Smart Central
User Manual

DIGISTAT® V4.2

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DIGISTAT® version 4.2

SOFTWARE LICENSE

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

WARNING

The information contained herein is subject to change without further notice. ASCOM UMS holds the right to make changes to all described products in order to improve its functions and performance.

LICENSES AND REGISTERED TRADEMARKS

DIGISTAT® is produced by ASCOM UMS srl
http://www.unitedms.com
DIGISTAT® is a Trademark of ASCOM UMS srl
Information is accurate at the time of release.
All other trademarks are the property of their respective owners.

DIGISTAT® product is CE marked according to 93/42/CEE directive (“Medical devices”) amended by the 2007/47/EC directive.

ASCOM UMS is certified to UNI EN ISO 9001:2008 and UNI CEI EN ISO 13485:2012 standards for the design, development, production, installation and servicing of software.

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® system and to allow the manufacturer identification. Furthermore, this document aims to describe every single part of the system, it also intends to offer a reference guide to the user who wants to know how to perform a specific operation and a guide to the correct use of the system so that improper and potentially hazardous uses can be avoided.

The use of DIGISTAT® requires a basic knowledge of information systems concepts and procedures. The comprehension of this manual requires the same knowledge.

Always remember that DIGISTAT® systems are highly configurable, in order to satisfy the requirements of every user. This extreme flexibility makes a description of all the system's possibilities impossible. Hence the decision to describe a "probable", or "standard" configuration, so that we can explain what we feel to be the fundamental parts of the system, and their purposes. Consequently, the user may come across descriptions of pages and functions that are different in the configuration he is using.

To be more precise, the differences may concern

The appearance of the page (a page may appear different from that shown here).
The functions (certain operations may or may not be enabled).
The flow of use (certain procedures can be performed following a different sequence of pages and operations).

Care has been taken to highlight and emphasize this concept every time the configuration possibilities are such as to prevent a univocal description of the system operation.
Should you require more details regarding a specific configuration, please contact your system administrator or the ASCOM UMS technical support service.
Remember that, by specific request, ASCOM UMS is able to provide custom-made documentation for every specific type of procedure and/or configuration.

1.2 Characters used and terminology

The use of DIGISTAT® systems requires a basic knowledge of the most common IT terms and concepts. In the same way, the comprehension of this manual is subject to such knowledge.

Remember that the use of DIGISTAT® systems must only be granted to professionally qualified and properly trained personnel.

When consulting the on-line version as opposed to the paper version, cross-references in the document work like hypertextual links. This means that every time you come across the reference to a picture ("Fig 7", for example) or to a paragraph ("paragraph 2.2.1", for example), you can click the reference to directly access that particular figure or that particular paragraph.

Every time 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 page 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®. 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.

1.4 Characters used and terminology

The use of DIGISTAT® systems requires a basic knowledge of the most common IT terms and concepts. In the same way, the comprehension of this manual is subject to such knowledge. However, in order to improve access to the document and clarify the use of certain terms relating to the DIGISTAT® systems, we have included a glossary for quick (and obviously concise) reference for the clarification of terms.

Remember that the use of DIGISTAT® systems must only be granted to professionally qualified and properly trained personnel.

When consulting the on-line version as opposed to the paper version, cross-references in the document work like hypertextual links. This means that every time you come across the reference to a picture ("Fig 7", for example) or to a paragraph ("paragraph 4.4", for example), you can click the reference to directly access that particular figure or that particular paragraph.

Every time 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 page 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.

2. Introduction to DIGISTAT®

The DIGISTAT® clinical modules suite is an advanced patient data management software system that is designed specifically for use by clinicians, nurses and administrators.

The software package comprises a set of modules that can either work alone or be fully integrated to provide a complete patient data management solution.

From the Intensive Care Unit to the Ward, from the Operating Room to the Administrative Department, DIGISTAT® can be used in a wide range of environments.

DIGISTAT®'s modular architecture and extensive customization capabilities allow you to build your own patient data management system and to expand the system to meet your new demands when required.

DIGISTAT® system can only be accessed by entering username and password. Every user is defined by a detailed profile and can access only the allowed areas. A record of every action performed is automatically generated by the system.

2.1 Modular architecture

"Modular Architecture" means that different products (or modules) having particular goals can be implemented within the same software environment (DIGISTAT® in the present case) that is characterized by a determined graphic design, general goals and terms of use.
Different modules can be added at different times, and in a way that is agreed with the user. The resultant software suite fits the specific user needs and can change in time, according to the possible changes in the user needs.

2.2 Intended use

The DIGISTAT Software (hereafter "Product") acquires records, organizes, transmits and displays patient information and patient related data, including data and events from connected clinical devices and systems as well as information entered manually, in order to support caregivers in diagnosis and treatment of patients as well as to establish electronic patient records.

- The Product produces configurable electronic patient records based on acquired data and information, as well as on manual and automated documentation of the clinical unit's activity.
- The Product provides automated, secondary visual and audible annunciating and displaying of acquired data, events, current status and operating conditions of connected clinical devices and systems on designated display device(s). The Product can also be configured to forward data and information about events, statuses and operating conditions to the Ascom messaging system.

- The Product supports the improvement of nursing workflows related to the management of alarms from the connected clinical devices and systems.
- The Product supports documentation of the prescribed therapy, of its preparation and of its delivery.
- The Product supports the recording, validation and display of vital signs charting based on the acquired data and information.
- The Product provides configurable reports, charts and statistics based on recorded data for use by healthcare professionals to analyze the unit's efficiency, productivity, capacity and resource utilization, and the quality of care.

The Product **does not** replace or replicate the original display of data and alarms of the connected devices and systems and **does not** control, monitor or alter the behavior of these connected devices and systems, or their associated alarm annunciations.

The Product **is not** intended to be used for direct diagnosis or monitoring of vital physiological parameters.

The Product is intended for use by trained healthcare professionals within a hospital/clinical environment and relies on proper use and operation of the IT and communication infrastructure in place at the healthcare facility, the display devices used and the connected clinical devices and systems.
Additionally, the Product provides specific functions and interfaces intended to be used by non-professional users in remote locations for non-clinical purposes for display of information, reports, charts and statistics, without any possibility to add, change or delete any information or data.

The Product is a stand-alone software that is installed on servers and computers, which shall comply with the technical hardware and software specifications provided with the Product.

2.2.1 Safety Advisories

The Product, even if designed to provide very high accuracy, cannot guarantee the perfect correspondence of the acquired data, nor can it substitute the direct verification of the same by the User.
The User shall base therapeutic or diagnostic decisions and interventions solely on the direct examination of the original source of information. It is exclusive responsibility of the User to check that the information displayed by the Product is correct and to make appropriate use of it**.**
In any case, the Product must be used in compliance with the safety procedures reported in the user documentation accompanying the Product.

Only printouts that are signed with digital or ink signature by authorized medical professionals shall be considered valid clinical records. In signing the aforementioned printouts, the User certifies that he/she has checked the correctness and completeness of the data present in the document.
Only these signed documents are a valid source of information for diagnostic or therapeutic processes and/or procedures.

The Product can be used in the proximity of the patient and to the connected clinical devices in order to speed up the data entry, to reduce the probability of errors and to allow the User to verify the correctness of the data through the immediate comparison with the actual data and activities.

When entering patient related data the User shall verify that the patient identity, hospital department/care unit and bed displayed in the Product are correct. This verification is of utmost importance in case of critical interventions as, for instance, drug administration.

The responsible organization must establish and implement appropriate procedures to ensure that potential errors occurring in the Product and/or in the use of the Product are promptly detected and corrected and do not constitute a risk to the patient and the operator. These procedures depend on the configuration of the Product and the method of use preferred by the organization.

The Product may provide, depending on the configuration, access to information on drugs. The responsible organization shall, initially and periodically, verify that this information is current and updated.

The Product does not substitute a “Nurse Call” system and does not in itself constitute a “Distributed Alarm System”. Therefore, it must not be used in place of the direct monitoring of the alarms generated by the medical devices. This limitation is due, among the other reasons, to the specifications and limitations of the communication protocols of the medical devices.

In case some devices used for the Product are located in the patient area or are connected to equipment present in the patient area then the responsible organization

shall ensure that the whole combination complies with the international standard IEC 60601-1 and any additional requirement established by the local authorities.

Use of the Product must be granted, by means of specific configuration of the passwords and active surveillance, only to User 1) trained according to Product indications by personnel authorized by the manufacturer or distributors and 2) in possession of the professional qualifications to correctly interpret the information supplied and to implement the appropriate safety procedures.

The Product is a stand-alone software that can run on standard computers and/or standard mobile devices connected to the hospital local network. The computers, devices and the local network shall be adequately protected against cyber-attacks.
The Product shall be installed only on computers and devices fulfilling the minimum hardware requirements and on supported operating systems.

2.2.2 Patient Population

The minimum patient height is 20 cm.
The maximum patient height is 250 cm.
The minimum patient weight is 0,2 Kg.
The maximum patient weight is 250 Kg.

2.3 “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 Responsible Organization. The manufacturer does not guarantee in any form the Product safety and suitability for any purpose when the Product is used outside what explicitly stated by the “Intended use”.

2.4 Manufacturer's responsibility

The CE seal is a safety warranty of the product introduced on the market.
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 formed and authorized by ASCOM UMS ;
- The Product's usage environment complies with safety regulations;
- The environment's wiring system is highly efficient and complies with related regulations.

! Should the supply cause the establishment of a "medical electrical system" through electrical and functional connection of devices, the hospital organization is in charge of the required safety verification and acceptance tests, even in case that ASCOM UMS performed in whole or in part the wiring and the necessary connections.

2.5 Product tracking

In order to ensure device tracking and on-going safety and efficiency checks on site, in compliance with ISO 9001 and EN 13485 quality standards and European law on medical devices 93/42/EEC, amended by the directive 2007/47/EC, the former owner is recommended to inform ASCOM UMS/Distributor about any ownership transfer by giving written notice stating the product, former owner and new owner identification data.
Device data can be found in the product labeling (either paper label provided at installation time or "About box" displayed within the product – see paragraph 5.8.5).
In case of doubts/questions about product labeling and/or product identification please contact ASCOM UMS/Distributor technical assistance (for contacts see paragraph 9).

2.6 Post-market surveillance

The CE marked device is subject to a post-market surveillance - which ASCOM UMS, its distributors and dealers must provide for each marketed copy - concerning actual and potential risks, either for the patient or the User, during the Product's life cycle.
In case of deterioration of the device 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, one of its branches or nearest authorized dealer.

The device details can be found on its labeling.

On reception of a user feedback ASCOM UMS will immediately start the review and verification process and, when required, solve the reported nonconformity.

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 hardware (PC and server) and is therefore assessed as 5 years since the release date of the product-specific version, period in which the manufacturer is committed to keeping technical documentation and provide technical support.

2.8 CE mark and regulation conformity

ASCOM UMS DIGISTAT® product is CE marked according to 93/42/EEC directive ("Medical devices"), amended by the directive 2007/47/EC, and is therefore compliant with the EU basic safety standards there specified (received in Italy with Legislative Decree n. 37/2010 and subsequent variants and integrations).

ASCOM UMS declines all responsibility for the consequences on the safety and efficiency of the device determined by technical repairs or maintenance not performed by its own Technical Service personnel or by ASCOM UMS-authorized technicians.

The attention of the user and the legal representative of the health structure where the device is used is drawn to their responsibilities, in view of the legislation in force on the matter of safety in the workplace (Italian Legislative Decree no. 81 of 09/04/2008) and of on-site security for hazardous or potentially hazardous incidents.

The ASCOM UMS Service is able to offer clients 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.

3. Software/Hardware specifications

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 an electrical equipment is positioned close to the bed, the use of "Medical grade" devices is required. In these places medical grade PANEL PCs are usually used. If explicitly requested, ASCOM UMS is able to provide information on some suitable devices of this kind.

3.1 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 (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- 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 x86/x64 Professional
Microsoft Corporation Windows 10

3.2 Central

3.2.1 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 (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

3.2.2 Operating System

Microsoft Corporation Windows 7 SP1 x86/x64 Professional
Microsoft Corporation Windows 8.1 x86/x64 Professional
Microsoft Corporation Windows 10

3.3 Server

3.3.1 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
- Monitor: 1024 x 768 or higher (1280 x 1024 suggested, 65.000 colors minimum)
- Mouse or other compatible device
- Ethernet interface 100 Mb/s (or higher)
- CD/DVD Drive or possibility to copy the installation files

3.3.2 Operating System

Microsoft Corporation Windows Server 2012 R2

3.3.3 System Software

Microsoft SQL Server 2012/2014

3.4 Smart Central Mobile

Smart Central Mobile has been verified on the Ascom Myco (SH1) device, with Android version 4.4.2 (build from 5.3.0 to 6.5.1). The application may be compatible with other Android devices, but such compatibility shall be tested and validated before the release.

To correctly use DIGISTAT®, 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® 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® is configured to run in full-screen mode or if the Windows tray bar is in Auto-hide mode.

In compliance with on-going product improvement policies pursued by ASCOM UMS, this User Manual's specifications can be changed at any moment.

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 responsible organization shall implement for the DIGISTAT® workstations a date/time synchronization mechanism to a reference source.

3.4.1 Firewall and Antivirus

To protect the DIGISTAT® system from possible cyber-attacks, it is necessary that:

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

The Responsible Organization shall ensure that these two protections are activated. ASCOM UMS tested the Product with ESET Antivirus but, considering the strategies and policies already existing in the hospital, the actual choice of the antivirus is left to the Responsible Organization. ASCOM UMS cannot ensure that the DIGISTAT® system is compatible with any antivirus or antivirus configuration.

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

It is suggested to keep open only the TCP and UDP ports actually needed. These may change according to the system configuration. Please refer to the ASCOM UMS technical assistance for more information.

3.5 Local network features

This paragraph lists the features of the local network on which DIGISTAT® is installed in order to guarantee the system's full functionality.

- DIGISTAT® uses a TCP/IP traffic protocol.
- The LAN must not be congested and/or full loaded.
- DIGISTAT® requires at least a 100 Mbps LAN available to the end user. 1 Gbps 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 UMS/Distributors the maintenance calendar in order to let ASCOM UMS or the authorized Distributor efficiently support the healthcare structure in managing the possible disservices caused by maintenance activities.

If the network does not match the requested features, DIGISTAT® performance gradually deteriorates until timeout errors occur. The system 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 system unavailability. The Responsible Organization shall ensure an optimal network coverage and stability, and train the personnel in the management of these temporary disconnections.

3.5.1 DIGISTAT® impact on the hospital network

DIGISTAT® impacts the local network of the healthcare structure. This paragraph provides information on the traffic generated by DIGISTAT® on the network in order to make it possible for the structure to evaluate and analyze the risks related to the introduction of DIGISTAT®.

The bandwidth used by a DIGISTAT® system 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 (either only or as well dedicated).
- Interfaces with external systems,
- DIGISTAT® configuration and mode of use.

In a configuration with 100 clients 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® product. They must be strictly respected.

DIGISTAT® must absolutely be installed and configured 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® must absolutely be performed according to the ASCOM UMS company guidelines only by ASCOM UMS/Distributor personnel or another person specifically trained and authorized by ASCOM UMS/Distributor.

! DIGISTAT® must absolutely be installed and configured 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.

- Only use devices approved by ASCOM UMS/Distributors bearing the CE mark.
- Only use devices approved by ASCOM UMS/Distributors. It is not possible to install devices without proper training.
- Only use devices approved by ASCOM UMS/Distributors . There is a risk of injury to the patient and operators.
- Scrupulously observe the manufacturer's instructions for the hardware installation.
- Make provision for regular maintenance of the inner disk and checks on the operating system.
- The DIGISTAT® 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 "Patient Area" (see Fig 1) it is recommended to use washable waterproof of devices.
- Within "Patient Area" (see Fig 1) it is recommended to use washable, sterilizable rubber keyboards and mouse devices. For "touch screens"

capacitive technology (insensitive if used with gloves) is recommended because it discourages using gloves (sometimes contaminated).

4.2 Cleaning

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

Check the suggested cleaning procedures in the manuals of the hardware products that accompany DIGISTAT®.

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.

Place the PC in order to ensure adequate anterior and posterior ventilation. Failure to meet hardware ventilation requirements may cause equipment failure, thus jeopardizing patient data management system functions.

The holder of the hardware (individual, hospital or institution) and the user of the device and the software are personally responsible for ensuring that the devices follow a meticulous maintenance schedule to guarantee safety and efficiency and reduce the risk of malfunctioning and the occurrence of possible hazards to the patient and user.

The device and software are destined for use only under the supervision of properly trained and authorized medical personnel.

4.3.1 Electrical safety

The hardware devices used together with DIGISTAT® (PC, display, barcode reader, etc...) must comply with the relevant CE mark prescriptions, in particular with those indicated by the 2006/95/EC directive and subsequent amendments.

The device complies with the characteristics envisaged by the CE marking in accordance with directive 2006/95/EC and subsequent amendments.

The electrical devices installed within the Patient Area must have the same security level of an electromedical device.

It is moreover 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 hospital structure is responsible for these measurements.

The hospital structure 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 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 concurrently 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.

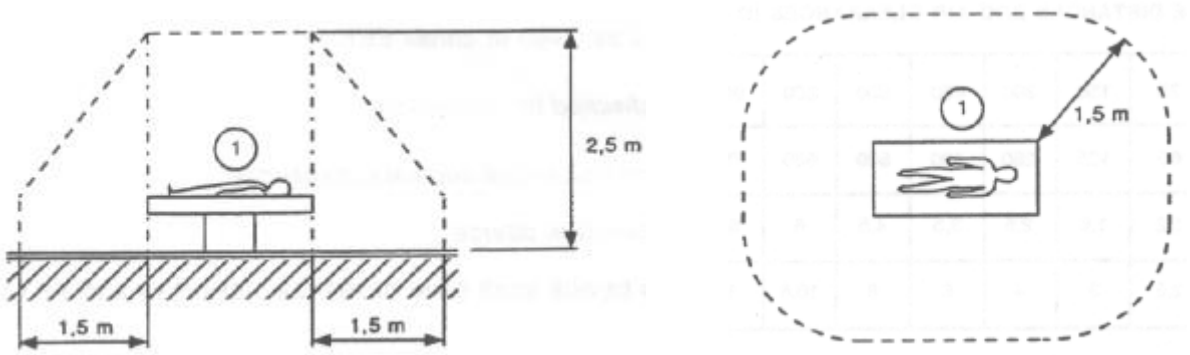

Fig 1

It is the direct responsibility of the hardware license (individual, hospital or institution) to perform all the required measurements on the electrical safety of the electro-medical system in use (PC, display and other possible connected devices) considering the environment in which it is used.

!

Should the supply cause the establishment of a “medical electrical system” through electrical and functional connection of devices, the hospital organization is in charge of the required safety verification and acceptance tests, even in case that ASCOM UMS/Distributor performed in whole or in part the wiring and the necessary connections.

4.3.3 Electromagnetic compatibility

The hardware devices used together with the DIGISTAT® system (PC, display, barcode reader, etc...) must comply with electromagnetic emission and immunity characteristics envisaged by the CE seal, in compliance with Directive 2004/108/EC and following amendments.

4.3.4 Devices eligibility

It is mandatory to use devices that are suitable for the environment in which they are installed and used (meeting, for instance, the directives LVD 2006/95/EC, EMC 2004/108/EC, penetration by liquids, et al.).

4.4 Privacy Policy

The following precautions should be taken in order to protect the privacy of users and patients, and to ensure that personal data are processed by respecting data subjects' rights, fundamental freedoms and dignity, particularly with regard to confidentiality, personal identity and the right to personal data protection.

"Sensible data" are those personal data that reveal the race, the religious and/or philosophic beliefs, the personal political opinions, the support to political parties and/or trade unions and/or associations and organizations having political, religious or philosophical aims. Moreover, "sensible data" are those data providing information on the health conditions and/or the sexual life.

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.
- Sensible data saved in the system, as passwords or users' and patients' personal data, must be protected from possible unauthorized access attempts through adequate protection software (antivirus and firewall). It is the hospital structure responsibility to implement this software and keep them updated.
- The user is advised against the frequent use of the lock function (paragraph 5.5.2). Automatic log out allows protecting the system from unauthorized accesses.

In some circumstances, personal and/or sensible data 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 Responsible Organization is responsible for providing adequate security measures to comply with the local privacy laws and regulations.

4.4.1 User credentials features and use

This paragraph explains the user's DIGISTAT® credentials (username and password) features, use and update 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 the system (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 homogeneity of the users' tasks.

- When user accounts are created, it is recommended to always use a nominal identification. Generic users as, for instance, "ADMIN" or "NURSE" must be avoided. Every account must be used by one and only one user.

- Each user is characterized by a profile enabling him/her to access only the functionalities that are relevant to his/her 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® 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, birthdate 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 5.8.4 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 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® configuration manual.

The following information is reserved to system administrators:

The password must match a regular expression defined in the DIGISTAT® 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 choose a personal one. 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®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 and deal with personal sensible data stored in the DIGISTAT® database.
ASCOM UMS srl or Distributor, for issues relating to management of personal sensible data, adopts procedures and working instructions complying with the current privacy regulation (D.Lgs 196/2003 of the 30th of June 2003).
In performing the abovementioned activities the ASCOM UMS/Distributor technical staff is configured as “System Administrator” for the DIGISTAT® system (see regulation of 25/11/2008 of the Privacy Guarantor on “System Administrators”). ASCOM UMS/Distributor staff performing this kind of procedures is appropriately trained on privacy issues and, in particular, in sensible data treatment issues.

In order to comply with the requests of the “System administrators” regulations, the responsible healthcare structure must:

- define nominal accesses;
- activate the access log both at operating system and at client and at server level;
- activate the access log to the database server Microsoft SQL Server (Audit Level);
- configure and manage all these logs to keep track of the accesses for at least one year.

4.4.3 System logs

DIGISTAT® 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 corresponding to warning messages are kept for 20 days;

- logs corresponding to alarm messages are kept for 30 days.

These times are configurable. See DIGISTAT® configuration manual for the configuration procedures.

4.5 Back up policy

It is recommended to regularly perform system backups.

The responsible healthcare structure using DIGISTAT® system 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 responsible healthcare structure must ensure that backup files are stored in a way that makes them immediately available in case of need.

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

4.6 Out-of-order procedure

This paragraph describes the policy suggested by ASCOM UMS in case a DIGISTAT® workstation gets out of order. The goal of the procedure here described is to minimize the time required to replace the out-of-order workstation with one properly working.
ASCOM UMS suggests for this purpose to have at disposal, as substitute equipment, an additional PC on which DIGISTAT® is already installed.
In case of a DIGISTAT® workstation is out-of-order, the substitute equipment can promptly replace the DIGISTAT® workstation.
Always remember that DIGISTAT® 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. Missing an explicit, direct authorization from ASCOM UMS/Distributor, the hospital staff is not authorized to perform installation procedures and/or to modify DIGISTAT® configuration.
The risk related to the DIGISTAT® workstation deactivation and substitution is that of associating 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® 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. 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 be, mandatorily, 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 display this way data that don't belong to the relevant patients/beds.

In case a DIGISTAT® 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.
We suggest the hospital management (or anyone who is in charge) to define for this purpose a clear, univocal operating procedure and to share this procedure with all the staff members involved.

In order to speed up replacement times, we suggest to have at disposal one or more substitution equipment with all the necessary applications already installed (OS, firewall, antivirus, RDP, ...) and with DIGISTAT® already installed, but disabled (i.e. not executable by a user without the assistance of an ASCOM UMS technician).
In case of out of order of a DIGISTAT® workstation, the substitution equipment availability assures the minimization of restoration times (hardware substitution) an limits at the same time the risk of patient exchange.

In case of out of order of a DIGISTAT® workstation we suggest to adopt the following procedure if a "substitution equipment" is available:

1) The hospital staff replaces the out of order PC with the "substitution equipment"
2) The hospital 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 instruction on how to enable/disable and replace a DIGISTAT® workstation, reserved to system administrators, are in the DIGISTAT® 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® data acquisition, the hospital staff must promptly call ASCOM UMS/Distributor and schedule the substitution/reconfiguration procedure to allow ASCOM UMS staff to either reconfigure DIGISTAT® as well or provide all the necessary information. 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® configuration manual.

4.7 Preventive maintenance

It is suggested to perform the maintenance of DIGISTAT® system at least once a year. It must be considered, by the way, that maintenance frequency must be a function of system complexity. In case of high complexity, it is suggested to perform maintenance more often, up to twice a year.

This is the maintenance checklist:

Preparatory checks

- DIGISTAT® update necessity check.
- Check minimum requirements for a possible DIGISTAT® update (both HW and SW).
- Check the Server Service Pack version and state.
- Schedule the server/s restart to apply possible updates.
- Check the SQL Server Service Pack version and state.

SELECT SERVERPROPERTY('productversion'),
SERVERPROPERTY ('productlevel'),
SERVERPROPERTY ('edition')

- Schedule possible updates with the technical staff

Checks to be performed

Antivirus

- Check that an Antivirus Software is installed and updated (both the application and the virus list definition).
- If viruses are present, inform the competent technician and, if authorized, try to clean the PC.

Database

- Check that an effective DIGISTAT® database clean-up and back-up policy is configured.
- Check that the clean-up and back-up store procedures exist (UMSBackupComplete, UMSBackupDifferential, UMSCleanLog, UMSCleanDriver) and the related schedule.
- Check that back-up files exist (both full and differential).
- Check with the hospital technical department that back-up, configuration folders and data folders are correctly copied to another storage device.
- Restore a back-upped DB to verify its correctness.
- Delete the old back-up files (.bak) and the possible files that are not inherent to DIGISTAT® configuration on the network shared path.

- Check that the other jobs on SQL Agent or scheduled tasks (for instance those that are support to integration with third-parties systems) are present, and that their schedule is adequate.
- On SQL Agent check that the different JOBs are executed and that there are not hanging JOBs or JOBs in error.
- Check the SQL Server LOGs.
- Check the DB total size and the number of records in the main tables. Script for checking all the tables size:

```
USE [DATABASENAME]
GO

CREATE TABLE [#SpaceUsed]
(
   [name] [nvarchar](250) NULL,
   [rows] [nvarchar](250) NULL,
   [reserved] [nvarchar](250) NULL,
   [data] [nvarchar](250) NULL,
   [index_size] [nvarchar](250) NULL,
   [unused] [nvarchar](250) NULL
) ON [PRIMARY]

DECLARE @INS AS nvarchar(MAX)
SET @INS = '';

SELECT @INS = @INS + 'INSERT INTO #SpaceUsed exec sp_spaceused ''' +
TABLE_NAME + '''; '
FROM INFORMATION_SCHEMA.TABLES
WHERE TABLE_TYPE = 'BASE TABLE'
ORDER BY TABLE_NAME

EXEC (@INS);

SELECT *
FROM #SpaceUsed
ORDER BY CAST([rows] AS INT) DESC

DROP TABLE [#SpaceUsed]
```

Server

- Check the Windows™ server event log.
- Check the permissions on the shared folders (es: Backup folder).
- Useless files and directories clean up to free up space on server disk.
- Check the displays (if any) on the server rack and verify that there are neither visual nor sound alarms.
- Check that on the different disk units there is enough space available.

- Disk check with dedicated tools (checkdisk, defrag, etc.).
- In case there are disks in RAID, check the health conditions of the RAID unit on the RAID management software.
- Check the leds of the non-alarmed RAID units.
- If an UPS is connected, check its health conditions with its management software.
- In case of UPS schedule an electric interruption (an electric failure simulation) and check that the server is configured ti perform a CLEAN shutdown.

Workstations

- Check if the Regional Settings on the workstations are coherent with the DIGISTAT® installation language.
- Check if every workstation has a default printer.

DIGISTAT®

- Check data presence (SELECT) Patient, Admission, Bed, Location tables and some random others.
- Check on the network table that no workstation has the ALL value in the “modules” field.
- Check and in case clean the service and/or ASCOM UMS Gateway LOG.
- Check and in case clean the DAS LOGs for the Drivers (if enabled).
- Check that the privacy policy is respected as stated in this manual in paragraph 4.4.

Connection to devices

- Check the connections (cables and wiring system) with data acquisition devices.

Instruction for use

- Check that the user documentation in PDF format (PDF provided together with the product) is present on the server and is coherent with DIGISTAT® version.
- Check that the folder containing the user documentation in electronic format on the server is accessible to DIGISTAT® users.
- Check that the HELP button opens the user documentation.
- Check that all the other contents provided by ASCOM UMS and integrated in the HELP of DIGISTAT® system are updated and coherent.

4.8 Compatible devices

Please contact Ascom UMS/Distributor for the list of available drivers

4.9 System unavailability

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

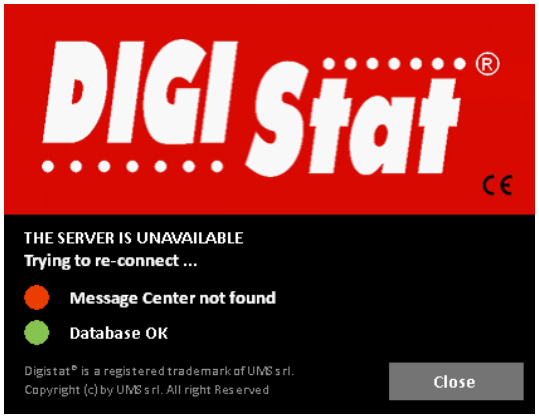

Fig 2

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 paragraph 9 for the contacts list).

There are extrema cases, rare but possible, in which it is physically impossible using the DIGISTAT® system (it is the case of natural disasters, or long black outs etc.).

It is responsibility of the healthcare structure using DIGISTAT® 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 system availability (back-up policy is part of this management. See paragraph 4.5).

It is responsibility of the healthcare structure using DIGISTAT® to define an emergency procedure to put into effect in case of system unavailability.

ASCOM UMS/Distributor offers full support for the definition of the above-mentioned procedure.

See paragraph 9 for the contacts list.

5. “Control Bar” and DIGISTAT® environment

5.1 Introduction

This section of the manual describes the features and functionalities of the DIGISTAT® environment. Namely, here are described the functionalities of the system that are general and mainly independent from the specific modules installed.
Please remember that DIGISTAT® is a software environment that, depending on the modules that are actually implemented, can be used in different kinds of locations (as, for instance, intensive care, operating rooms, outpatients departments etc....) and for different goals.

5.2 Touch screen

DIGISTAT® can run both on touch and non-touch workstations. The same procedure can be performed using both fingers and mouse device. In this manual a “mouse”, terminology is used (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
Click	Tap
Double click	Double tap
Drag	Flick
Use scrollbars	Scroll
Zoom in	Two fingers tap

5.3 Launching DIGISTAT®

To launch DIGISTAT®,

- Double click the desktop icon (Fig 3).

Fig 3

The following splash-screen appears while the system is loading.

Fig 4

5.4 DIGISTAT® Work Area

The DIGISTAT® Work Area is defined and delimited by Control Bar, a tool that is common to all DIGISTAT® installations (Fig 5).
Control Bar manages the installed modules and systems, the patients, the users.
DIGISTAT® Control Bar is formed by a horizontal command bar (Fig 5 **A**), by a vertical selection bar on the left (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**).

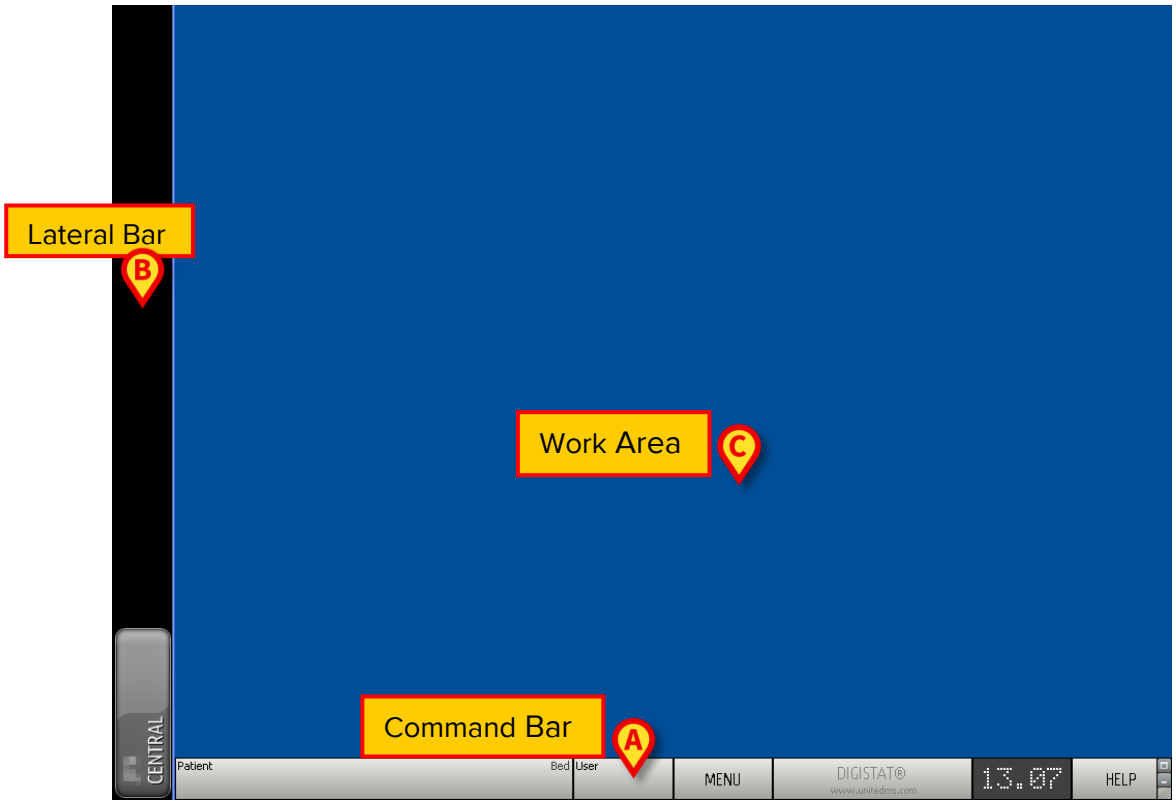

Fig 5

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

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

Fig 6

The module currently selected is highlighted (yellow).

5.4.1 Selecting a module

To select a module

- Click the corresponding icon.

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

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

5.5 Accessing the system

The DIGISTAT® system 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 **E**).

The following page is displayed.

Fig 7

To access the system,

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

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

- Click the **Cancel** button (Fig 7 **D**).

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 the DIGISTAT® system.

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

After accessing the system, 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®. It is strongly recommended to log out before leaving the DIGISTAT® workstation to avoid improper use of the system.

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 page shown in Fig 7 will appear again.

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

a) User 1 launches DIGISTAT®,
b) User 1 switches to User 2 without logging out User 1,
c) User 2 attempts to launch DIGISTAT® again,

Then the second DIGISTAT® instance cannot be launched because the first one is still running.

5.5.1 Barcode log-in

It is possible, if the functionality is implemented, to log in through barcode scanning.

To use this functionality, when the system displays the login screen (Fig 7),

- Scan the user's personal barcode.

Fig 9

The user is immediately logged in.

! Barcode technology is recommended when selecting an item. Scanning the item's barcode (as, for instance, the user's personal badge), instead of selecting it manually, helps the user to diminish selection errors.

5.5.2 Disabling the automatic log out

If the system 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 this from happening it is necessary when logging in, after username and password specification and before clicking **Ok**, to

- click the **Lock** button on the “Login” screen command bar (Fig 10 **A**)

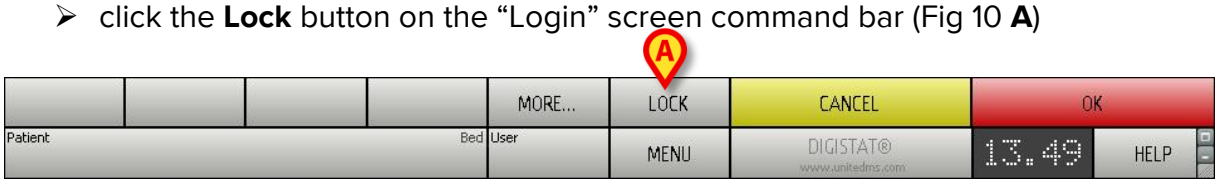

Fig 10

If the user is locked, the name of the user appears in red on the control bar (Fig 11).

Fig 11

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

5.5.3 Recent users

The “Recent” area of the “Login” page (Fig 12 **A**) displays the names of users who have accessed the system recently.

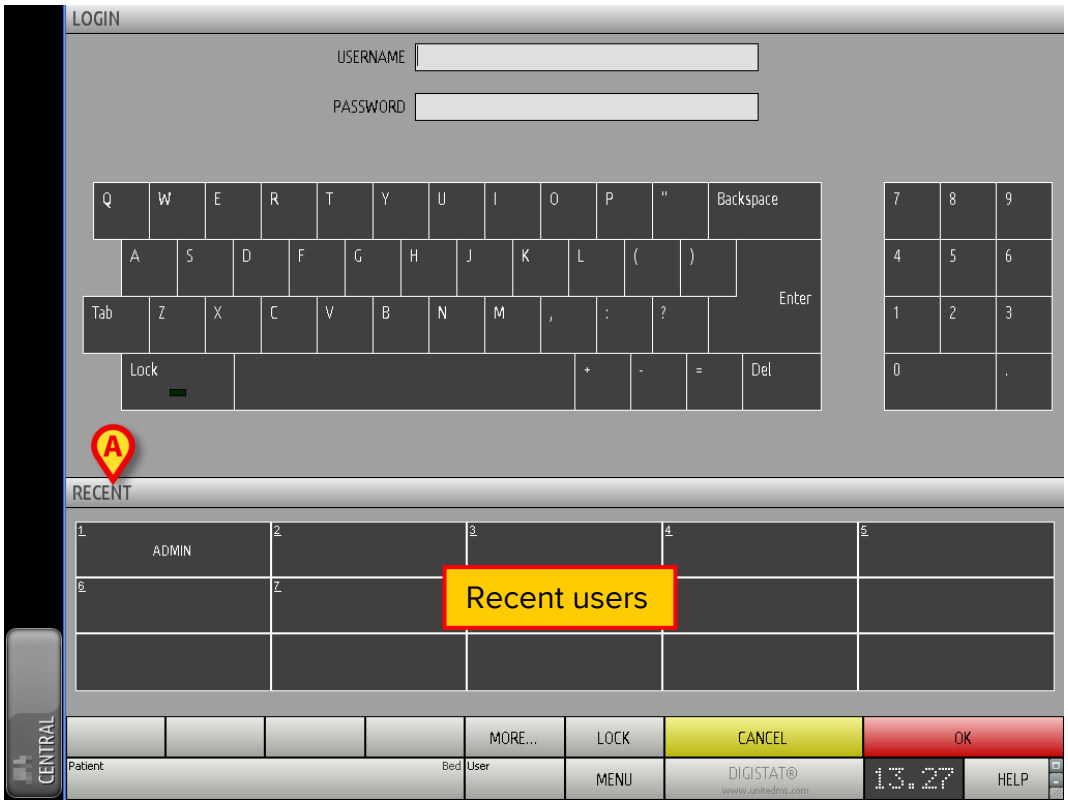

Fig 12

The area is divided into rectangles. The names of the users who accessed the system 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.

5.5.4 How to use the “User List”

The **More** button on the control bar (Fig 13) makes it possible to display the complete list of possible users.

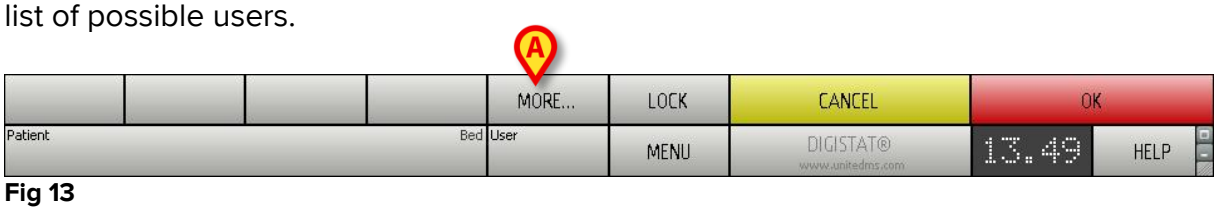

Fig 13

To display the “User List”,

- Click the **More** button.

The following window is displayed (Fig 14).

Fig 14

The window shown in Fig 14 can be used as an index book enabling to search and select 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 14 **A**).

The letters on the left side of the window (Fig 14 **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 14 **C**) to see the list of all possible users.

Use the **Local** button (Fig 14 **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 14 **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 14 **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**" page (Fig 7 **A**).

Use the **Cancel** button (Fig 14 **G**) to cancel the operation and close the "User list" window without selecting any user.

5.6 DIGISTAT® Control Bar

The control bar that appears in the lower part of the screen is common to all DIGISTAT® modules. Its main characteristics are listed below. If required, a more detailed explanation of its functionalities is provided in the following paragraphs.

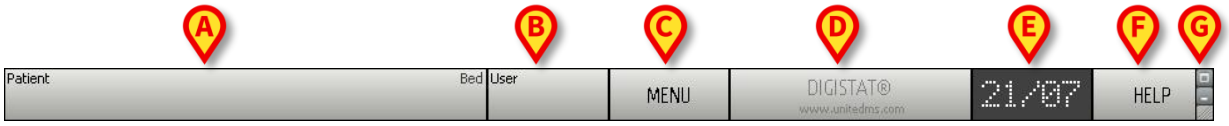

Fig 15

- The **Patient** button (Fig 15 **A**) will contain after a patient has been selected, the patient's name and, if the patient has been admitted, his/her bed number.
- The User button (Fig 15 **B**) shows the name of the user connected. See Fig 8.
- Use the Menu button (Fig 15 **C**) to open the following window (Fig 16).

Fig 16

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

- The button quoting the DIGISTAT® brand name and the ASCOM UMS srl web address (Fig 15 **D**) is used by the system to signal that there are alarms or warnings going on in one of the modules. This feature is explained in the context of the specific module.

- The display indicated in Fig 15 **E** alternately shows the current date and time.
- Use the Help button (Fig 15 **F**) to access the on-line documentation available.
- The small buttons highlighted in Fig 15 **G** can be used to:
  1) minimize the DIGISTAT® window (button);
  2) select the full-screen display mode (button);
  3) select the window display mode (button).

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 17 **A**). See the documentation of the specific modules for the patient selection procedure.

Fig 17

Patient admitted

When a patient is admitted the **Patient** button displays, besides the patient name, the bed number and the name of the department where he/she is admitted (Fig 18).

Fig 18

The department name and the bed number are black if the patient belongs to the workstation domain (see Fig 18).
The department name and the bed number are red if the patient is located in a domain that does not belong to the workstation domain (Fig 19 - the workstation domain is defined by configuration).

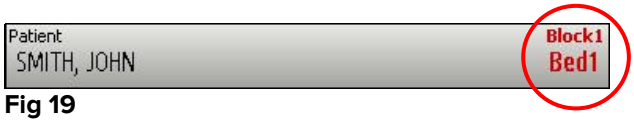

Fig 19

Every workstation is associated by configuration to 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 20) appears when, at patient admission time, the user specified that the patient is not in one of the configured departments.

Fig 20

5.7 Help

Click the **Help** button on Control Bar (Fig 15 **E**) to access the on-line documentation available. The page shown in Fig 21, or an analogous one, depending on the available documentation, will open.

Fig 21

The command bar (Fig 22) offers some navigation possibilities.

Fig 22

- 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 on-line help.

5.8 DIGISTAT® Main Menu

The **Menu** button placed on the DIGISTAT® Control Bar (Fig 23)

Fig 23

opens a menu containing several options (Fig 24).

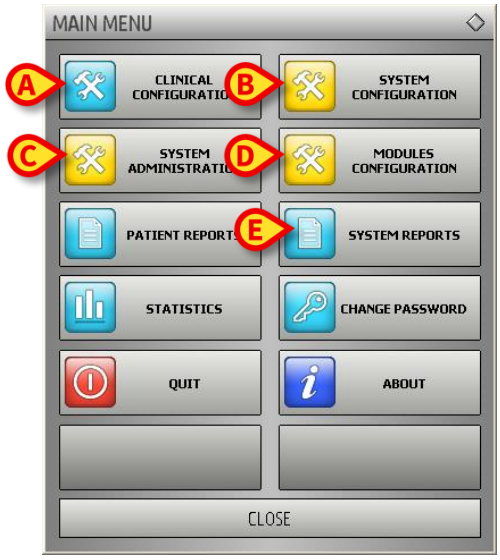

Fig 24

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 24 **A**)

System configuration - (Fig 24 **B**)

System administration - (Fig 24 **C**)

Modules configuration- (Fig 24 **D**)

System reports - (Fig 24 **E**)

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

The other buttons, indicated in Fig 25, 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 paragraphs.

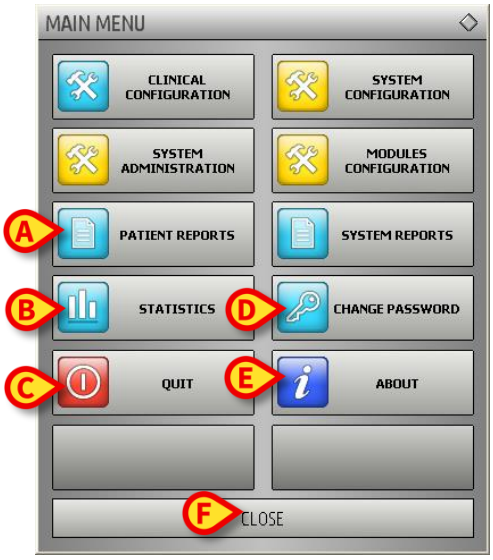

Fig 25

Patient reports - (Fig 25 **A**, paragraph 5.8.1)

Statistics - (Fig 25 **B**, paragraph 5.8.3)

Quit - (Fig 25 **C**, paragraph 5.8.6)

Change Password - (Fig 25 **D**, paragraph 5.8.4)

About - (Fig 25 **E**, paragraph 5.8.5)

The **Close** button (Fig 25 **F**) closes the “Main menu” window (Fig 25).

5.8.1 Patient reports

The "**Patient reports**" button (Fig 25 **A**) makes it possible to access a set of options enabling the user to print reports of different kinds for the selected patient.

The button opens a menu containing different options (the one shown in Fig 26 is an example)

Fig 26

5.8.2 Print reports

Use the buttons on the menu displayed in Fig 26 to access the system's print functionalities.

The type and the contents of some reports are customizable. Please refer to the system administrators for any request regarding the print reports customization.

To print a patient report

- Click one of the buttons on the menu.

A print preview of the selected document will open (Fig 27).

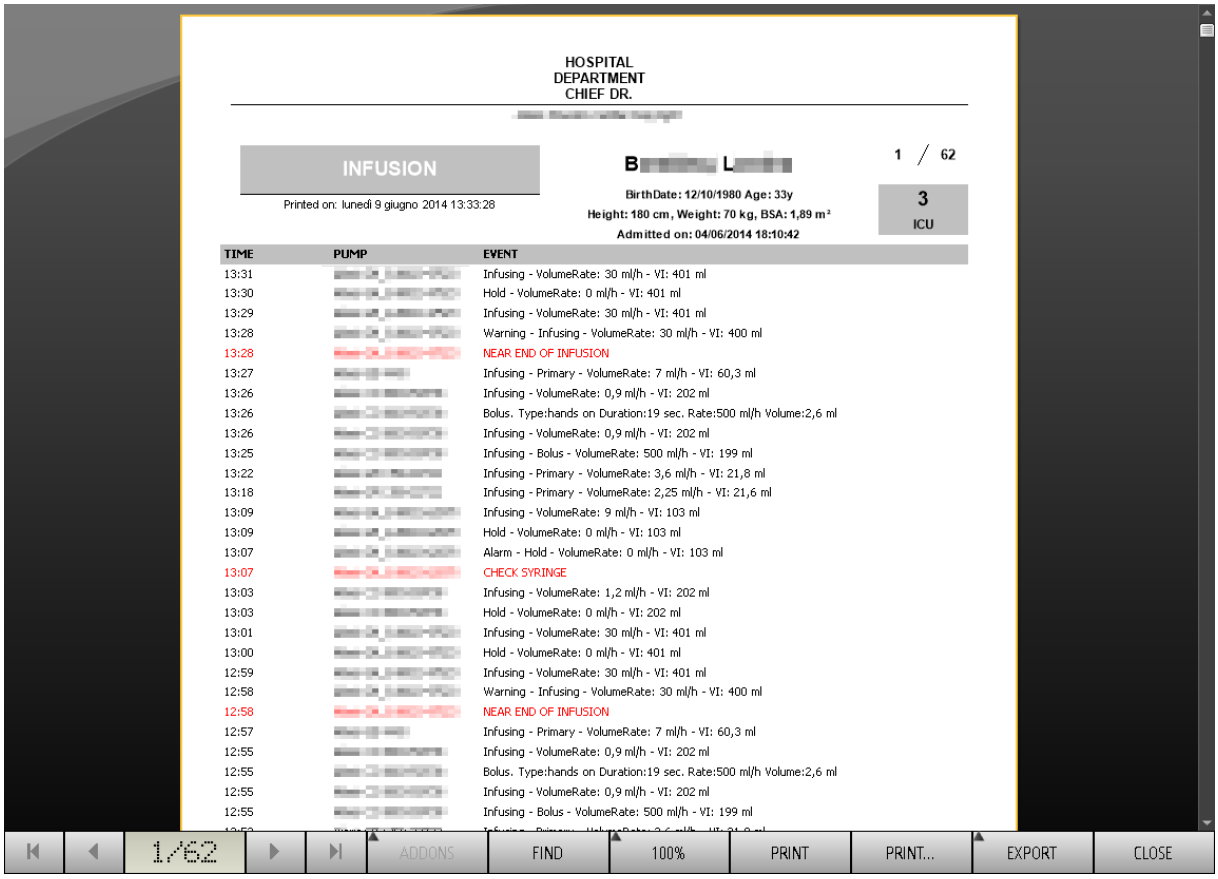

Fig 27

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  indicates the current page number.

The **Addons** button activates the possible additional print management options (in this configuration the “Watermarks” option is available - see paragraph 5.8.2.2 for a description of these options).

The **Find** button makes it possible to search the displayed document. See paragraph 5.8.2.2 for more instructions.

The button indicating the **100%** percentage is a zoom, making it possible to change the display mode. See paragraph 5.8.2.3 for more instructions.

Use the **Print** button (Fig 27 **G**) to print the report.

Use the **Print...** button (Fig 27 **H**) to display the print options window (Fig 33). See paragraph 5.8.2.4 for a description of this window and the related procedures.

Use the **Export** button (Fig 27 **I**) to export the document contents to different file extensions. See paragraph 5.8.2.5 for more instructions.

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

5.8.2.1 Addons

The **Addons** button (Fig 27 **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 28).

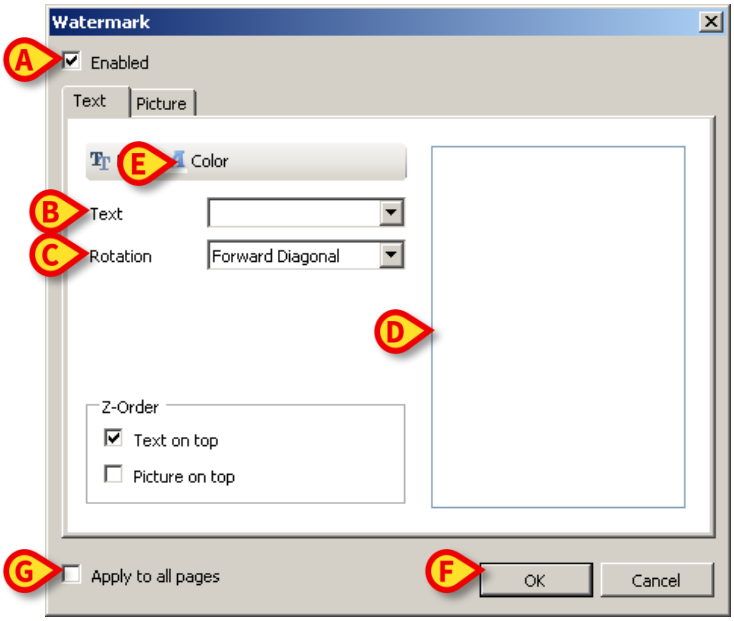

Fig 28

To add a textual watermark,

- Ensure that the "**Enabled**" checkbox is checked (Fig 28 **A**). If not, the window's contents cannot be edited.
- Insert the text in the "**Text**" field (Fig 28 **B**).
- Use the "**Rotation**" menu (Fig 28 **C**) to specify the watermark orientation (diagonal, horizontal, vertical).

A print preview is displayed in the area indicated in Fig 28 **D**.

- Use the buttons indicated in Fig 28 **E** to select the watermark font and color.
- Click the **Ok** button (Fig 28 **F**).

The text is this way inserted as watermark.

If the "**Apply to all pages**" checkbox is selected (Fig 28 **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 29 **A**.

The following window is displayed (Fig 29).

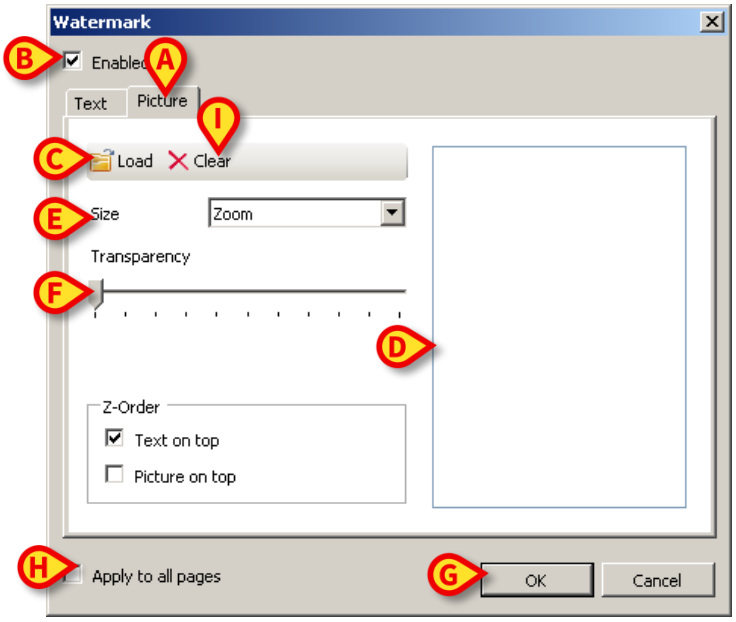

Fig 29

Follow these steps to insert an image as watermark,

- Ensure that the "**Enabled**" checkbox is checked (Fig 29 **B**). If not, the window's contents cannot be edited.

- Click the "**Load**" button indicated in Fig 29 **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 29 **D**.

- Use the "**Size**" drop-down menu to set the size of the image (Fig 29 **E**).

- Use the "**Transparency**" cursor to set the transparency level of the watermark image (Fig 29 **F** - maximum transparency when the cursor is on the left).

- Click the **Ok** button (Fig 29 **G**). The watermark image is this way inserted.

If the "**Apply to all pages**" checkbox is selected (Fig 29 **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 29 **I**.

5.8.2.2 Find

The **Find** button (Fig 27 **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 30).

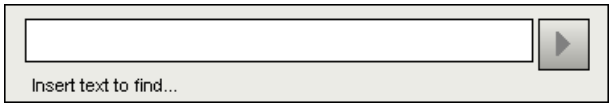

Fig 30

- Insert in the window the text to be found in the print report (Fig 31 **A**).

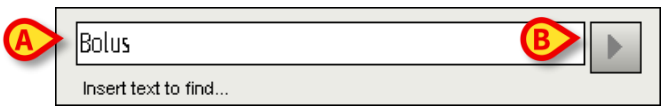

Fig 31

- Click the  button (Fig 31 **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.

5.8.2.3 Zoom

The **Zoom** button (on which, by default, the **100%** size is displayed - Fig 27 **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 32).

Fig 32

- Click the wanted 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 100 to 200 %. The selected value is also displayed on the **Zoom** button on the command bar after selection.

5.8.2.4 Print

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

- Click the **Print...** button (Fig 27 **H**) to display the print options window (Fig 33)

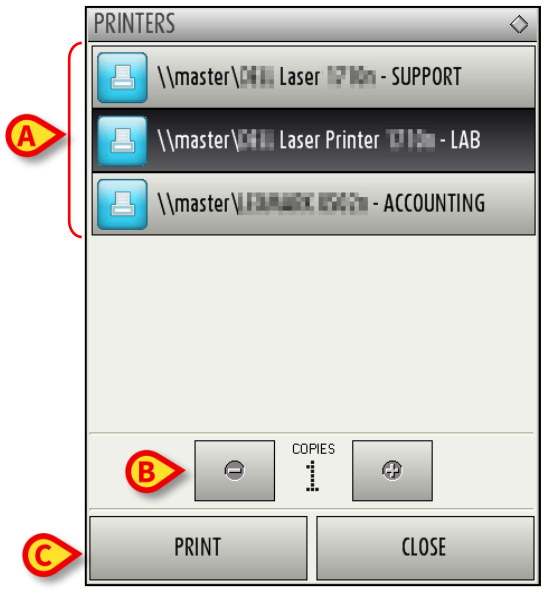

Fig 33

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

- Click the wanted option on the menu to select the printer (Fig 33 **A**).
- Use the  (one less copy) and the  (one more copy) buttons to specify the number of copies (Fig 33 **B**).
- Click the **Print** button (Fig 33 **C**) to print the report.

5.8.2.5 Export

The **Export** button (Fig 27 **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 extensions currently supported by the system in use.

- Click the option corresponding to the wanted extension.

The document is this way exported to the corresponding extension.

5.8.3 Statistics

The **Statistics** button on the main menu (Fig 34) makes it possible to access the system's statistical calculation tools.

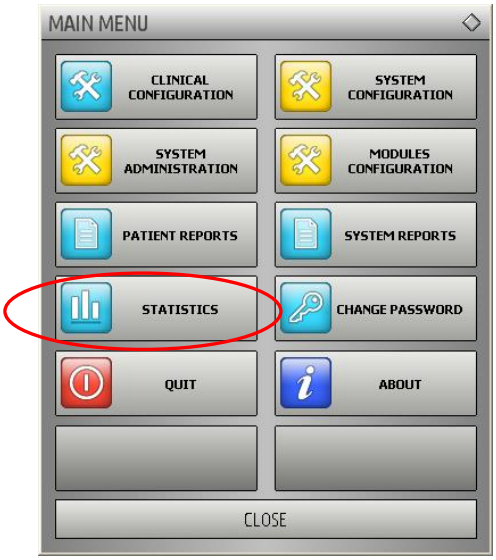

Fig 34

The button opens another menu (Fig 35) that enables to access 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 paragraph.

Fig 35

5.8.3.1 Query Assistant

The **Query Assistant** button (Fig 35) accesses a tool making it possible to create, save and execute queries on the DIGISTAT® database (Fig 36).

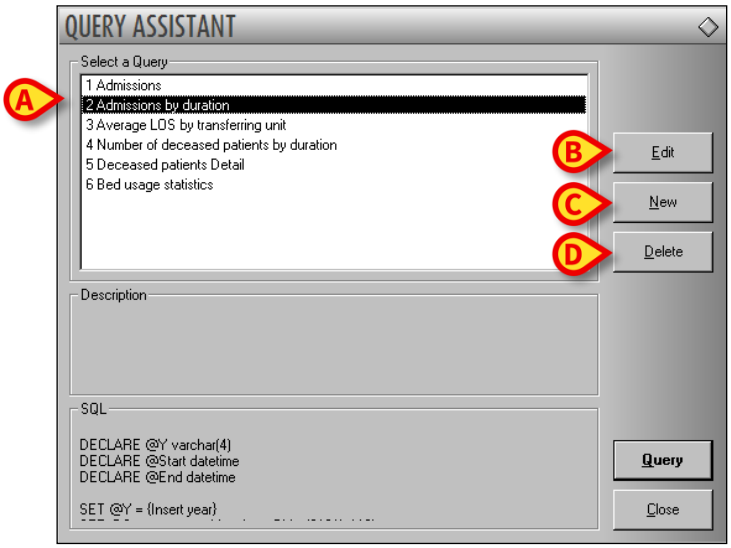

Fig 36

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

The “Select a Query” area displays the list of all the pre-defined queries (Fig 36 **A**).

To run a query

- Click the corresponding name on the list,

The name will be highlighted (Fig 37 **A**).

A textual description of the query is displayed in the “Description” area (Fig 37 **B**).

The “SQL” area (indicated in Fig 37 **C**) displays the content of the query in SQL language (Structured Query Language).

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

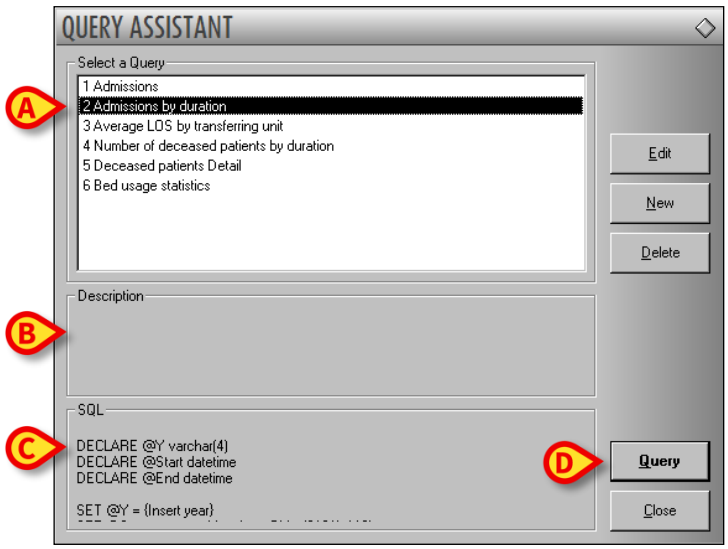

Fig 37
To run the query

- Click the **Query** button (Fig 37 **D** - bottom-right).

The results are displayed in a new window, as a table (Fig 38).

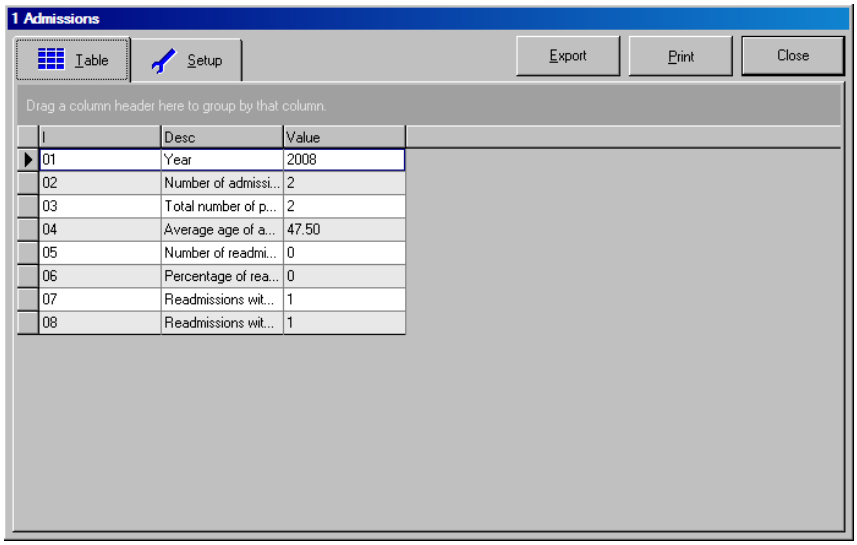

Fig 38

The **Edit** button placed on the right of the “Query Assistant” window (Fig 36 **B**) makes it possible to edit an existing query.

The **New** button placed on the right of the “Query Assistant” window (Fig 36 **C**) makes it possible to create a new query.

The **Delete** button placed on the right of the “Query Assistant” window (Fig 36 **D**) makes it possible to cancel an existing query.

5.8.4 Change password

The **Change Password** button on the DIGISTAT® main menu (Fig 39 **A**) opens a window making it possible to change the password of the user currently logged to the system.

Fig 39

To change the user password

- Click the **Change Password** button (Fig 39 A).

The "Change password" window will open.

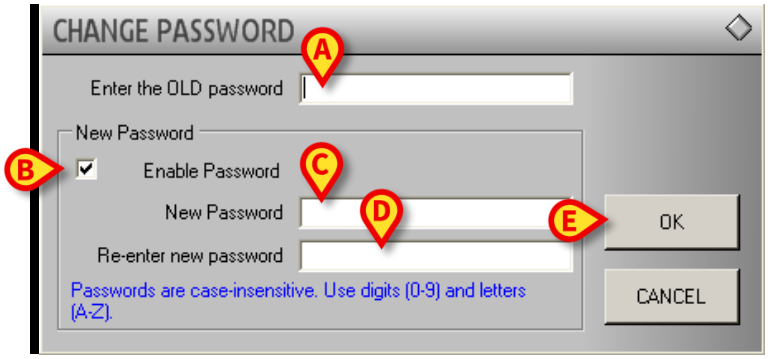

Fig 40

- Type the current password in the "**Enter the OLD password**" field (Fig 40 **A**).
- Verify that the "**Enable password**" checkbox (Fig 40 **B**) is selected.

- Type the new password in the field indicated in Fig 40 **C**.
- Type again the new password in the field "**Re-enter new password**" (Fig 40 **D**).
- Click the **Ok** button (Fig 40 **E**).

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

5.8.5 About DIGISTAT®

The **About** button on the DIGISTAT® main menu (Fig 39 **B**) displays a window containing information on the DIGISTAT® version installed and the related licenses (Fig 41).

Fig 41

5.8.6 Quit DIGISTAT®

The **Quit** button on the DIGISTAT® main menu (Fig 43 **A**) makes it possible to quit the DIGISTAT® environment.

To quit DIGISTAT®

- Click the **Menu** button on the control bar (Fig 42).

Fig 42

The DIGISTAT® main menu will open (Fig 43).

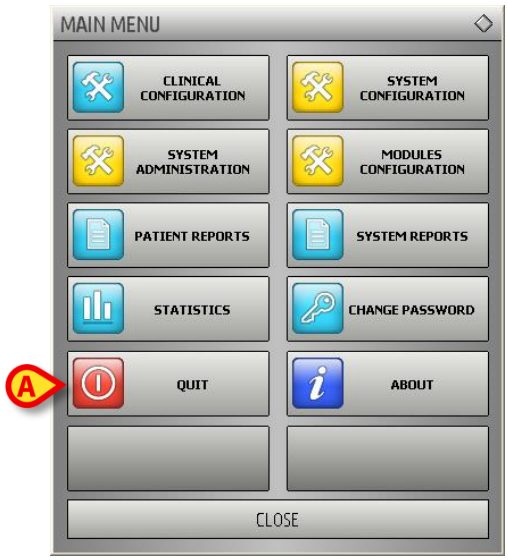

Fig 43

- Click the **Quit** button (Fig 43 **A**).

Another menu is displayed (Fig 44).

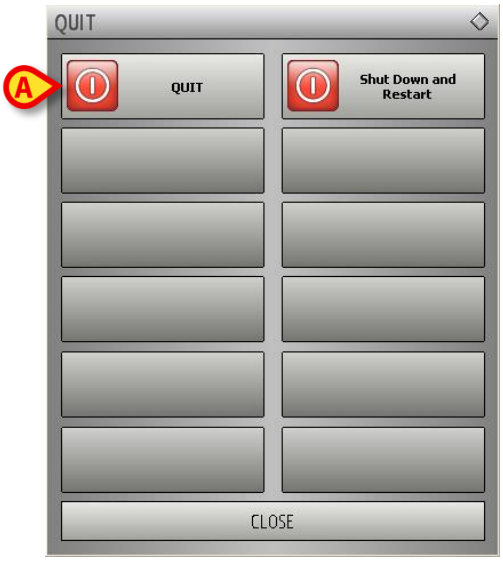

Fig 44

➢ Click the **Quit** button again (Fig 44 **A**).

User confirmation is required (Fig 45).

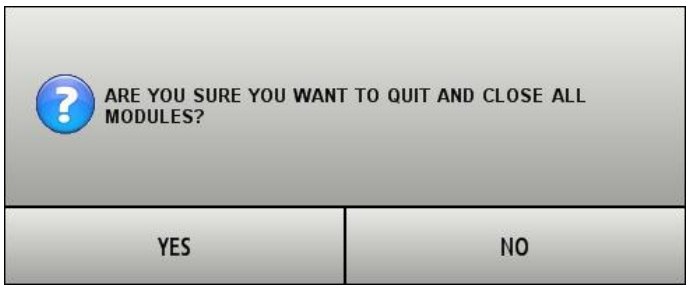

Fig 45

➢ Click **Yes** to exit DIGISTAT®.

A user must have the required permissions level to exit DIGISTAT®.

---

6. DIGISTAT® Smart Central

6.1 Information for the user

Please read carefully the following warnings.

The purpose of the system is to help the 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 the 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 are 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 out of the cases allowed by the usual hospital procedures.

The correctness of each alarm/warning notified by DIGISTAT® “Smart Central” must be always double-checked on the actual device that supposedly generated it.

Never disable the alarm systems on the medical devices out of the cases allowed by the usual hospital procedures.

Never disable the audio on the workstations on which DIGISTAT® “Smart Central” is running.

For reasons that are not under software control (as, for instance, the way the actual physical devices are installed/cabled) delays are possible between the alarm generation and the actual alarm display.

6.2 Module selection

To select the DIGISTAT® “Smart Central” module

➢ Click the corresponding icon on the lateral bar (Fig 46).

Fig 46

The “Smart Central” screen, shown in Fig 47, opens.

In most of the “DIGISTAT® “Smart Central” configurations, the “Smart Central” module is the only one available and is automatically selected after user log in.

6.3 DIGISTAT® "Smart Central"

The "Smart Central" screen displays a schematic representation of the situation of each patient in the ward (Fig 47).

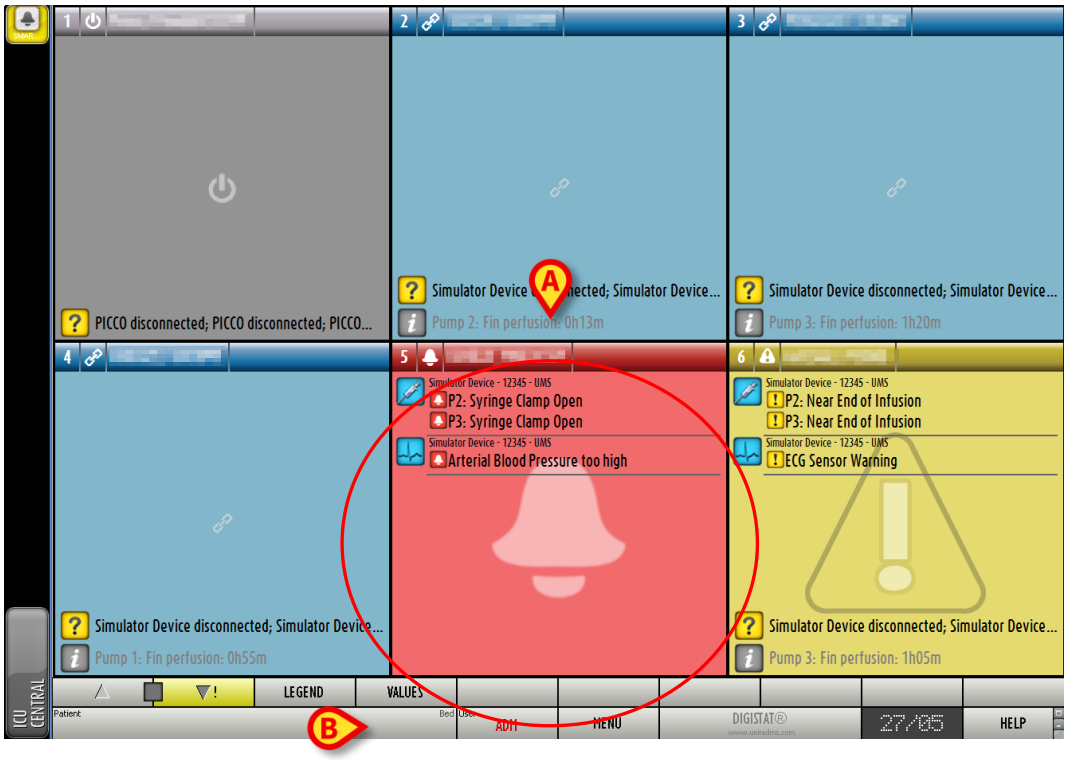

Fig 47

The screen is divided into rectangular areas, named "Bed areas" (Fig 47 **A**). Every area refers to a bed and contains information on the devices connected to a patient. By default, only the data referring to either alarmed or in warning state beds are displayed (Fig 49), and only data relating to alarms/warnings are displayed. A bed is alarmed or in warning state if at least one of the devices connected to the bed is alarmed or in warning state. If alarms and warnings occur at the same time on the same bed, the bed is displayed as alarmed.
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 47 **B**).

To display all the available data

- Click the **Values** button on the command bar (Fig 47 **B**).

The button will be selected. The available information will be displayed as in Fig 48.

Fig 48

6.4 Bed areas

Each “Bed area” displays some of the data provided by the devices connected to the patient (Fig 49). The kind of data displayed depends on the way the device is designed and configured.

Fig 49

If the “Bed area” is yellow, as in Fig 49, it means that there is at least one warning message, and no alarms, coming from the connected devices.

If the “Bed area” is red, as in Fig 50, it means that at least one of the connected devices is in alarm state.

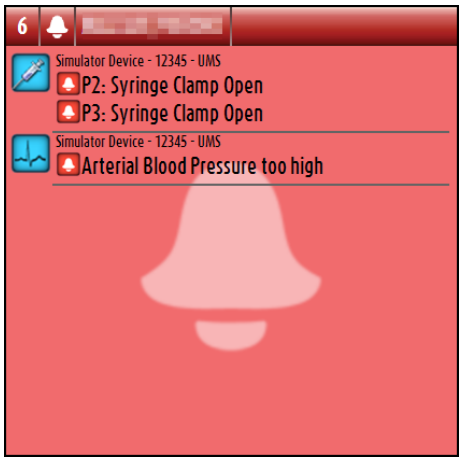

Fig 50

The connected beds from which neither alarms nor warnings are received appear as in Fig 51. No device data is here displayed to facilitate reading possible alarms and warnings occurring on the other beds.

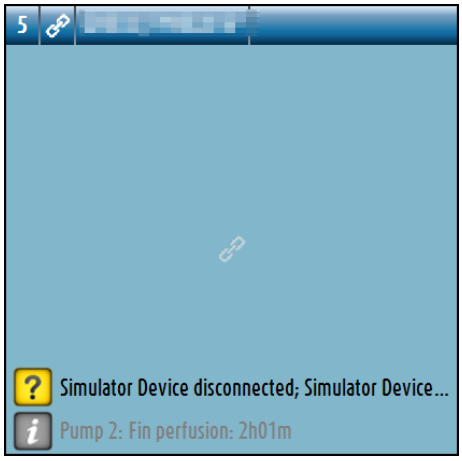

Fig 51

To display device data on these pumps click the **Values** button on the command bar (Fig 47 **B**). The “Bed area” will appear as in Fig 52.

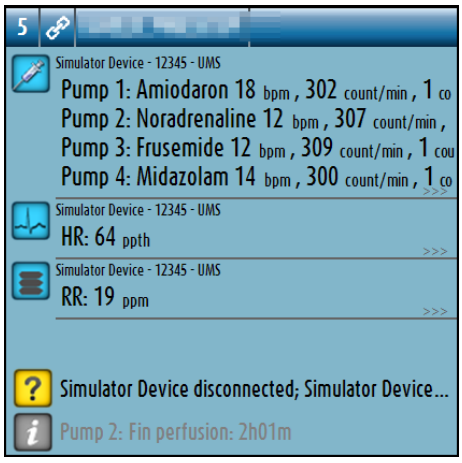

Fig 52

Disconnected beds are displayed as in Fig 53.

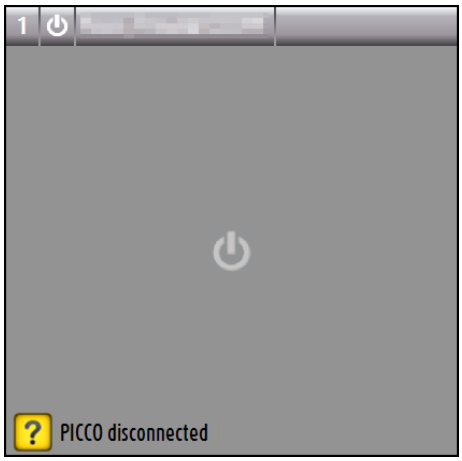

Fig 53

6.4.1 Bed area description

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

On top of the “Bed area” the bed number and the patient name are displayed (Fig 54 refers to bed number 7, with patient name “Test Test”). The icon means that the bed is connected to “Smart Central” and that “Smart Central” is currently receiving data from the bed. If one of the devices connected to the bed is providing a warning message the icon is displayed instead. If one of the devices connected to the bed is providing an alarm the icon is displayed instead.

Fig 54

The information in the bed area is divided by “Device type”. Each device type is characterized by a specific icon (Fig 55 **A**).

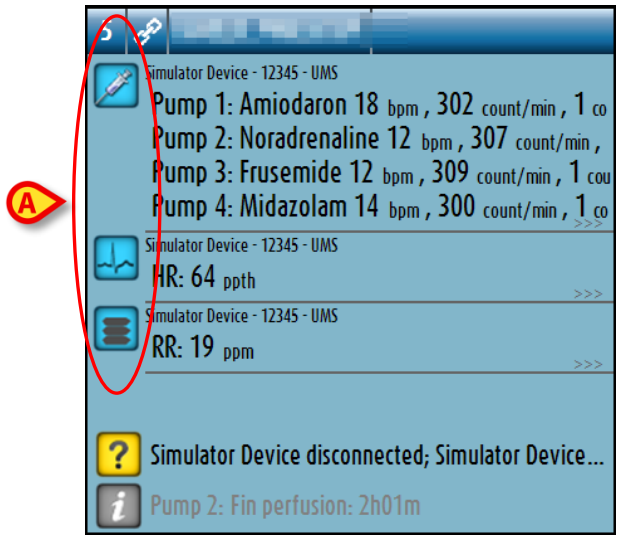

Fig 55

A legenda is available to know the correlation between an icon and a device type (i.e. to which device type a specific icon refers).

To display the legenda

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

Data coming from the same kind of device are grouped together. In Fig 56, for instance, three groups are indicated: pulmonary ventilator, infusion pumps and patient monitor.

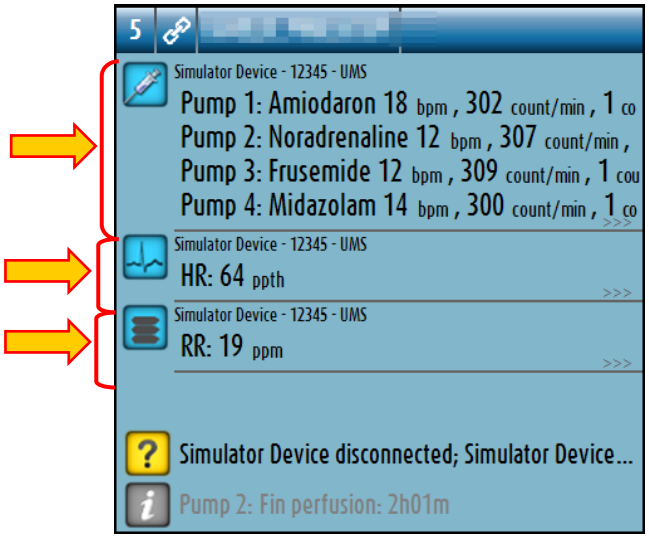

Fig 56

Possibly, not all the data coming from the devices are displayed in the box. If there are, hidden data the >>> signal is displayed at the end of every group (see Fig 57 **A**).

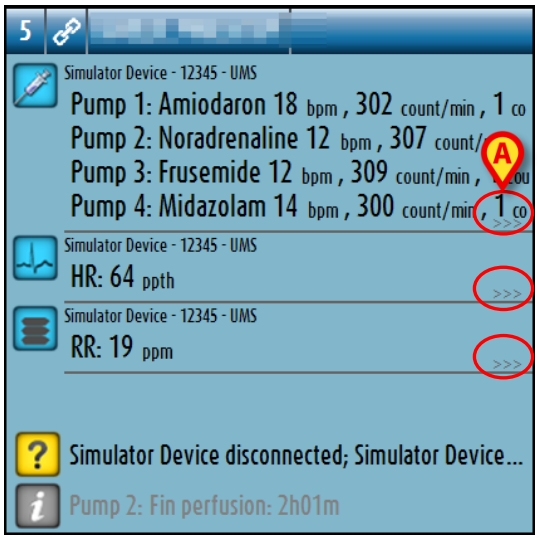

Fig 57

Hidden data can be displayed by clicking the “Bed area”, which is this way enlarged to full-screen mode (Fig 58). All the available information is this way displayed.

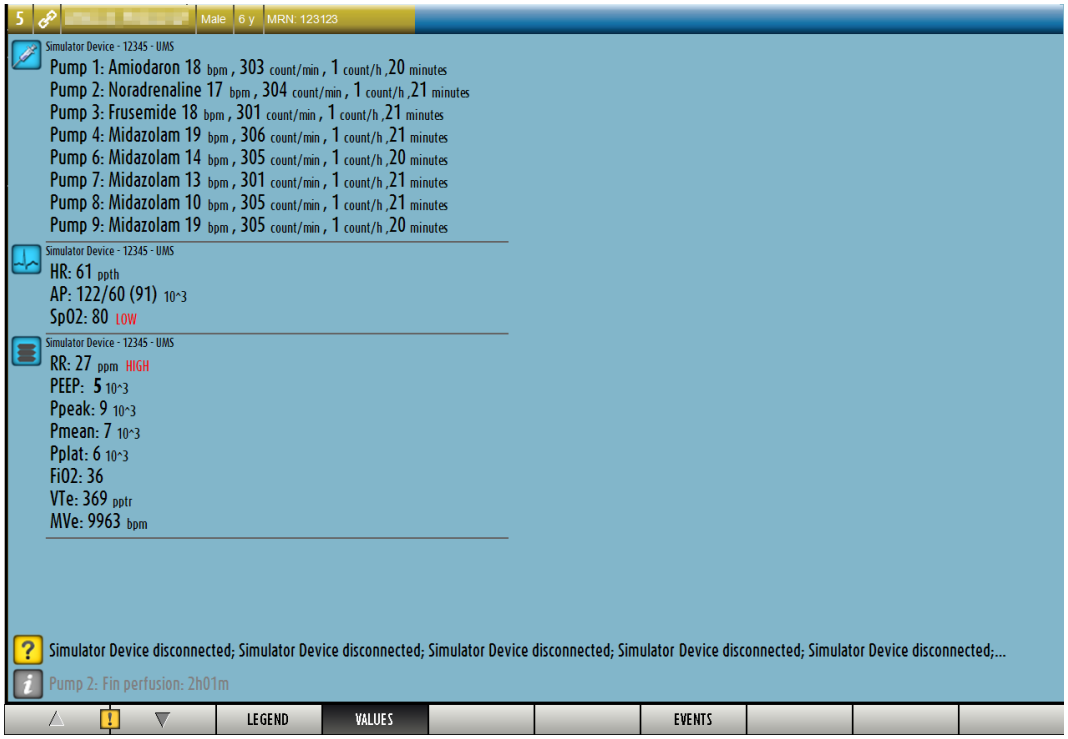

Fig 58

If there is a warning message coming from a device, the  icon is displayed on top of the group to which the device providing the message belongs. A short text explains the kind of warning occurring (Fig 59).

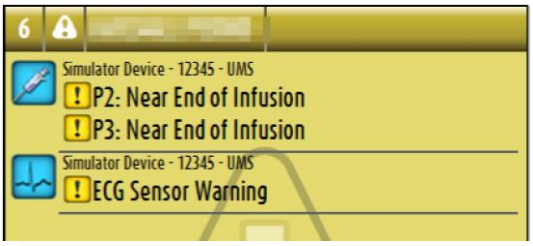

Fig 59

If there is an alarm on a device, the icon is displayed on top of the group to which the alarmed device belongs. A short text explains the kind of alarm (Fig 60).

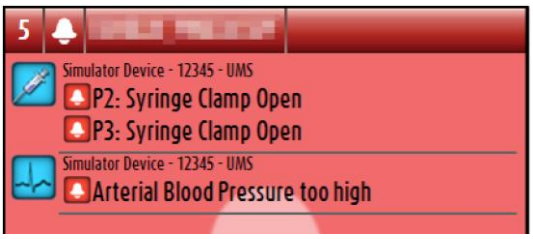

Fig 60

Additional information on the connected devices and the list of the possible disconnected devices are displayed at the bottom of the "Bed area" (Fig 61 **A**). Disconnected devices are indicated by the icon. Additional information is indicated by the icon.

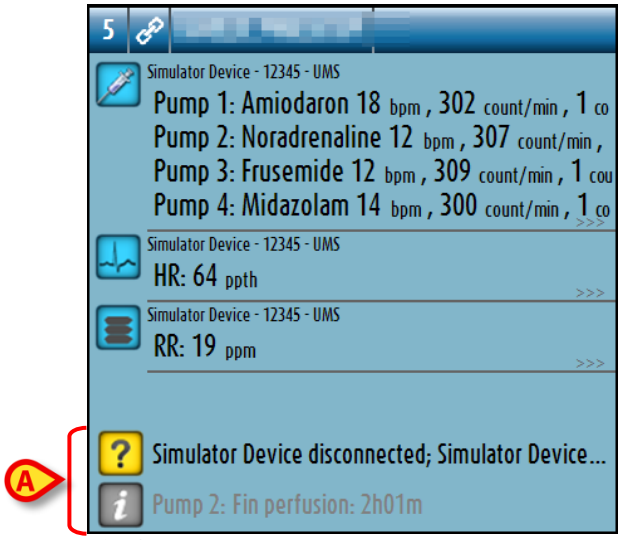

Fig 61

It is possible, by configuration, to associate a message to the displayed values. I.e. it is possible to define a range of values that is "normal" and configure the system to inform the user if the collected values are outside this range. See for instance Fig 62 **A**, in which the values are defined as "Low".

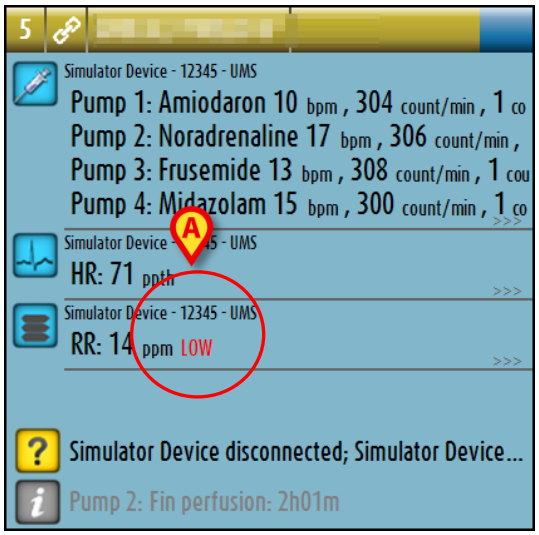

Fig 62

A visual feature on the upper bar on each bed area keeps temporarily track of the last alarm/warning occurred on a bed after it has changed to a different state. This makes it possible to be aware of alarms/warnings occurring and rapidly passing.

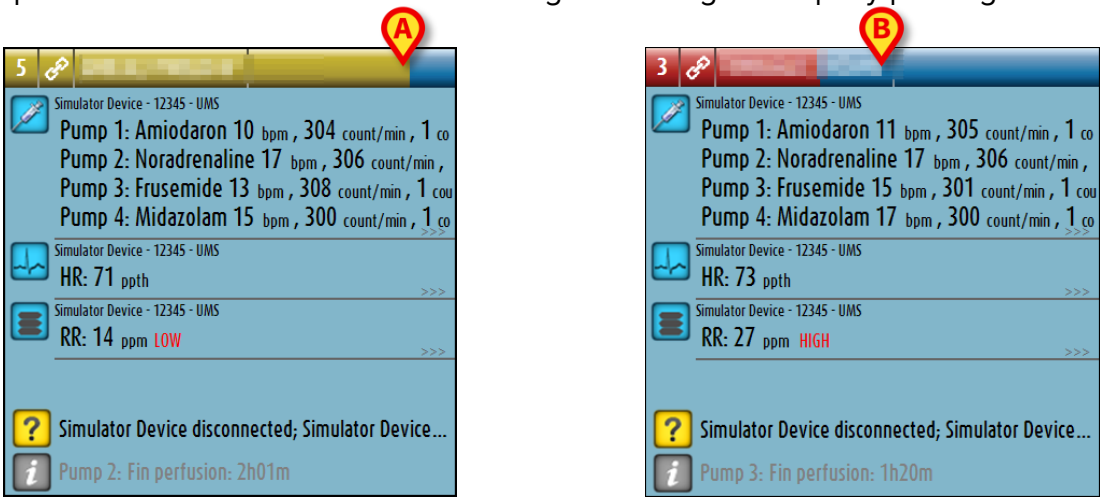

Fig 63 a/b

When the state of a bed area changes to a lower level alarm (or no alarm), the color relating to the previous state remains on the heading bar for a certain configurable time. In Fig 63 **A** the yellow bar is fading to the left, meaning that the previous state was a warning state. In Fig 63 **B** the red bar is fading to the left, meaning that the previous state was an alarm state.

6.5 The “Smart Central” command bar

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

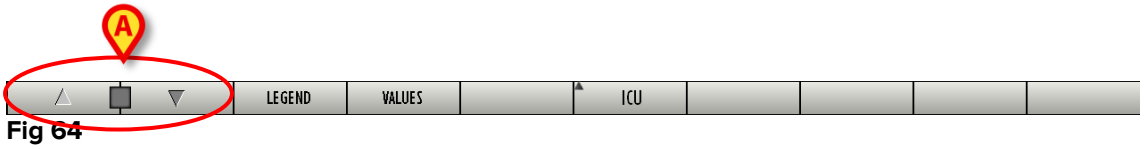

Fig 64

The arrow buttons on the left (Fig 64 **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 alarmed, the corresponding button turns red.

When one (at least) of the non-displayed “Bed areas” is in warning state and no pump is alarmed the corresponding button turns yellow.

In case of alarms and warnings occurring together the arrow button turns red.

The bell icon placed in the box between the arrow buttons (Fig 65) indicates that there is an alarm occurring on one of the “Bed areas” currently displayed and that it has not been taken in charge. Red refers to alarms, yellow refers to warnings. The exclamation mark indicates that there is a warning occurring on one of the “Bed areas” currently displayed and that it has not been taken in charge.

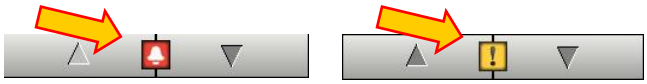

Fig 65

When the alarm/warning is taken in charge, the bell-icon/exclamation mark icon disappears, remaining the yellow/red color inside the box (Fig 66).

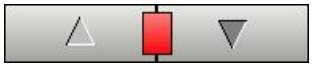

Fig 66

See paragraph MMM (Alarms and Warnings notification) for a more detailed description of the way “Smart Central” notifies the alarms/warnings.

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

The **Values** button displays the values of the beds in which no alarms or warnings are occurring.

The **ICU** button contains an acronym indicating the ward currently displayed. If the system is configured to cover more than one ward, the button can be clicked to open a menu displaying all the configured wards are displayed (Fig 67).

Fig 67

- Click a button on the menu to display the “Bed areas” of another ward, i.e. to monitor a different ward.

When a single “Bed area” is displayed in full-screen mode (as in Fig 58) an additional button – **Events** - is present on the command bar (Fig 68).

Fig 68

- Click this button to display the detailed list of all the events occurred to the devices connected to the selected bed (see paragraph 6.6).

6.5.1 Legend

The **Legend** button makes it possible to display 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 69).

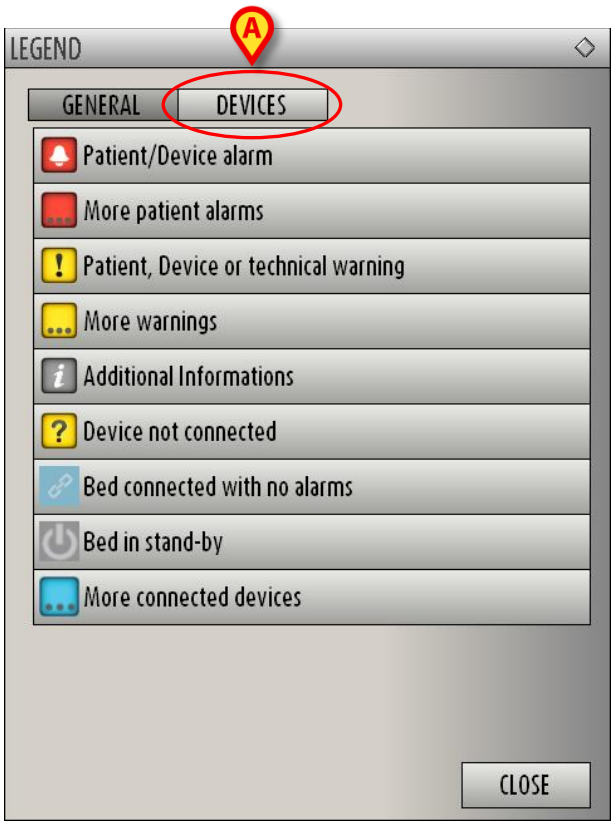

Fig 69

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 69 **A**.

To see the “Device” icons

- Click the **Devices** button indicated in Fig 69 **A**.

The “Devices” legend is this way displayed (Fig 70)

Fig 70

On this window all the possible icons are listed. Alongside the icon the device name is specified, with the corresponding acronym (INF, for instance, 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 71).

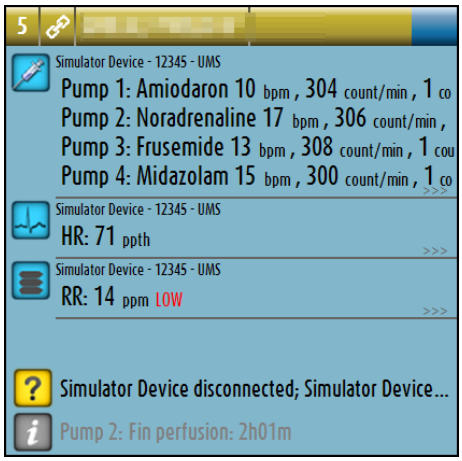

Fig 71

The bed area is this way enlarged to full-screen mode (Fig 72).

- Click the **Events** button on the command bar (Fig 72 **A**).

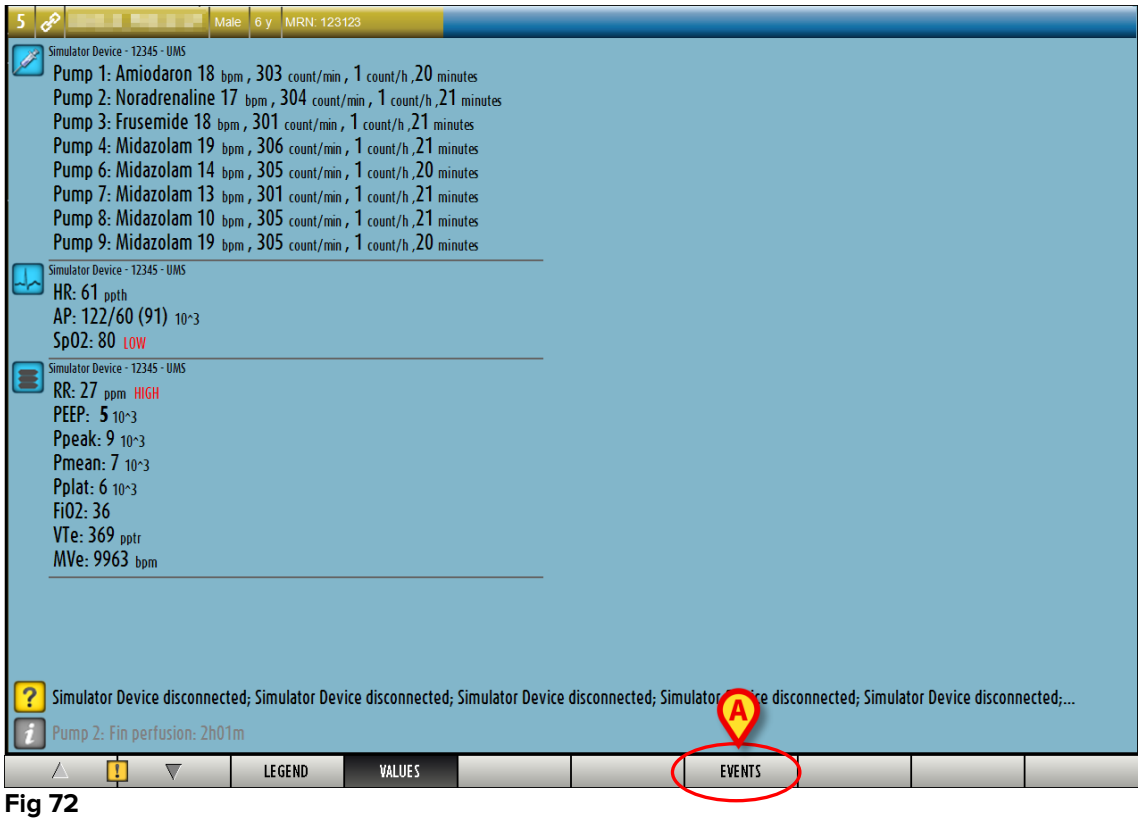

Fig 72

The events list will be displayed on the right (Fig 73).

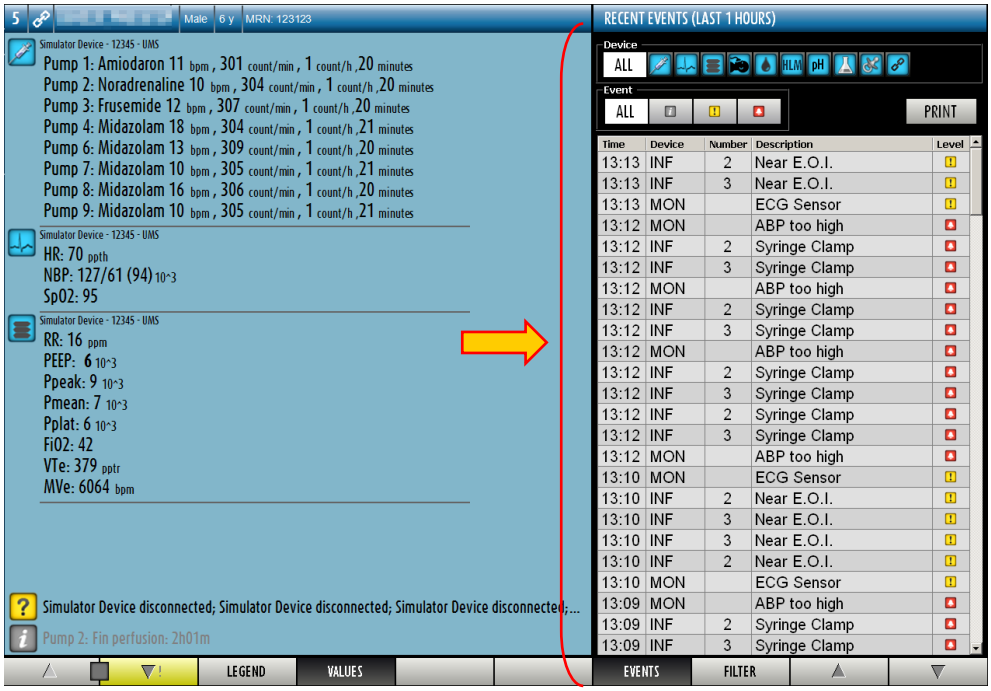

Fig 73

6.6.1 Events list description

The table shown in Fig 74 contains the list of all the events occurred on all the devices connected to the selected patient during his/her stay.

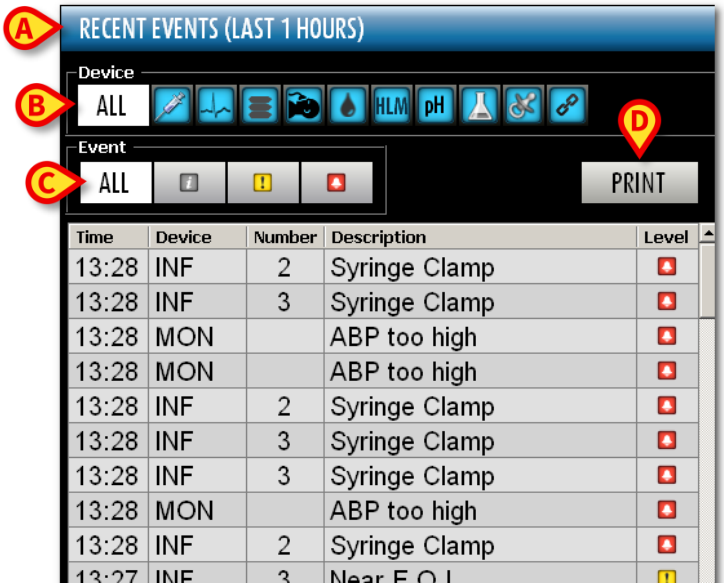

Fig 74

The headline “Recent events” (Fig 74 **A**) can also display if chosen by configuration, the time period to which the events list refers.

The “Device” buttons indicated in Fig 74 **B** are 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 configured 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 selections is possible to display the events referring to two or more devices at the same time.

The “Event” buttons indicated in Fig 74 **C** are also filters making it possible to display only certain types of events. Again, the **All** button, selected by default, displays all the events occurred in the configured time period; the  button only displays the “Information” events; the  button only displays the “Warnings”; the  button only displays the “Alarms”. Multiple selections is possible to display two kinds of events at the same time (i.e. only alarms and warnings).

The **Print** button indicated in Fig 74 **D** makes it possible to print the list of events displayed (Fig 75).

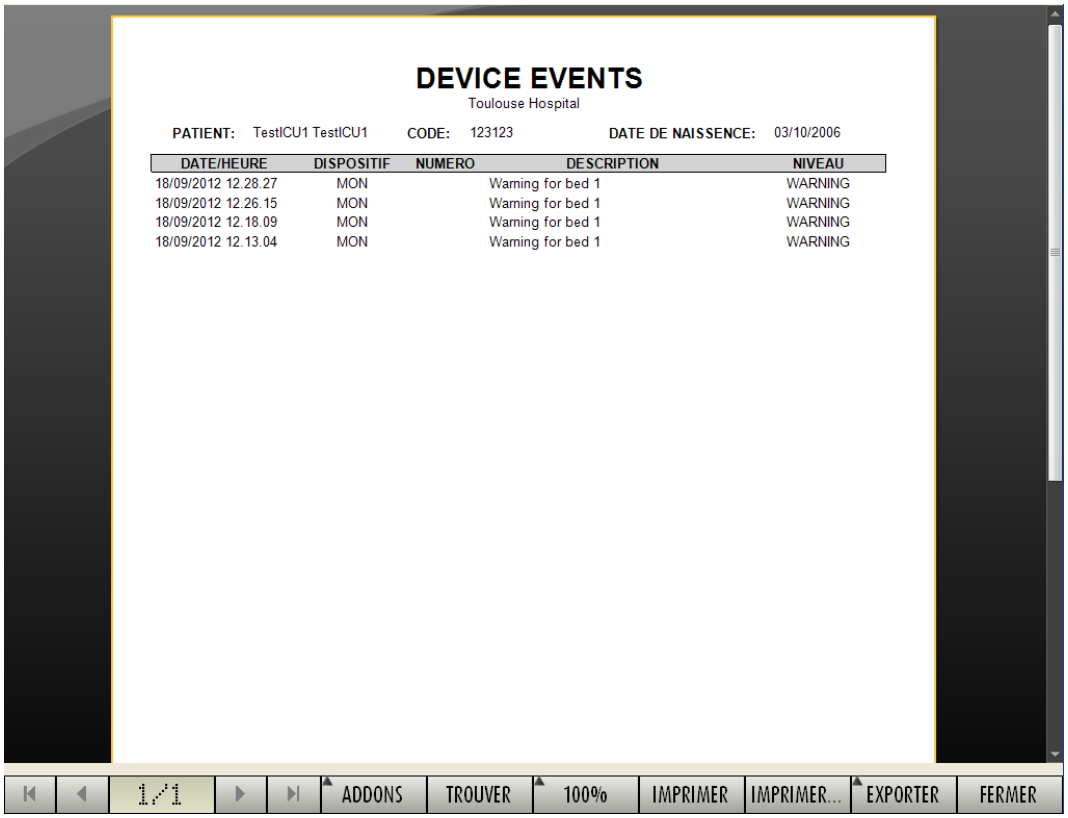

Fig 75

See paragraph 5.8.2 for the system’s print functionalities.

The events table is displayed below (Fig 76).

Time	Device	Number	Description	Level
13:28	INF	2	Syringe Clamp	
13:28	INF	3	Syringe Clamp	
13:28	MON		ABP too high	
13:28	MON		ABP too high	
13:28	INF	2	Syringe Clamp	
13:28	INF	3	Syringe Clamp	

Fig 76

The events table provides the following information:

- Event time (indicated as hh:mm).
- Kind of device in which the event occurred.
- Number (in case of infusion pumps it indicates the pump number).
- Event description.
- Event level (Information, Warning or Alarm).

6.6.2 Filters

The **Filter** button on the command bar opens a tool making it possible to filter the events list.

To filter the events list

➢ Click the **Filter** button.

The following window is displayed (Fig 77).

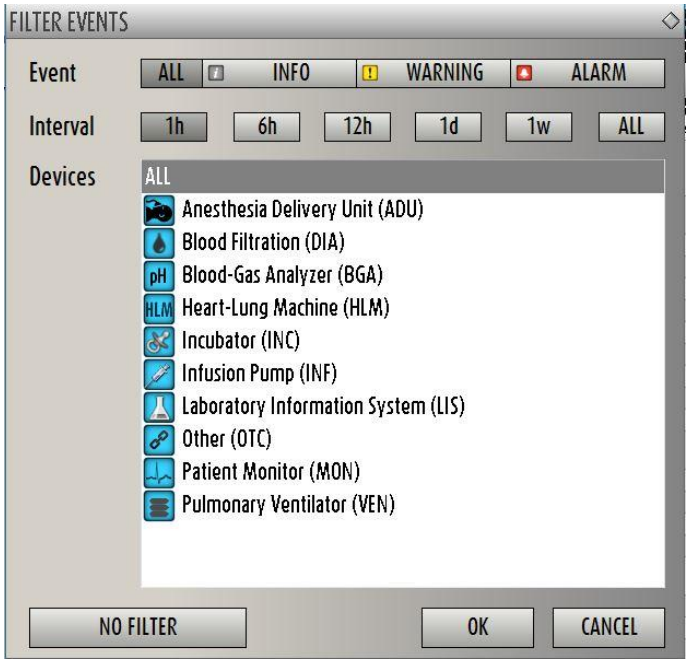

Fig 77

This window makes it possible to filter the events list by:

- Type of event – only the events of a certain type are displayed (either info, warning or alarm).
- Time interval – only the events occurred in a certain period of time are displayed (either 1-6-12-24 hours or 1 week).
- Device – only the events occurred on a specific device are displayed.

To select a filter

➢ Click the corresponding button.

Multiple filter selection is possible (for example it is possible to display “only warnings occurred in the last 6 hours on infusion pumps”).

Once the filters are selected

➢ Click **Ok** to display the corresponding events list.

When a filtered list is displayed the **Filter** button on the command bar is red.

The **Clear Filters** button clears the filters previously selected. So, to go back to the unfiltered display mode,

➢ Click the **Filter** button on the command bar,

The window shown in Fig 77 is displayed.

➢ Click the **Clear Filters** button on the window

➢ Click **Ok**.

The unfiltered list is this way displayed again.

6.7 Alarms and Warnings notification

! The purpose of the system is to help the alarm management and shall not be used as a remote alarm system or as an alarm replicator.

By default, the “Smart Central” screen displays the data referring to a bed only if there is a warning or alarm coming from one of the devices connected to that bed.

In a condition of “No alarm/warning” the “Smart Central” screen would appear as in Fig 78, where five connected “Beds” are displayed and no device on no bed is alarmed or in warning state.

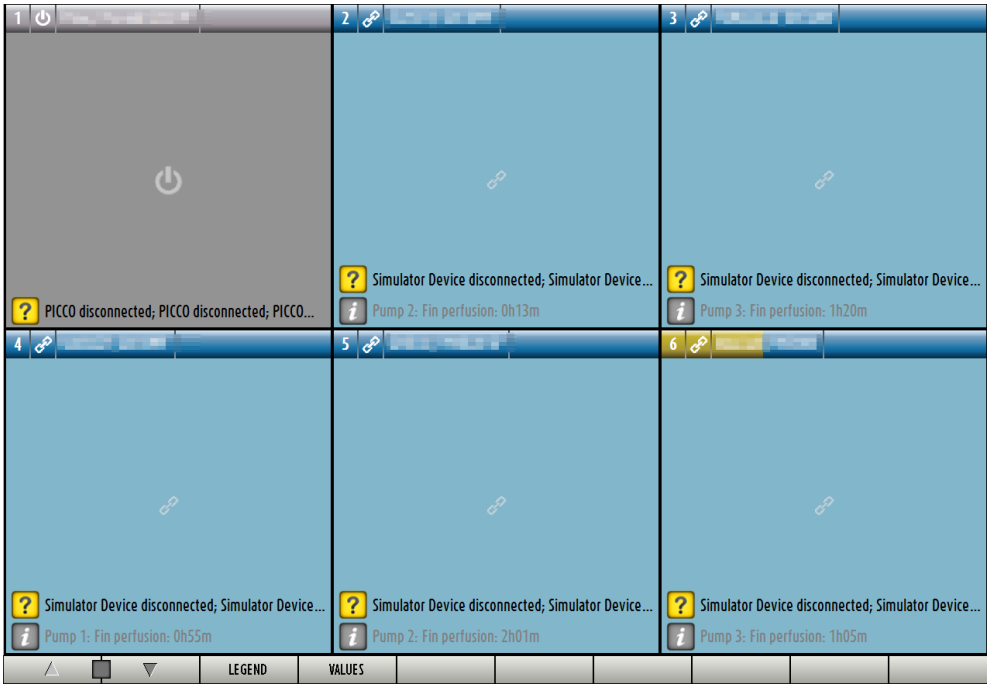

Fig 78

Each time a warning or alarm occurs on one of the devices, the data relating to the bed to which the device is connected are displayed. In Fig 79, for instance, bed 3 is alarmed and bed 6 is in warning state. A short text specifying the kind of alarm/warning occurring is displayed on the “Bed area”, notified by the (alarms) and (warnings) icons.

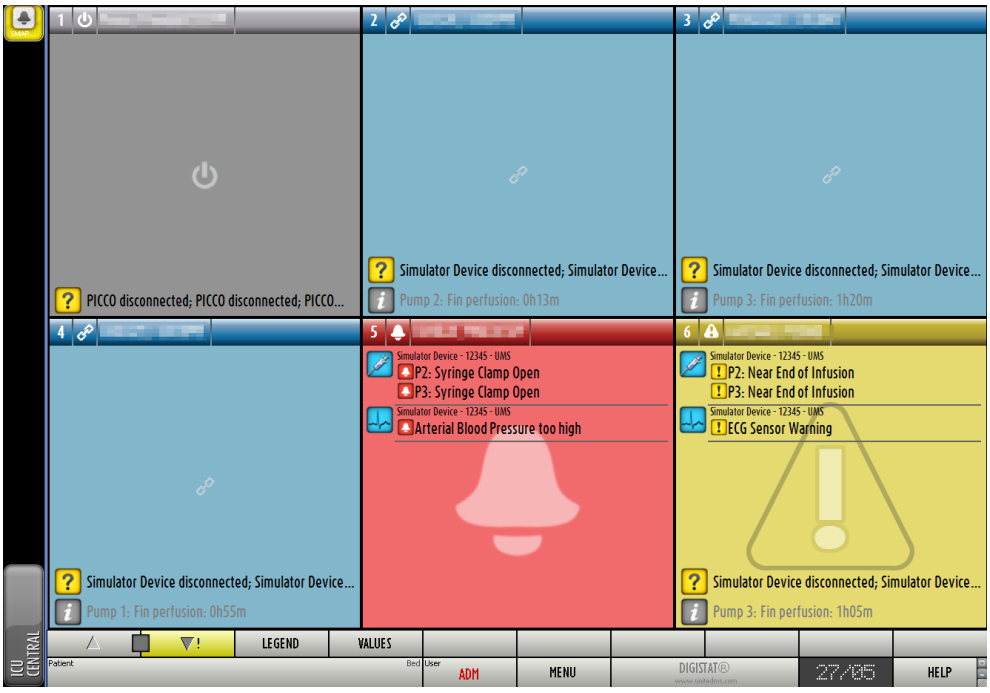

Fig 79

At the same time a sound alarm is provided. Two different sounds exist, one for warnings and one for alarms. Each sound is repeated three times. If alarms and warnings occur at the same time the sound indicating alarms is provided.
When an alarm/warning is provided, the bed areas appear as in Fig 80. Notice the icons in the background (a bell for the alarm, an exclamation mark for the warning).

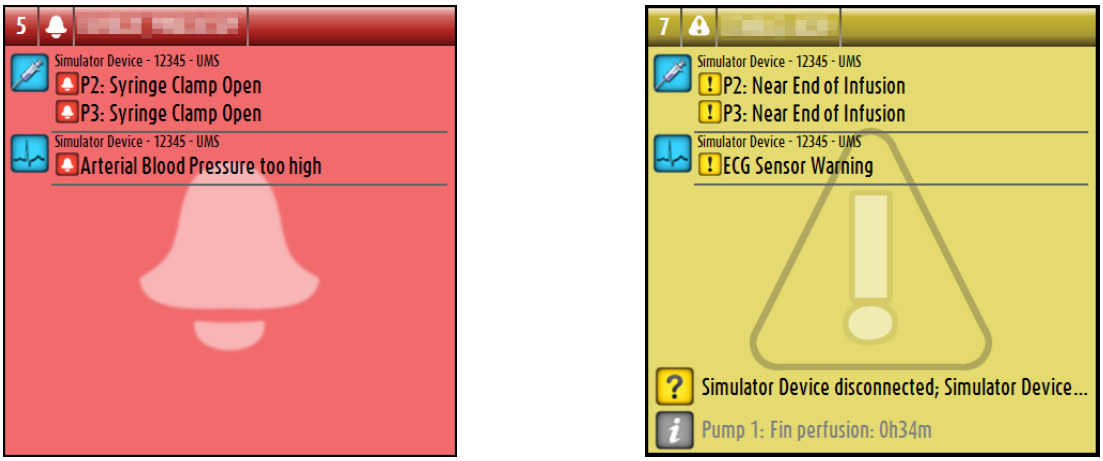

Fig 80

When the "Bed areas" are in the state shown in Fig 80 it means the the alarms/warnings notified have not been taken in charge yet. In order to take charge of the alarm/warning displayed it is necessary to click on the bed area. After clicking the background disappears, as shown in Fig 81

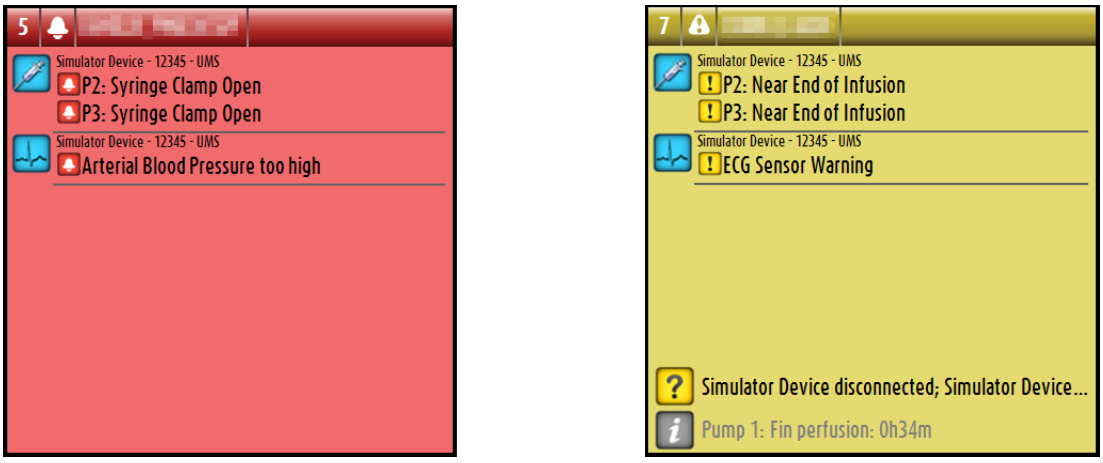

Fig 81

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

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 alarmed the corresponding button turns red.

When one (at least) of the non-displayed “Bed areas” is in warning state and no pump is alarmed the corresponding button turns yellow.

In case of alarms and warnings occurring together the arrow button turns red.

The bell icon or exclamation mark icon placed in the box between the arrow buttons (Fig 84) indicates that there is an alarm or warning occurring on one of the “Bed areas” currently displayed and that it has not been taken in charge. The bell refers to alarms, the exclamation mark refers to warnings.

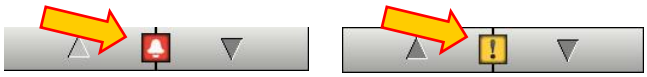

Fig 84

When the alarm/warning is taken in charge the exclamation mark/bell icon disappears, remaining the yellow/red color inside the box to indicate the presence of alarms/warnings.

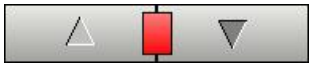

Fig 85

A visual feature on the upper bar on each bed area keeps temporarily track of the last alarm/warning occurred on a bed after it has changed to a different state. This makes it possible to be aware of alarms/warnings occurring and rapidly passing.

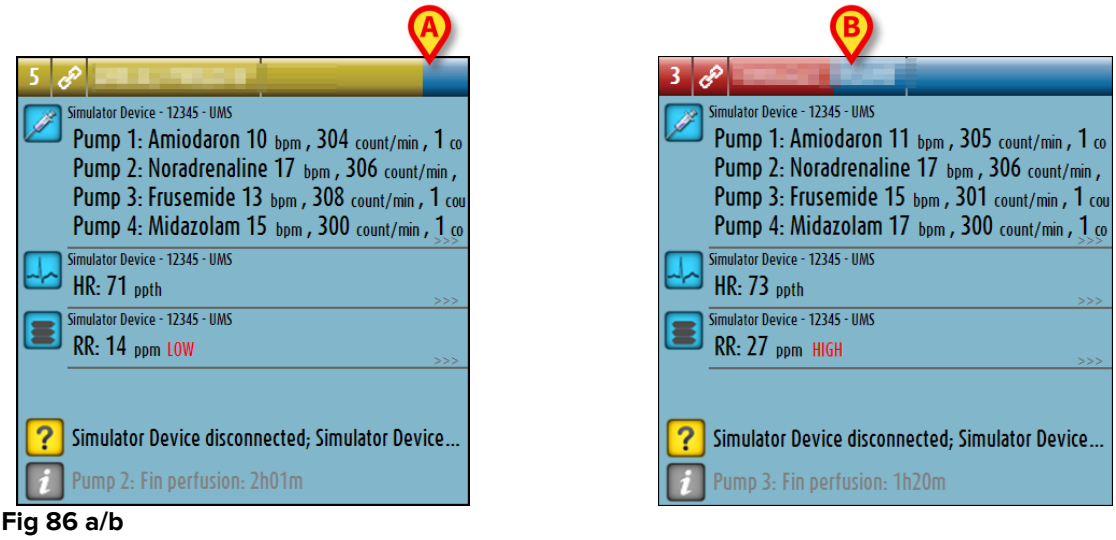

Fig 86 a/b

When the state of a bed area changes to a lower level alarm (or no alarm), the color relating to the previous state remains on the heading bar for a certain configurable

time. In Fig 86 **A** the yellow bar is fading to the left, meaning that the previous state was a warning state. In Fig 86 **B** the red bar is fading to the left, meaning that the previous state was an alarm state.

6.8 Sound Check procedure

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

When “Smart Central” is started, it provides a specific sound indicating that the sound notification of alarm/warning states of devices is properly working.

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).

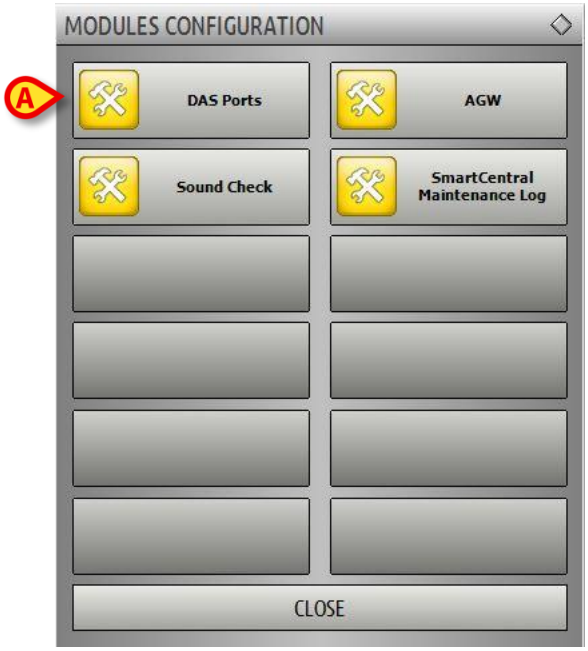

Fig 89

- 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).

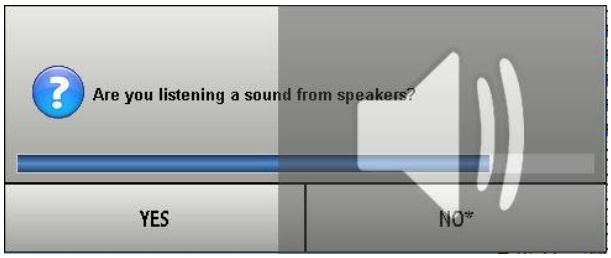

Fig 90

If a sound is heard, then click **Yes**. The pop-up window disappears and nothing else happens (meaning that the system 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 and Fig 92).

Fig 91

Fig 92

The notification remains while working with “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, of its causes and possible solutions.

6.9 Patient search and selection

Although “Smart Central” is commonly used as a monitor in the ward or unit to facilitate alarms and warnings notification and management, in some installation it is possible, for users having specific permissions, to use patient search and selection tools.

To access these functionalities

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

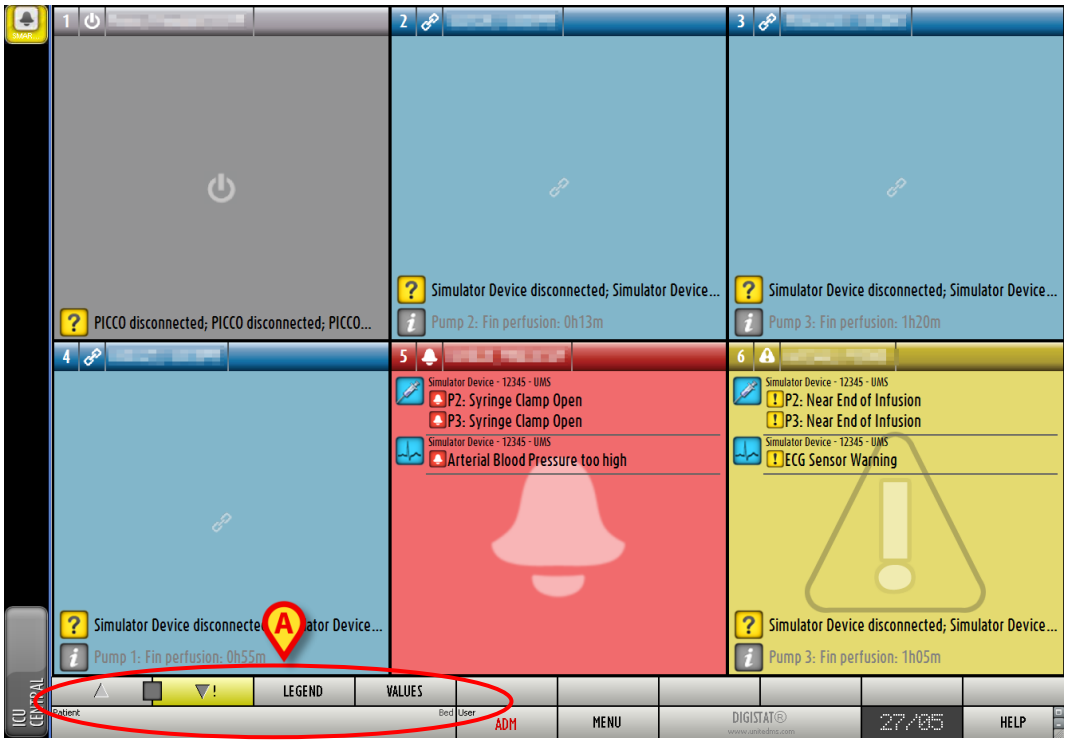

Fig 93

Fig 94

The following screen will open (Fig 95).

Fig 95

The rectangular buttons on the screen (Fig 95 **A**) represent the beds in the ward. If a patient is admitted to a bed, the patient name is displayed on the area (Fig 96 **A**). Below the patient name you can read the admission date. Areas with no name correspond to empty beds (Fig 96 **B**).

Fig 96

- 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 97).

Fig 97

The system displays the current situation of the patient on the “Smart Central” (i.e. the corresponding “Bed area”) in full-screen mode (Fig 98).

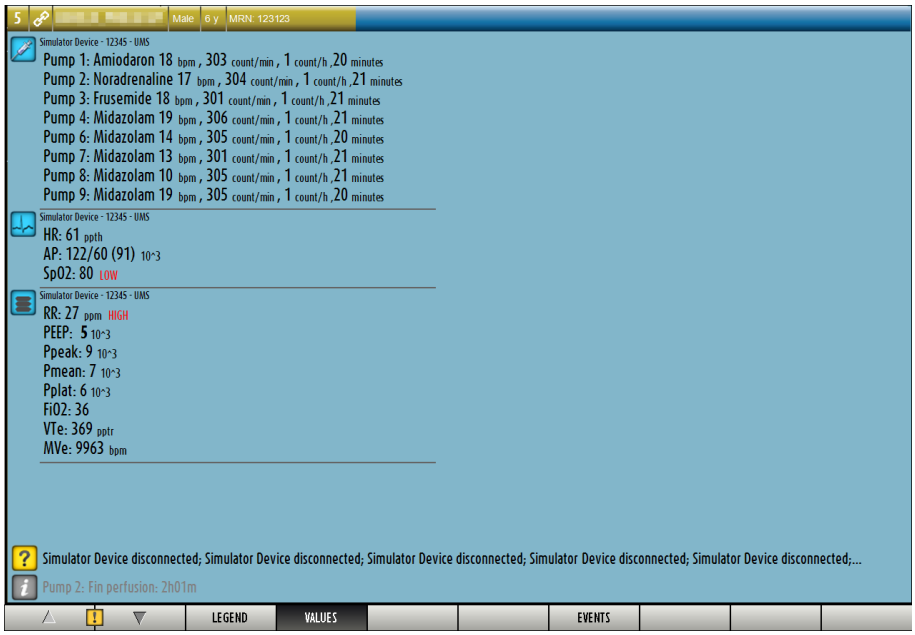

Fig 98

6.10 Patient search

It could be necessary to search the hospital patient archive to retrieve the data relating to a patient that is not currently admitted. To do that

- Click the 

button indicated in Fig 99 **A**

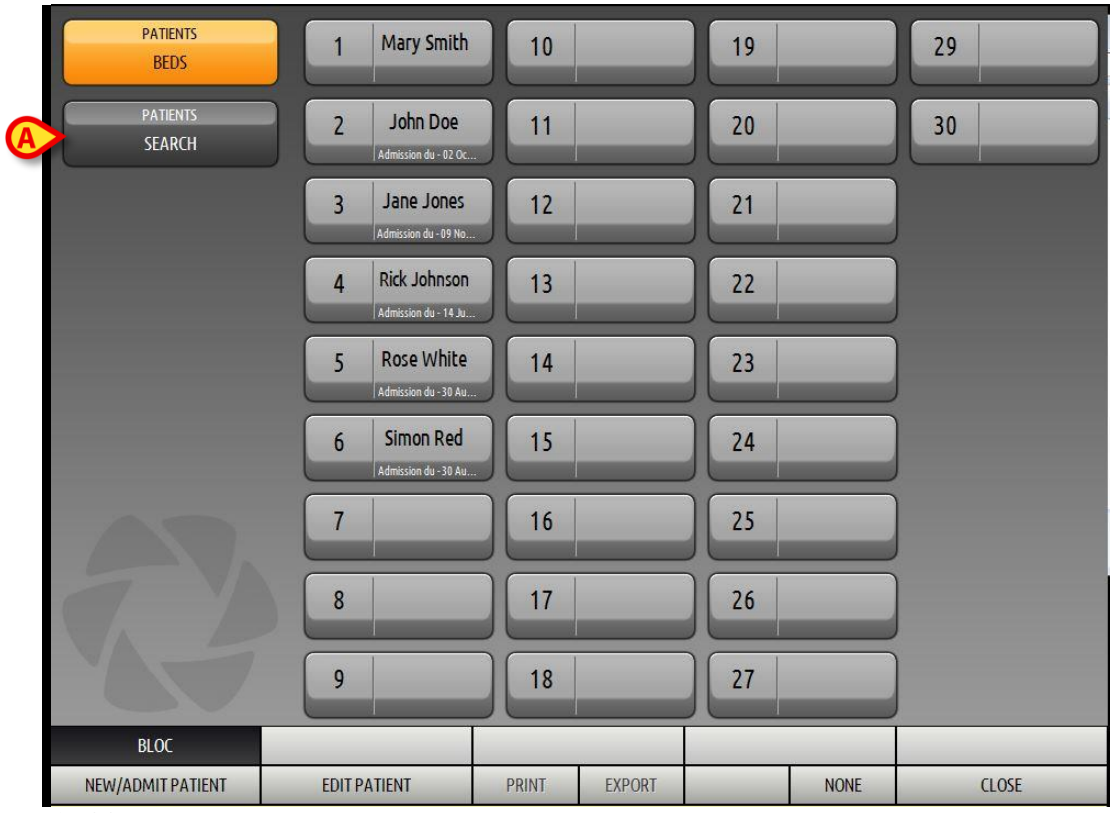

Fig 99

The following screen will open (Fig 100).

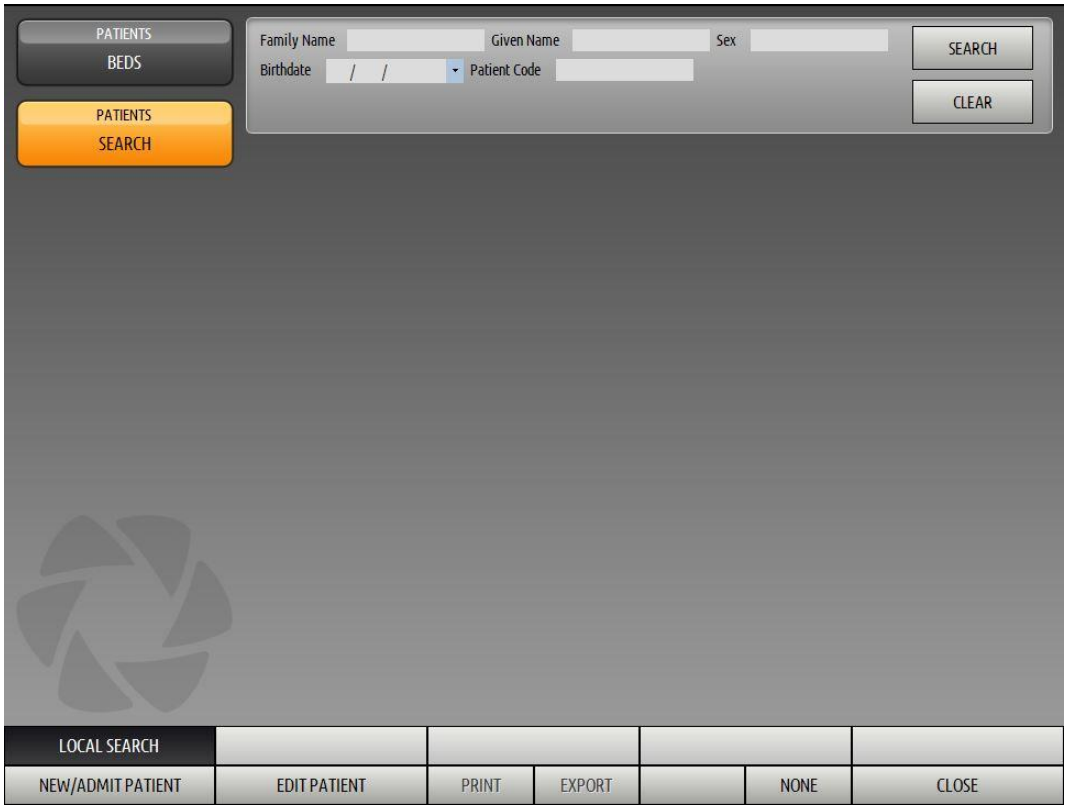

Fig 100

The search fields in the upper area make it possible to specify the relevant patient's information (Fig 101).

Fig 101

To search for a patient

- Enter the data of the patient you are searching for in one or more fields (Fig 101 **A**).
- Click the **Search** button (Fig 101 **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 birthdate, the result is the list of all patients born on that date. If a search is performed by entering the

patient's birthdate **and** sex the result is the list of 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.

6.10.1 The search results

The search results are shown in the central part of the screen (Fig 102).

Family Name	Given Name	Sex	Birthdate	Patient Code
??	0030028216	M		
??	0030028216	M		
ABILENE	LUGO	M		
AKRON	RHO	M		
AKRON	RHO	M		
ALAMEDA	PORDENONE	M		
ALAMOGORDO	CARPI	M		
ALBANY	MOLFETTA	M		
ALBUQUERQUE	FELTRE	M		
ALBUQUERQUE	CASTELNOVODISOTTO	M		
ALEXANDRIA	MILANO	M		
ALISO VIEJO	RIVADELGARDA	M		
ALLEN	MODIGLIANA	M		
ALLENTOWN	PALMANOVA	M		
ALLENTOWN	FOGGIA	M		
ALTAMONTE SPRINGS	IGLESIAS	M		
ANCHORAGE MUNICIPALITY	ASCOLISATRIANO	M		
ANDERSON	CLUSONE	M		

Fig 102

The results are displayed in alphabetical order. The information provided for each result depends on the configuration in use. In the example shown in Fig 102 the columns indicate the name, last name, sex, code and birthdate 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 the patient required.

6.11 The Command bar

The command bar (Fig 103) contains buttons making it possible to perform different actions.

Fig 103

1) **Block** (Fig 103 **A**) – This button indicates the current ward or department.

2) **New/Admit Patient** (Fig 103 **B**) – This button makes it possible to enter a new patient in the database and to admit him/her to a bed (see paragraph 6.11.1 for the detailed procedure).

3) **Edit Patient** (Fig 103 **C**) – This button makes it possible to edit the patient's data (see paragraph 6.11.2).

4) **None** (Fig 103 **D**) – 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 6.11.8).

5) **Close** (Fig 103 **E**) – This button closes the search page (see paragraph 6.11.9).

6.11.1 New/Admit patient

The **New/Admit Patient** button (Fig 104) makes it possible to enter a new patient in the database and to admit him/her to a bed.

Fig 104 - Command bar

To enter a new patient

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

The following window opens (Fig 105).

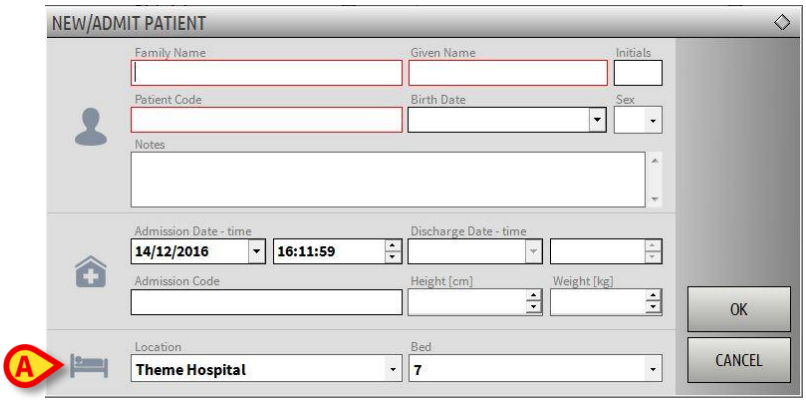

Fig 105

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

The new patient is this way registered in the database and admitted to the bed/department specified in the "Location" and "Bed" fields (Fig 105).

6.11.2 Edit patient

The **Edit Patient** button (Fig 106) makes it possible to edit the data of a selected patient.

Fig 106

Remember that this button can only be used if a patient is selected. The name must appear on the **Patient** button of the DIGISTAT® Control Bar (Fig 107).

The "edit" operations performed are always referred to the patient whose name appears on the **Patient** button (Fig 107).

Fig 107

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 108).

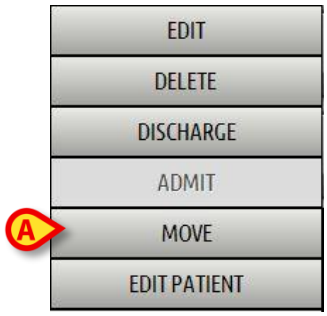

Fig 108

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 paragraphs.

6.11.3 Move

The **Move** button (Fig 108 **A**) makes it possible to register the transferal of a 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 108).

- Click the **Move** button (Fig 108 **A**).

The following window opens (Fig 109).

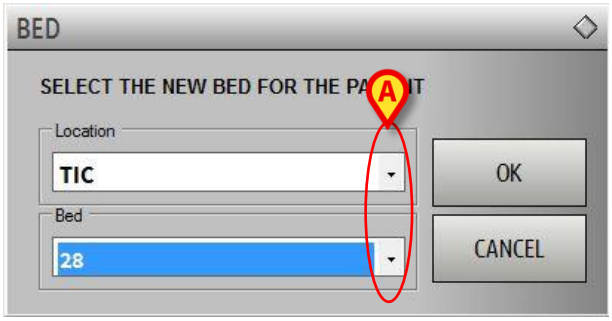

Fig 109

- Use the arrow buttons (Fig 109 **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.

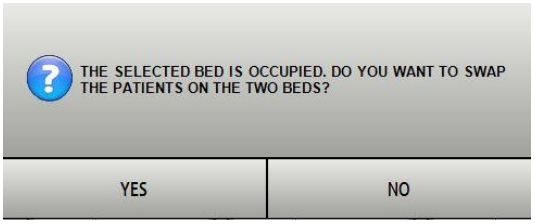

Fig 110

6.11.4 Admit

The admission button is disabled. The admission procedure is performed together with the “New patient” recording procedure. See paragraph 6.11.1.

6.11.5 Discharge

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

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 menu containing various options opens (Fig 111).

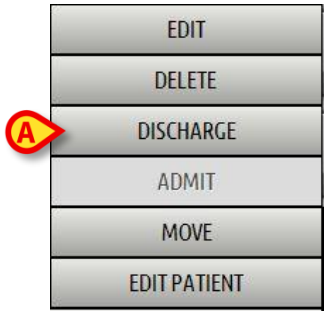

Fig 111

- Click the **Discharge** button (Fig 111 **A**).

A pop-up message requesting confirmation of the operation opens (Fig 112).

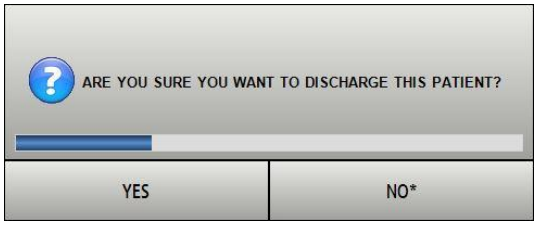

Fig 112 – Discharge patient

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

This action opens the window containing the patient's data (Fig 113 – unlike the window shown in Fig 105, here you can change the date and time of discharge).

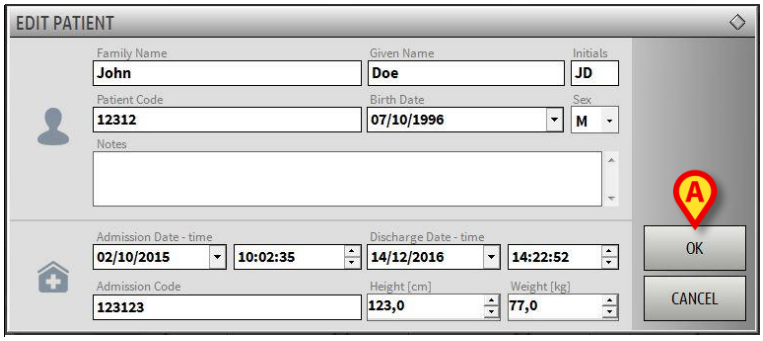

Fig 113

- Click **Ok** to complete the discharge procedure (Fig 113 A)

6.11.6 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 114).

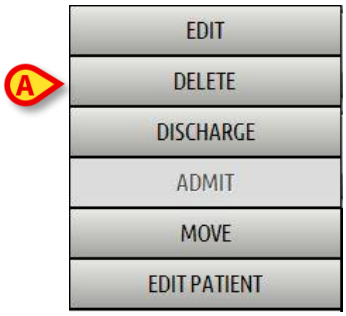

Fig 114

- Click the **Delete** button (Fig 114 **A**).

A pop-up message requesting confirmation is provided (Fig 115).

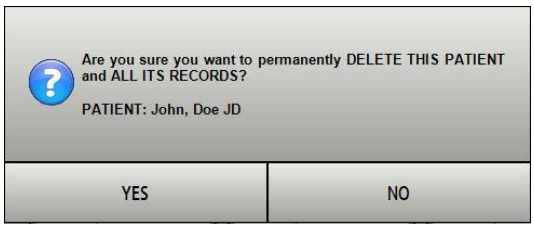

Fig 115

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

Deleting a patient from the Database is an irreversible operation. Once a patient has been deleted it is no longer possible to access any document regarding him/her acquired through the DIGISTAT® systems.

Therefore, it is necessary to perform this operation with extreme caution.

6.11.7 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 116).

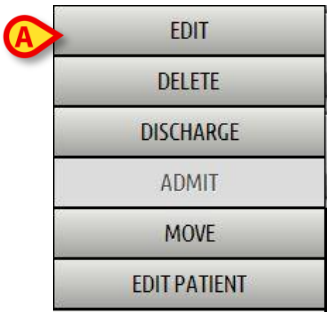

Fig 116

- Click the **Edit** button (Fig 114 **A**).

A window containing the patient's data opens (Fig 117).

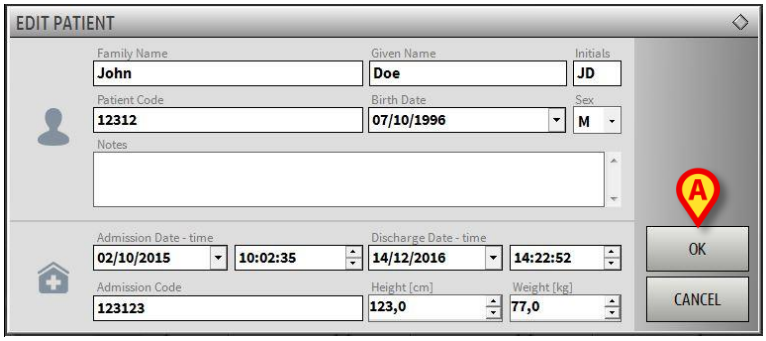

Fig 117 – Edit patient

- Edit the patient's data.
- Click **Ok** to confirm (Fig 117 **A**).

6.11.8 Deselect patient

The **None** button (Fig 118) makes it possible to deselect the selected patient (whose name is shown on the PATIENT button).

Fig 118 - Command bar

To deselect a patient

- Click the **None** button (Fig 118).

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

6.11.9 Close

The **Close** button (Fig 119) makes it possible to close the search screen.

Fig 119 - Command bar

To close the patient search screen

- Click the **Close** button on the page (Fig 119).

7. Bedside configuration

The “Smart Central” system 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 120 the workstation is locked to bed 1.

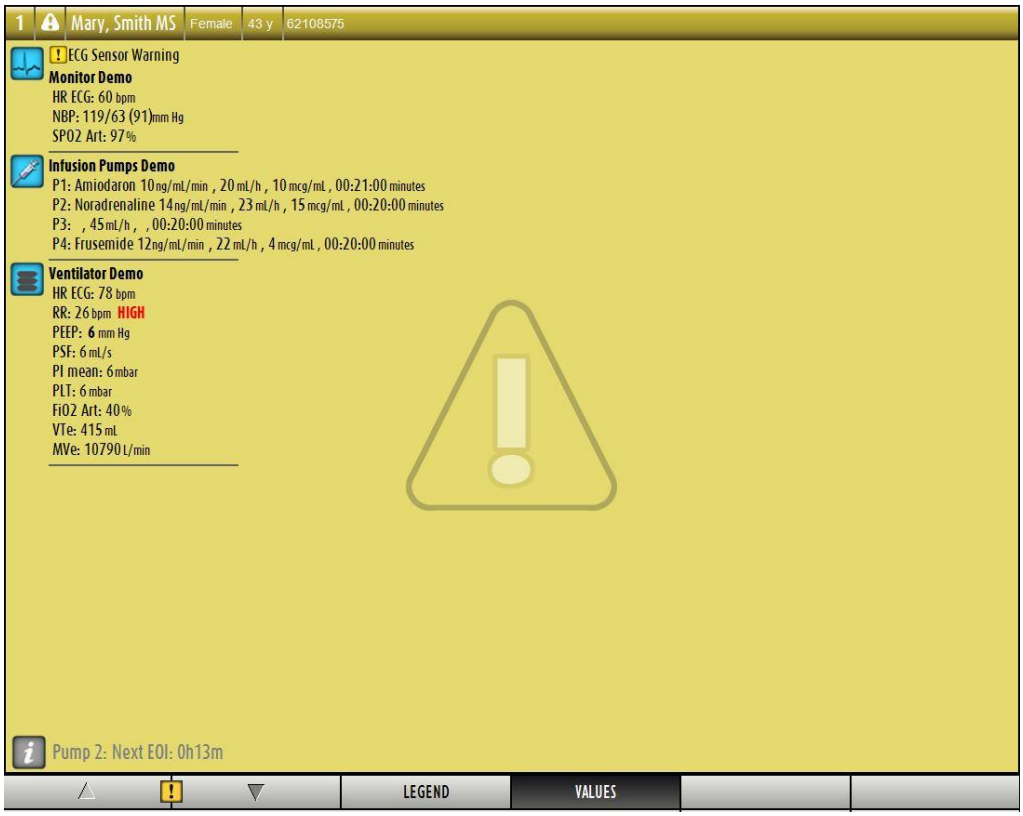

Fig 120

The “Bed area” is the same 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/warning is provided (see paragraph 6.4.1).

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

7.1 My Patients

The “My patients” functionality makes it possible to display up to 4 additional “Bed areas” on a “Bedside” workstation.

To use this functionality

➢ Click the **MyPatients** button on the command bar.

The following window opens (Fig 121).

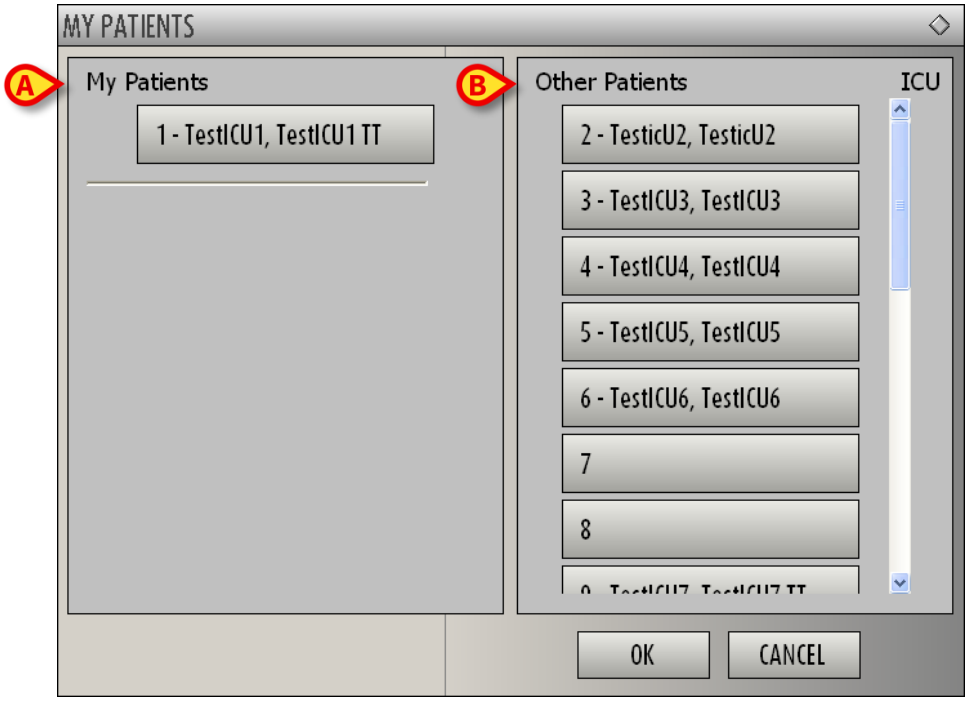

Fig 121

On the left, on the “My patients” column, is the list of “Bed areas” currently displayed (Fig 121 **A**). Each box represents a “Bed area”. The box on top represents the patient to which the workstation is locked.

On the right, on the “Other Patients” column, all the existing “Bed areas” are listed (Fig 121 **B**).

To select a bed area to be displayed on screen,

➢ Click on the “Other Patients” column, the corresponding box.

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.

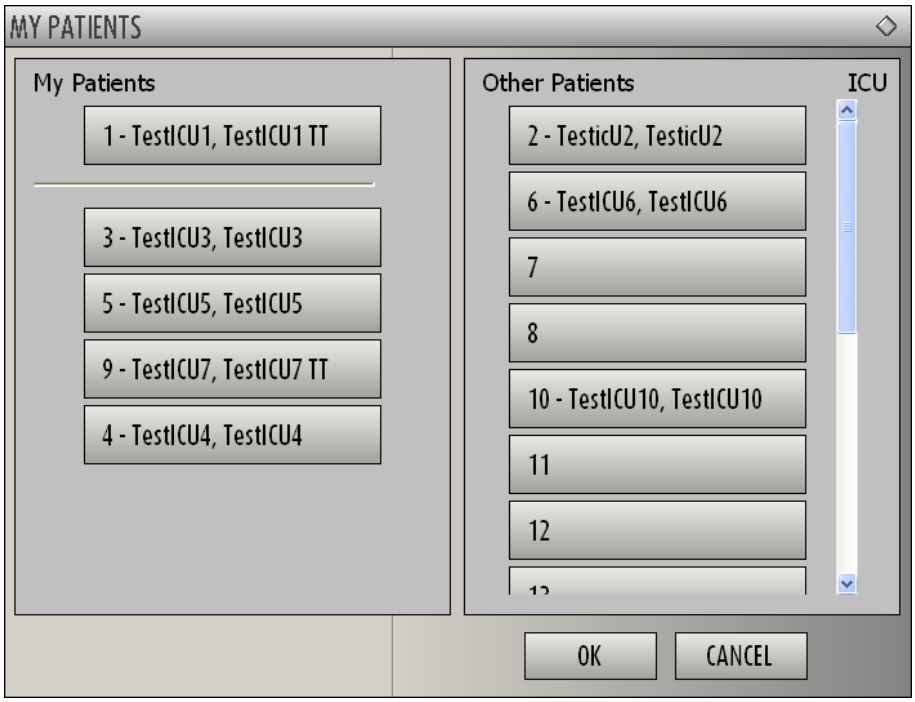

Fig 122

In Fig 122 “Bed areas” 3, 5, 9 and 4 are selected.

- Then click the **Ok** button.

The “Smart Central” screen appears like in Fig 123.

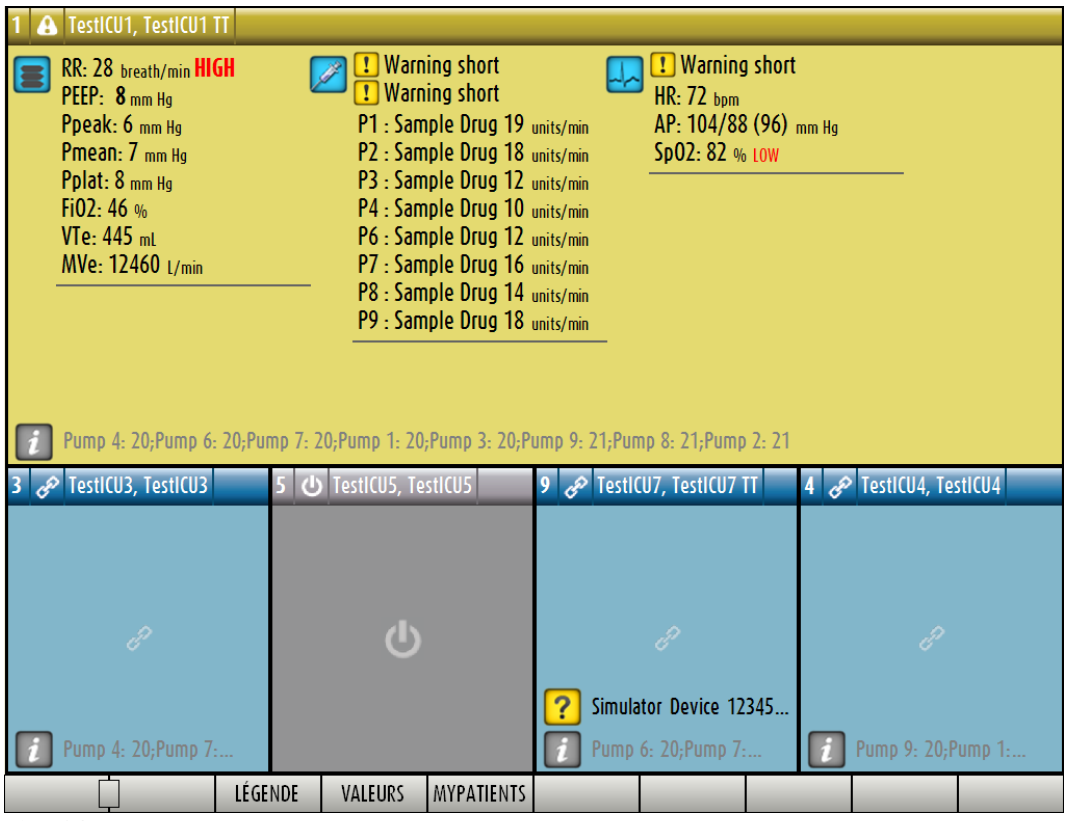

Fig 123

The “Bed area” to which the workstation is locked is n. 1 (large, on top). Bed Areas 3, 5, 9, 4 are displayed below, 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 again the **MyPatients** button on the command bar.

The “My Patients” window is displayed (Fig 122).

To remove an additional “Bed area”,

- Click, on the “My Patients” column, the box corresponding to the “Bed area” to be deselected.

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

8. Smart Central Mobile

8.1 Introduction

The Digistat® Smart Central module displays data and alarms in quasi-realtime from medical devices associated with the patient (e.g. infusion pumps, patient monitor, ventilator, dialysis machine, etc.) with a simple and intuitive user interface. It provides an overview of the devices' status, highlighting alarms and/or warnings occurring on a connected device so that the user is informed at a glance about the situation in the ward. It is designed to support the improvement of nursing workflows related to the management of alarms from the connected clinical devices and systems.
See the specific module documentation for more information

8.2 Overview

Digistat® Smart Central Mobile is a mobile application designed to bring the Smart Central directly "in the hands" of nurses and clinicians. Available for Ascom Myco and selected Android devices, Digistat® Smart Central Mobile supports alarm management by consolidating contextual information from multiple sources and presenting it to the staff in a clear and concise way.

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

8.2.1 Information for the user

Please read carefully the following warnings.

!	In case of disconnection of the 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 by himself/herself or close enough to be clearly audible.
!	Smart Central Mobile can be terminated by the user. After such event, 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 terminate the Smart Central Mobile application. After such event, the application will not send any other notification.
!	The Smart Central Mobile application can be terminated (either by the user or by the operating system). In this case a specific notification is generated, consisting of a characteristic sound and vibration. Sound duration is configurable.

8.3 Application start-up

To start the Smart Central Mobile application

- Touch the corresponding icon (Fig 124).

Fig 124

The “Smart Central” screen, shown in Fig 125, opens.

8.4 “Central” screen

The “Central” screen displays a schematic summary of the status of the medical devices connected to each patient-bed configured in the specific handheld device (Fig 125).

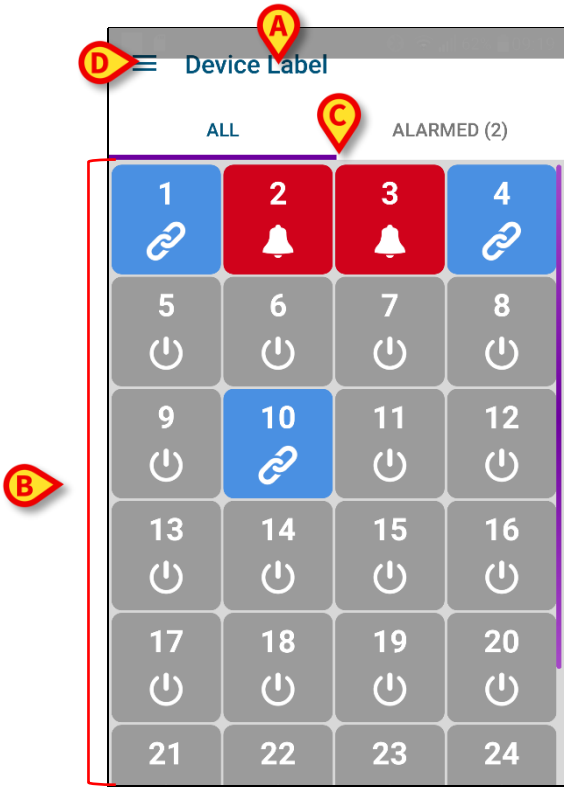

Fig 125

On top, the name of the handheld device in use is indicated (Fig 125 **A**).

The numbered squares displayed on screen represent the beds configured in the handheld device (Fig 125 **B**). The squares visible on a single screen are the “domain” 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 patient-bed are on hold.

- There is at least one connected medical device running.

- At least one of the connected medical devices is sending a warning message.

- At least one of the connected medical devices is alarmed.

You can use the filters indicated in Fig 125 **C** to display either all the configured beds or only the beds sending an alarm/warning message.

The  icon indicated in Fig 125 **D** opens the following menu (Fig 126). Flip left to go back to the “Central” screen.

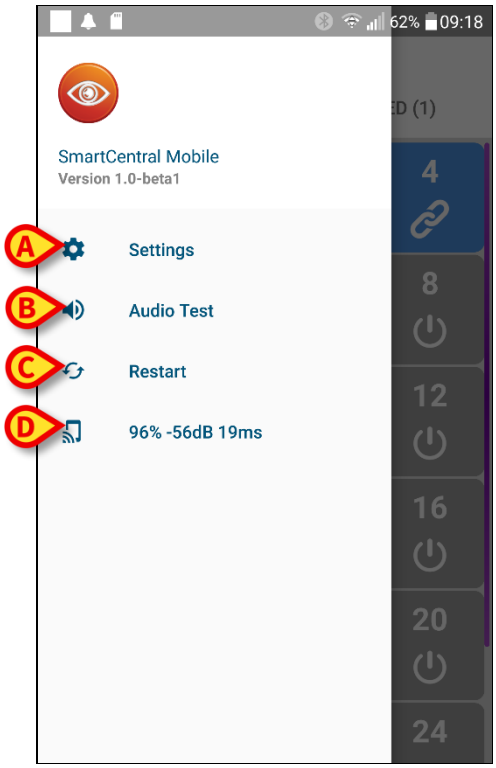

Fig 126

The items on the menu are:

Settings
Use the Settings button (Fig 126 **A**) to access the “Settings” screen (Fig 127). A specific password is required to access this area.

Fig 127

On top, the IP address of the device in use is displayed. The editable fields on this screen are:

- Client ID
- Server IP address
- Server port

After editing:

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

Use the back-arrow button on the top-left corner to go back to the previous menu.

Audio test
Touch the Audio-Test button (Fig 126 **B**) to test the sound-vibration associated to the notifications (alarms and warnings). Touch the button again to stop testing.

Restart
Touch the Restart button (Fig 126 **C**) to restart the application.

Connection Status
The last row displays the connection status.

8.5 Medical devices list

Touch one of the squares on the “Central” screen to display the list of medical devices connected to the patient-bed (Fig 128).

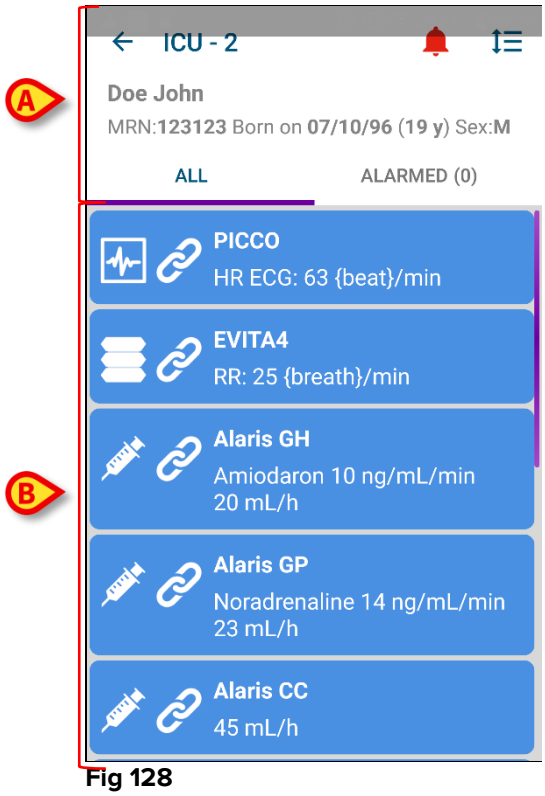

Fig 128

This screen is formed of two areas: a heading area (Fig 128 **A**) and the medical devices list (Fig 128 **B**).

8.5.1 Heading

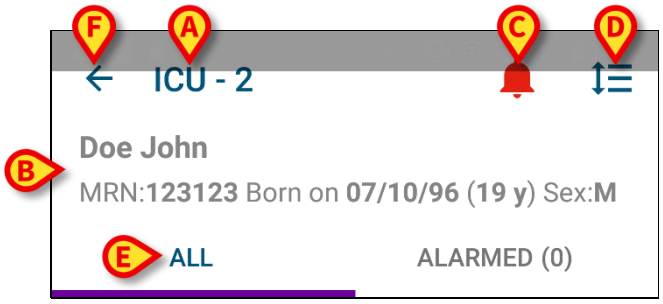

Fig 129

In the heading area (Fig 129) the following information and tools are available:

- Department and bed (Fig 129 **A**).

- Patient data (Fig 129 **B**). The number and type of patient data provided are configurable (these are: patient name, patient code, birthdate and sex in the example shown in Fig 129).
- The red bell icon (Fig 129 **C**) indicates that there is at least one medical device either alarmed or in warning state on one of the other beds (those not currently displayed).
- Use the icon indicated in Fig 129 **D** to enlarge the device-areas and display this way more information for each connected medical device (Fig 130). The type of information displayed depends on the configuration and the specific device.

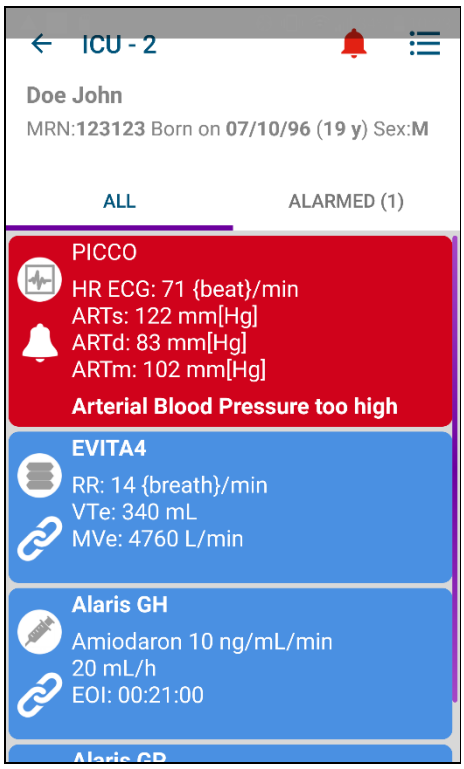

Fig 130

Touch the icon again to go back to compact display mode.

- Use the filters indicated in Fig 129 **E** to display either all the connected medical devices or only the ones providing notifications (warnings/alarms).

Use the back-arrow button (Fig 129 **F**) to go back to the “Central” screen.

8.5.2 Devices list

On the lower part of the “Bed” screen the single medical devices are represented as shown in Fig 131:

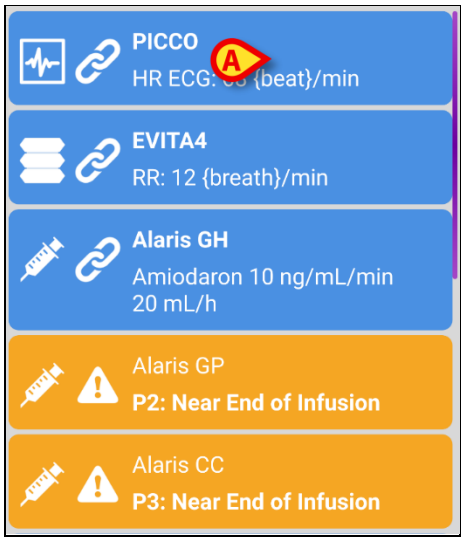

Fig 131

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

- An icon indicating the medical device type. The list of possible icons changes according to the hospital structure 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

 - Alarmed

 - Sending a warning message

The background color of the “card” also indicates the medical device status: grey (on hold); cyan (running); yellow (warning); red (alarm).

For each medical device, some basic information is displayed inside the “card”. The type of information depends on configuration.

In case of Alarm/Warning the “card” displays the alarm/warning message.

8.6 Notification history

Each “card” can be touched to access the list of all the notifications provided by the medical device (“Notification History” – Fig 132).

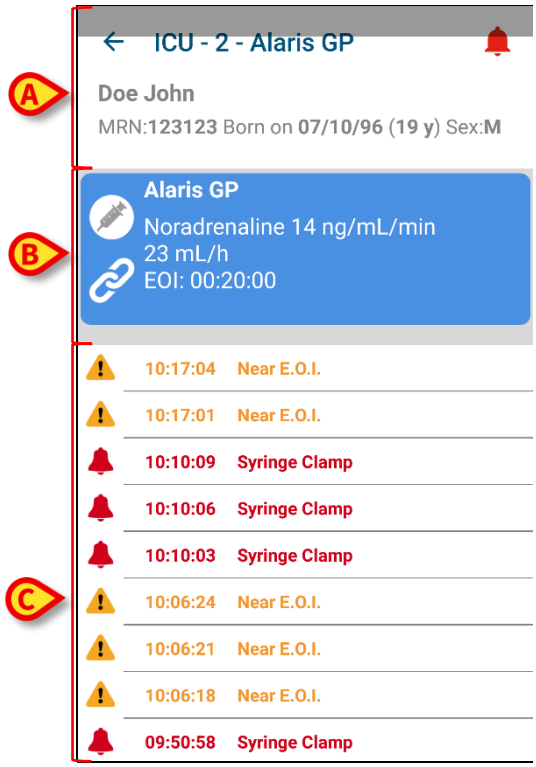

Fig 132

This screen is formed of three areas.

Patient data (Fig 132 **A**). Including the indication of the department, the bed and the medical device name (“ICU – 3 – Alaris GP” in the figure).
Medical device current data. The data displayed on this “card”, again depend on configuration (Fig 132 **B**).
Notification history. Displaying, in chronological order, all the notifications (alarms and warnings) sent by the device. For each notification, a short description and the time of occurrence are provided (Fig 132 **C**).

9. Contacts

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Fax (+39) 055 8290392

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800999715 (toll free, Italy only)

Sales and products information

sales@unitedms.com

General info

info@unitedms.com

10. Residual risks

The risk management process has been actualized for the DIGISTAT® medical device according to the relevant technical regulations (EN14971, EN62304, EN62366). All the possible control measures have been defined to reduce all residual risks to the minimum level and make them this way acceptable considering the benefits brought in by the product. The total residual risk is also acceptable if compared to the same benefits.

The risks listed below have been taken into consideration and reduced to the minimum level possible. Yet, given the inherent nature of the “risk” concept, it is not possible to completely remove them. It is therefore necessary, according to the regulations, let the users know each and every possible risk (even though remote).

- Impossibility in using the system or some of its functionalities, which can cause delays and/or errors in the therapeutic/diagnostic actions.
- Slowdown of device performance, which can cause delays and/or errors in the therapeutic/diagnostic actions.
- Circulation of users’ and/or patients’ sensible data.
- Unauthorized actions carried out by users, which can cause errors in the therapeutic/diagnostic actions and in the attribution of responsibilities of these actions.
- 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 patient data to the wrong patient (patient exchange), which can cause errors in the therapeutic/diagnostic actions.
- Accidental data deletion, resulting in loss of data, which can cause delays and/or errors in the therapeutic/diagnostic actions.

RISKS RELATING TO THE HARDWARE PLATFORM IN USE

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

11. Appendix: end-user license agreement

The following document is the ASCOM UMS end-user license agreement for the DIGISTAT® product. If the Product was delivered by a distributor, then the License agreement may be different from the one here published. In that case, please refer to the distributor to get the applicable license-agreement.

END-USER LICENSE AGREEMENT (EULA)
FOR "DIGISTAT®", AN ASCOM UMS PRODUCT

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5. **BACKUP COPY.** After installing a copy of the PRODUCT in compliance with the terms of this EULA, the User may preserve the original media on which Ascom UMS supplied him the PRODUCT only for backup or storage purposes. If the User needs the original media to use the PRODUCT, he/she may create only one copy of the PRODUCT for backup or storage purposes. Except for this EULA's express specifications, the User may not run copies of the PRODUCT or of the annexed printed material for other purposes.

LIMITED WARRANTY

Ascom UMS warrants for a period of twelve (12) months from the date of delivery of the PRODUCT to the User that: (a) the media on which the PRODUCT is supplied shall be free of material and of manufacturing defects under normal conditions of use; and (b) the PRODUCT shall perform substantially in accordance with the user manual.
Except for the above specifications, the PRODUCT is supplied "as is". This Limited Warranty shall apply only to the initial User/licensee.
The sole obligation of Ascom UMS under this warranty shall be, to the discretion of Ascom UMS, either to repair or replace the PRODUCT or to refund the price paid for the purchase of the PRODUCT, provided that the defect of the PRODUCT is technically attributable to Ascom UMS and that Ascom UMS has authorized its return.
Responsibility for loss or damages suffered by the PRODUCT during its shipment in connection with this warranty shall vest on the party shipping the PRODUCT.

Ascom UMS does not guarantee that the PRODUCT will be free from errors or that the User can operate the system without problems or interruptions.
Furthermore, due to the ongoing development of intrusion methods and attacks of networks, Ascom UMS does not guarantee that the PRODUCT or other equipment systems, or the network itself on which the PRODUCT is used, will not be vulnerable to intrusions and attacks.

It is the responsibility of the User to install and to maintain software means for the protection against intrusions or attacks (i.e. antivirus, firewall, etc.) and the maintenance of the software platform used to execute the PRODUCT. Ascom UMS is not responsible of any possible malfunction due to the installation and maintenance of such systems.

Limitations. This warranty does not apply if the PRODUCT: (a) has been installed, repaired, maintained or in any other way altered by persons not authorized by Ascom UMS, (b) has not been used in compliance with PRODUCT user manual, (c) has been subjected to abnormal physical or electronic stress, improper or negligent use or accident, or (d) is granted only for pilot testing, evaluation, testing, demonstration purposes or free of charge, for which Ascom UMS receives no payment as license fee.

Limitation of Liability. IN NO CASE WILL ASCOM UMS OR ITS SUPPLIERS BE HELD RESPONSIBLE FOR THE LOSS OF INCOME, PROFIT OR DATA OR FOR SPECIAL, INDIRECT, SUBSEQUENTIAL, INCIDENTAL OR PUNITIVE DAMAGES EITHER CAUSED, TRIGGERED OR RESULTING FROM THE USE OR INABILITY TO USE THE PRODUCT, EVEN IF ASCOM UMS OR ITS SUPPLIERS WERE INFORMED ABOUT THE POSSIBILITY THAT SUCH DAMAGES COULD OCCUR.
Under no circumstance will either Ascom UMS or its suppliers' responsibility cover compensation exceeding the price paid by the customer.
UNDER NO CIRCUMSTANCE WILL THESE GENERAL CONTRACT CONDITIONS INVOLVE ACKNOWLEDGEMENT OF ASCOM UMS OR IT'S SUPPLIERS' RESPONSIBILITY IN CASE OF DEATH OR PERSONAL INJURY RESULTING FROM THE USE OF THE PRODUCT.

The said limitations shall apply even if this warranty fails to meet its essential purpose. THE ABOVEMENTIONED LIMITATIONS SHALL NOT APPLY IN THE STATES AND IN THE JURISDICTIONS THAT DO NOT ALLOW LIMITATION OR EXCLUSION OF INCIDENTAL OR CONSEQUENTIAL DAMAGE.

This EULA and the warranty concerning the PRODUCT shall be subject to the Italian law. The United Nations Convention on the International Sales of Goods shall not apply. Should one or more provisions of this EULA be held as null or void by a Court of competent jurisdiction, the remaining provisions shall be considered as fully valid and effective.
Except for what expressly provided for herein, this EULA constitutes the complete agreement between the parties on the license of the PPRODUCT and replaces any other conflicting or additional provision of the purchase order.
The date of delivery of the PRODUCT to customer is recorded in the shipment documentation or in the PRODUCT delivery documentation.

INTENDED USE

The DIGISTAT Software (hereafter "Product") acquires, records, organizes, transmits and displays patient information and patient related data, including data and events from connected clinical devices and systems as well as information entered manually, in order to support caregivers in diagnosis and treatment of patients as well as to establish electronic patient records.

- The Product produces configurable electronic patient records based on acquired data and information, as well as on manual and automated documentation of the clinical unit's activity.
- The Product provides automated, secondary visual and audible annunciating and displaying of acquired data, events, current status and operating conditions of connected clinical devices and systems on designated display device(s). The Product can also be configured to forward data and information about events, statuses and operating conditions to the Ascom messaging system.
- The Product supports the improvement of nursing workflows related to the management of alarms from the connected clinical devices and systems.
- The Product supports documentation of the prescribed therapy, of its preparation and of its delivery.
- The Product supports the recording, validation and display of vital signs charting based on the acquired data and information.
- The Product provides configurable reports, charts and statistics based on recorded data for use by healthcare professionals to analyze the unit's efficiency, productivity, capacity and resource utilization, and the quality of care.

The Product **does not** replace or replicate the original display of data and alarms of the connected devices and systems, and **does not** control, monitor or alter the behavior of these connected devices and systems, or their associated alarm annunciations.

The Product **is not** intended to be used for direct diagnosis or monitoring of vital physiological parameters.

The Product is intended for use by trained healthcare professionals within a hospital/clinical environment and relies on proper use and operation of the IT and communication infrastructure in place at the healthcare facility, the display devices used and the connected clinical devices and systems.
Additionally, the Product provides specific functions and interfaces intended to be used by non-professional users in remote locations for non-clinical purposes for display of information, reports, charts and statistics, without any possibility to add, change or delete any information or data.

The Product is a stand-alone software that is installed on servers and computers, which shall comply with the technical hardware and software specifications provided with the Product.

CONFLICTING TERMS

Should the User and Ascom UMS enter into an agreement for the supply and/or the license of the PRODUCT containing terms different from those contained herein, the terms of that agreement shall prevail on the terms of this EULA which are not compatible with them, it being understood that all the remaining terms of this EULA shall remain fully valid and the enforceable.

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Should you have any questions concerning this EULA, please contact the Ascom UMS representative in your area or write to Ascom UMS srl, Customer Service, Via Amilcare Ponchielli 29, 50018 Scandicci (Firenze), Italy.

Date Signature

SPECIFIC ACCEPTANCE OF CERTAIN PROVISIONS IN THIS EULA

IMPORTANT—READ CAREFULLY

In compliance with articles 1341 and 1342 of the Italian Civil Code or to any other equivalent provision applicable in any other jurisdiction, I hereby declare that I have read, fully understood and specifically accept the following clauses of the EULA concerning the PRODUCT:

- COPYRIGHT
- LIMITED WARRANTY
- LIMITATIONS
- LIMITED LIABILITY
- INTENDED USE
- RESTRICTIONS.

Date Signature