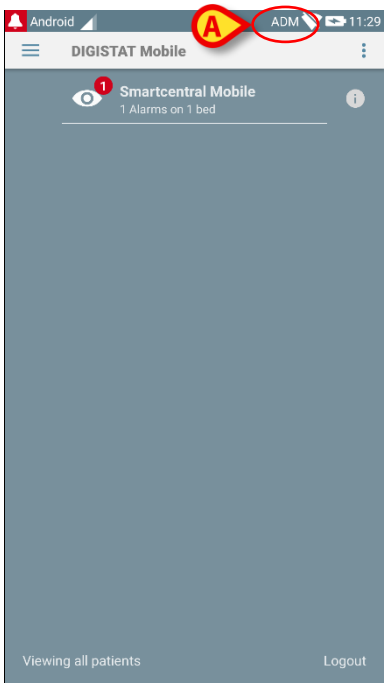


Fig 142

8.5 Upper notification bar

The upper notification bar (Fig 143 **A**) is always visible and displays general information.

Fig 143

The red bell icon placed on the top-left corner (only visible in non-Myco/UNITE devices - Fig 143 **A**) is displayed if there are notifications for one of the patients. It is as well displayed if the Smart Central Mobile is not active.

On the top-right corner the following information is displayed (Fig 143 **B**):

- Acronym of the logged user (non-Myco/UNITE devices);
- Wi-fi connection status;
- Battery charge status;
- Time.

8.6 General System Notifications

Digistat Smart Central Mobile provides short notifications when the application is not active as well (Fig 144 **A**).

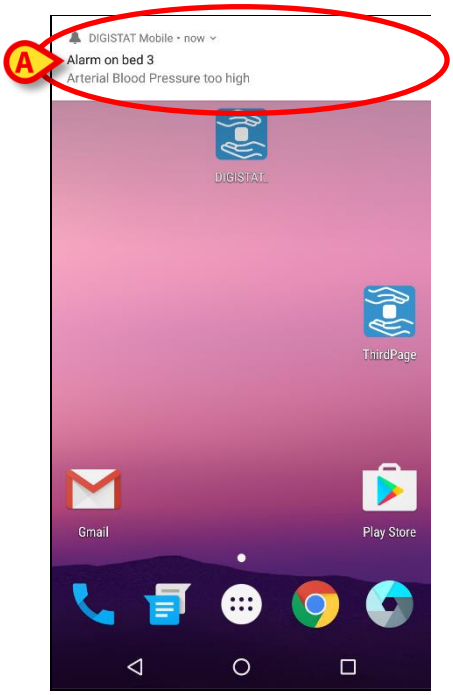


Fig 144

➢ Swipe the notification to make it disappear.

➢ Touch the notification to directly access the relevant patient (see an example in Fig 145).

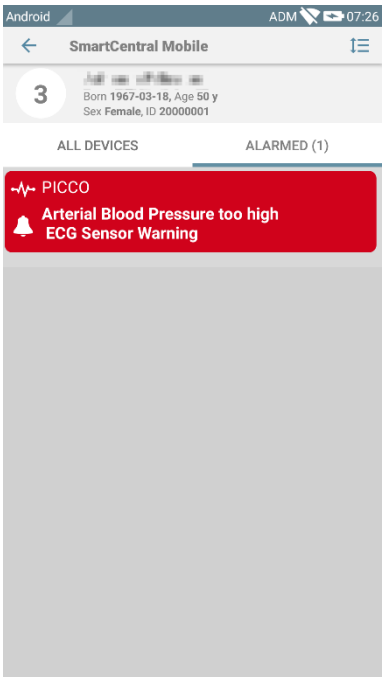


Fig 145

8.7 Sound Check procedure

The Sound Check procedure shall be performed at least once per shift.

The Sound Check Procedure makes it possible to verify if the sound and vibration notification of alarms is working properly.

To perform the “Sound Check” procedure

- On the home screen of the Digistat Smart Central Mobile Application, touch the icon on the top-left corner of the screen (Fig 146 **A**)

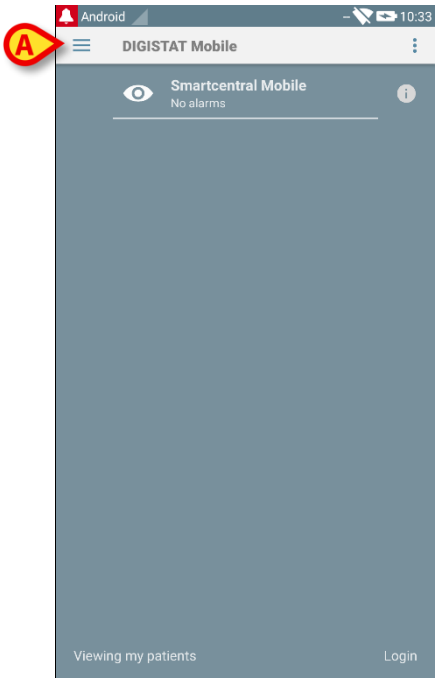


Fig 146

The following menu will be displayed (Fig 147).

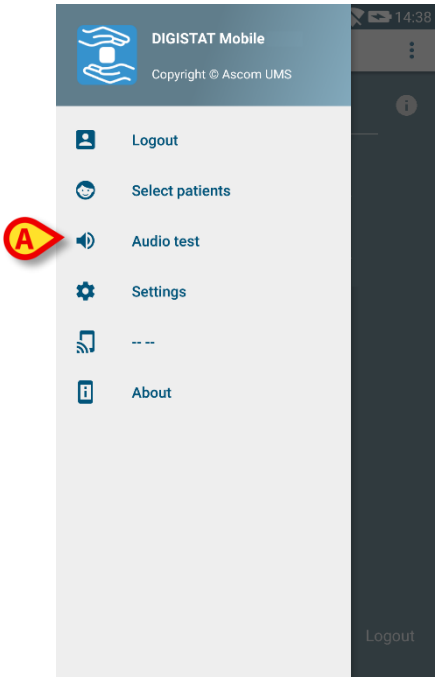


Fig 147

➢ Touch the **Audio test** option (Fig 147 **A**).

A test notification/sound will be this way provided (Fig 148 **A**).

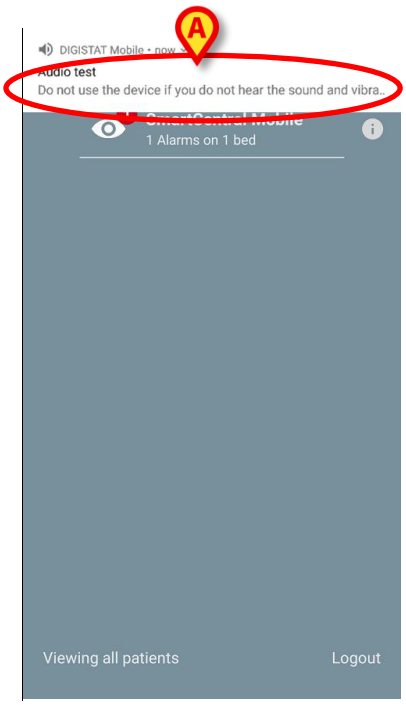


Fig 148

Do not use the device if you do not hear the alarm sound and/or feel the device vibration.

8.8 Patients search functionalities

The application implements some patients search tools. These tools can be accessed from the Patients List screen.

To access the Patients List

- Touch the “mode” indication on the lower-left corner of the screen (Fig 149 **A** - this indication shows the current application mode, i.e. either “All Patients” or “My Patients” or “One Patient”, see paragraph 8.9 for a more detailed explanation).

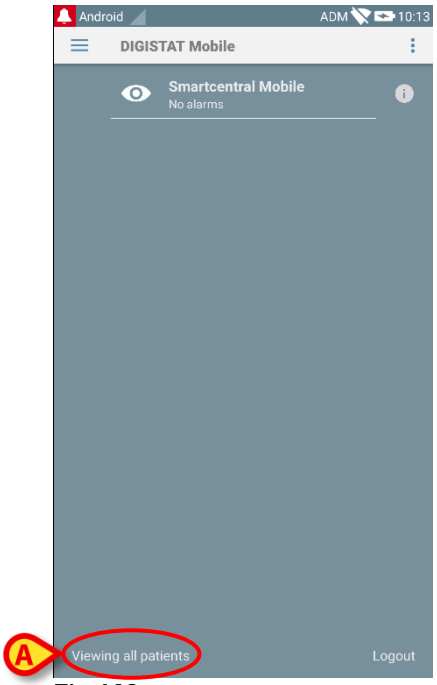


Fig 149

On the non-Myco/UNITE application the same screen can also be accessed touching the **Select Patients** option on the lateral menu (Fig 150 **A** - touch the ☰ icon on the top-left corner to open the menu).

Fig 150

In both cases, the following screen will open, containing the list of all the patients configured on the device domain (Fig 151).

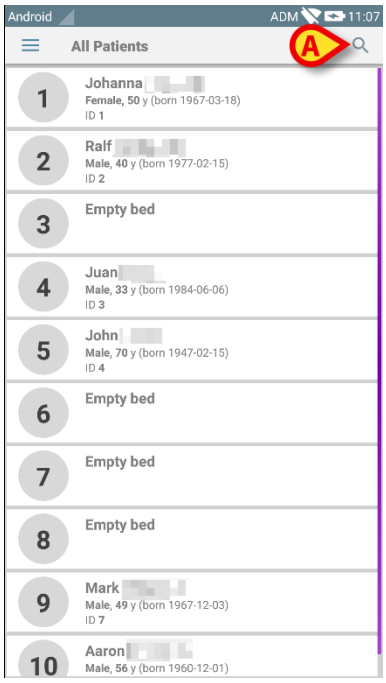


Fig 151

To access the search functionalities

- Touch the icon indicated in Fig 151 **A**.

The following screen will open (Fig 152).

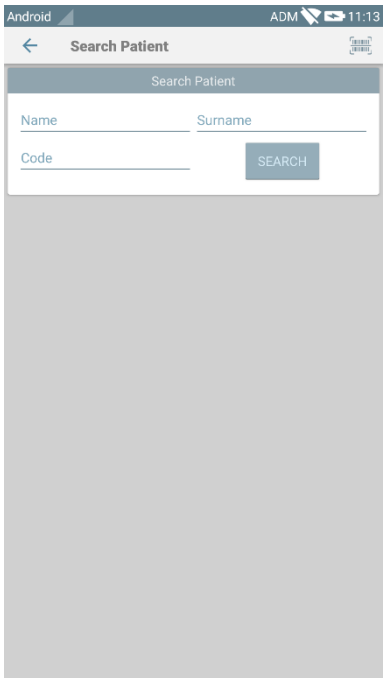


Fig 152

Three search options are available:

1 - textual search (see paragraph 8.8.1)
2 - barcode scan (see paragraph 8.8.2)
3 - NFC code scan (see paragraph 8.8.3)

8.8.1 Textual search

➢ insert patient data in the fields indicated in Fig 153 **A** (name, surname, code), then click the **Search** button (Fig 153 **B**). Partial information is allowed.

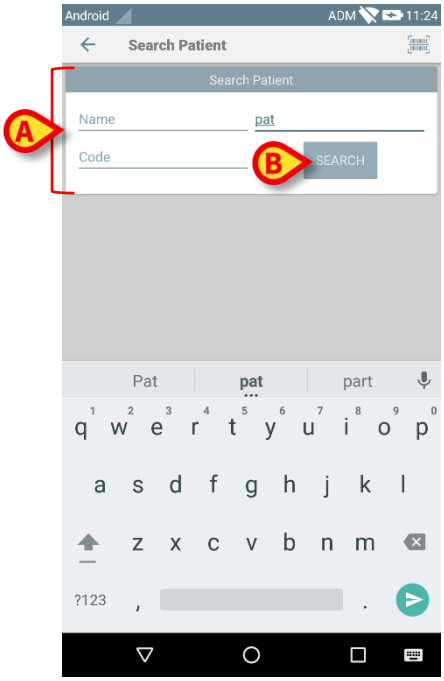


Fig 153

The list of patients whose data match those specified will be displayed (Fig 154).

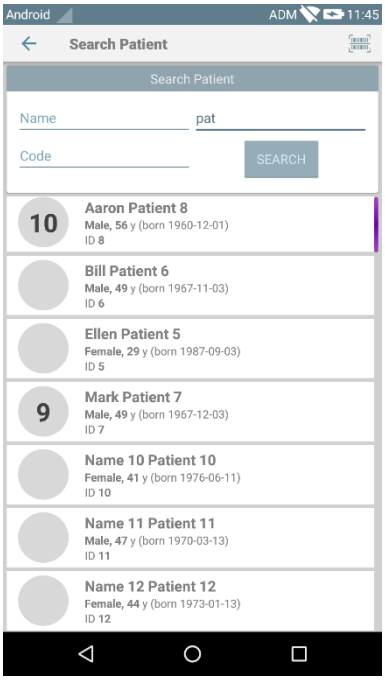


Fig 154

The search is performed among all patients, both belonging and not belonging to the device domain. If the patient is currently in bed, the bed number is displayed on the left.

➢ Touch the box corresponding to a patient to select the patient. User confirmation is required (Fig 155).

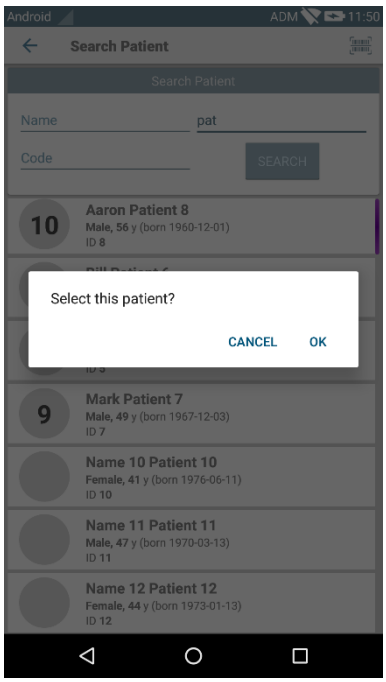


Fig 155

➢ Touch **Ok** to confirm.

The patient will be this way selected (Fig 156).

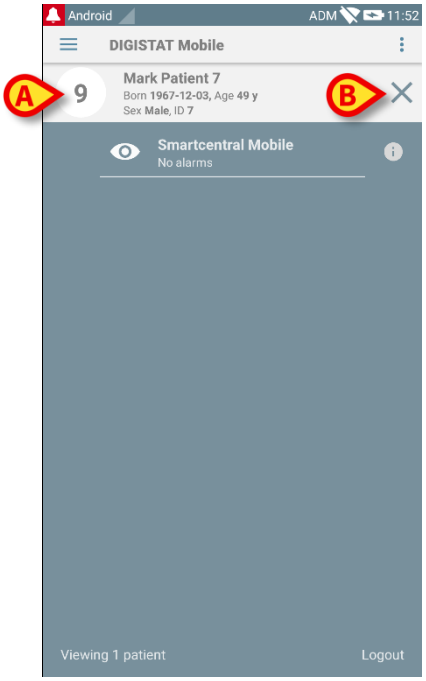


Fig 156

Patient data are on top of the page (Fig 156 **A**). All the data in the Digistat Smart Central Mobile are now filtered by patient (i.e. all and only the selected patient alarms/notifications are displayed).

- Touch the cross indicated in Fig 156 **B** to deselect the patient and turn to “All Patients” mode again.

8.8.2 Barcode Scan search

The Barcode Scan functionality makes it possible to select a patient by scanning his/her code .

To access the Barcode Scan functionality

- Access the search page as described in paragraph 8.8.
- Touch the icon indicated in Fig 157 **A**.

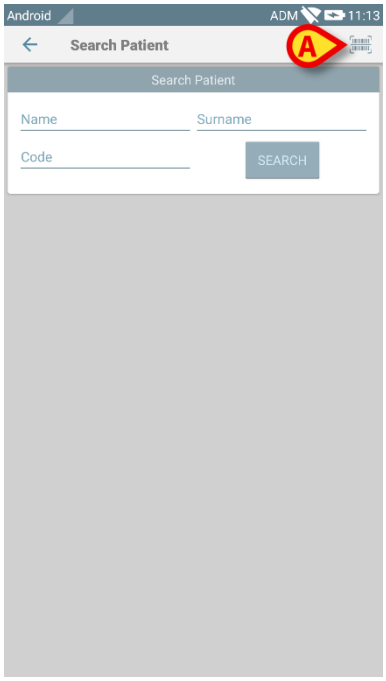


Fig 157

The device camera will be in this way activated.

- Scan the wanted patient’s barcode.

The patient will be this way selected. The screen shown in Fig 156 (example) will be displayed.

8.8.3 NFC Reader search

The NFC Scan makes it possible to select a patient using the device's own Near Field Communication sensor.

To do that:

- Access the search page as described in paragraph 8.8.

The device NFC reader will be this way activated.

- Position the device close to the patient's Tag.

The patient will be this way selected. The screen shown in Fig 156 will be displayed.

8.9 “My patients” mode

“My patients” mode makes it possible for a user to select one or more patients and create a “group” of patients who are under their charge.

“My patients” can be enabled or not by configuration and applies to the handheld device. So, there can be devices with “My patients” enabled and devices with “My patients” disabled.

Depending on the device configuration, if the “My patients” mode is activated, the following notifications can be displayed on the handheld device:

a) The notifications related to the patients selected as “My patients”;
b) The notifications related to the patients selected as “My patients” and those related to the patients that no one has explicitly taken in charge;
c) The notifications related to the patients selected as “My patients”, those related to the patients that no one has explicitly taken in charge and those related to other patients if the devices which had them in charge “lose” them (for any reason, low wi-fi signal for instance).

On the lower-left corner of the modules list screen, it is specified if the device is currently set on “My patients” or “All patients” (Fig 158 **A**).

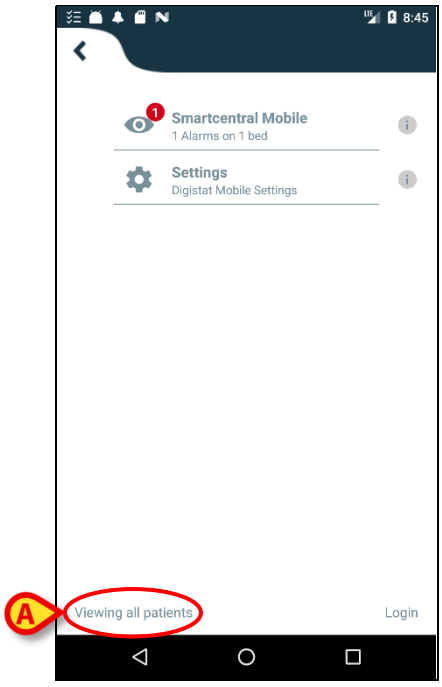


Fig 158

➢ Touch the indication (Fig 158 **A**) to display the managed patients list (Fig 159).

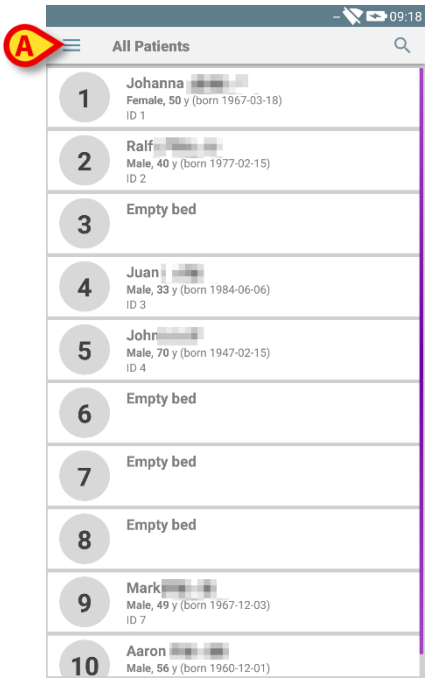


Fig 159

8.9.1 “My patients” activation

To activate “My patients”

- Touch the ☰ icon (Fig 159 **A**).

The following menu will open (Fig 160).

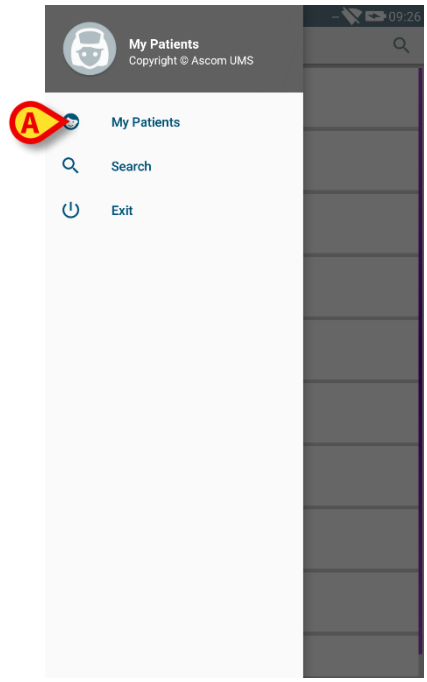


Fig 160

- Touch **My Patients** (Fig 160 **A**).

The device switches this way to “My patients” mode. “My patients” list will be displayed (Fig 161). In Fig 161 no patients is selected to be part of “My patients” list. See next paragraph for instructions on how to select “My patients”.

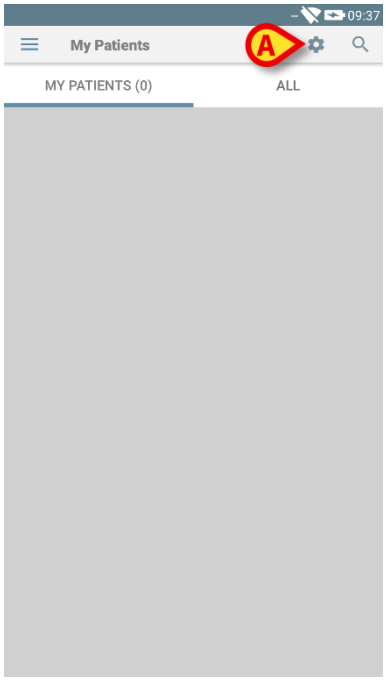


Fig 161

NOTE: The same procedure can be performed to switch back to “All patients”.

8.9.2 How to select “My patients”

To select the list of patients forming “My patients” list, on “My patients” list screen,

- touch the icon (Fig 161 **A**).

The following screen will be displayed (Fig 162 - “My patients setup”).

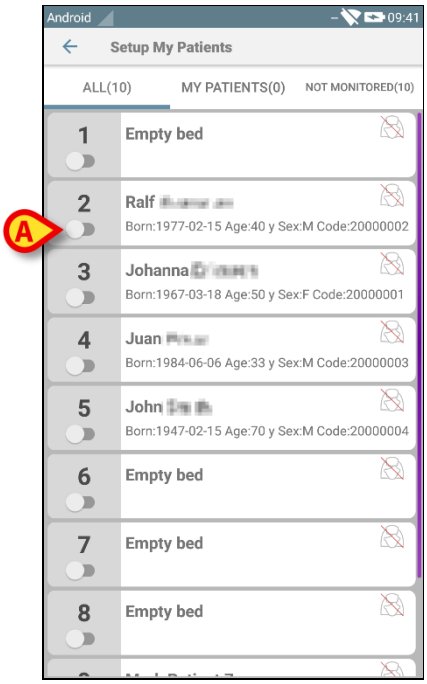


Fig 162

A patient can be selected/deselected by touching the corresponding “tile”. Each tile corresponds to a bed. In Fig 163 patients in bed 2, 3 and 5 are selected as “My patients”.

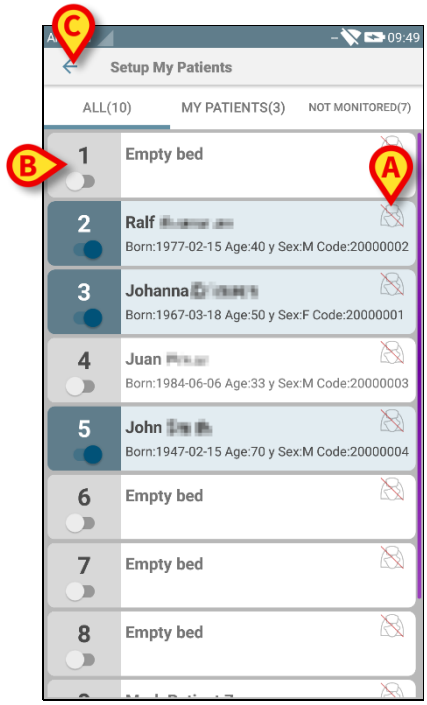


Fig 163

The icons on the right of the patient names (Fig 163 **A**) have the following meanings:

- Patient is part of “My patients” of another user. It is still possible to select the patient. If two users select the same patient, the patient will be grouped under “My patients” for both users.

- Patient is not monitored. I.e. another user has him/her in charge, but at the moment, due (for example) to wi-fi connection failure, no one is monitoring him/her.

No icon means that no one has the patient in their “My patients” list, so the patient is not monitored.

The filters indicated in Fig 163 **B** make it possible to display:

- all patients;
- only the selected patients (“My patients”);
- only the patients that are not monitored.

The icon indicated in Fig 163 **C** makes it possible to go back to “My Patients” list screen.

Use the filter indicated in Fig 164 **A** to display all patients again. The patients are now grouped as “My patients”, “Assigned to others” patients and “Unattended patients”.

NOTE: the number displayed alongside the filter refers to the total number of patients being part of “My patients” of any user.

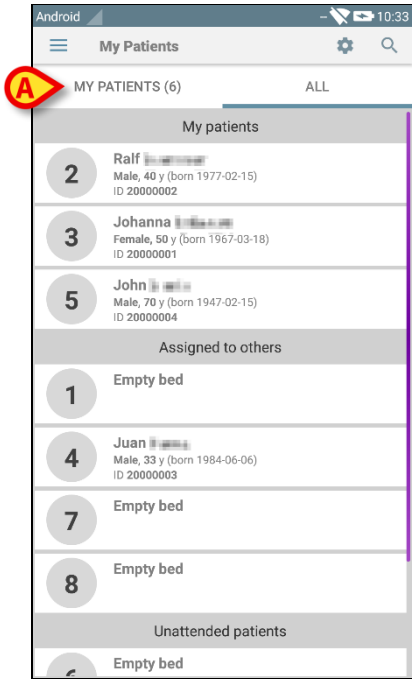


Fig 164

NOTE: When "My Patients" mode is active only the information relating to "My patients" is notified.

8.10 Single Patient Selection

One single patient can be selected by touching the tile corresponding to his/her bed.

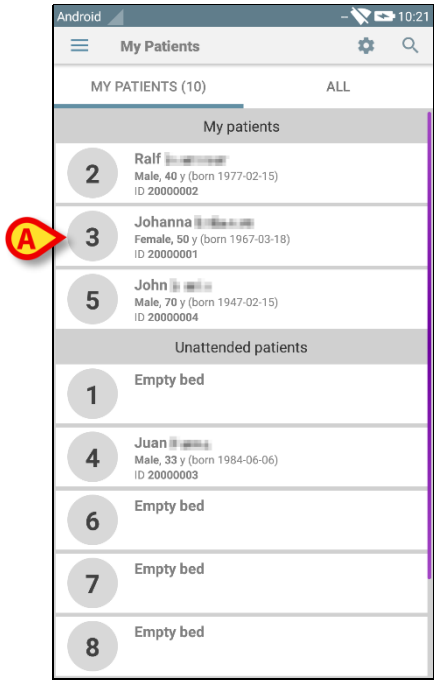


Fig 165

For instance, to select the patient on bed 3,

- Touch the tile indicated in Fig 165 **A**. User confirmation is required (Fig 166).

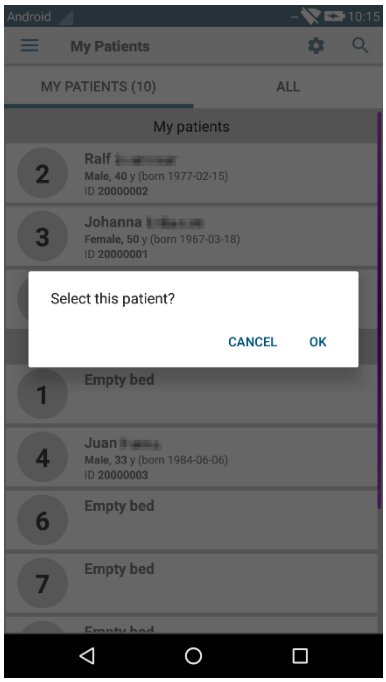


Fig 166

➢ Touch **Ok** to confirm. After confirmation the following screen is displayed.

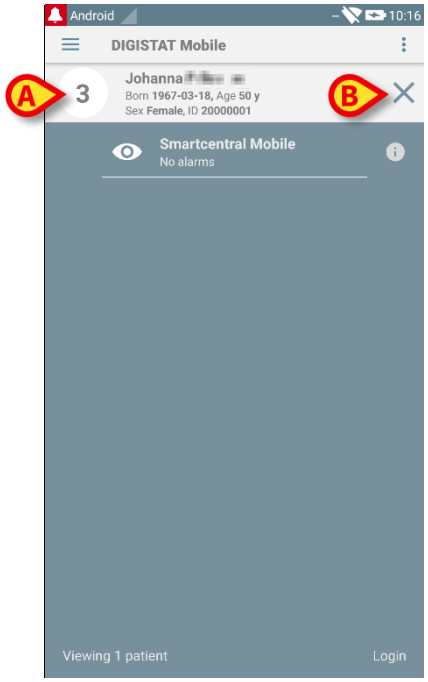


Fig 167

Patient data are on top of the page (Fig 167 **A**). All the Digistat Smart Central Mobile modules data is now filtered by patient (i.e. all and only the selected patient alarms/notifications are displayed).

➢ Touch the cross indicated in Fig 167 **B** to deselect the patient and turn to “All Patients” mode again.

9. Digistat Smart Central Mobile Application

9.1 Application start-up

To start the Digistat Smart Central Mobile application

- Touch the corresponding row on the handheld device screen.

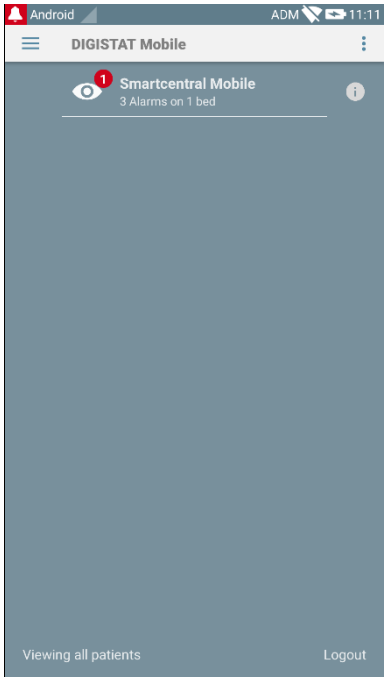


Fig 168

The “Smart Central” screen, shown in Fig 169, opens.

9.2 “Smart Central” screen

The “Smart Central” screen displays a schematic summary of the status of the medical devices connected to each bed configured in the specific handheld device (Fig 169).

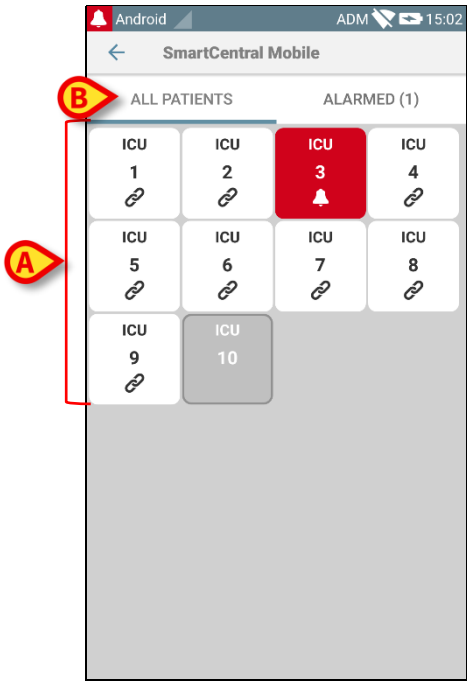


Fig 169

The numbered squares displayed on screen represent the beds configured in the handheld device (Fig 169 **A**). The squares visible on a single screen form the “domain” of beds covered by the handheld device. The “domain” is defined by configuration.

The number displayed inside the square indicates the bed number. On each square, the status of the connected medical devices is indicated in graphic form by the background color and the related icon:

- All the medical devices connected to the bed are on hold.

- There is at least one connected medical device running.

- At least one of the connected medical devices is sending a low priority alarm.

- At least one of the connected medical devices is sending a medium priority alarm.

- At least one of the connected medical devices is sending a high priority alarm.

You can use the filters indicated in Fig 169 **B** to display either all the configured beds or only the beds sending an alarm.

9.2.1 “My Patients” screen

In My Patients mode, the Smart Central screen displays a summary of the status of the selected patients (see 8.9.2, How to select “My Patients”)

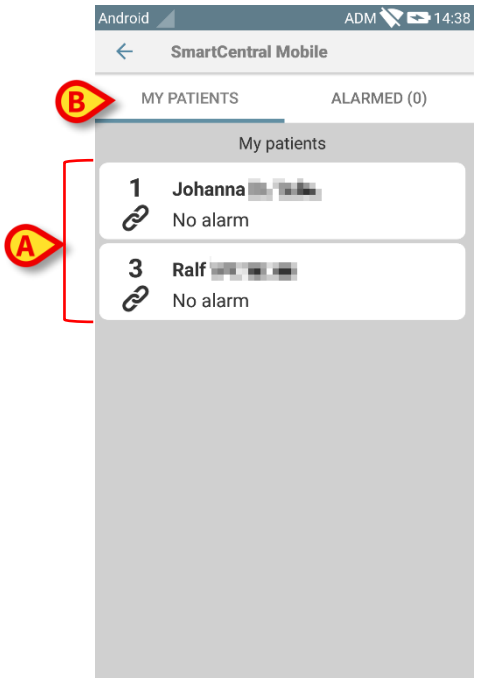


Fig 170

The numbered boxes displayed on screen represent the patients configured in the handheld device (Fig 170 **A**)

You can use the filters indicated in Fig 170 B to display either all the configured patients or only the patients sending an alarm.

The status of the connected medical devices is indicated in graphic form by the background color and the related icon described in section 9.2.

9.3 Medical devices list

To display the list of medical devices connected to the bed

- Touch one of the squares on the “Central” screen (Fig 171).

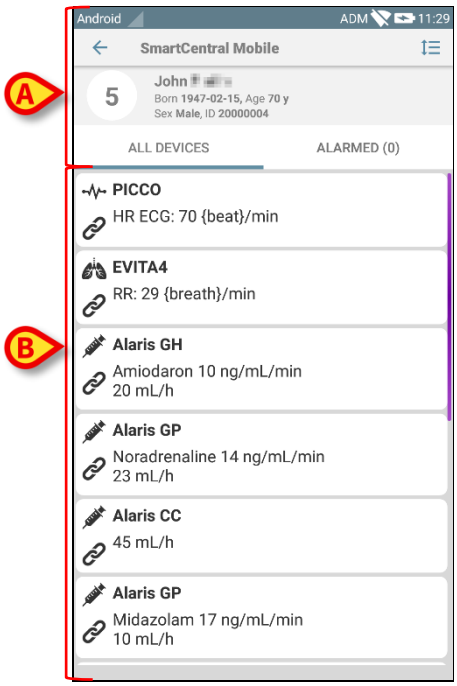


Fig 171

This screen is formed of two areas: a heading area (Fig 171 **A**) and the medical devices list (Fig 171 **B**).

9.3.1 Heading

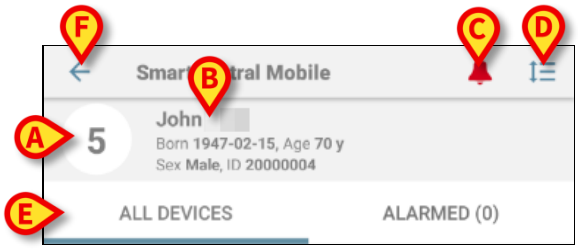


Fig 172

In the heading area (Fig 172) the following information and tools are available:

- Bed number (Fig 172 **A**).
- Patient data (Fig 172 **B**).
- The red bell icon (Fig 172 **C**) indicates that there is at least one medical device alarmed on one of the other beds (those not currently displayed).
- Use the icon indicated in Fig 172 **D** to enlarge the device-areas and display more information for each connected medical device (Fig 173). The type of information displayed depends on the configuration and the specific device.

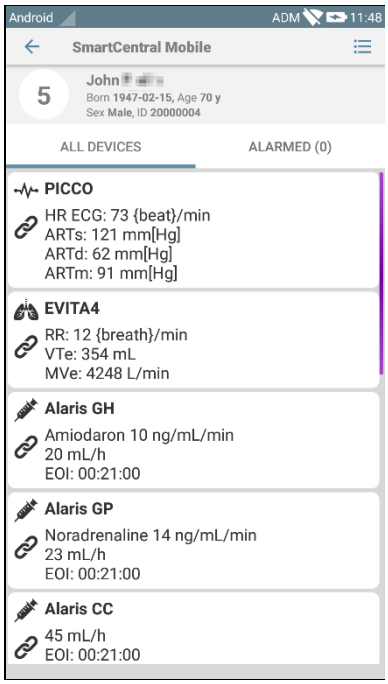


Fig 173

- Touch the icon (Fig 172 **D**) again to go back to compact display mode.

- Use the filters indicated in Fig 172 **E** to display either all the connected medical devices or only the ones providing notifications.
- Use the back-arrow button (Fig 172 **F**) to go back to the “Central” screen.

9.3.2 Devices list

On the lower part of the “Bed” screen the individual medical devices are represented as shown in Fig 174:

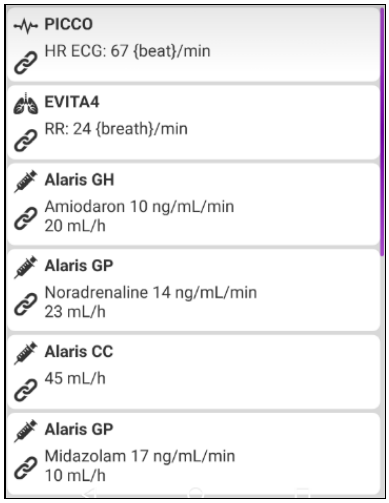


Fig 174

Each medical device is represented within a “card”. Each “card” displays the following information:

- An icon indicating the medical device type. The list of possible icons changes according to the healthcare organization needs. Here are some common examples:

 - Infusion Pump

 - Respirator

 - Cardiac Output Measurement Machine

- An icon indicating the medical device status. These are:

 - On hold

 - Running

 - Sending a low priority alarm notification.

 - Sending a medium priority alarm notification.

 - Sending a high priority alarm notification.

The background color of the “card” also indicates the medical device status: grey (on hold); white (running); cyan (low priority alarm); yellow (medium priority alarm); red (high priority alarm).
For each medical device, some basic information is displayed inside the “card”. The type of information depends on configuration.
In case of alarm the “card” displays the alarm message.

9.4 Alarms history

Each “card” can be touched to access the list of all the alarms provided by the medical device (Fig 175).

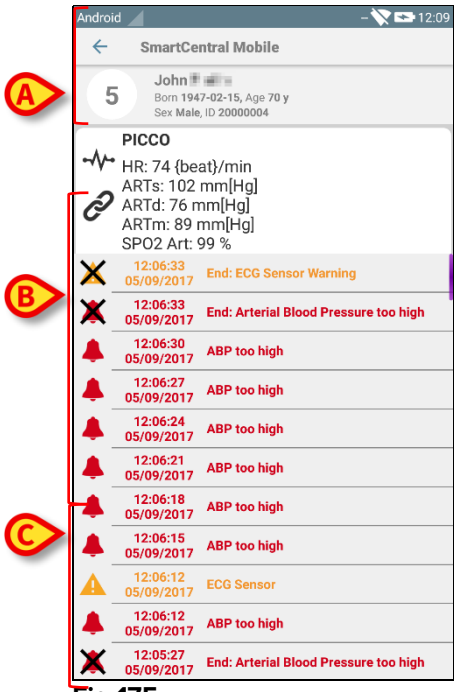


Fig 175

This screen is formed of three areas.

Patient data (Fig 175 **A**).
Medical device current data. The data displayed on this “card”, again depend on the device type and configuration (Fig 175 **B**).
Notification history. Displaying, in chronological order, all the alarms occurred on the device. For each alarm, a short description and the time of occurrence are provided (Fig 175 **C**). For each alarm are displayed the beginning time and end time (black cross on the icon).

10. Manufacturer and Distributor Contacts

For any issue, please refer first to the Distributor who installed the Product.

Distributed in the U.S. and Canada by

Ascom US Inc.
Ascom Wireless Solutions
300 Perimeter Park Drive
Morrisville, NC 27560
USA

Phone: (877) 712-7266
www.ascom.us

Manufacturer contacts:

Ascom UMS s.r.l unipersonale

Via Amilcare Ponchielli 29
50018, Scandicci (FI)
Italy

Phone: (+39) 055 0512161
Fax: (+39) 055 8290392
www.ascom.it

11. Residual risks

A risk management process has been implemented in the life cycle of Digistat Smart Central adopting the relevant technical regulations. The risk control measures have been identified and implemented in order to reduce the residual risks to the minimum level and make them acceptable compared to the benefits brought in by the product. The total residual risk is also acceptable if compared to the same benefits.
The residual risks listed below have been taken into consideration and reduced to the minimum level possible. Given the inherent nature of the “risk” concept, it is not possible to completely remove them. It is therefore necessary, according to the regulations, to let the users know each and every possible risk (even though remote).

- Inability to using the system or some of its functionalities, which can cause delays and/or errors in the therapeutic/diagnostic actions.
- Slowdown of Digistat Smart Central performance, which could cause delays and/or errors in the therapeutic/diagnostic actions.
- Circulation of users’ and/or patients’ sensitive data.
- Wrong data insertion and display, which can cause errors in the therapeutic/diagnostic actions.
- Display of either partial or hard-to-read information, which can cause delays and/or errors in the therapeutic/diagnostic actions.
- Attribution of device data to the wrong patient (patient exchange), which can cause errors in the therapeutic/diagnostic actions.

RISKS RELATING TO THE HARDWARE PLATFORM IN USE (NOT PART OF THE PRODUCT)

- Electric shock for the patient and/or the user, which can cause injury and/or death for the patient/user.
- Hardware components overheating, that can cause injury for the patient/user.
- Infection contraction for the patient/user.